
**“EFFECT OF ABDOMINAL MASSAGING ON
PROGRESSION TO FULL ORAL FEEDING IN
PRETERM INFANTS - ONE YEAR HOSPITAL
BASED OBSERVATIONAL STUDY”**

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LIST OF ABBREVIATIONS

BPD	–	Broncho Pulmonary Dysplasia
CPAP	–	Continuous Positive Airway Pressure
DMN	–	Dorsal Motor Nucleus of vagus
EoE	–	Eosinophilic Esophagitis
FiO ₂	–	Fraction of Inspired Oxygen
GER	–	Gastro Esophageal Reflux
HIE	–	Hypoxic Ischemic Encephalopathy
IGF - 1	–	Insulin Growth Factor - 1
IUGR	–	IntraUterine Growth Restriction
IVH	–	IntraVentricular Hemorrhage
LBW	–	Low Birth Weight
NA	–	Nucleus Ambiguous
NEC	–	Necrotising Entero-Colitis
NICU	–	Neonatal Intensive Care Unit
NNS	–	Non Nutritive Sucking
NTS	–	Nucleus Tractus Solitarius
PIOMI	–	Premature Infant Oral Motor Intervention
PVL	–	PeriVentricular Leukomalacia
RDS	–	Respiratory Distress Syndrome
sCPG	–	Suck Central Pattern Generator
WHO	–	World Health Organisation

ABSTRACT

Background :

In preterm infants, one of the limiting factors for early discharge is the inability to feed adequately to gain weight consistently. One of the most important problems preterm babies encounter is feeding difficulty. These result from incomplete oral structural development, as well as issues with their cardiorespiratory and central neurological systems. Hospital stays are prolonged and costs are increased when oral feeding is difficult. Evidence-based interventions which facilitate development of oral motor skills are required in order to improve oral feeding, reduce hospital stays, and minimize the costs. The purpose of this study was to test whether abdominal massage therapy, provided before feeding would result in shorter transition time from gavage to full oral feedings, weight gain and shorter duration of hospital stay.

Materials and methods :

This observational study was conducted from January 2023 to December 2023 in the Department of Paediatrics, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi. During the study period 92 babies between 30-34 weeks were enrolled but 88 babies were followed up for study outcomes, out of which 44 babies were in the intervention group and 44 in the control group. Subjects were randomly allocated to intervention and control groups. Maternal and newborn data was collected in a structured proforma. In the intervention group, a standard procedure of abdominal massage was performed for 5 minutes by the nursing staff or mother on a daily basis (two times a day), 20 minutes before feeding for seven days. On the other hand, the control group received only routine NICU care. Then the

groups were compared in terms of transition time from gavage to full oral feeds, length of hospital stay and weekly weight gain. The data was analyzed using SPSS 23.0 statistical software. Chi-square test, Wilcoxon matched test, student t-test were used.

Results :

There is no significant difference in the mean gestational age, gender and birth weight between intervention and control groups. The mean transition time from gavage to full oral feeds is significantly less in intervention group (5.37 ± 2.59 days) compared to control group (8.19 ± 3.82 days) with $P = 0.00019$. The mean length of hospital stay is significantly less in intervention group (14.81 ± 6.21 days) compared to control group (19.16 ± 7.06 days). In our study, we observed significant weight loss in both groups during 1st week of life. There is significant weight gain in intervention group compared to control groups in the 2nd, 3rd and 4th week. We also noticed shorter duration of transition time in babies who were initiated on feeds on first day.

Conclusions :

Feeding difficulty is one of the major challenges in preterm babies. Abdominal massage therapy is simple prefeeding stimulation techniques that assisted in earlier transition to full spoon feeds, shortened the length of hospital stay and improved weekly weight gain. Therefore this intervention can be performed for all stable preterm infants admitted to NICU to enhance feeding skills.

Keywords : Preterms, Feeding issues, Abdominal massage, Transition time, Length of hospital stay, Weekly weight gain.

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INTRODUCTION

Preterm birth, defined as a pregnancy of <37 weeks, is a global burden that is primarily linked to the risk of neonatal mortality ¹. Prevalence of prematurity was 9.9% worldwide in 2020. In India, the preterm birth rate is 13 per 100 live births ².

Preterm infants have problems like respiratory difficulties, electrolyte imbalances, feeding difficulties, cardiovascular problems due to their anatomical and functional immaturity and need to be taken care to prevent long term complications. Nutritional deficiencies are common among preterm infants due to gastrointestinal issues like reduced intestinal motility and enzyme function which hampers nutrient absorption. Feeding intolerance is one of the major problem in premature infants, resulting in prolonged hospitalisation, increased risk of sepsis and predisposition to serious clinical problems ³.

Advances in newborn intensive care have resulted in a significant improvement in the survival rate of premature neonates. Many premature neonates admitted in the Neonatal Intensive Care Unit (NICU) receive enteral feeds by gavage due to their increased risk of aspiration which is because of their incoordinated suck-swallow-breathing pattern. The immaturity of motor function poses a significant hurdle to the success of enteral feeding. Achieving successful oral feeding requires synchronisation of breathing, sucking, and swallowing amidst maintaining motor stability and processing sensory inputs ⁴. So, one of the last steps in their care before they are discharged is successful oral feeding. Oral feeding difficulties are typically common in premature neonates due to the functional immaturity of multiple systems ⁵.

Due to the immature digestive, respiratory, and central nervous systems of preterm infants, their ability to tolerate oral feeds is low. Therefore, they need to be admitted to neonatal intensive care for a few days to weeks before they can learn how to coordinate sucking, swallowing, and breathing to achieve safe and effective oral feedings. As the fetal age progresses until 34 weeks, the coordinated suck swallow breathing patterns become more complete. Hence infants with higher gestational age will have better sucking skills⁶. Depending on the baby's condition the switch from gavage to oral feeding may take days to weeks. This delays the achievement of direct breastfeeding and lengthens stay in NICU, which increases risk of morbidity later on in life⁷.

Numerous prefeeding stimulation techniques are used in preterm babies to overcome the feeding problems. They enhance the physiological and nutritional status of premature neonates. Some of those interventions are Non Nutritive Sucking (NNS), perioral stimulation, infant positioning, oral support, soft human touch etc⁷. One among them is abdominal massage therapy that has a positive impact on the feeding challenges faced by preterm neonates during their stay in the NICU. In stable preterm infants receiving minimal enteral nutrition in NICU, it promotes weight gain and shortens hospital stay by improving food absorption and facilitates the transition from gavage to full oral (spoon/paladai) feeds. This intervention helps to reduce the feeding intolerance by stimulating the parasympathetic nervous system innervation to the gastrointestinal tract and thereby increases the gastrointestinal motility and helps in digestion⁸. It also increases the activity of the vagus nerve, which when stimulated releases hormones like insulin and gastrin resulting in food absorption, thus explains the weight gain in preterm babies receiving abdominal massage therapy⁹.

Providing abdominal massage is not only simple, safe and cost effective intervention but also mother can be engaged in the process. Currently, there is not enough literature on abdominal massage therapy on transition time to achieve full oral feeds, duration of hospital stay. Hence, the study is being undertaken.

OBJECTIVES

PRIMARY :

- To determine the effect of abdominal massaging in preterm infants on transition time from gavage to full oral feeds (spoon / paladai feeds).

SECONDARY:

- To determine the effect of abdominal massaging in preterm infants on :
 1. Weekly weight gain.
 2. Length of hospital stay.

REVIEW OF LITERATURE

Prevalence of prematurity :

Preterm or premature birth, as defined by the World Health Organisation (WHO), is a birth that occurs < 37 weeks of gestational period¹. Preterm birth accounts for 5-9% of all births in developing countries¹⁰. The main factor contributing to neonatal mortality is prematurity, which is associated with long-term physical and neurodevelopment problems³. Prematurity ranks second in terms of causes of child mortality after pneumonia. Because of the complications associated with premature birth, one million of the fifteen million prematurely born babies die each year in their first year of life¹¹. In India every year 3.02 million preterm babies are born which accounts for 20% of all preterm births worldwide. The United States, the Democratic Republic of the Congo, Ethiopia, Bangladesh, Nigeria, China, and Pakistan come next².

Problems associated with prematurity :

One of the key elements that contribute to neonatal complications and inhibit normal development is premature birth. Preterm birth is linked to a higher risk of hyaline membrane disease, underdeveloped immune systems, feeding problems, cardiovascular abnormalities, cerebral palsy, and developmental delays. Preterm birth is associated with several long-lasting medical, educational, and social implications (Table -1)¹². One major factor contributing to infant mortality as well as morbidity is premature birth. Premature births can be prevented, and the outcomes for premature newborns can be improved, by identifying risk factors and providing appropriate management¹³.

