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Maternal role in sensory motor stimulation for oral feed establishment in preterm neonates: MSMS trial

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Abstract

Background: The transition from gavage to full oral feeding is a critical and challenging milestone for preterm neonates. Sensory–motor stimulation (SMS) has been shown to improve feeding performance; however, evidence regarding mother-administered SMS remains limited.

Objective: To compare the maternal-administered versus nurse-administered sensory–motor stimulation on oral feeding outcomes in preterm neonates.

Methods: This prospective, single-blind, parallel-group randomized controlled trial double-blind randomized controlled trial was conducted in a tertiary neonatal intensive care unit between March 2022 and September 2023. Clinically stable preterm neonates of 28 to 34 weeks of gestation were randomized to receive sensory–motor stimulation administered either by trained mothers (intervention group) or trained nurses (control group). The primary outcome was time to achieve full oral feeding. Secondary outcomes included feeding efficiency (Level 4 achievement), feeding proficiency (PRO), rate of transfer (RT), overall transfer (OT), coordinated suck–swallow–breathe (SSB) patterns, and adverse events. Time-to-event outcomes were evaluated using Kaplan–Meier analysis, log-rank testing, and Cox proportional hazards regression, with gestational age adjustment as a sensitivity analysis.

Results: Of 130 randomized neonates, 97 completed the study and were included the per-protocol analysis (experimental group, $n = 49$; control group, $n = 48$). Baseline maternal, neonatal, and feeding characteristics were comparable between groups. No significant between-group differences were observed in median time to achieve full oral feeding, RT, OT, PRO, feeding volumes, coordinated SSB patterns, or adverse events. Kaplan–Meier analysis demonstrated similar time to full oral feeding trajectories between groups (log-rank p = 0.984). Cox regression analysis showed no significant association between intervention group and time to full oral feeding (hazard ratio 1.016, 95% CI 0.637–1.619; $p = 0.948$), with similar results after gestational age adjustment (adjusted HR 1.045, 95% CI 0.655–1.668; $p = 0.854$).

Conclusion: Maternal-administered SMS achieved feeding outcomes comparable to nurse-administered SMS in clinically stable preterm neonates. Although not powered for non-inferiority or equivalence, these findings support the feasibility of involving trained mothers in structured feeding interventions and justify larger trials evaluating family-centered neonatal care in resource-limited settings.

Keywords

preterm neonate, oral feeding, sensory–motor stimulation, family-centered care, oral feeding skills, randomized controlled trial

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Introduction

Establishing oral feeding is a major milestone for preterm neonates and an important marker of neurodevelopmental progress. Yet this transition from gavage to independent oral feeding proves difficult for a substantial proportion of neonates. Approximately 40% of preterm neonates face a challenging transition from gavage to oral feeding.[1]

Prolonged dependence on tube feeding in preterm neonates is associated with several adverse consequences, including mechanical complications, feeding intolerance, nutritional inadequacy, and infection.[2–5] These concerns highlight the clinical imperative to develop and devise approaches that promote earlier and safer transition to oral feeding. These challenges underscore the need for safe, evidence-based interventions that facilitate an earlier and more efficient transition to full oral feeding.

According to Heidelise Als' Synactive Theory, neonatal development is shaped by the interaction between physiological stability and multisensory environmental experiences.[6,7]

Based on this developmental framework, both oral and non-oral (tactile and kinesthetic) sensorimotor stimulation improve suck–swallow coordination and facilitate the establishment of full oral feeding.[8,9]

The optimal timing for initiating oral feeding in preterm infants remains a subject of ongoing debate.

Oral feeding competence depends on coordinated sucking, swallowing, and breathing (SSB), which matures by approximately 34 weeks' gestation.[10] However, clinically stable preterm infants may achieve efficient oral feeding by 30 weeks' postmenstrual age.[11]

Family-centered care (FCC) is a cornerstone of modern neonatal practice and supports neurodevelopment through enhanced parental involvement and bonding.[12] Interventions such as kangaroo mother care (KMC) have demonstrated benefits for both infants and families.[13]

At our institution, mothers are routinely involved in tube and oral feeding as part of standard neonatal care. However, structured oromotor sensorimotor stimulation is delivered exclusively by trained NICU nurses due to limited access to occupational therapists and lactation consultants. Beyond questions of access, maternal proximity, voice, and touch may themselves enhance an infant's physiological stability during stimulation, potentially strengthening its effect. Whether trained mothers can deliver structured oromotor stimulation with comparable effectiveness therefore remains uncertain, representing an important knowledge gap for family-integrated neonatal care.

This randomized controlled trial was therefore designed to compare maternal-administered with nurse-administered sensorimotor stimulation in establishing independent oral feeding among preterm neonates. Against this background, this study aimed to compare the time to achieve full oral feeding and other predefined feeding-related outcomes between preterm neonates receiving an identical structured sensorimotor stimulation protocol administered either by trained mothers or by trained NICU nurses. This trial is hereafter referred to as the Maternal Sensori-Motor Stimulation (MSMS) trial.

Methodology

Study design and setting

This was a prospective, single-blind, hereafter the MSMS trial, parallel-group randomized controlled trial (RCT) conducted in the Neonatal Intensive Care Unit (NICU) of Fatima Memorial Hospital, Lahore, Pakistan, from March 2022 to September 2023.

The study was approved by the Institutional Review Board of Fatima Memorial Hospital (FMH-07-2021-IRB-929-M) and conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from parents or legal guardians of all enrolled neonates before participation.

The trial was registered and approved at ClinicalTrials.gov (NCT05484726). The study was reported according to CONSORT guidelines.

