

# Effect of Combined Modalities of Prefeeding Stimulation and Kinesitherapy on Oral Motor Response, Feeding Tolerance and Body Weight Among Preterm Newborns Admitted at SNCU in Tertiary Care Hospital in West Bengal: Study Protocol

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## ABSTRACT

**Background:** Preterm newborns experience immature oral motor function, feeding intolerance, and inadequate weight gain due to underdeveloped neurological, gastrointestinal, and musculoskeletal systems. These problems are the main cause of delay the transition to full oral feeding, prolong hospitalization, feeding intolerance and increase the risk of complications.

**Need for the study:** Oromotor stimulation before feeding has been shown to improve oral motor skills and feeding readiness, while kinesitherapy enhances neuromuscular function, physiological stability, and motor development. But there is limited evidence available regarding the combined effect of these two interventions on oral motor response, feed tolerance, body weight and duration of hospital stay among preterm newborns.

**Aim:** To assess the effect of combined modalities of prefeeding stimulation and kinesitherapy on oral motor response, feeding tolerance, and body weight among

preterm newborns admitted to the Sick Newborn Care Unit (SNCU) of a selected hospital in West Bengal.

**Methods:** A quasi-experimental study will be conducted among preterm newborns admitted to the SNCU according to their inclusion criteria. Participants will be allocated to an intervention group receiving combined modalities of prefeeding stimulation and kinesitherapy along with standard care and a comparison group receiving standard care alone. The prefeeding stimulation and kinesitherapy will be administered according to PIOMI and Field's tactile kinesthetic stimulation protocol respectively for ten consecutive days. Oral motor response, feeding tolerance, and body weight will be assessed using PROFAS and PIBBS scale, feeding tolerance log sheet and calibrated digital wing scale on day 5, day 11 at the time of discharge and during the time of 1<sup>st</sup> follow up. Data will be analysed using appropriate descriptive and inferential statistics to compare outcomes between the two groups.

**Conclusion:** This study is expected to generate evidence on the effectiveness of combined prefeeding stimulation and kinesitherapy as a nursing intervention for improving feeding-related outcomes and weight gain and early discharge from hospital in preterm newborns admitted to SNCUs.

**Keywords:** Prefeeding stimulation, kinesitherapy, preterm, oromotor response, feeding tolerance

## INTRODUCTION

Preterm birth, defined as delivery before 37 weeks of gestation, is a significant contributor to neonatal morbidity and mortality worldwide. Globally, approximately 13.4 million preterm births occur each year, with India accounting for a substantial proportion of these cases—around 3.5 million annually [1]. In West Bengal, current NMR is 14/1000 live birth [4] which is low from the National average of Neonatal mortality rate that is 17 per 1000 live birth [3] and near far from the targeted SDG that is reduce neonatal mortality to at least 12 deaths per 1,000 live births by 2030. [3] To achieve the goal preterm birth related mortality and morbidity has to be targeted. Preterm infants are often admitted to Sick Newborn Care Units (SNCUs) due to complications associated with underdeveloped organ systems, particularly the gastrointestinal (GI) tract, which can lead to feeding difficulties, poor weight gain, and extended hospital stays.

The prevalence of feeding-related challenges in preterm infants is considerable, with studies indicating that up to 40% of these infants experience significant difficulties in achieving adequate feeding[5, 6]. Addressing these issues is

crucial for improving survival rates and quality of life for preterm infants.