Table - 1 . Poor outcomes related to prematurity

Respiratory issues	<ul style="list-style-type: none"> • Respiratory Distress Syndrome • Bronchopulmonary dysplasia • Higher risk of recurrent hospitalizations due to respiratory/infectious disease (such as bronchiolitis)
Cardiovascular issues	<ul style="list-style-type: none"> • Increased risk of heart failure and ischemic heart disease • Increased risk of higher systolic and diastolic pressure
Gastrointestinal issues	<ul style="list-style-type: none"> • Poor feeding tolerance • Necrotizing enterocolitis • Short bowel syndrome
Metabolic issues	<ul style="list-style-type: none"> • Higher and altered adiposity • Lipid disorders • Increased risk of higher insulin resistance and diabetes mellitus type 2 • Increased risk of metabolic syndrome
Kidney issues	<ul style="list-style-type: none"> • Chronic kidney disease • Low nephron number
Growth issues	<ul style="list-style-type: none"> • Extrauterine growth restriction • Failure to thrive • Impaired Catch-up growth
Neurological and cognitive issues	<ul style="list-style-type: none"> • Motor delay (both fine motor and gross motor delays) • Cerebral palsy • Cognitive impairment with lower intelligence quotient scores and academic performances in several areas
Mental health issues and social interactions	<ul style="list-style-type: none"> • Internalising problems (eg, anxiety, depression) • Attention Deficit—Hyperactivity Disorder (ADHD) • Autism spectrum disorder • Social issues, with a tendency to be shy, have fewer friends, be more socially withdrawn, and be more likely to be bullied than term born peers

Functional immaturity of various systems in premature babies can lead to a range of clinical challenges that need to be addressed for proper care. For infants whose weight is < 1800 grams or born < 35 weeks of gestation, immaturity of the neurological system might manifest as lethargic behaviour, ineffective cough reflex, and difficulty with coordinated suckling and swallowing. Additionally, these preterm newborns are at a higher risk of intraventricular hemorrhage, leukomalacia, retinopathy of prematurity, hyaline membrane disease, broncho-pulmonary dysplasia, necrotising enterocolitis, cerebral palsy¹³, cognitive impairments, including decreased scholastic performance and intelligence quotient (IQ) scores¹⁴. Along with these problems, premature babies have poor weight gain, and prolonged hospital stays because of feeding problems, which makes it more challenging.

Feeding in preterm babies presents challenges as the gastrointestinal system is still immature, leading to issues like incoordinated sucking and swallowing, limited stomach capacity, and an underdeveloped cardioesophageal junction, which increase the risk of regurgitation and aspiration¹³.

Impact of feeding problems in preterms :

In preterm babies, because of the insults during organogenesis and tissue differentiation, they have various short-term and long-term implications (Table-2)¹⁵.

Table - 2 . Impact of feeding problems

SHORT TERM	LONG TERM
Aspiration	Gastroesophageal reflux
Dysphagia	Failure to thrive
Infections	Chronic lung disease of prematurity
Necrotising enterocolitis	Eosinophilic esophagitis
Bronchopulmonary dysplasia	Speech and language delays
	Visual and hearing impairment
	Neurodevelopmental delays
	Cerebral palsy

Feeding problems and associated risk factors in preterm babies :

Nearly twenty-five percent of all babies have feeding issues. Nonetheless, compared to term babies, prematurely born neonates are more likely to experience feeding problems which is observed in 30-40% of preterm infants. Oral feeding difficulties in preterm neonates are a major public health concern, due to detrimental implications on the well-being and standard of life of babies ¹⁴.

Improvements in newborn intensive care have resulted in a significant increase in the survival rate of preterm neonates. One last step in their care before they are discharged is successful oral feeding. A wide range of clinical issues are brought on by the functional immaturity of multiple systems, oral feeding issues are typically being common in premature infants ⁵.

Multiple life-saving interventions are experienced by preterm infants, especially those born < 32 weeks, during their NICU stay that are contributed by painful orofacial sensory stimulation during a time of physiologic maturation. Furthermore, extended oxygen supplementation brought on by respiratory conditions,

brain injury, surgeries, and underlying craniofacial anomalies might change oral sensory-motor responses during such a critical stage of brain development, which can affect normal sucking and swallowing development. Frequently encountered illnesses related to feeding problems in preterm babies are shown below in Figure 1¹⁵.

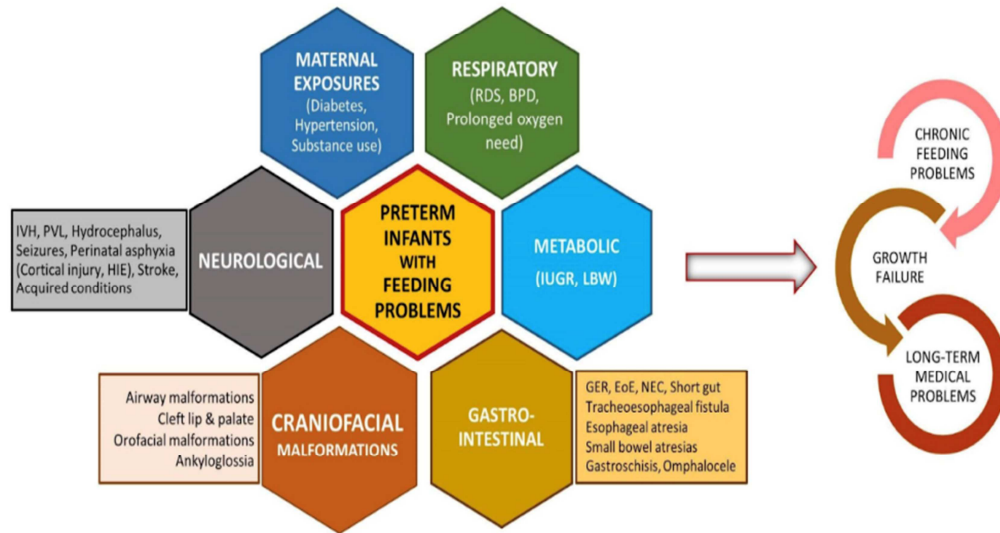


Figure 1 . Risk factors & Common clinical conditions associated with feeding problems in premature babies.

(BPD: Bronchopulmonary Dysplasia, EoE: Eosinophilic Esophagitis, GER: Gastro-Esophageal Reflux, HIE: Hypoxic-Ischemic-Encephalopathy, IUGR: IntraUterine-Growth-Restriction, IVH: IntraVentricular Hemorrhage, LBW: Low Birth Weight, NEC: Necrotizing Enter-Colitis, PVL: PeriVentricular-Leukomalacia)

Causes for feeding issues in preterm babies :

Feeding problems in infants born before 37 weeks of pregnancy can be caused by ¹⁶

1. Hypotonia
2. Lack of coordination in movements
3. Irritability
4. Unstructured motor activities
5. Physiological instability.

For neonates with a gestational age of less than 34 weeks, the main obstacle to oral feeding is the inability to coordinate breathing, swallowing, and sucking. Because of this, babies who are younger than 32 weeks, cannot be fed orally either by spoon / paladai and must receive nutrition through tube feeds. These babies often need to stay in the hospital for an extended period, because of their feeding issues, which can be stressful for families, especially mothers, and increase the financial burden ¹⁷.

The infant's health and weight gain are negatively impacted by feeding difficulties, which are also a result of the oromotor systems' immaturity. Even after reaching physiological stability, a sizable portion (30%) of preterm infants still struggle to make the switch from nasogastric tubes to full oral feeding ¹⁸. The suck Central Pattern Generator (sCPG), made up of bilateral internuncial circuits within the pontomedullary reticular formation is the main regulator of oro-rhythmic motor activity. Suck is a sophisticated sensorimotor activity that helps to assess the central nervous system's integrity ¹⁹.

Therefore, interventions are needed to support the advancement of oromotor skills to enhance oral feeding in infants ≤ 34 weeks and decrease the duration of hospital stay and hospital costs.

Solutions to alleviate oral feeding problems :

A comprehensive approach can minimize or avoid problems with infant oral feeding, which will lower the expense of care (Fucile et al, 2011). Early intervention is necessary to support preterm infants in developing their best oral feeding skills ¹⁴. This is crucial for reducing hospital care costs, preventing long-term hospitalization, and easing parental anxiety. In 2017, Mousa et al. noted that oral feeding necessitates the coordinated interaction of several intricate processes, including breathing, swallowing, and sucking which are all regulated by the neurological, gastrointestinal, behavioral, cardio-respiratory, and musculoskeletal systems ²⁰.