This was a prospective, randomized controlled trial designed to compare mother-administered versus nurse-administered sensorimotor stimulation in preterm neonates. The study was conducted to evaluate whether there was a difference between the two approaches; it was not powered as a non-inferiority or equivalence trial.

Sample size

The initial sample size of 46 neonates (23 per group) was estimated using OpenEpi software based on an assumed prevalence of feeding difficulties of 40%, a 95% confidence level, and a 5% level of significance.

As this calculation was not based on the primary outcome of time to achieve full oral feeding, no formal sample size estimation was performed for the primary endpoint.

During the recruitment period, enrollment continued beyond the initial target because a greater number of eligible mother–neonate pairs than anticipated fulfilled the eligibility criteria and provided informed consent to participate. No formal recalculation of the sample size was undertaken. Consequently, 130 preterm neonates were randomized. Following post-randomization exclusions according to the prespecified study criteria, 97 neonates (49 in the mother-administered/experiment group and 48 in the nurse-administered group) were included in the final analysis, as shown in the CONSORT flow diagram (Figure 1).

Participants

Inclusion criteria. The eligible participants were all preterm neonates of gestational age between 28 and 34 weeks) who

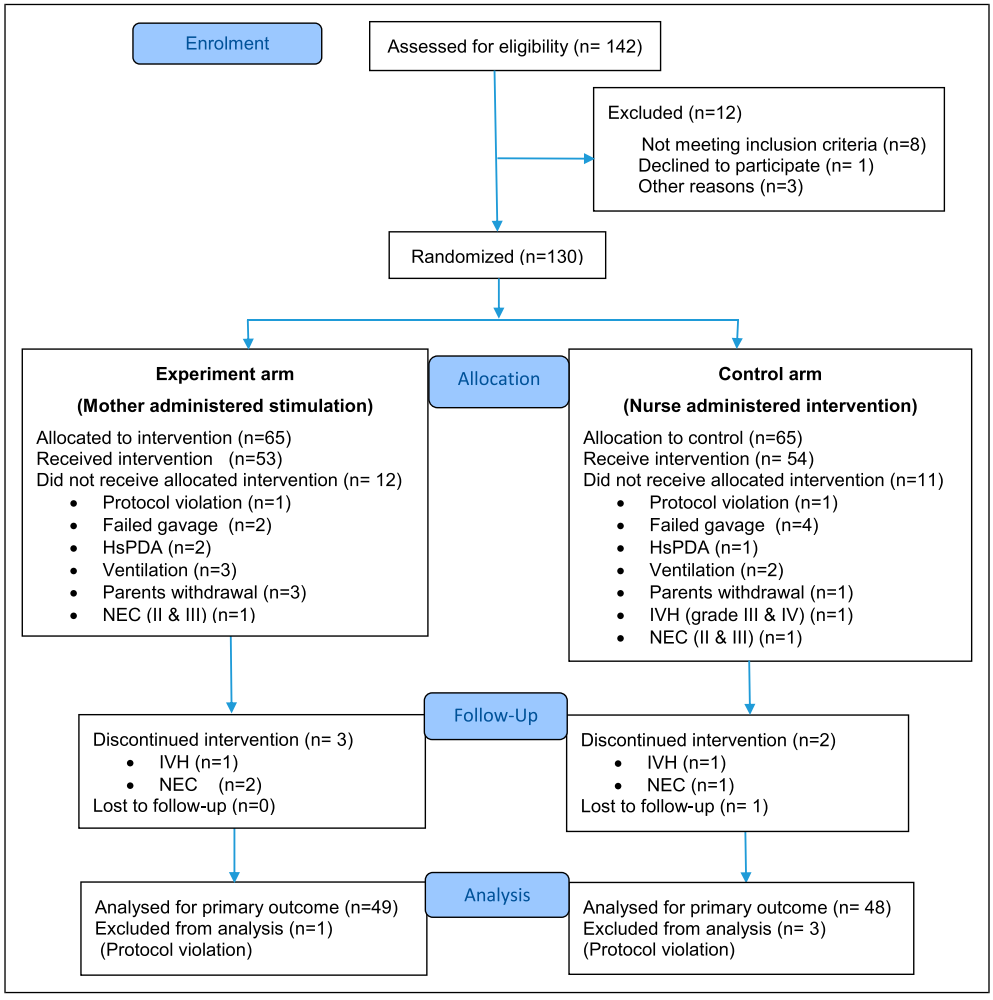


Figure 1. Consort diagram. HsPDA, hemodynamically significant patent ductus arteriosus; NEC, necrotizing enterocolitis; IVH, intraventricular hemorrhage. Protocol violation: oral feeding given without the preceding stimulation session, identified either before intervention initiation ("did not receive allocated intervention") or on subsequent data review ("excluded from analysis").

were admitted to the NICU and enrolled within the first 72 hours of life after written informed consent had been obtained from their parents or legal guardians. Randomization was performed within this period in accordance with the study protocol.

Intervention eligibility. Following randomization, infants remained under routine NICU care. The allocated sensorimotor stimulation protocol was initiated only after the infant had established full gavage feeding 120–140 ml/kg/day without any signs of feed intolerance, achieved clinical stability, and required no respiratory support beyond low-flow nasal cannula (LFNC). As attainment of these milestones depended on gestational age and clinical progress, the interval between randomization and initiation of the intervention varied among participants.

