



Full length article

## Effectiveness of multistimulation approach on feeding habits of low-birth-weight babies-A randomized control trial

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## ABSTRACT

**Introduction:** Low- birth- weight neonates face oral feeding difficulties due to hemodynamic instability, immaturity of central nervous systems, and incomplete development of oral functions. Use of several interventions might help in improvement of the feeding ability of neonates. The objective of the study was to evaluate the effect of the multistimulation approach in low-birth-weight babies on the oral feeding performance, oral intake volume, weight gain and transition time from tube to total oral intake.

**Methods:** A Randomized, parallel-group, multiple arm trial study was conducted, and a total of 44 low birth weight babies were randomized into three parallel groups with a 2:1:1 ratio. Babies who are Hemodynamically stable were included in the trial. In two Intervention groups, one received an oral stimulation program, another intervention group received tactile stimulation, and the control group received routine newborn procedures for the same duration of time. Oral feeding performance was determined by Oral Feeding Skills (OFS) on a daily basis for five days after providing ten days of intervention. Neonates were monitored until hospital discharge.

**Results:** Infants in the stimulation groups had significantly better oral feeding performance than infants in the control group in terms of mean proficiency, transfer rate and overall transfer of feeding volume. There was a substantial increase in mean feeding score, daily weight, oral intake volume, and early transition time in both intervention groups compared to control. There was no significant difference in feeding behaviours between the oromotor and multistimulation groups, but the multistimulation group gained more weight compared to the oromotor group.

**Conclusions:** Infants exposed to the stimulation programme had better feeding skills and a shorter transition period from tube feeding to oral feeding; however, the babies who received multistimulation gained greater weight than babies who received only oromotor stimulation. The study recommends multi stimulation in the form of oromotor, and tactile stimulation can be used as an effective NICU procedure for maintaining an infant's ability to take feeds orally before being discharged from the hospital.

### 1. Introduction

Low birth weight (LBW) babies are babies with a birth weight of less than 2500 gm regardless of gestational age [1]. According to the National Family health survey-4, the prevalence in India is 18.2 % [2]. Odisha contributes to 20.8 % of LBW babies in India [2].

Oral feeding difficulty is the primary concern for LBW babies. Immature oromotor skills and incoordination of sucking, swallowing, and breathing is the causes of feeding difficulties in LBW babies. Ineffective and disorganized feeding may lead to exhaustion in the infant

and further contributes to weight loss or inadequate weight gain.

Oromotor intervention includes manipulative actions that activate muscle contractions, enhance movement, and help in building the strength of the oral cavity. There are two main objectives of the oromotor stimulation; one is to increase functional response to pressure and movement, and the other is to maintain the rhythm in sucking- swallowing activity [3]. Oromotor stimulation has a positive effect on oral feeding performance in preterm infants, which is proved by many studies [4-6].

The greatest sense organ and the first sensory system to function is

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the skin. Touch is the best modality to ensure and strengthen the everlasting mother-infant bond [7]. A touch experience is also essential for physical and cognitive development [8]. Tactile stimulation involves gentle stroking massage for a specified period in a sequence of upper and lower body parts in the supine position. A review has indicated that massage has various beneficial effects on weight gain, better sleep-wake patterns, more neuromotor development, emotional bonding, and decreased nosocomial infection in neonates and preterm babies [9].

A persistent unorganized suck-swallow pattern is a barrier to the early beginning of breastfeeding in low-birth-weight babies admitted to the NICU. Stimulation is the best key to success in achieving oral feeding performance and sustaining breastfeeding. Many studies have been done on oromotor stimulation, but few studies have been done on the multistimulation approach for improving the feeding ability of preterm babies. Therefore, the present study was aimed to evaluate the effectiveness of the multistimulation approach in LBW babies on the oral feeding performance, the first oral feeding and transition time from tube to total oral intake.

## 2. Methods

### 2.1. Trial design

A double-blinded with three parallel groups was conducted to compare the effect of multistimulation technique on the feeding habits of low-birth-weight babies. The Institutional Ethics Committee approved the study protocol, and the local authorities in the study setting had granted authorization. The study followed the Consolidated Standards of Reporting Trials (CONSORT) guidelines, and the Clinical Trials Registry was used to register the study.