Incomplete development of the gastrointestinal motility system in preterm babies, lengthens the time it takes for the stomach to empty and slows down bowel movements, which eventually results in symptoms like constipation, abdominal distention, and an increase in the gastric residual volume. Necrotising enterocolitis (NEC) is one gastrointestinal complication that is more likely to occur in babies with a high gastric residual volume ²¹. One of the main factors contributing to preterm infants' weight loss is feeding intolerance, which also lengthens hospital stays and increases the infection risk ²². Little is known about the pathophysiology of feeding intolerance, which restricts the available treatments. Ileus of prematurity, delayed stomach emptying, intestinal immaturity, and gastroesophageal reflux all could be contributing factors. Whether any one of these mechanisms or all of them contributes to the observed feeding intolerance is unclear ²³.

Intervention strategies for feeding issues :

Numerous interventions are available to improve the nutritional and physiological status of preterm babies by reducing their feeding intolerance which are as follows

1. Abdominal massage therapy
2. Oro motor stimulation
3. Non-Nutritive sucking
4. Oral support

1. Abdominal massage therapy

a) Background :

Over the last two decades, researchers provided a variety of effective strategies for premature infants to overcome feeding problems due to the functional immaturity of the gastrointestinal system to help them with their effective growth and development²⁴. In India, abdominal massage is one of those interventions that has been an important part which is being evaluated scientifically in recent times.

b) Prerequisites :

- Preterm newborns should exhibit impulses of hunger and should be physiologically stable.
- Baby's neuro-behavioral state of calmness and alertness should be checked before starting the defined abdominal massage.

- One should keep a check on the vitals (heart rate, oxygen saturation, respiratory rate), and pattern of breathing of the baby before carrying out the procedure.
- Massage should not be done post-bath as it may overstimulate the baby.

c) Procedure :

Abdominal massage is started by smearing the palms with a few drops of soothing agent and then perform the abdominal massage on the babies. The massage is given two times a day for 5 minutes, 20 minutes before feeding, for 7 consecutive days, in a circular, clockwise motion, with the fingertips around the umbilicus³. Then down-stroke on the left side of the baby's abdomen and give a stroke starting from right to left and then downwards. Then a stroke is given starting from below on the baby's right side, upwards and then horizontally, and finally downwards on the left which is combinedly known as the "I Love U" stroke (Figure -2)¹⁰ and then fingers are moved around the umbilicus, clockwise.

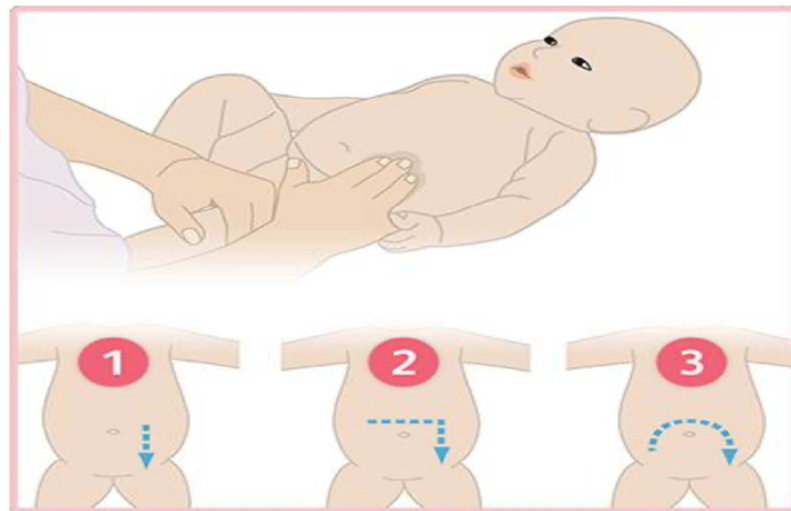


Figure -2. "I Love U" stroke abdominal massage

d) Mechanism of action :

It has been discovered that massage improves an infant's serotonin level, vagal activity, gastrointestinal motility, lowers colic and stress hormone levels, controls sleep, improves the infant's motor skills and integration, and promotes weight gain⁸.

Massage therapy is based on evidence. Anatomical studies show that vagal afferents projecting to Nucleus-Tractus-Solitarius (NTS), the main source of afferent inputs to the efferent-neurons of the Nucleus-Ambiguus (NA), and the Dorsal Motor Nucleus(DMN), innervate baro and mechanoreceptors within the dermis (i.e. Pacinian-corporcles). The gastric (stomach, proximal-duodenum), hepatic and celiac (pancreas, spleen, kidneys) branches of the vagus nerve, which in turn supply the majority of the efferent fibers responsible for parasympathetic regulation of the gastrointestinal tract, originate from the DMN^{25,26}.

e) Impact of abdominal massage :

Abdominal massage therapy in preterm babies helps in early transition to achieve full oral feeding by increasing the vagal nerve response and thereby decreases the duration of hospital stay and also helpful for the weight gain of the premature babies.

Tekunduz, et al carried out a quasi-experimental study regarding the efficacy of abdominal massaging on feeding intolerance in 27 preterm infants (14 in intervention and 13 in control group). Results showed that daily weight gain, frequency of vomiting, and abdominal circumference from the first day to the last day were statistically significant ($P < 0.05$) in the intervention group when compared to the control group. Hence the study concluded, that preterm babies who receive abdominal massage are less likely to develop feed intolerance²⁷.

Another trial by Diego, et al on preterms who were admitted in NICU were randomised with 36 in the intervention and 34 in the control group. Study was conducted to determine whether preterm infant massaging helps with the greater weight gain or not. The results obtained showed 30% increase in weight in the intervention group preterm infants ($P < 0.05$) than in the control group, after a 5-day study period²⁸.

A randomised control trial by Field et al., in 2008, in which a total of 42 preterm babies were randomised (21 in the intervention and 21 in the control group) to receive massage therapy, and a control group that received standard care. The massaged preterm neonates demonstrated higher increases in weight gain, serum insulin levels, and insulin-like growth factor-1 (IGF-1) throughout the 5 days. Improved weight gain was observed in the intervention group ($P < 0.05$)²⁹.

2. Oro Motor Stimulation (OMS)

According to Premature Infant Oral Motor Intervention (PIOMI), the oral motor stimulation technique is a 5-minute intervention 3 times per day, 20 minutes before feeding for 7 consecutive days. This method consists of the following steps - Liproll, Lipcurl or Lipstretch, Gum massage, and Cheek stroke, followed by suck elicitation (Figure -3)³⁰.










 PREMATURE INFANT ORAL MOTOR INTERVENTION		
8 Steps	Technique	
Cheek C - Stretch (30 Sec.)	One finger in the cheek and one outside cheek. Slide and stretch tissue front to back toward the ear, & back to front. Move slowly. Do both cheeks twice.	
Lip Roll (30 Sec.)	Gently roll the lip between your thumb and finger (like rolling a pea). Roll both sides of upper lip once. Roll both sides of lower lip once.	
Lip Curl or Lip Stretch (30 Sec.)	Compress lip between thumb and finger, and curl downward. Curl both sides of upper lip once, and both sides of lower lip once. If lip is too small to grip for the curl, do the Lip Stretch: Lay finger across upper lip, gently compress and stretch side to side. Repeat on lower lip.	
Gum Massage (30 Sec.)	Use finger to put gentle pressure on outside of upper gum. Move finger slowly around upper gum to other side of mouth. (Be sure to touch outer gum surface, not biting surface.) Repeat on lower gum.	
Lateral Borders of Tongue/Cheek (15 Sec.)	Put finger beside tongue and push to the middle. Then move finger back into cheek, stretching it. Repeat on the other side of tongue/cheek.	
Midblade of Tongue/Palate (30 Sec.)	Use finger to put pressure on roof of mouth for 3 seconds. Move finger down to tongue and gently press tongue down. Move finger back up to hard palate. Repeat these movements twice.	
Elicit a Suck (15 Sec.)	Put finger or pacifier on tongue and gently stroke to allow sucking.	
Support for Non-Nutritive Sucking (2 Min.)	Allow sucking on finger or pacifier for 2 minutes.	