Exclusion criteria. All neonates with major congenital anomalies or syndromic conditions, cleft lip and/or palate, suspected genetic or metabolic disorders, intraventricular hemorrhage (Grade III–IV), hemodynamically significant patent ductus arteriosus (HsPDA) requiring active treatment, necrotizing enterocolitis (Stage II or higher), or a requirement for blood transfusion or significant cardiorespiratory instability were excluded. Neonates who developed adverse clinical instability before randomization were also excluded. No post-randomization exclusions were applied in the final analysis. Protocol violations—oral feeding administered without the preceding stimulation session—were classified as non-receipt of the allocated intervention if identified before initiation, or as exclusion from the per-protocol analysis if identified on subsequent data review.

Randomization and allocation concealment. Participants were randomly assigned to mother-administered or nurse-administered sensorimotor stimulation group per protocol. This randomization was done using a sequence that was generated with the help of a computer. Stratified block randomization was employed, with stratification based on gestational age across three strata: 28–30, 30^{+1}–32, and 32^{+1}–34 weeks.

Allocation concealment was ensured using sequentially numbered, opaque, sealed envelopes (SNOSE).

The randomization sequence was generated by an independent researcher not involved in any step of recruitment intervention delivery, outcome assessment, or data analysis Allocation was hidden using sequentially numbered, sealed, opaque envelopes and was opened only after participant enrollment. Following participant enrollment, the envelopes were opened sequentially by a study coordinator who was not involved in outcome assessment, thereby ensuring concealment of the allocation sequence until assignment. The study coordinator subsequently informed the bedside nursing staff of group allocation to initiate the assigned intervention.

Study Groups

Participants were randomly assigned to one of the following groups.

- Experiment Group/Mother-administered sensorimotor stimulation: Mothers delivered structured sensorimotor oral stimulation after initial training by NICU nurses.
- Control Group/Nurse-administered sensorimotor stimulation: The identical stimulation protocol was delivered by trained NICU nurses.

Intervention protocol

The intervention consisted of a standardized 7-min sensorimotor stimulation protocol comprising 5 minutes of structured perioral and intraoral stimulation, followed by 2 minutes of non-nutritive sucking using a pacifier.

The protocol was adapted from the Premature Infant Oral Motor Intervention (PIOMI) and the oral stimulation program described by Fucile et al.[14–16] Both study groups received the identical intervention protocol, differing only in the individual administering the stimulation. Interventions were performed twice daily, 15 minutes before the scheduled feeding.

Feeding frequency was standardized at 12 feeds per day across both groups; daily milk intake (ml/kg/day) and prescribed feed volume per feed are therefore mathematically related and are reported together to characterize feeding status at baseline.

Maternal training and competency

Mothers in the experiment group underwent structured, competency–based training in three stages:

- Observation of a trained nurse performing a procedure, for 2 days
- Supervised practice under nurse guidance, for 2 days,
- Independent performance demonstration of competency

Training was conducted over 2 sessions per day for a total of 4 days prior to independent performance, with mothers practicing directly with their own enrolled neonate under nurse supervision at each stage. Mothers were allowed to independently perform the intervention only after satisfactory demonstration using a standardized checklist under supervision.

Feeding protocol

Oral feeding was initiated according to the unit's standardized feeding protocol once predefined criteria for feeding readiness were fulfilled. Oral feeding was provided using a bottle with a slow-flow nipple. Each oral feeding session was limited to a maximum of 20 minutes. Feeding sessions discontinued earlier if signs of intolerance or adverse events occurred. Advancement of oral feeding followed the unit's standardized feeding protocol and was identical in both study groups.

Blinding

Due to the nature of the intervention, blinding of mothers and personnel delivering the intervention was not feasible. However, outcome evaluators responsible for evaluating feeding performance and determining study outcomes were blinded to group allocation.

Outcomes

Primary outcome

The primary outcome was time to attain full oral feeding, defined as the number of days from initiation of sensorimotor stimulation to the ability to achieve an oral intake of 120–140 ml/kg/day.

Secondary outcomes

- Total volume transferred per feed (TV)
- Volume transferred during the first 5 minutes of feeding (TV5)
- Rate of milk transfer (RT, ml/min)
- Overall transfer (OT %)

- Feeding proficiency (PRO %)
- Suck–swallow–breathe coordination (SSB clinical assessment)
- Adverse events during feeding or stimulation
- Feeding efficiency levels (L1–L4) were derived from PRO and RT classifications, with Level 4 representative of the most mature and efficient feeding pattern.

Adverse events monitoring

All neonates were continuously monitored for adverse events throughout the intervention period, including bradycardia, tachycardia, apnea, desaturation, and choking or coughing during feeds. All such events were systematically documented in the data sheet.

Outcome

Baseline characteristics and predefined outcome data were recorded prospectively throughout the study period. Any adverse events occurring during stimulation or feeding sessions were also documented.

Data collection

The maternal and neonatal baseline characteristics were collected prospectively using a standardized proforma.

Following initiation of the intervention, feeding-related outcomes were assessed daily at a fixed time (11:00 a.m.) to ensure consistency in data collection. For longitudinal analysis, outcome data recorded on study days 1, 2, 3, 5, 7, and 14 were included.

Baseline variables

Maternal variables. Maternal data collected included age, gravidity (primigravida, 2–3, or ≥4 pregnancies), educational attainment (none, primary, secondary, or higher), history of previous preterm birth, employment status (employed or homemaker), and the presence of any relevant comorbidities like diabetes mellitus (DM), hypertensive disorders (PIH), and anemia.

Neonatal variables. Neonatal baseline data encompassed gender, gestational age at birth, birth weight, weight for gestational age (appropriate, small, or large for gestational age), mode of delivery (vaginal or cesarean), and place of birth (inborn or outborn).