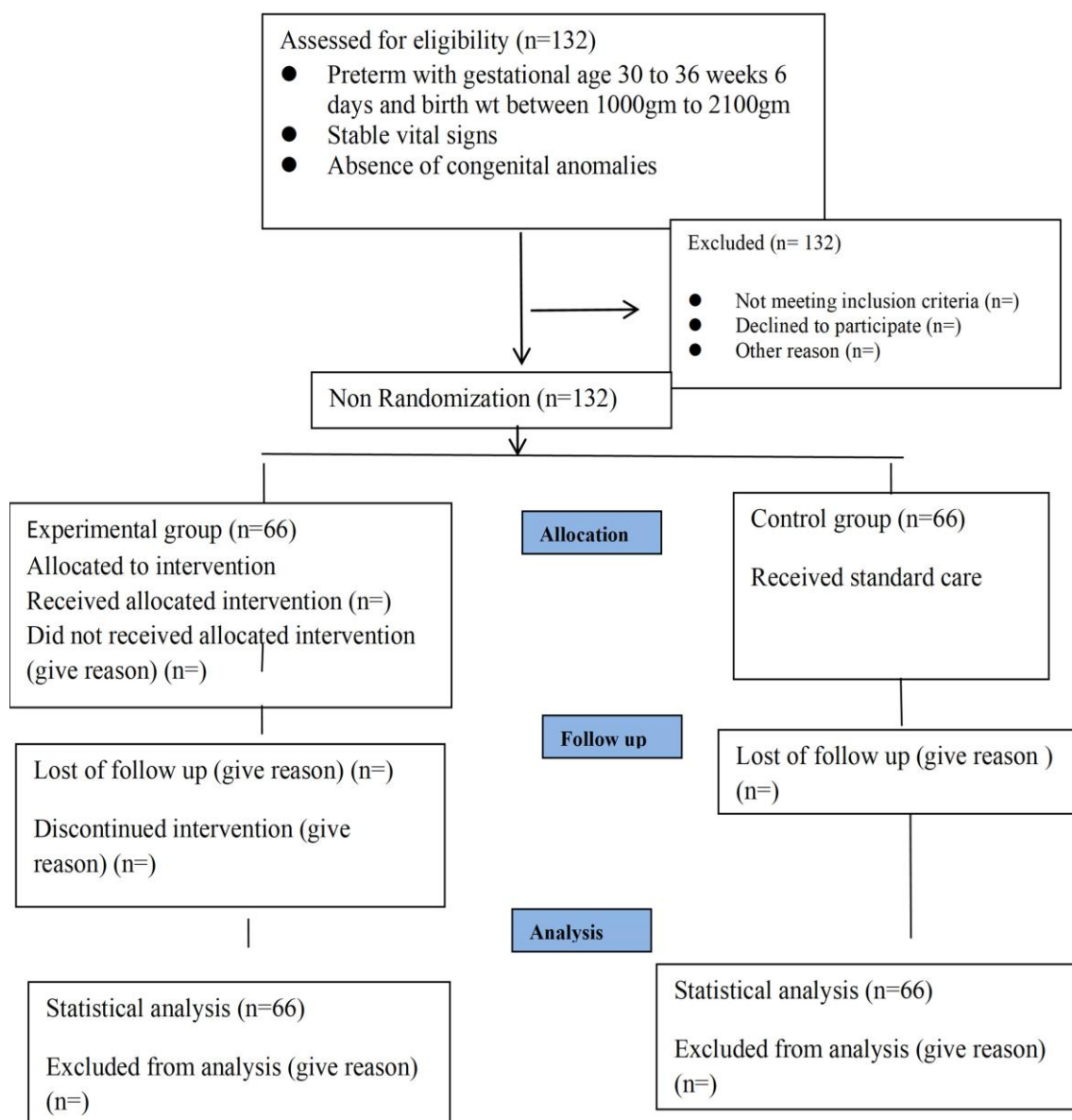
Recent evidence has highlighted the potential benefits of integrating various therapeutic modalities to enhance feeding outcomes in preterm infants. Prefeeding stimulation, including gentle tactile and oral techniques, prepares infants for feeding by improving their sucking reflex and coordination. [ Sasmal et al.2023 and Arora et al.2018] kinesitherapy, that is Tactile kinaesthetic stimulation, which stimulates the vagal nerve, has been shown to enhance GI motility and nutrient absorption, potentially reducing the risk of feeding intolerance. These are essential for effective feeding. [Mahalakshmi.B et al. (2024)]

A critical review of existing literature reveals a significant gap in integrated intervention strategies that holistically address the feeding difficulties of preterm neonates. Most studies focus on either oral motor stimulation or kinesiotherapy in terms of tactile kinesthetic stimulation in isolation, without exploring their synergistic potential. There is also limited region-specific data from rural and semi-urban SNCUs in India, particularly in West Bengal, where such evidence could directly inform and improve neonatal care practices.

This novel approach integrates two non-invasive, low-cost modalities that could be feasibly implemented even in resource-limited settings.

## MATERIALS & METHODS

The proposed study is a quasi-experimental study. Neonates will be recruited from the sick Care Unit (SNCU) of a tertiary hospital using convenience sampling. Informed consent will be obtained, and it will be duly signed by the parents before recruiting the neonates for present study.