### 2.2. Eligibility of participants and study setting

The recruitment period was from October 2020 to December 2020. Eligibility criteria were hemodynamically stable babies with weight  $\geq$  1500 gm to  $<$  2500 gm. Babies with other co-morbidities like congenital malformations, intracranial haemorrhage and necrotizing enterocolitis were excluded from the study. The study was conducted in the special newborn care units (SNCU) of the District Headquarters Hospital, Khurda, Odisha, located in rural south-eastern India.

### 2.3. Sample size calculation

Based on a prior study [10], the minimum sample size in each group was determined using the standard accepted method for a randomized control trial, given a significance level of 5 % and power of 80 %. However, the final sample size in each group was taken 22, including a 10 % attrition rate.

### 2.4. Randomization and blinding

Following the screening for inclusion criteria, the participants' parents were informed regarding the study's goals, and informed consent was taken by detailing the care involved in the routine, oromotor, and multistimulation groups and assuring confidentiality of the information submitted. The statistician performed the randomization process using the Random Allocation Software environment ([www.rando mizer.org/form.htm](http://www.rando mizer.org/form.htm) (2018)) to prepare the numbered sealed opaque envelopes. Concealment was done through sealed, opaque envelopes. Participants were randomly assigned to three parallel groups with a 2:1:1 ratio. The control group received routine care, one experimental group received oromotor group, and another group received multistimulation (oromotor and tactile stimulation). The nursing officer opened the consecutively numbered envelope to allocate the participants into intervention groups and informed the investigator of the assigned treatment. The used envelopes were discarded after the allocation of participants.

Double blinding was ensured to minimize the bias. The parents of the study were unaware of the treatment received by the baby as the babies were in NICU. The nursing officer assessed the outcomes who didn't know about what type of intervention was welcomed by which baby.

### 2.5. Procedures

The study intervention was started according to the clinical stability of newborn babies. All 22 infants were taken away from parents and nursing staff during the intervention periods, 15–30 min before tube feeding. The intervention group (G I) received an actual oral stimulation programme, as proposed by Fucile et al. [11], consisting of stroking the cheeks in a circular motion and stroking the vestibular region of the lips, gums, and tongue with the fingertips in an anteroposterior direction for the first 12 min of stimulation. Non-nutritive sucking was used for the last three minutes of stimulation. Another intervention group (G II) had received tactile stimulation followed by oral stimulation one minute apart. Tactile stimulation consisted of gentle rubbing with each step for 5 s period in the sequence of gentle rubbing of the infant's neck, gentle rubbing of the back or chest (from the neck to the waist), gentle rubbing of the infant's legs (from thigh to foot), rubbing of infant's arms (from shoulder to hand), lastly gentle rubbing of the infant's head (from forehead to ear). All neonates received standard care, and the intervention was administered for 10 consecutive days for blinding purposes. The control group (G III) received routine newborn care that consisted of staying near the incubator for the same amount of time as the intervention group, positioning the newborn in the proper posture, and providing breastfeeding support, but without giving any stimulation procedures. This routine intervention was also administered for 10 consecutive days.

The investigator had undergone skill training from a speech therapist and occupational physiotherapist for oromotor and tactile stimulation. The same therapist reassessed the accuracy of performing the procedure while performing the pilot study intervention. The feeding procedures were identical for all the groups. Feeding habits were assessed daily for 5 days, including feeding habit score, intake volume, transition time, and daily weight by the nursing officer through an observational checklist. Informed written consent was taken from all the parents of babies before administering the procedures, and it was assured that confidentiality would be maintained.

### 2.6. Outcome assessment

Once the neonate was clinically stable, primary outcome parameters were assessed at 33 weeks or older postmenstrual age (regardless of weight). The feeding assessment was performed during the first attempt at oral feeding, as prescribed by the attending physician. The primary feeding outcome in terms of oral feeding performance and daily oral intake was measured on a daily basis for five days after providing ten days of intervention.