Clinical characteristics documented included the type and duration of respiratory support (invasive mechanical ventilation (IMV), non-invasive ventilation (NIV), or low-flow nasal cannula (LFNC)), use of caffeine therapy prophylactically, and the presence of respiratory distress syndrome (diagnosed on clinical and radiological grounds), apnea (defined as cessation of breathing for more than 20 seconds, with or without associated bradycardia), hemodynamically significant patent ductus arteriosus (confirmed by echocardiography), necrotizing enterocolitis (classified according to modified Bell's criteria), feeding intolerance, sepsis (defined by clinical and laboratory criteria), and seizures. Hospital outcome data included discharge weight and total duration of NICU stay.

Feeding characteristics at intervention initiation.

Feeding-related baseline variables recorded at the time of enrollment included postmenstrual age, chronological age, time taken to achieve full gavage feeding, daily milk intake at the point of intervention initiation (ml/kg/day), and prescribed feed volume per feed.

Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics version 21 (IBM Corp., Armonk, NY, USA).

The primary analysis was conducted on a per-protocol basis, comprising randomized neonates who received the allocated sensorimotor stimulation protocol. Neonates who developed a prespecified exclusion criterion or protocol violation after randomization but before intervention initiation did not receive the allocated intervention and were excluded from the analysis, with reasons detailed in the CONSORT flow diagram (Figure 1). As several exclusion criteria (e.g., Grade III–IV intraventricular hemorrhage, hemodynamically significant patent ductus arteriosus, and necrotizing enterocolitis) are associated with greater illness severity, this per-protocol approach may not fully preserve the prognostic balance achieved by randomization; this is addressed further in the Limitations section.

Baseline maternal and neonatal characteristics, feeding characteristics, and study outcomes were summarized using descriptive statistics. The distribution of continuous variables was assessed using the Shapiro–Wilk test; as continuous variables were not normally distributed, data are presented as median and interquartile range (IQR), while categorical variables are presented as frequencies and percentages within each group. Baseline and feeding characteristics were compared descriptively; statistical significance testing was reserved for study outcomes.

Categorical variables were compared between the two groups using the chi-square test or Fisher's exact test, as appropriate, while continuous variables were analyzed using the Mann–Whitney U test. All statistical tests were two-tailed, and a p-value <0.05 was considered statistically significant.

The primary outcome, time to achieve full oral feeding, was analyzed as a time-to-event variable using Kaplan–Meier survival analysis, with between-group differences assessed using the log-rank test. Cox proportional hazards regression was performed in addition to the log-rank test to provide an effect estimate (hazard ratio [HR] and 95%

confidence interval [CI]), as the log-rank test alone yields a significance test without a quantified effect size.

As this study was not powered on the primary outcome, a post-hoc power analysis was performed using Schoenfeld's formula, based on the observed hazard ratio and the total number of events (all 97 neonates achieved full oral feeding by day 14, with no censoring). Given the achieved sample size, the study had approximately 80% power to detect a hazard ratio of ≥1.77 or ≤0.57 at $\alpha = 0.05$; smaller differences between groups, including the observed hazard ratio, could not be reliably excluded or confirmed by this sample size.

Table 1. Maternal and neonatal characteristics.

Characteristic	Experimental group (*n* = 49)	Control group (*n* = 48)
Neonatal characteristics		
Male sex, *n* (%)	27 (55.1)	22 (45.8)
Gestational age (weeks)	30 (29–32)	31 (29.3–32)
Birth weight (kg)	1.29 (1.20–1.52)	1.34 (1.15–1.67)
Weight for gestational age, *n* (%)		
Appropriate (AGA)	27 (55.1)	30 (62.5)
Small (SGA)	16 (32.7)	15 (31.3)
Large (LGA)	6 (12.2)	3 (6.3)
Inborn, *n* (%)	30 (61.2)	33 (68.8)
Mode of delivery (SVD), *n* (%)	26 (53.1)	29 (60.4)
Invasive mechanical ventilation, *n* (%)	26 (53.1)	30 (62.5)
Duration of invasive mechanical ventilation (days)	1 (0–4)	2 (0–5)
Non-invasive ventilation, *n* (%)	45 (91.8)	48 (100)
Duration of non-invasive ventilation (days)	3 (1–7)	4 (2–6.75)
Low-flow nasal cannula, *n* (%)	47 (95.9)	43 (89.6)
Duration of low-flow nasal cannula (days)	4 (2–5)	3.5 (2–5)
Apnea, *n* (%)	18 (36.7)	20 (41.7)
Respiratory distress syndrome, *n* (%)	25 (51.0)	25 (52.1)
Caffeine therapy, *n* (%)	28 (57.1)	28 (58.3)
Hemodynamically significant PDA, *n* (%)	17 (34.7)	20 (41.7)
NEC (bell stage I), *n* (%)	9 (18.4)	12 (25.0)
Feeding intolerance, *n* (%)	20 (40.8)	25 (52.1)
Sepsis, *n* (%)	43 (87.8)	41 (85.4)
Seizures, *n* (%)	7 (14.3)	5 (10.4)
Enrollment characteristics		
Postmenstrual age at enrollment (weeks)	32 (31–33)	32 (31–33)
Chronological age at enrollment (days)	13 (6–14)	9 (7–16)
Weight at enrollment (kg)	1.35 (1.25–1.54)	1.35 (1.21–1.60)
Maternal characteristics		
Maternal age (years)	29 (26–32)	30 (26.5–33)
Gravidity, *n* (%)		
Primigravida	20 (40.8)	26 (54.2)
2–3	22 (44.9)	15 (31.3)
≥4	7 (14.3)	7 (14.6)
Education, n (%)		
Uneducated	2 (4.1)	2 (4.2)
Primary	11 (22.4)	10 (20.8)
Secondary	15 (30.6)	20 (41.7)
Higher	21 (42.9)	16 (33.3)
No previous preterm birth, *n* (%)	42 (85.7)	38 (79.2)
Housewife, *n* (%)	29 (59.2)	31 (64.6)
Hypertensive disorder, *n* (%)	29 (59.2)	32 (66.7)
Diabetes mellitus, *n* (%)	17 (34.7)	17 (35.4)
Maternal anemia, *n* (%)	25 (51.0)	21 (43.8)