Flow diagram of research design

**Fig 1: CONSORT flow diagram of research study**

**Ethical considerations:** The study protocol adheres to the principles outlined in the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) [29]. The research protocol has received approval from the Institutional Research Advisory Committee (RAC), and ethical clearance has been obtained from the Institutional Ethical Committee Memo no: BMC/I.E.C/736 Dated 4<sup>th</sup> December, 2025. The study has been registered in clinicaltrials.gov with ID – REF/2026/07/135077. and with the

Universal Trial Number CTRI/2026/07/113853. The research will be conducted in accordance with the 2013 revision of the Helsinki Declaration and the 2017 National Ethical Guidelines for Biomedical Research Involving Human Participants [28].

**Study sample and recruitment:** The study aims to include preterm neonates (<37 weeks) who are admitted to the SNCU and within 72 hours of birth with stable vitals.

### **Inclusion and exclusion criteria:**

1. Preterm with gestational age 30 0/7 to 36 6/7 weeks and birth weight between 1000gm to <2500gm
2. APGAR score of  $\geq 6$  at 5 min after birth, without respiratory support
3. Absence of congenital anomalies

### **Exclusion criteria**

1. Requirement of mechanical ventilation.
2. Severe asphyxia.
3. Prenatal illicit drug exposure history
4. Prior enrollment in other studies.
5. Diagnosis of necrotizing enterocolitis (NEC)
6. Diagnosis of intracranial haemorrhage.
7. Positive blood culture
8. Fracture bone and presence of shoulder dystocia.
9. Presence of neonatal jaundice that required exchange blood transfusion

**Samples size:** G\*Power tool is used to calculate sample size under the statistical test category of deference between two independent means, with an anticipated effect size of 0.8 and a desired power of 90%, resulting a sample size 56. The significance level is set at 0.05. Additionally, accounting for a 20% drop out rate, the final size considered is 66, total 132 preterm will be selected. 66 preterm newborns in each group.

### **Intervention**

**experimental group:** In the experimental group, infants will receive prefeeding stimulation and kinesitherapy. Prefeeding stimulation will be provided by Premature Infant Oromotor Intervention (PIOMI) developed by Dr. Brenda Knoll [27], consisting of 3 mins of oral stimulation and 2 minutes of non-nutritive sucking. This is not a routine practice in the unit. It will be administered only twice a day, 15–30 min

before any two scheduled feeding with ongoing monitoring of vital signs for 10 consecutive days to avoid overstimulation. Before providing the therapy, the investigator will be washed her hands thoroughly and put on a new pair of clean latex gloves. A summary of prefeeding stimulation in the experimental group is provided in [Table-1]

kinesitherapy will be given in forms of Tactile Kinesthetic stimulation developed by T. Field [16,23]. It should be performed between two feeds after giving prefeeding stimulation 2 times a day for 10 days. Avoid performing stimulation on infants who are too full or hungry. During and after kinesitherapy session, closely observe the conditions of the infant's heart rate, oxygen saturation, respiration rate, skin temperature, and skin color prior to the start of the therapy, every 5 min during the session, and then every 15 min for an hour after the session. Therapy should be stopped if abnormal vital signs or visible signs of distress occur which include significant color change, more than 30 s of crying, or hyper extension of extremities. Kinesitherapy involves tactile and kinesthetic stimulation for 15 min. Divided into three phases. 1st and 3rd phase is tactile phase where moderate pressure stroking moving the skin and 2<sup>nd</sup> phase is kinesthetic stimulation which newborn lays on its back and its limbs are passively moves into flexion and extension. Total duration is 10 to 15 minutes. A summary of kinesitherapy in the experimental group is provided in [Table 2]. Along with the prefeeding stimulation and kinesitherapy experimental group will be also received standard care according to the SNCU protocol.