Figure- 3 . Steps of premature infant oromotor intervention

A randomised controlled trial by Arora, et al., included 30 preterm infants (16 in intervention and 14 in the control group) to determine the effect of oromotor stimulation on time to achieve full spoon feeds. This study reported that neonates in the intervention group began full oral feeding earlier than those in the control group ($P = 0.001$). Study results also showed significant weight gain in the intervention group compared to the control group ($P = 0.001$)²¹.

According to systematic review and meta analysis by Calk P, with the use of both intra & peri-oral preceding stimulation, there was a statistically significant improvement in feeding efficiency, lesser duration in reaching full oral feeding & increased weight as well as lesser duration of hospital stay³¹.

Another trial by Younesian et al, focussing on impact of oromotor stimulation on feeding performance, weight gain, and duration of hospital stay in 20 preterm neonates (10 in each group) of 30 - 32 weeks gestation, reported that neonates in the intervention group reached full spoon feeds sooner than the control group ($P < 0.001$). The duration of stay in the hospital was significantly less in the group that received the study technique than in the control group ($P < 0.05$). The two groups did not show a significant difference in weight gain³².

3. Non-Nutritive Sucking (NNS)

Unlike nutritive sucking, which requires introducing milk and causing a volume of it to accumulate in the oral cavity and throat, non-nutritive sucking refers to any sucking that doesn't involve introducing any kind of liquid³³. NNS is self-soothing behavior and its application has been demonstrated to shorten premature newborns 'hospital stays³⁴. It helps to improve neonatal behavioral and physiological

states, in addition to coordination in sucking, swallowing, and breathing by increasing strength and endurance.

Fucile et-al, enrolled a total of 84 preterm babies with 42 babies in each group, to determine the combined effects of oromotor stimulation and non nutritive sucking on time taken for the attainment of full oral feeding, length of hospital stay and volume of the milk intake. Oral feeding significantly increased when non-nutritive sucking was combined with oromotor stimulation. It was discovered that preterms who received oromotor stimulation together with non-nutritive sucking were discharged earlier compared to babies who did not receive intervention ¹⁴.

A case-control study by Asadollahpour, et al evaluated the impact of prefeeding oromotor stimulation and non-nutritive sucking on feeding behaviors in 32 premature babies (16 in intervention and 16 in control group) in the 26 - 32 weeks gestation period. The intervention group's babies needed less time than the control group to achieve full spoon feeds ($P < 0.05$). The intervention group's weight gain at discharge was significantly greater than that of the control group ³⁵.

4. Oral support

Oral support enhances cheeks and jaw strength and assists in deglutition coordination³⁶. At the time of oral feedings, oral support should be employed to stabilise the sucking rhythm and enhance it. To strengthen swallowing, the 5th finger is used to compress the floor of the mouth below the chin, while the thumb and index finger compress cheeks toward lips, the 3rd digit is utilised for exerting pressures on the mandible ^{6,37}.

A study conducted by Einarsson et al, to determine the effect of oral support in improving suckling efficiency in thirteen premature newborns (seven in the intervention, six in the control group), at Children's Hospital and Medical Center in Seattle. Intervention group was given oral support once a day while feeding. They observed that there was a significant improvement in volumetric intake in the oral support group in comparison to the non-oral support infants³⁸.

MATERIALS AND METHODS

This is an observational study conducted at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, affiliated to Jawaharlal Nehru Medical College, Belgaum over a period of one year from January 2023 to December 2023.

Study Design :

Observational study

Study Period :

One year (January 2023 to December 2023)

Study Setting :

KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, affiliated to Jawaharlal Nehru Medical College, Belgaum

Study Subjects :

Preterm infants admitted to the NICU of KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, affiliated to Jawaharlal Nehru Medical College, Belgaum.

Sample Size :

The formula used for sample size calculation,

$$n = \frac{2 \left(\frac{Z_{\alpha} + Z_{\beta}}{2} \right)^2}{d^2}$$

$$\text{where, } d = \left(\frac{|\mu_1 - \mu_2|}{\sigma} \right)$$

where, μ_1 is mean of the first group,

μ_2 is mean of the second group,

σ^2 is the common error variance,

$Z_{\frac{\alpha}{2}}$ value is 1.96 for 95% confidence level and

Z_{β} value is 1.036 for 85% power.

Considering the effect size of transition time from gavage to full oral (spoon/paladai) feeds in preterm neonates between abdominal massaging group and control group to be at least 0.65, at 5% level of significance, and 85% power, the sample size obtained to be 44 subjects for each group. Hence, the total sample size required was $44 \times 2 = 88$ subjects.

Ethical Clearance :

Before starting, study was approved by the Ethical and Research Committee, Jawaharlal Nehru Medical College, Belgaum.

Eligibility Criteria

Inclusion Criteria :

1. Preterm babies between 30-34 weeks of gestation.
2. Medically and hemodynamically stable babies on minimal respiratory support (CPAP with $\text{FiO}_2 \leq 40\%$ and $\text{PEEP} \leq 5$ cm for 24 to 48 hours).
3. Willing to participate in the study.

Exclusion Criteria :

1. Major congenital anomalies (craniofacial malformation, cardiovascular and neural tube defects, congenital diaphragmatic hernia, intestinal obstruction).
2. Intraventricular hemorrhage grade 3 and 4.
3. Necrotising enterocolitis stage 2 and 3.
4. Perinatal asphyxia with Hypoxic Ischemic Encephalopathy stage 2 and 3.
5. Any other conditions where abdominal massage is contraindicated.
6. Infants who don't receive complete intervention for 7 days due to any reason.

Informed consent :

All the babies admitted to NICU who fulfilled the eligibility criteria were enrolled into the study within 24 to 48 hours of admission to NICU, after obtaining written informed consent (Annexure - I) from parents.

Methodology

Sampling technique :

Eligible infants were allocated to two groups by simple random sampling technique. Infants born on even dates were allocated to intervention group (Group A) and those on odd dates to control group (Group B). Both groups received care as per NICU protocol, in addition Group-A received study intervention (abdominal massage).

Infant and Maternal Data :

Detailed information of enrolled neonates like Name, Sex, Date of birth, Gestational age (weeks), Age at enrollment (day of life), Birth weight (grams), Weight at enrollment (grams), Day of initiation of tube feeds (day of life), Transition time to achieve full oral feeds (days), Weekly weight gain (grams), Weight at discharge (grams) and maternal demographic details (name, age, address) were recorded in a structured proforma (Annexure - II).

Intervention :

After a thorough hand wash, the trained nursing staff or the mother was asked to smear the palms with a few drops of coconut oil and perform the abdominal massage on the enrolled babies. The massage was given two times a day (12pm, 4pm) for five minutes, 20 minutes before feeding, for 7 consecutive days. The massage was given in circular, clockwise motion, with the fingertips around the umbilicus. Then stroke down on the left side of the baby's tummy (like the letter 'I'). Then a stroke was given starting from right to left and then downwards (like upside down 'L'). Then gave a stroke starting from below on the baby's right side, up and gave stroke horizontally, and then down on the left side (as an inverted 'U') which is combinedly known as "I Love U" stroke and then the fingers were moved around the umbilicus, clockwise. Mothers and nursing staff were trained through video demonstrations and handouts having detailed display of abdominal massage were provided to mothers (Annexure - II).

The intervention was discontinued if the infants became unstable i.e had an oxygen desaturation and apnea or bradycardia during the intervention and would be restarted to complete remaining days of intervention, when the baby was stabilized within 24 hrs.

From the time of admission until their discharge, every baby in both the groups was monitored. The intervention provided was captured by recording the massage provided, in the chart (Annexure - II). Enrolled subjects were monitored for study outcomes like time taken to achieve full oral feeds (spoon / paladai feeds), weekly weight gain and duration of hospital stay. Full oral feed is defined as infants taking feeds at 140-160ml/kg/day or lesser volume if the baby was gaining weight . Length of hospital stay defined as duration from date of admission to date of discharge from the hospital. Weight was recorded by using a digital weighing scale.

Statistical Analysis :

The data was collected and tabulated on excel sheet and master chart was prepared. Data was analyzed using statistical software R version 4.2.2. Frequency tables were used to represent categorical variables. Continuous variables were represented by Mean \pm SD. The Chi-Square test was used to check the association between categorical variables. Two sample t test was used to compare mean between the groups. To compare distributions between the groups Mann Whitney U test was used. Paired t test/ Wilcoxon test used to compare the time points between both groups. P value \leq 0.05 indicates statistical significance.