The oral Feeding Skills (OFS) checklist was administered to measure the infants' oral performance, which included total volume prescribed (ml), total volume taken during feeding (ml), volume taken during the first 5 min of feeding (ml), duration of oral feeding (min), and any episodes of adverse events, such as cough, oxygen desaturation, apnea, and/or bradycardia. Neonates' feeding performance was timed with a stopwatch. Infants were fed for a maximum of 20 min; the assessment was early discontinued if adverse events occurred. Feeding outcomes such as proficiency (PRO, % volume taken during the first 5 min/total volume prescribed), overall transfer (OT, % volume taken/total volume prescribed) and rate of transfer (RT, ml/minute) were calculated from the datasheet. A nursing officer of the NICU filled the oral feeding checklist.

2.7. Statistical analysis

The collected data were coded and entered into an excel spreadsheet, cleaned, and checked for missing values. SPSS Statistics version 20 (IBM, Armonk, NY) analyzed the data. The baseline neonatal characteristics and clinical parameters were expressed in frequency ( %), mean, and standard deviation. One-way ANOVA (mean and standard deviation), Kruskal–Wallis test (median and interquartile range) and Fisher’s exact test were used to determine the significant improvements in the feeding outcome parameters.

3. Results

3.1. Sample characteristics

During the study period, 117 LBW babies were admitted to the NICU. Of these, 109 preterm neonates were considered to be eligible, among which eight babies were excluded; hence 44 were randomized into three groups. There were three samples lost, and 41 remained in the study

until hospital discharge (Fig. 1).

The newborn characteristics of the study population are shown in Table 1. Three groups were comparable in terms of gestational age, birth weight, Apgar score at 5-minutes or 10-minutes and use of mechanical ventilation. During the clinical assessment of OFS, the mean gestational age was  $34.25 \pm 2.78$  in the control group,  $35.2 \pm 0.919$  in oromotor stimulation group and  $34.55 \pm 1.572$  g in the multistimulation group ( $P = 0.535$ ). Mean weight at oral feeding assessment was  $2182.5 \pm 259.02$  g in the control group,  $1930.91 \pm 269.6$  g in the oromotor stimulation group and  $1965.5 \pm 279.27$  g in the multistimulation group ( $P = 0.077$ ). There was no significant difference in gestational age, birth weight, heart rate or oxygen saturation before or after assessment, or between the three groups.

3.2. Comparison of oral feeding performance among LBW babies

Table 2 shows a significant difference in oral feeding performance among the three groups. Infants in the intervention groups had significantly better rates than infants in the control group in: mean proficiency