AGA, appropriate for gestational age; SGA, small for gestational age; LGA, large for gestational age; SVD, spontaneous vaginal delivery; IMV, invasive mechanical ventilation; NIV, non-invasive ventilation; LFNC, low-flow nasal cannula; RDS, respiratory distress syndrome; HsPDA, hemodynamically significant patent ductus arteriosus; NEC, necrotizing enterocolitis (Bell stage I); DM, diabetes mellitus; PIH, pregnancy-induced hypertension (hypertensive disorder). Data presented as median (interquartile range) or *n* (%).

Table 2. Feeding characteristics and hospitalization outcomes (descriptive).

Characteristic	Experimental group (n = 49)	Control group (n = 48)
Time to full gavage feeding (days)	7 (5.5–13.5)	7 (6–14)
Discharge weight (kg)	1.48 (1.42–1.66)	1.48 (1.43–1.75)
Duration of NICU stay (days)	21 (15–29.5)	30 (16–30.75)
Prescribed milk intake (ml/kg/day)		
Day 1	120 (120–120)	120 (120–120)
Day 2	120 (120–140)	120 (120–140)
Day 3	140 (140–140)	140 (140–157.5)
Day 5	150 (150–160)	160 (150–160)
Day 7	160 (160–160)	160 (160–160)
Day 14	160 (160–180)	160 (160–180)

Values presented as median (interquartile range). D, day; ml/kg/day, milliliters per kilogram per day.

A gestational-age-adjusted Cox proportional hazards model was performed as a sensitivity analysis, given gestational age was a stratification variable at randomization. The proportional hazards assumption was assessed using log-minus-log survival plots stratified by intervention group; the plots demonstrated closely parallel, non-crossing curves across the observed time range, supporting the validity of the proportional hazards assumption for the Cox regression models used.

Secondary feeding-related outcomes—including total volume transferred per feed, volume transferred during the first 5 minutes, rate of milk transfer, overall transfer, feeding proficiency, suck–swallow–breathe coordination, and feeding efficiency level—were assessed at predefined time points (days 1, 2, 3, 5, 7, and 14) and compared between groups independently at each time point using the statistical tests described above. Secondary outcomes were compared between groups independently at each predefined time point rather than through a repeated-measures model accounting for within-subject correlation over time, and no correction for multiple comparisons was applied across the numerous outcomes and time points tested; both are acknowledged as limitations of the current analysis.

Results

During the study period, 1009 neonates were admitted to the neonatal intensive care unit (NICU), of whom 142 were preterm neonates born between 28 and 34 weeks of gestation. After initial exclusions, 130 eligible neonates were randomized equally into experimental and control groups (n = 65 each). A final analysis was performed on a total of 97 neonates who completed the study (experimental: n = 49; control: n = 48), as illustrated in the CONSORT flow diagram (Figure 1).

Baseline maternal and neonatal characteristics were similar between the two groups, with no statistically significant differences observed (Table 1).The median time to achieve full oral feeding was 10 (IQR 7–13) days in the experimental group and 9 (IQR 7–13) days in the control group and was statistically insignificant (p = 0.531). Given the achieved sample size, the study had 80% power to detect a hazard ratio of 1.77 or greater (or 0.57 or lower); smaller differences, including the observed effect, could not be reliably excluded (Table 2).

Feeding efficiency, assessed by achievement of Level 4 (L4), was also similar between groups at all predefined time points (Day 5, 7, and 14). Additionally, no statistically significant differences were observed in adverse events, feeding volumes, rate of transfer (RT), overall transfer (OT), or proficiency (PRO) between the two groups (Table 3).

The incidence of adverse events during stimulation and feeding sessions was low in both groups and did not differ significantly. No adverse events were recorded beyond Day 5 in either group. The proportion of neonates demonstrating coordinated suck–swallow–breathe (SSB) patterns increased progressively over time in both groups, with no significant between-group differences at any assessed time point.

Kaplan–Meier survival analysis demonstrated comparable time-to-event distributions for achieving full oral feeding between the experimental and control groups (Figure 2). The log-rank test confirmed no statistically significant difference between groups (p = 0.984).

Unadjusted Cox proportional hazards regression analysis showed no significant association between the intervention provider and time to achieve full oral feeding (hazard ratio [HR] 1.016, 95% confidence interval [CI] 0.637–1.619; p = 0.948).

After adjustment for gestational age, the association between intervention group and time to full oral feeding remained non-significant (adjusted HR 1.045, 95% CI

Table 3. Comparison of feeding outcomes between mother-administered and nurse-administered stimulation groups".