RESULTS

Table 3: Maternal age among the study groups

Maternal Age (years)	Intervention group (n= 44)	Control group (n= 44)	Total (N=88)
20-25	14 (31.8%)	10 (22.7%)	24 (27.3%)
26-30	16 (36.4%)	19 (43.2%)	35 (39.8%)
≥31	14 (31.8%)	15 (34.1%)	29 (32.9%)
Total	44	44	88
Mean ± SD	26.6 ± 4.02	27.47 ± 4.89	27.03 ± 4.46
X^2 value= 0.709, P value= 0.70, Not significant			

In our study, 67.05% of the mothers were less than 30 years of age. There is no statistically significant difference observed for maternal age among study groups ($P = 0.7$).

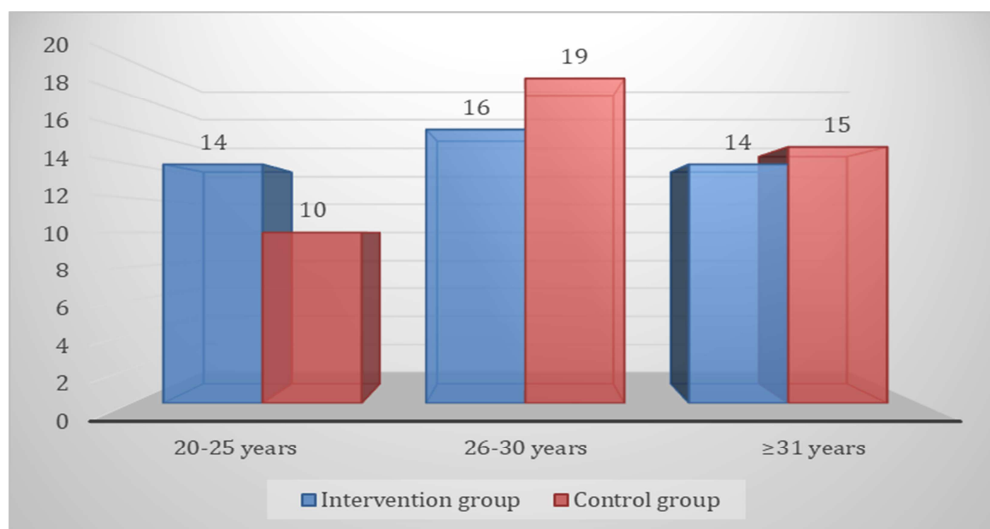


Figure – 4. Maternal age among the study groups

Table 4: Gender of study participants

Gender	Intervention group (n= 44)	Control group (n= 44)	Total (N=88)
Female	19 (43.2%)	21 (47.7%)	40 (45.5%)
Male	25 (56.8%)	23 (52.3%)	48 (54.5%)
Total	44	44	88
X^2 value= 0.115, P value= 0.735, Not significant			

In our study, out of 88 participants, 40 were female and 48 were male. No statistical significant difference observed between groups ($P = 0.735$).

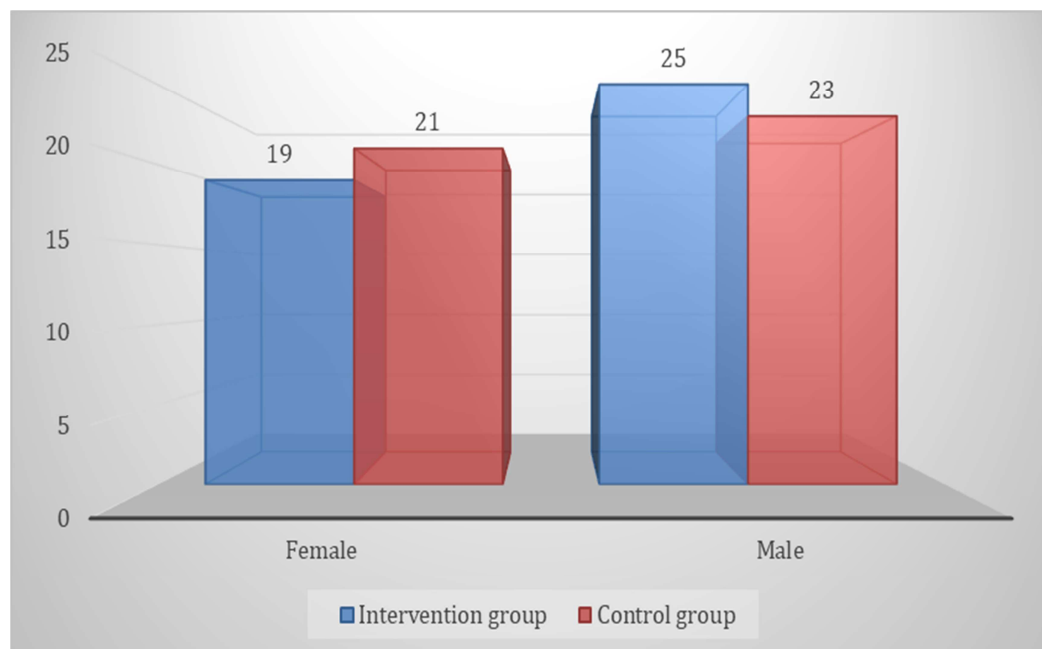
**Figure – 5. Gender of study participants**

Table 5: Gestational age of enrolled subjects

Gestational age (weeks)	Intervention group (n= 44)	Control group (n= 44)	Total (N=88)
30-32	10 (22.7%)	7 (15.9%)	17 (19.3%)
32 ⁺¹ - 34	34 (77.3%)	37 (84.1%)	71 (80.7%)
Total	44	44	88
Mean \pm SD	32.93 \pm 1.20	32.61 \pm 1.08	32.8 \pm 1.14
X^2 value= 0.0515, P value= 0.820, Not significant			

In the current study, the majority 71 (80.7%) were > 32 weeks and rest were < 32 weeks of gestation. The gestational age of neonates in the intervention group was 32.93 \pm 1.20 weeks and 32.61 \pm 1.08 weeks in the control group. There is no statistically significant difference observed among groups (P =0.820).

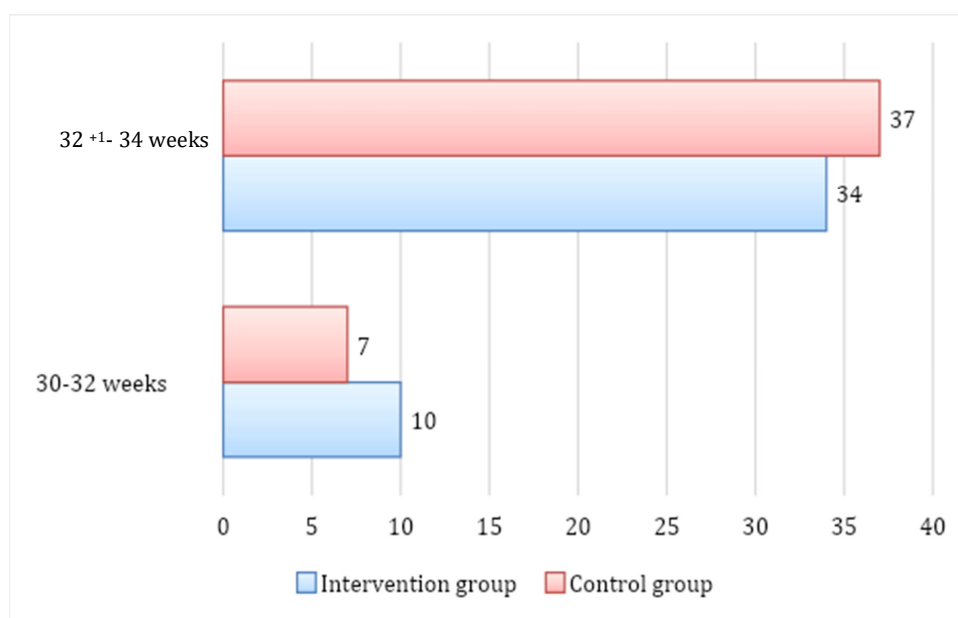


Figure – 6. Gestational age of enrolled subjects

Table 6: Birth weight of enrolled subjects

Birth weight (grams)	Intervention group (n= 44)	Control group (n= 44)	P value
≤1000	2 (4.5%)	2 (4.5%)	1.000
1001-1500	16 (36.4%)	16 (36.4%)	
> 1500	26 (59.1%)	26 (59.1%)	
Mean ± SD	1564.18 ± 291.34	1522.5 ± 293.58	

In our study, 4.5% of the neonates were <1000 grams, 36.4% were between 1001 to 1500 grams and 59.1% were > 1500 grams. The birth weight in the intervention group was 1564.18 ± 291.34 grams and 1522.5 ± 293.58 grams in the control group, with no significant statistical difference (P = 1.000).