**Control group:** In control group preterm newborn will receive standard care according to the SNCU protocol.

**Table-1: Steps of Premature Infant oral motor intervention [27]**

| Sl no | Steps                             | Time   |
|-------|-----------------------------------|--------|
| 1.    | Cheek                             | 30 sec |
| 2.    | Lip Roll                          | 30 sec |
| 3.    | Lip curl or lip stretch           | 30 sec |
| 4.    | Gum massage                       | 30 sec |
| 5.    | Lateral border of tongue/palate   | 15 sec |
| 6.    | Mid blade of tongue/palate        | 30 sec |
| 7.    | Elicit a suck                     | 15sec  |
| 8.    | Support for non-nutritive sucking | 2 min  |
|       | Total time                        | 5 min  |



**Fig-2: Steps of PIOMI**

**Table-2: Steps of tactile kinesthetic stimulation according to Field's protocol [16].**

| Sl no                                                                                                                                                                                     | Steps                                                                                                                                                | Time                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| 1.                                                                                                                                                                                        | Prone position and enclosing the newborn with cupped hands in a resting hand position.                                                               | 30 sec                     |
| Maintaining the resting hand to the back the investigator will slowly stroke the newborn with the palm of her other hand with a gentle but firm, rhythmic motion. Following the sequence. |                                                                                                                                                      |                            |
| Tactile phase (1 <sup>st</sup> & 3 <sup>rd</sup> phase)                                                                                                                                   |                                                                                                                                                      |                            |
| 2.                                                                                                                                                                                        | Head to the neck-6 times                                                                                                                             | 30 sec                     |
| 4.                                                                                                                                                                                        | Shoulder to the head left side- 6 times                                                                                                              | 30 sec                     |
| 5.                                                                                                                                                                                        | Shoulder to the head right side- 6 times                                                                                                             | 30 sec                     |
| 6.                                                                                                                                                                                        | Neck to the back to the bottom-6 times                                                                                                               | 30 sec                     |
| 7.                                                                                                                                                                                        | Bottom to the feet left side- 6 times                                                                                                                | 30 sec                     |
| 8.                                                                                                                                                                                        | Bottom to the feet right side- 6 times                                                                                                               | 30 sec                     |
|                                                                                                                                                                                           | Total time taken                                                                                                                                     | 3 minsx 2 times=<br>6 mins |
| Kinesthetic phase (2 <sup>nd</sup> phase)                                                                                                                                                 |                                                                                                                                                      |                            |
| 1.                                                                                                                                                                                        | kinesitherapy phase, the newborn is placed in supine position. Place the palms on the newborn's body to embrace the chest in a resting hand position | 30 sec                     |
| 2.                                                                                                                                                                                        | Flexion and extension of the right upper limb-6 times                                                                                                | 1 min                      |
| 3.                                                                                                                                                                                        | Flexion and extension of the left upper limb-6 times                                                                                                 | 1 min                      |
| 4.                                                                                                                                                                                        | Flexion and extension of the right lower limb-6 times                                                                                                | 1 min                      |
| 5.                                                                                                                                                                                        | Flexion and extension of the left lower limb-6 times                                                                                                 | 1 min                      |
| 6.                                                                                                                                                                                        | Flexion and extension of the right and left lower limb together -6 times                                                                             | 1 min                      |
|                                                                                                                                                                                           | Total time taken for tactile kinesthetic stimulation                                                                                                 | 10-12 min                  |

### Outcome measures:

1. Time to full oral feeding (days):  
Definition: Number of days from allocation to the first day the infant takes all feeds orally and receives  $\geq 150$  ml/kg/day orally for 48 consecutive hours without need for gavage/tube

feeding or supplemental parenteral nutrition.

Measurement: Recorded in days. Check feed chart daily; confirm 48-hour sustainment.

2. Change in oral-motor function (PROFAS) from baseline to day 11 and

- at the time of discharge and PIBBS scale at the day of introduction of oral feeding and day of discharge and at the time of 1<sup>st</sup> follow up.
3. Measurement of feeding tolerance by log sheet for assessment of feeding tolerance.
  4. Weight outcomes: Daily weight (g) and average weight gain expressed as g/kg/day over specified periods.
  5. Length of NICU/SNCU stay (days).