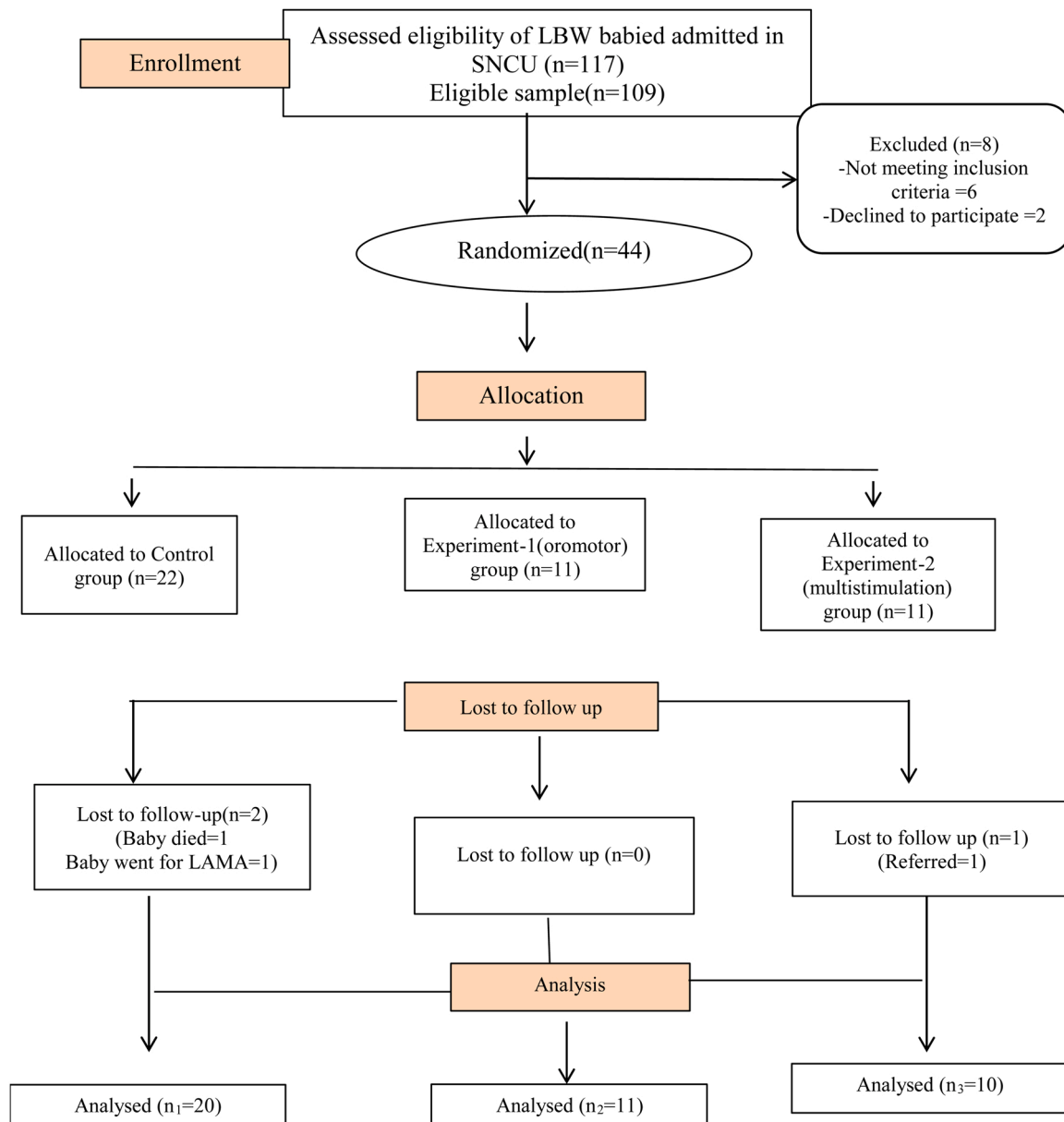


Fig. 1. Consolidated Standards of Reporting Trials (CONSORT) flow diagram of the study.

**Table 1**  
Base line comparison of neonatal characteristics and clinical characteristics.

Neonatal characteristics	GI (Control) (n = 22)	GII (Oromotor stimulation) (n = 11)	GIII (Multistimulation) (n = 10)	P-value
<b>Baseline assessment</b>				
<i>Gender<sup>a</sup></i>				
Male	12 (60 %)	9 (81.8 %)	6 (60 %)	0.441
Female	8 (40 %)	2 (18.2 %)	4 (40 %)	
<i>Gestational Age (wk)<sup>b</sup></i>				
28–29 <sup>a</sup>	30.25 ± 2.78	30.55 ± 1.572	31.2 ± 0.919	0.535
30–31 <sup>a</sup>	4(18.18 %)	2(18.18 %)	2(20.00 %)	0.960
32–33 <sup>a</sup>	8(36.36 %)	4(36.36 %)	3(30.00 %)	
Birth weight (gm) <sup>b</sup>	1923.5 ± 315.03	1868.2 ± 271.986	2076 ± 248.471	0.077
Apgar score at 5min <sup>c</sup>	7 (4–8)	6 (5–8)	7 (5–8)	1.000
Apgar score at 10min <sup>c</sup>	8 (8–9)	8 (7–9)	8 (8–9)	0.684
Mechanical ventilation <sup>a</sup>	6 (27.27)	4 (36.36)	3 (30.00)	1.000
<b>Clinical assessment of OFS</b>				
<i>Gestational Age (wk)<sup>b</sup></i>				
Birth weight (gm) <sup>b</sup>	34.25 ± 2.78	35.2 ± 0.919	34.55 ± 1.572	0.535
	1965.5 ± 279.27	1930.91 ± 269.6	2182.5 ± 259.02	0.067