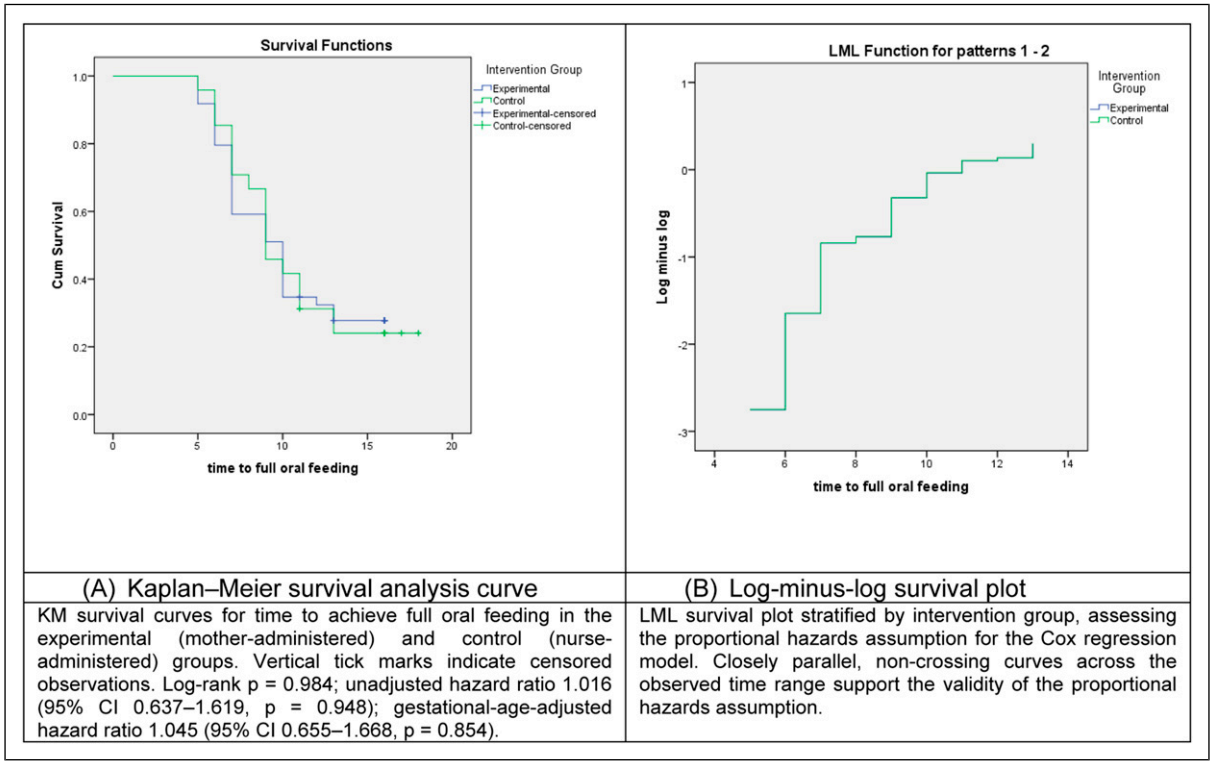
Outcome	Day	Experimental (n = 49)	Control (n = 48)	p-value
Time to full oral feed (days)	—	10 (7–13)	9 (7–13)	0.531
Adverse events, n (%)	D1	36 (73.5%)	31 (64.6%)	0.234
	D2	14 (28.6%)	14 (29.2%)	0.563
	D3	12 (24.5%)	12 (25.0%)	0.570
	D5	2 (4.1%)	0 (0.0%)	0.253
	D7 & 14	0 (0.0%)	0 (0.0%)	NA
L4 efficacy, n (%)	D1–3	0 (0.0%)	0 (0.0%)	NA
	D5	12 (24.5%)	9 (18.8%)	0.331
	D7	16 (32.7%)	15 (31.3%)	0.528
	D14	35 (71.4%)	36 (75.0%)	0.434
Volume taken each feed (mL), median (IQR)	D1	2.0 (2.0–7.0)	2.0 (2.0–7.0)	0.803
	D2	5.0 (2.0–9.0)	3.0 (2.0–7.0)	0.558
	D3	7.0 (3.0–11)	4.0 (3.0–10.0)	0.540
	D5	8.0 (5.0–15)	6.5 (5.0–15)	0.521
	D7	9.0 (7.0–18)	7.5 (7.0–20)	0.951
	D14	15 (13–20.5)	15.5 (14–22)	0.737
Volume in first 5 min (mL), median (IQR)	D1	2.0 (1.0–4.5)	2.0 (1.25–4.0)	0.938
	D2	3.0 (2.0–6.0)	3.0 (2.0–5.0)	0.988
	D3	3.0 (2.0–7.0)	3.0 (2.0–7.0)	0.723
	D5	5.0 (4.0–9.0)	5.0 (4.0–8.0)	0.817
	D7	7.0 (5.5–11)	7.0 (6.0–10)	0.895
	D14	10 (9.0–12.5)	10 (9.0–10)	0.618
RT (mL/min), median (IQR)	D1	0.42 (0.24–0.85)	0.42 (0.28–0.70)	0.835
	D2	0.70 (0.59–1.0)	0.71 (0.70–1.0)	0.663
	D3	0.70 (0.40–1.0)	0.70 (0.40–1.0)	0.941
	D5	0.83 (0.50–1.45)	0.90 (0.50–1.2)	0.645
	D7	1.0 (0.68–1.6)	1.0 (0.67–1.7)	0.584
	D14	1.6 (1.10–2.1)	1.6 (1.10–2.1)	0.913
OT (%), median (IQR)	D1	21 (15–36)	21 (15.3–36)	0.936
	D2	36 (15–44)	35.7 (15–36)	0.422
	D3	43.8 (21–55.5)	43.8 (21–50)	0.551
	D5	48 (33–65)	48 (33–65)	0.700
	D7	60 (46–73.5)	56 (46–100)	0.950
	D14	91 (87–100)	95.5 (87.9–100)	0.521
PRO (%), median (IQR)	D1	16 (7.8–24)	16 (9.2–21)	0.948
	D2	21.6 (15–32.5)	21 (15–27)	0.847
	D3	23 (14–37)	19.5 (14–31)	0.499
	D5	30 (25–39)	29 (24.5–39)	0.629
	D7	39 (33–49.5)	39 (32–46)	0.872
	D14	56 (50–60)	55.8 (46–56)	0.630
SSB-coordinated feeding, n (%)	D1	23 (46.9%)	22 (45.8%)	0.538
	D2	33 (67.3%)	27 (56.3%)	0.180
	D3	33 (67.3%)	32 (66.7%)	0.746
	D5	40 (81.6%)	37 (77.1%)	0.381
	D7	39 (79.6%)	36 (75.0%)	0.383
	D14	49 (100.0%)	48 (100.0%)	NA