**Table-3: Schedule of enrolment, interventions and assessments of the study protocol.**

|                            | Study period           |                        |                           |                        |                           |                                           |                                                      |
|----------------------------|------------------------|------------------------|---------------------------|------------------------|---------------------------|-------------------------------------------|------------------------------------------------------|
|                            | Enrollment             | Allocation             | Post allocation treatment |                        |                           |                                           | Close out                                            |
| Time point                 | t <sub>0</sub> (Day-0) | t <sub>0</sub> (Day-0) | t <sub>0</sub> (Day-0)    | t <sub>1</sub> (Day-5) | t <sub>2</sub> (Day-11)   | t <sub>3</sub> (At the time of discharge) | t <sub>4</sub> (1st follow up visit after discharge) |
| <b>Enrollment</b>          |                        |                        |                           |                        |                           |                                           |                                                      |
| Eligibility screen         | X                      |                        |                           |                        |                           |                                           |                                                      |
| Informed consent           | X                      |                        |                           |                        |                           |                                           |                                                      |
| Base line data             | X                      |                        |                           |                        |                           |                                           |                                                      |
| Allocation                 |                        | X                      |                           |                        |                           |                                           |                                                      |
| <b>Interventions</b>       |                        |                        |                           |                        |                           |                                           |                                                      |
| Experimental group         |                        |                        | Combined modalities       | Treatment              | ←————→<br>& standard care |                                           |                                                      |
| Control group              |                        |                        | Standard                  | care                   |                           |                                           |                                                      |
| <b>Assessments</b>         |                        |                        |                           |                        |                           |                                           |                                                      |
| POFRAS Scale & PIBBS Scale | X                      |                        | X                         | X                      |                           | X                                         | X                                                    |
| Feeding tolerance          | X                      |                        | X                         | X                      |                           | X                                         | X                                                    |
| Body Weight                |                        |                        |                           |                        |                           |                                           |                                                      |

### Statistical Analysis

Data will be analyzed using IBM Statistical Package for the Social Sciences (SPSS)

software, version 32.0. The assessment of normality will be conducted using the Kolmogorov-Smirnov Test. After the data

has been determined to have a normal distribution, repeated measures Analysis of Variance (ANOVA) will be employed for within-group analysis, while an independent t-test will be used for between-group comparison. In cases where the data does not follow a normal distribution, the Friedman's test is typically employed for within-group analysis, while the Mann-Whitney U test is commonly used for between-group analysis. The descriptive statistics will be expressed as the mean plus or minus the standard deviation, as well as the median and interquartile range, respectively.

### **Strength and Limitation(s):**

The strengths of the study are that this study will observe the effect of combined modalities of both prefeeding stimulation and kinesitherapy. Prefeeding stimulation and kinesitherapy individually has been proven to improve oral motor response, and increase body weight respectively. Additionally, to the best of authors knowledge, the proposed study will be the first of its kind to prove the effectiveness on combined effect of prefeeding stimulation and kinesitherapy in oral motor response, feeding tolerance and body weight. However, there are some weaknesses in the proposed study. First, it is not randomised due to ethical issues and feasibility problem. Second limitation is that neonates are not divided into subcategories of preterm. To address this, further studies can be planned randomization with data stratification based on subcategories of preterm neonates.

### **CONCLUSION**

The study is expected to generate scientific evidence regarding the effectiveness of combined prefeeding stimulation and kinesitherapy as a safe, feasible, and cost-effective nursing intervention for preterm newborns admitted to Sick Newborn Care Units (SNCUs). The intervention is anticipated to improve oral motor response, improve feeding tolerance, facilitate the

earlier achievement of full oral feeding, promote adequate body weight gain, and reduce duration of hospital stay among preterm newborns.

By improving feeding performance and nutritional outcomes, the intervention is also expected to contribute to a shorter duration of hospital stay and facilitate earlier discharge, thereby reducing healthcare costs and optimizing the utilization of neonatal intensive care resources. Furthermore, the findings of this study may strengthen the evidence base for integrating combined prefeeding stimulation and kinesitherapy into routine SNCU or NICU protocols for clinically stable preterm newborns.

The results are expected to provide valuable guidance for neonatal nurses, nurse educators, clinicians, and policymakers in developing standardized, evidence-based newborn individualised developmental care and assessment programme within SNCUs. In addition, the study may encourage the adoption of non-invasive developmental care interventions that support the growth, neurodevelopment, and overall well-being of preterm newborns. Ultimately, the findings have the potential to improve the quality of neonatal care, enhance clinical outcomes, and contribute to achieving better survival and long-term health prospects for this vulnerable population.

### **Declaration by Authors**

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**Conflict of Interest:** The authors declare no conflict of interest.

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