<sup>a</sup> Fisher's exact test (frequency and percentage)

<sup>b</sup> One-way ANOVA (mean and standard deviation)

<sup>c</sup> Kruskal–Wallis test (median and interquartile range)

**Table 2**  
Comparison of oral feeding clinical assessment between the groups.

	GI (Control) (n = 22)	GII (Oromotor stimulation) (n = 11)	GIII (Multistimulation) (n = 10)	P-value
PRO ( %) <sup>a</sup>	19.9 ± 11.6	39.5 ± 17.3	44.5 ± 16.4	< 0.001
RT (ml/min) <sup>b</sup>	2.3 (1.6–2.9)	1.3 (0.8–1.9)	1.1 (0.9–2.5)	< 0.001
OT ( %) <sup>a</sup>	35.0 ± 15.7	54.2 ± 16.7	58.2 ± 14.5	< 0.001
Initial heart rate <sup>a</sup>	162 ± 8.5	162 ± 8.3	162 ± 8.4	1.300
Final heart rate <sup>a</sup>	168 ± 9.7	166 ± 9.0	166 ± 9.0	0.526
Initial oxygen saturation <sup>b</sup>	97 (97–99)	98 (96–98)	97 (96–98)	0.365
Final oxygen saturation <sup>b</sup>	98 (95–99)	98 (97–100)	98 (96–100)	1.952

PRO (proficiency) RT (rate of milk transf) OT (overall transf).

<sup>a</sup> One-way ANOVA (mean and standard deviation)

<sup>b</sup> Kruskal–Wallis test (median and interquartile range)

(PRO) ( $P < 0.001$ ), transfer rate (RT) ( $P < 0.001$ ) and overall transfer (OT) ( $P < 0.001$ ). There was no significant difference in adverse events during the oral feeding assessment was reported. Desaturation was observed in 3 infants of each group ( $P > 0.5$ ). Bradycardia and vomiting were observed in 1 preterm neonate in each of the control and oromotor stimulation groups ( $P > 0.5$ ). Choking was observed in 1 preterm neonate of the control group and 1 preterm in the multistimulation group ( $P > 0.5$ ). Gag reflex was observed in 2 infants of control and oromotor stimulation ( $P > 0.5$ ). During the oral feeding assessment, there were no occurrences of apnea, cyanosis, pallor, or hiccups in any of the three groups.

### 3.3. Comparison of oral intake volume and daily weight gain among LBW babies

Table 3 illustrates the mean difference in the percentage of volume taken via the oral route in the first 5 days after the initial assessment. Infants in the oromotor and multistimulation group were less likely to achieve 100 % oral feeding than those in the control group, over the same period ( $P = 0.024$ ).

Fig. 2 shows Fisher LSD Post hoc tests to compare the weight gain among three groups, which revealed no statistically significant difference in mean weight gain between the control and Oromotor group (Mean difference = 37.25 g and  $P = 0.728$ ). In contrast, the mean weight in the multistimulation group showed a significant improvement as compared to the oromotor group (Mean difference = 272.67 g and  $P = 0.033$ ) and control group (Mean difference = 235.42 g and  $P = 0.033$ ).

### 3.4. Comparison of transition time to independent oral feeding

Table 4 indicates the difference in the mean transition time between the three groups using one-way ANOVA. Transition time in feeding was achieved early among babies who had received multistimulation followed by babies who had received oromotor stimulation as compared to babies who had received only routine newborn care with respect to 1–2 feeds/day ( $F = 10.271$ ,  $P < 0.001$ ), 4 feeds/day ( $F = 19.7911$ ,  $P < 0.001$ ) and 8 feeds/day ( $F = 44.484$ ,  $P < 0.001$ ).