RT, rate of milk transfer; OT, overall transfer; PRO, feeding proficiency; L4, feeding efficiency level 4 (most mature feeding pattern, derived from combined PRO and RT classification); SSB, suck–swallow–breathe coordination; D, day; IQR, interquartile range.

0.655–1.668; $p = 0.854$), indicating the null finding was not confounded by gestational age. Gestational age itself was a strong independent predictor of time to full oral feeding (HR 0.199, 95% CI 0.116–0.342; $p < 0.001$), consistent with expected clinical maturation of feeding skills.

Discussion

This MSMS trial found no statistically significant difference in time to achieve full oral feeding between maternal- and nurse-administered sensory-motor stimulation. The study is among the first to structurally integrate trained



(A) Kaplan–Meier survival analysis curve	(B) Log-minus-log survival plot
KM survival curves for time to achieve full oral feeding in the experimental (mother-administered) and control (nurse-administered) groups. Vertical tick marks indicate censored observations. Log-rank p = 0.984; unadjusted hazard ratio 1.016 (95% CI 0.637–1.619, p = 0.948); gestational-age-adjusted hazard ratio 1.045 (95% CI 0.655–1.668, p = 0.854).	LML survival plot stratified by intervention group, assessing the proportional hazards assumption for the Cox regression model. Closely parallel, non-crossing curves across the observed time range support the validity of the proportional hazards assumption.

Figure 2. Kaplan–Meier survival curves and log-minus-log plot for time to achieve full oral feeding by intervention group.

mothers as active providers of this intervention for preterm neonates.

Feeding efficiency progressed similarly between groups, without any increase in adverse events, with approximately 70% of neonates in both groups achieving Level 4 feeding by Day 14. As both groups received an identical standardized sensory–motor stimulation protocol, differing only in the provider, this trial was not intended to determine the efficacy of sensory–motor stimulation itself. Instead, it evaluated whether trained mothers could administer the intervention with outcomes comparable to those achieved by trained nurses. Within that scope, the similar progression observed across groups is consistent with the Synactive Theory of neonatal development, which emphasizes the role of coordinated multisensory input, including caregiver touch and voice, in supporting autonomic and motor maturation.[6,7]

These findings support the feasibility of incorporating structured oral motor stimulation into maternal participation in neonatal care within a supervised framework. This approach is consistent with the principles of family-centered care, which recognize parents as active partners in the care of hospitalized neonates and have been associated with improved neonatal outcomes, enhanced parent–infant bonding, and greater caregiver confidence.[17–19] Models such as Kangaroo Mother Care exemplify this approach in resource-limited settings by positioning mothers as active partners in neonatal care.[13,20]

Maternal involvement in neonatal care has gained increasing attention, particularly in resource-limited settings.[21] Majoli et al. demonstrated that parent-administered Preterm Infant Oral Motor Intervention (PIOMI) performed similarly to professional administration in reducing time to independent oral feeding and hospital stay, without additional adverse effects.[9] Reiter et al. reported that parental participation is associated with improved breastfeeding rates, reduced mortality, and lower readmission rates, particularly in middle-income countries.[22] Moreover, modest parental involvement in feeding has been linked to shorter time from feeding initiation to discharge.[23,24] In the present study, maternal-administered stimulation was implemented as a structured, supervised intervention with standardized competency-based training, and no significant difference in outcomes was observed relative to nurse-administered stimulation. Maternal involvement in feeding-related care may also enhance parent–infant interaction, which is relevant to emotional and physiological stability, although this was not directly assessed in the present study.[13,25,26]

Feeding readiness in preterm neonates does not depend solely on gestational age.[11,27] Lau et al. demonstrated that neonates around 30 weeks PMA can complete oral feeds despite immature sucking patterns, supporting an individualized, cue-based approach to feeding readiness.[28]

The literature on oral stimulation and time to full oral feeding is mixed, with some studies reporting benefit over

standard care and others finding no significant difference.[5,29–37] Unlike trials comparing active stimulation against no stimulation, the present study compared two active delivery approaches, which likely explains why no between-group difference emerged in either time to full oral feeding or NICU stay ($p = 0.848$)—a finding of who delivered the intervention, not of the intervention's effect itself. This was corroborated by the time-to-event analysis (Kaplan–Meier, log-rank, and Cox regression; see Results), which showed consistent null findings across all three approaches.[38,39]

Overall, no statistically significant difference was observed between maternal- and nurse-administered sensory–motor stimulation in time to full oral feeding or associated feeding outcomes. As this trial was not powered for non-inferiority or equivalence, these findings should be considered exploratory rather than confirmatory of comparable safety or effectiveness. They provide preliminary support for incorporating trained mothers as active participants in structured neonatal feeding interventions, consistent with family-centered care principles, and offer a rationale for a properly powered non-inferiority trial, particularly relevant to settings with limited healthcare resources.