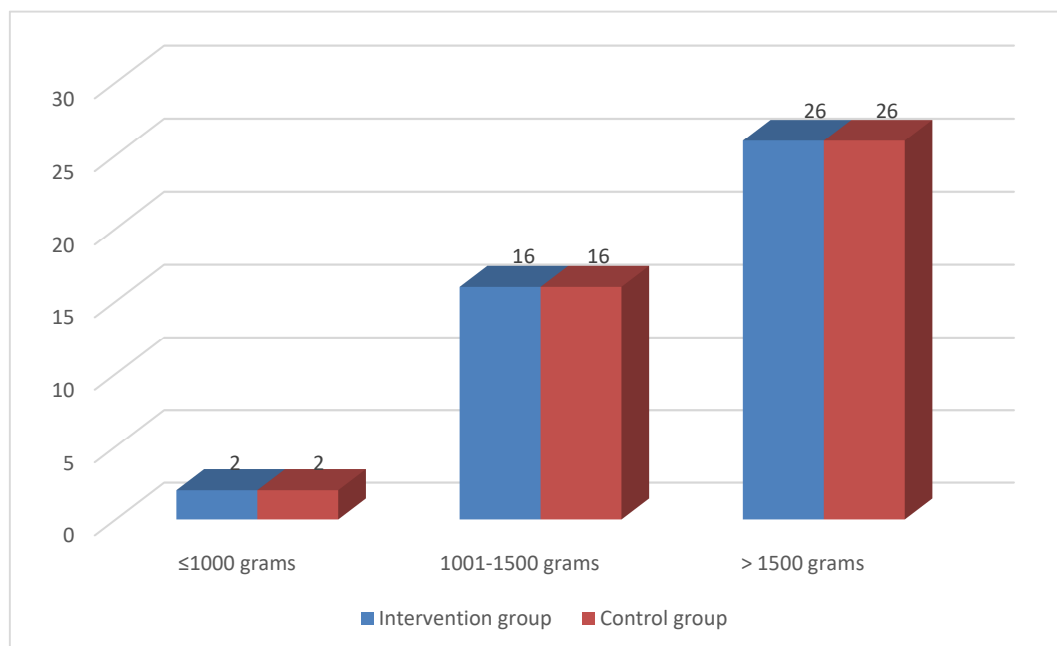
**Figure – 7. Birth weight of enrolled subjects**

Table 7 : Transition time from gavage to full oral feeds

Transition time (days)	Intervention group (n= 44)	Control group (n= 44)	P value
1 - 5 days	30 (68.2%)	9 (20.5%)	0.00019
6 – 10 days	10 (22.7%)	20 (45.5%)	
11 -15 days	4 (9.1%)	11 (25%)	
≥16 days	0	4 (9.1%)	
Mean ± SD	5.37 ± 2.59	8.19 ± 3.82	

The transition time from gavage to full oral feeds in the intervention group is 5.37 ± 2.59 days which is significantly less compared to the control group i.e 8.19 ± 3.82 days ($P = 0.00019$).

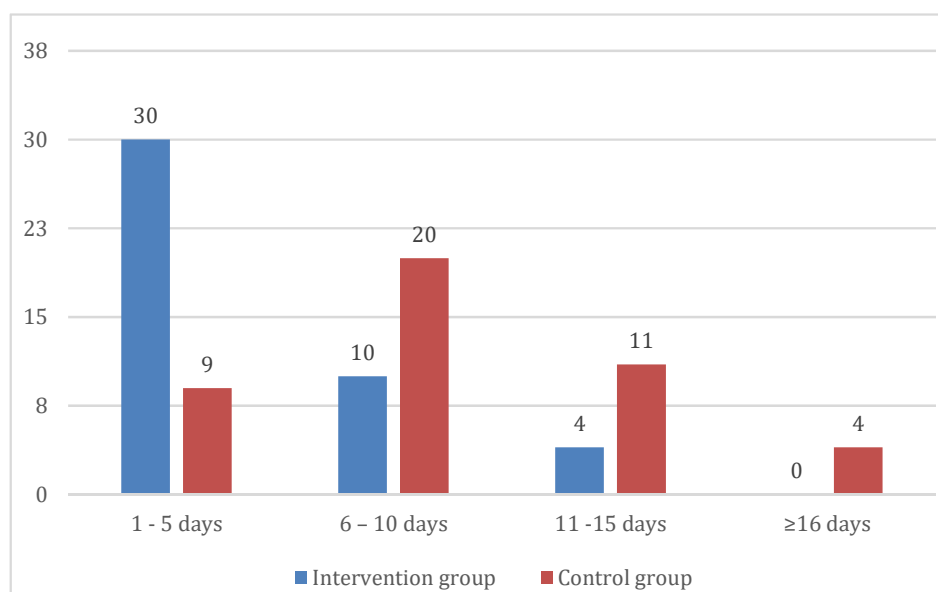
**Figure – 8. Transition time from gavage to full oral feeds**

Table 8: Transition time from gavage to full oral feeds versus birth weights

Birth weight (grams)	Transition time (days)		P value
	Intervention group (n = 44)	Control group (n = 44)	
≤1000 grams	6.28 ± 1.64	8.92 ± 2.27	0.024
1001-1500 grams	5.75 ± 1.53	8.61 ± 1.86	
> 1500 grams	5.12 ± 1.51	8.01 ± 2.48	
Mean ± SD (days)	5.37 ± 2.59	8.19 ± 3.82	

For neonates weighing <1000 grams, the transition time from gavage to full oral feeds was 6.28 ± 1.64 days in the intervention group and 8.92 ± 2.27 days in the control group. For neonates who weighed 1001-1500 grams, it was 5.75 ± 1.53 days in the intervention group and 8.61 ± 1.86 days in control groups. It was 5.12 ± 1.51 days and 8.01 ± 2.48 days for intervention and control groups respectively for babies who were > 1500 grams. The transition time for the entire intervention group was 5.37 ± 2.59 days and for the control group was 8.19 ± 3.82 days. Statistically significant difference is observed in transition time from gavage to full oral feeds for the entire study groups and also across birth weight categories ($P = 0.024$).

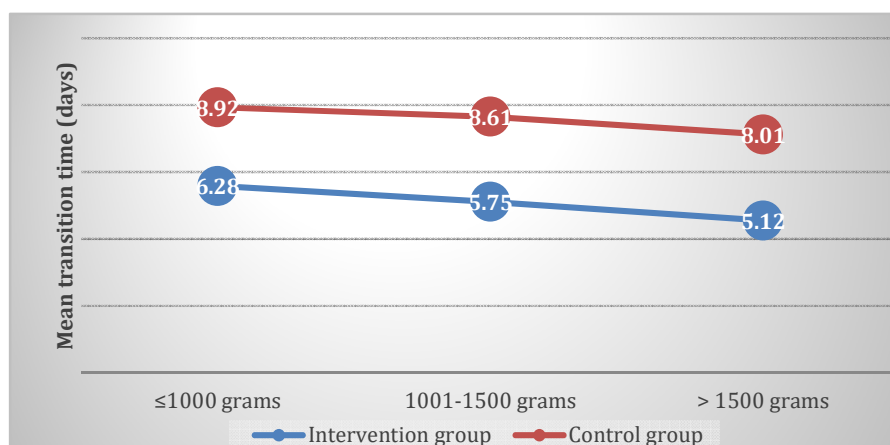
**Figure – 9. Mean transition time from gavage to full oral feeds versus birth weights**

Table 9: Transition time from gavage to full oral feeds versus Gestational age

Gestational age (weeks)	Transition time (days)		P value
	Intervention group (n= 44)	Control group (n= 44)	
30-32 weeks	8.3 ± 2.6	10.42 ± 2.95	0.03
32 ⁺¹ - 34 weeks	4.48 ± 1.98	7.74 ± 4.1	
Mean ± SD (days)	5.37 ± 2.59	8.19 ± 3.82	

In our study, transition time from gavage to full oral feeds was 8.3 ± 2.6 days in the intervention group and 10.42 ± 2.95 days in the control group for neonates with gestation 30 - 32 weeks. It was 4.48 ± 1.98 days and 7.74 ± 4.1 days in the intervention and control groups respectively for neonates between 32⁺¹-34 weeks. The transition time for the entire intervention group was 5.37 ± 2.59 days and for the control group was 8.19 ± 3.82 days. Statistically significant difference was observed for entire study groups and also across gestational age categories (P = 0.03).