## 4. Discussion

The present study revealed that improvement of mean feeding scores was significantly greater in the multistimulation group followed by the oromotor group as compared to babies who received only routine care. The results were supported by a quasi-experimental study done in Kolkata that showed that the breastfeeding efficiency score among preterm babies in the experimental group receiving oromotor stimulation was higher than that of the control group, which was statistically significant [12]. A meta-analysis proved the improvement of feeding efficiency in preterm infants after receiving oromotor intervention [13]. A quasi-experimental study in Indonesia revealed a significant increase in suckling frequency and duration in the interventional group (massage) compared to the non-interventional group [14]. On the contrary, a quasi-experimental study in Lebanon reported no significant difference in breastfeeding duration between the two groups, i.e., massage and control [15]. An RCT done in Korea demonstrated no significant difference in breastfeeding rate between the massage group and the control group among premature infants [16]. Thus, oromotor and multistimulation have a similar effect on the feeding habit score of LBW babies.

There is considerable evidence that the provision of oromotor intervention through non-nutritive sucking or sensory stimuli to the oral structures has beneficial effects on volume intake in hemodynamically stable preterm infants [17]. The intraoral stimulation applied to the upper and lower gum might have improved the movement of the tongue, which strengthens suction ability during sucking and maintain the swallow pattern, which increases the intake per suck [18]. Tactile stimulation given to babies might have resulted in an inactive state during feeding and increased oral intake [14]. The present study reported that as time progressed, babies of each group had increased oral intake volume. The oral intake volume had increased from day 0 to day 5 within all groups, but this increase was significantly higher within the multistimulation group, followed by the oromotor group than the control group. These findings were consistent with the meta-analysis done in China revealed that 5-minutes prefeeding oromotor intervention had significantly increased feeding intake volume [13]. A quasi-experimental study conducted in NICUs of Cairo University reported an increase in total oral intake rate following the second session

**Table 3**  
Comparison of oral intake volume (ml/feed) of LBWbabies within the groups across the days.

Group	Oral Intake volume (ml/feed) (Mean difference)						P-value
	Day 0	Day 11	Day 12	Day 13	Day 14	Day 15	
Oromotor vs Control	8.3 ± 7.09	9.95 ± 7.2	12.95 ± 6.1	15.25 ± 6.46	19.25 ± 5.91	22.5 ± 5.26	< 0.001 *
Multistimulation vs Control	8.3 ± 4.735	12.73 ± 7.198	17.27 ± 6.604	20.91 ± 6.252	25.27 ± 7.336	28.27 ± 6.405	< 0.001 *
Multistimulatio vs Oromotor	6.7 ± 2.98	12.8 ± 6.29	20.2 ± 5.6	22.2 ± 5.12	25.7 ± 4.9	30.2 ± 3.86	0.008

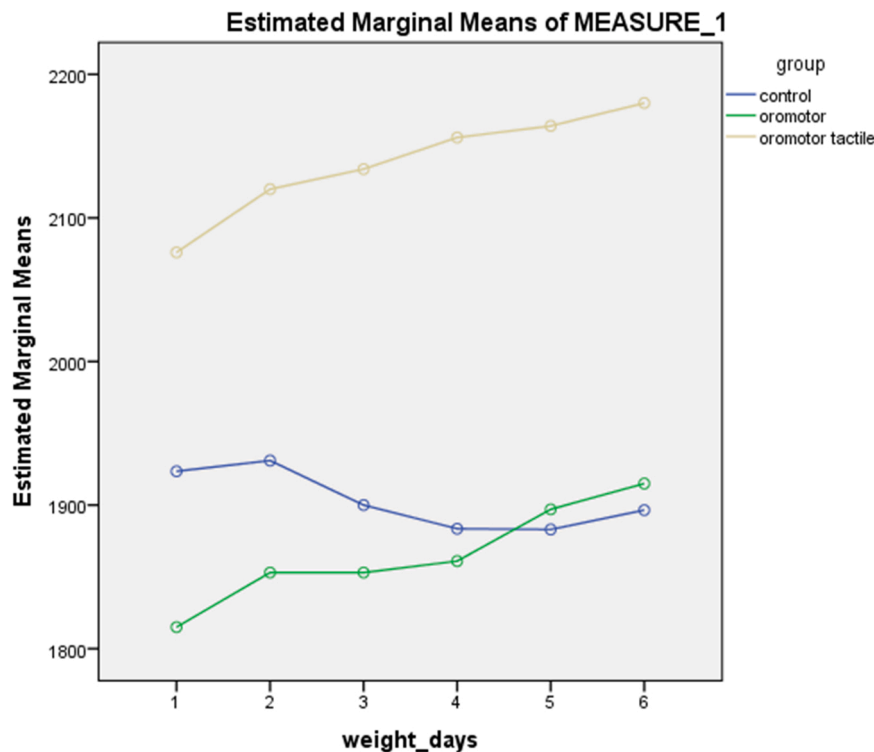


Fig. 2. Fishers LSD Post Hoc comparison of weight (grams) between experimental and control groups across time.