Strengths

Strengths of this MSMS trial include its randomized controlled design, blinded outcome assessment, use of standardized and competency-based training for the maternal-administered arm, and use of an identical stimulation protocol across both groups to isolate the effect of intervention provider. Statistical analysis incorporated time-to-event analyses using Kaplan–Meier and Cox regression methods and post-hoc power estimation. The study is also among the first from a resource-limited setting to evaluate structured maternal engagement of sensory–motor stimulation for oral feeding establishment in preterm neonates.

Limitations

This RCT has many limitations. The study was conducted at a single center and included only clinically stable preterm neonates, which may limit generalizability. The original sample size was not based on the primary outcome and was not formally recalculated after enrollment exceeded the initial target; the achieved sample had 80% power to detect a hazard ratio of ≥ 1.77 or ≤ 0.57, and as this was a superiority rather than non-inferiority trial, the null result should not be interpreted as evidence of clinical equivalence or equal safety. Blinding of intervention providers was not feasible, and the per-protocol analysis, which excluded 33 neonates who did not complete their allocated intervention (several for illness-related reasons), may not fully preserve randomization balance. Secondary outcomes were analyzed at each time point independently rather than through a repeated-measures model, without correction for multiple comparisons. As both groups received identical active stimulation, this trial evaluates who delivered the intervention rather than its effect relative to no stimulation, and longer-term neurodevelopmental outcomes were not assessed. Future multicenter studies with larger sample sizes are warranted to confirm these findings and evaluate long-term neurodevelopmental and feeding outcomes.

Conclusion

In this cohort of clinically stable preterm neonates, no statistically significant difference was observed between maternal- and nurse-administered sensory-motor stimulation in time to full oral feeding, feeding performance, or adverse events. As this trial was not powered for non-inferiority or equivalence, these findings should be considered exploratory rather than confirmatory of comparable safety or effectiveness. They provide preliminary support for integrating trained mothers into structured feeding interventions and for the broader value of family-centered care in resource-limited neonatal settings and highlight the need for a properly powered non-inferiority trial to confirm these findings.

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Ethical considerations

The study received approval from the Institutional Review Board of Fatima Memorial Hospital (FMH-07-2021-IRB-929-M) and was conducted in accordance with the Declaration of Helsinki. The trial was retrospectively registered at ClinicalTrials.gov (NCT05484726) on August 3, 2022, and participant enrollment began only after registration approval. The study was conducted from May 2022 to September 2023. The study protocol can be accessed at: https://www.clinicaltrials.gov/ct2/show/NCT05484726.

Consent to participate

Written informed consent was obtained from all participating mothers, and parental consent was secured for all neonates. Parents were fully briefed on the study purpose, procedures, potential risks, and expected benefits prior to enrollment.

Authors' contributions

Rafia Gul (RG) led the study from conception to completion, including study design, participant recruitment, intervention oversight, data collection, statistical analysis, and drafting the manuscript. She also serves as the corresponding author.
Saqib Aslam (SA) contributed to study design, statistical analysis, and manuscript revision.
Samer Fatima (SF) assisted with intervention delivery and neonatal assessments.
Sidra Nayamat (SN) supported data collection and study procedures.
Saher Gul Ahdi (SGA) provided methodological guidance and critical review.
Fizza Yaqoob (FY) contributed to data management and preparation of tables and figures. All authors read and approved the final manuscript.

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Declaration of conflicting interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Data Availability Statement

The data that support the findings of this study are not publicly available to protect participant confidentiality. However, details can be obtained from the corresponding author upon reasonable request and with institutional approval.

Trial registration

• Trial registered at ClinicalTrials.gov on August 3, 2022 (NCT05484726)
• The study protocol can be accessed at: https://www.clinicaltrials.gov/ct2/show/NCT05484726.

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Appendix

Abbreviations

MSMS	Maternal Sensory Motor Stimulation
RCT	Randomized Controlled Trial
CONSORT	Consolidated Standards of Reporting Trials
IRB	Institutional Review Board
NICU	Neonatal Intensive Care Unit
FCC	Family-Centered Care
TLC	Tender Loving Care
KMC	Kangaroo Mother Care
OFS	Oral Feeding Skills
SMS	Sensory Motor Stimulation
PIOMI	Preterm Infant Oral Motor Intervention
OMI	Oral Motor Intervention
NNS	Non-nutritive Sucking
SSB	Suck–Swallow–Breath Coordination
PMA	Postmenstrual Age
ChA	Chronological Age
AGA	Appropriate for Gestational Age
SGA	Small for Gestational Age
LGA	Large for Gestational Age
PRO (%)	Proficiency
OT (%)	Overall Transfer
RT (ml/min)	Rate of Transfer
TV	Total Volume
TV5	Volume Taken in the First 5 Minutes
L1–L4	Oral Feeding Efficiency Levels
PG	Primigravida
DM	Diabetes Mellitus
RDS	Respiratory Distress Syndrome
HsPDA	Hemodynamically Significant Patent Ductus Arteriosus
NEC	Necrotizing Enterocolitis
IEM	Inborn Error of Metabolism
IVH	Intraventricular Hemorrhage
IMV	Invasive Mechanical Ventilation
NIV	Non-Invasive Ventilation
LFNC	Low-Flow Nasal Cannula
SpO_2	Peripheral Capillary Oxygen Saturation
IQR	Interquartile Range
SD	Standard Deviation
SPSS	Statistical Package for the Social Sciences