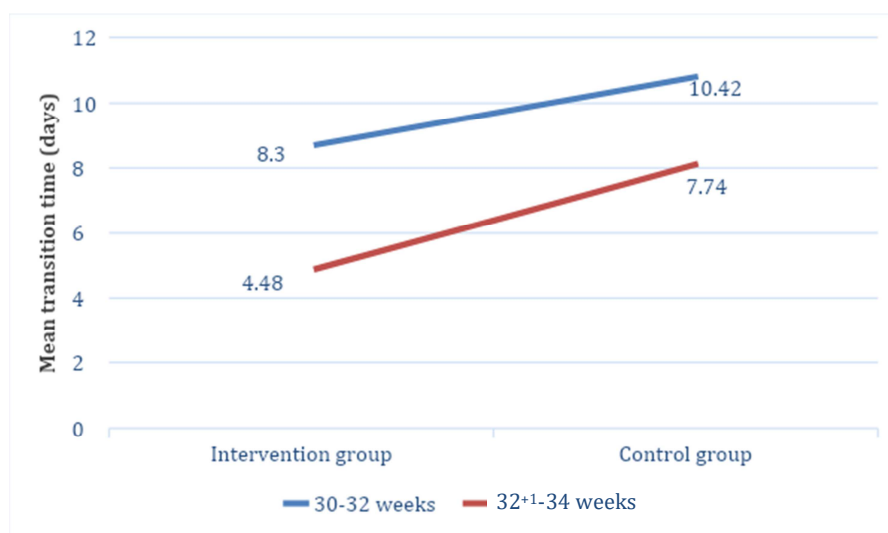


Figure – 10. Mean transition time from gavage to full oral feeds versus Gestational age

Table 10: Duration of hospital stay

Duration of hospital stay (days)	Intervention group	Control group	P value
<10 days	14	4	0.003
11- 20 days	21	20	
21-30 days	7	15	
>30 days	1	5	
Mean \pm SD	14.81 \pm 6.21	19.16 \pm 7.06	

The length of hospital stay in the intervention group is 14.81 \pm 6.21 days which is significantly less compared to the control group i.e 19.16 \pm 7.06 days (P = 0.003).

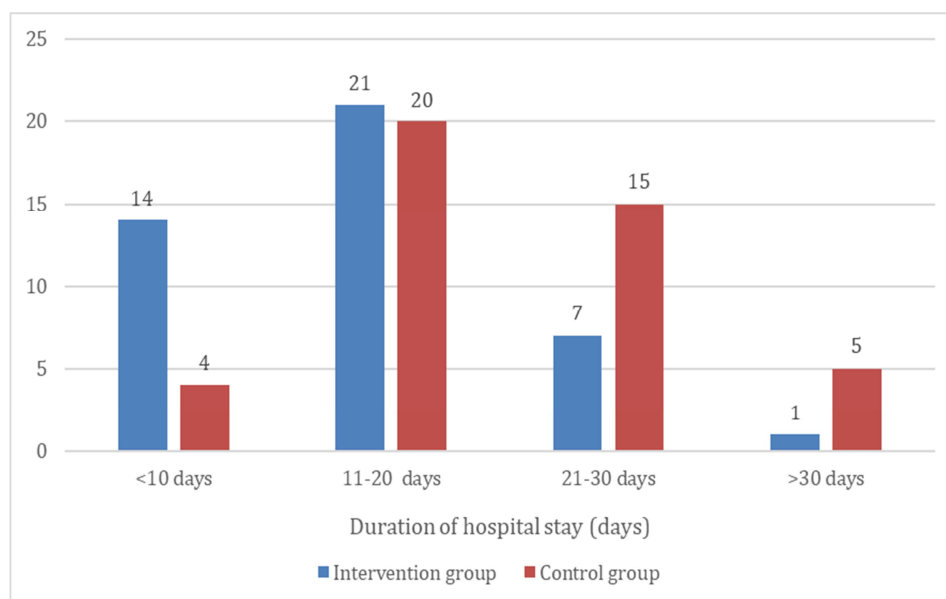
**Figure – 11. Duration of hospital stay**

Table 11: Duration of hospital stay versus birth weight

Birth weight (grams)	Duration of hospital stay (days)		P value
	Intervention group (n = 44)	Control group (n = 44)	
≤1000 grams	29.5 ± 10.43	31.5 ± 2.35	0.001
1001-1500 grams	17.37 ± 9.24	22.12 ± 12.14	
>1500 grams	12.1 ± 8.59	16.64 ± 11.89	
Mean ± SD (days)	14.81 ± 6.21	19.16 ± 7.06	

In our study, the duration of hospital stay was 29.5 ± 10.43 days in the intervention group and 31.5 ± 2.35 days in the control group in neonates < 1000 grams. For neonates weighing 1001-1500 grams, the length of hospital stay in the intervention group was 17.37 ± 9.24 days and 22.12 ± 12.14 days in control groups. In the intervention and control groups for babies > 1500 grams it was 12.1 ± 8.59 days and 16.64 ± 11.89 days respectively. Duration of hospital stay for the entire intervention group was 14.81 ± 6.21 days and for the control group was 19.16 ± 7.06 days. Statistically significant difference is observed for duration of hospital stay for entire study groups and also across birth weight categories ($P = 0.001$).

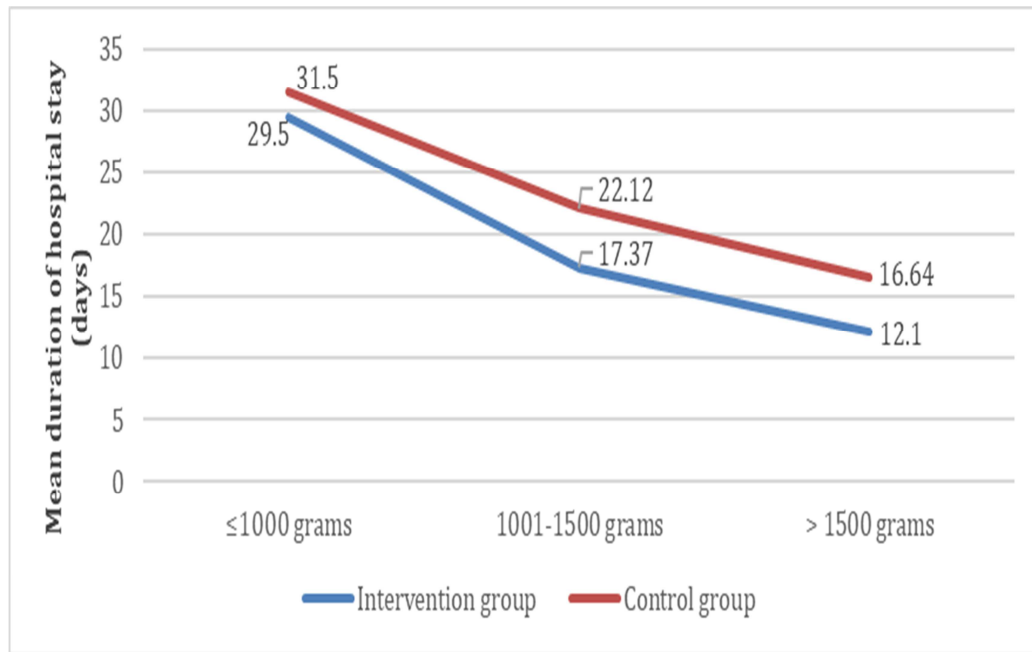


Figure – 12. Mean duration of hospital stay versus birth weight

Table 12: Duration of hospital stay versus Gestational age

Gestational age (weeks)	Hospital stay (days)		P value
	Intervention group (n = 44)	Control group (n = 44)	
30-32 weeks	21.7 ± 5.95	23.8 ± 6.48	0.04
32 ⁺¹ - 34 weeks	12.72 ± 6.24	18.2 ± 4.91	
Mean ± SD (days)	14.81 ± 6.21	19.16 ± 7.06	

In our study, the duration of hospital stay was 21.7 ± 5.95 days in the intervention group and 23.8 ± 6.48 days in the control group for neonates between 30 - 32 weeks. It was 12.72 ± 6.24 days and 18.2 ± 4.91 days in the intervention and control groups respectively for neonates between 32⁺¹ - 34 weeks. The duration of hospital stay for the entire intervention group was 14.81 ± 6.21 days and 19.16 ± 7.06 days for the control group. Statistically significant difference observed for entire study groups and also across gestational age categories ($P = 0.04$).