**Table 4**  
Comparison of transition time (number of days to reach independent oral feeding) across the groups(n = 41).

Parameters (Breastfeeding)	Transition time			F-test	P value
	GI (Control)	GII (Oromotor stimulation)	GIII (Multistimulation)		
1-2 feeds/day	2.80 ± 0.410	2.10 ± 0.568	2.20 ± 0.422	10.271	< 0.001
4 feeds/day	5.40 ± 0.883	3.90 ± 0.568	4.00 ± 0.471	19.791	
8 feeds/day	9.25 ± 1.293	6.20 ± 0.632	6.30 ± 0.483	44.484	

F: One-way ANOVA, level of significance P < 0.05

of oromotor stimulation compared to the control group [19]. However, the evidence generated by an RCT done in Chandigarh had refuted the increased oral intake in the group who received oromotor intervention [20].

The early transition to independent feeding was demonstrated by regular intervention with specific perioral and intraoral stimulation [11]. The present study also resulted in enhanced oral feeding skills. The intake volume increased rapidly and progressed to full independent oral feeding earlier in the oromotor and multistimulation groups compared with the control group. An RCT done in Chandigarh reported that significantly less median transition time (days) taken to reach partial spoon feed and full spoon feed by the intervention group (oromotor stimulation) as compared to the control group, which is consistent with the results of the present study [20]. Some studies have shown no significant difference in the transition time between the oromotor and

control groups, which contradicts the result of the present study [21,22]. In comparison, some literature had found that preterm infants who received 15 min of tactile/kinaesthetic stimulation thrice a day, for 10 days had better motor activity, weight gain, gastrointestinal motility, more alert behavioural states, and better neurobehavioral organization than those who did not receive the intervention [23,24]. Thus, our study supports that multistimulation is an essential intervention for improving infants' growth and motor development and might also have a synergic effect on enhancing oral feeding skills.

4.1. Study limitations

Although the multistimulation programme in the double-blinded RCT study presented significant effectiveness for improving the feeding outcomes among premature babies, the study had some

limitations which should be cautiously considered when interpreting the results. First, all of the babies in the study were recruited from the NICU of a single health centre. Thus, the results may not be generalized to the population in different centres. Another limitation was multistimulation programme only covered oromotor and tactile stimulation, whereas auditory, olfactory, gustatory, or kinaesthetic stimulation, among other things, could be included for a better outcome.

## 5. Conclusion

Based on our findings, significant improvement in feeding habits and weight was seen in the LBW babies who had received oromotor and multistimulation compared to the babies who had received only received conventional NICU treatment. It concludes that oromotor stimulation or a combination of oromotor with tactile stimulation (multistimulation) are equally beneficial and effective approaches for the improvement of feeding habits of LBW babies. Furthermore, when comparing newborns who had received only oromotor stimulation to babies who had received multistimulation (oromotor and tactile stimulation), the study found that multistimulation resulted in a substantial improvement in mean weight gain. The study suggested the provision of multistimulation (oromotor and tactile stimulation) to LBW babies to get maximum output in their feeding ability and growth.

## Ethical Approval

This study was approved by the Institutional Review Committee of AIIMS, Bhubaneswar, Odisha, India (Ref No: IEC/ AIIMS BBSR/ Nursing / 2019–20 /29).

## CRediT authorship contribution statement

**Deepa Negi:** Conceptualization, Methodology, Investigation, Formal analysis, Data curation, Resources, Writing – original draft. **Swain Dharitri:** Conceptualization, Methodology, Formal analysis, Writing – original draft. **Tapas Kumar Som:** Methodology, Software, Writing – review & editing.

## Conflict of interest

No conflict of interest has been declared by the authors.

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