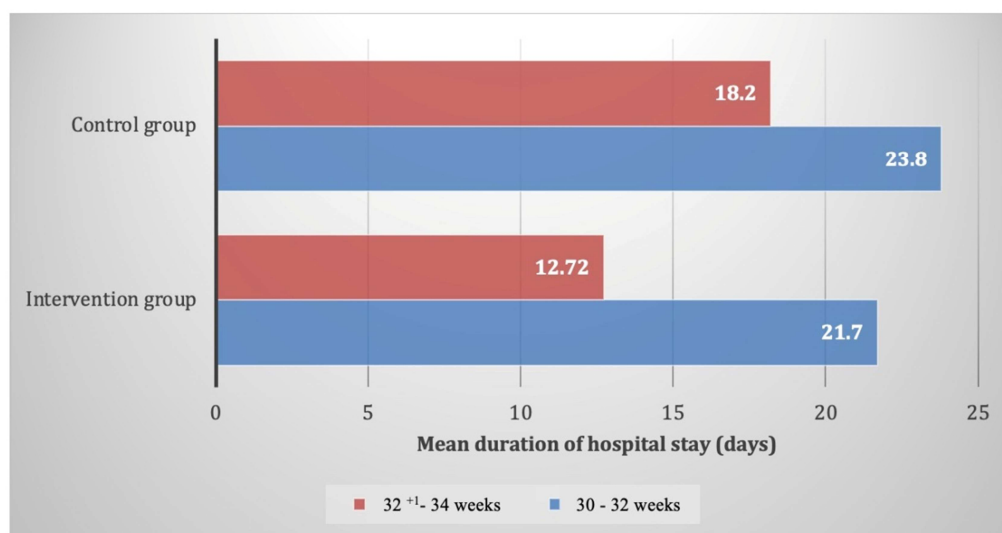


Figure – 13. Mean duration of hospital stay versus Gestational age

Table 13: Weekly weight gain in study subjects

Week	Weight gain (grams)		P value
	Intervention group	Control group	
First	-45.56 ± 15.68	-61.19 ± 29.12	0.02
Second	47.57 ± 21.59	44.2 ± 21.25	0.04
Third	61.5 ± 26.57	51.3 ± 29.54	0.0001
Fourth	86 ± 46.21	63.6 ± 31.86	0.0001
Fifth	80 ± 51.2	28.33 ± 19.27	0.0001

In our study, weight loss was observed in the first week in both groups and it was -45.56 ± 15.68 grams in the intervention group and -61.19 ± 29.12 grams in the control group. Weight loss in the control group was more than the intervention group ($P = 0.02$). Enrolled babies started gaining weight from the second week. Weight gain in the intervention group was 47.57 ± 21.59 grams and in the control group it was 44.2 ± 21.25 grams in the second week, which is statistically significant ($P = 0.04$). In the third week, weight gain was 61.5 ± 26.57 grams and 51.3 ± 29.54 grams, in the intervention and control groups respectively, which is statistically significant ($P = 0.0001$). Similarly, for the fourth and fifth week, weight gain is statistically significant in the intervention group ($P = 0.0001$)

Table 14: Transition time from gavage to full oral feeds versus day of initiation of tube feeds

Initiation of tube feeds	Transition time (days)		P value
	Intervention group (n = 44)	Control group (n = 44)	
Day 1	4.66 ± 2.49	7.36 ± 3.82	0.001
Day 2	7.7 ± 2.90	10.25 ± 3.81	
Mean ± SD (days)	5.37 ± 2.59	8.19 ± 3.82	

Our study showed, transition time from gavage to full oral feeds was 4.66 ± 2.49 days in the intervention group and 7.36 ± 3.82 days in the control group, in babies with feed initiated on the first day. It was 7.7 ± 2.90 days and 10.25 ± 3.81 days in intervention and control groups respectively, when feeds initiated on the second day. The transition time for the entire intervention group was 5.37 ± 2.59 days and 8.19 ± 3.82 days for the control group, which is statistically significant ($P = 0.001$).

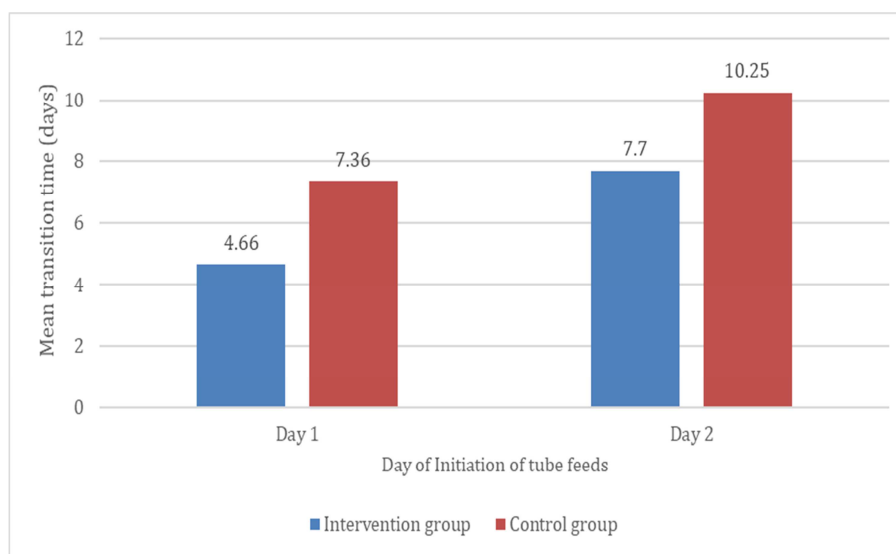


Figure – 14. Mean transition time from gavage to full oral feeds versus day of initiation of tube feeds

DISCUSSION

Premature babies face a variety of challenges after birth, with feeding problems being probably the most common. Preterm infants born before 34 weeks of gestation cannot be successfully fed by mouth because of their incoordinated suck-swallow-breath pattern and have issues of feeding intolerance which is one of the main causes for longer duration of hospital stay. There are numerous prefeeding techniques like oromotor stimulation, non-nutritive sucking, tactile kinesthetic stimulation, infant positioning and abdominal massage is one among them to overcome the feeding issues faced by premature babies. Abdominal massaging in preterm babies helps them with their problem of feeding intolerance by increasing vagus nerve activity of the gastrointestinal tract, thereby improving gastric motility and decreasing duration of parenteral nutrition. Thus it is important to determine whether an intervention like abdominal massage therapy can help premature neonates to increase the pace at which they feed orally. Our study evaluated the effect of abdominal massaging on transition time from gavage to full oral feeds (spoon / paladai feeds), duration of hospital stay and weekly weight gain in enrolled babies.

We enrolled 92 babies into the study, but only 88 subjects were followed up for study outcomes. Forty four neonates were allocated to the intervention group and remaining forty four to the control group.

There were no difference between the intervention and control group with respect to maternal age, gestational age, birth weight (Table - 3,5,6). Thus indicating study groups were comparable, which ensures that study results are due to intervention but not related to difference in study groups.

Our study results showed significant difference in the mean transition time from gavage to full oral feeds between the intervention and control groups ($P = 0.00019$) and also across the birth weight (Table - 8) and gestational age categories (Table - 9). As there is no published data on transition time, we couldn't compare our results with others. Studies conducted by Arora et al.,²¹ Fucile S et al.,³⁹ Bala, et al.,⁴⁰ showed that another prefeeding intervention i.e Premature Infant Oral Motor Intervention (PIOMI), demonstrated that babies who received oromotor stimulation had reached full spoon feeds significantly earlier than babies in control group. However, research done by Govindarajan et al.,⁷ reported that, when multiple prefeeding interventions are given, no significant difference is observed in time taken to reach full oral feeds. The lack of difference between study groups may be related to multiple interventions not being administered as per protocol.

Our study also showed significant difference in transition time between study groups irrespective of day of initiation of feeds ($P = 0.001$).

Results of current study revealed that the mean duration of hospital stay is significantly less ($P = 0.003$) in the intervention group as compared to the control group. We also observed that the duration of hospital stay across the individual birth weight and gestational age categories in the intervention and control groups is statistically significant (Table - 11,12) . Similarly Lessen and Brenda S⁴¹ reported that length of hospital stay is significantly short in the intervention group compared to controls.

In our study, as expected we noticed significant weight loss in both the groups in first week of life but the degree of weight loss was more in the controls ($P = 0.02$). There was significant weight gain in the intervention group compared to the control group in the subsequent weeks (Table -13). Similar observations regarding significant weight gain in the intervention group were made by Elrazek et al.,¹⁰ Abou Heiba et al.⁴².

LIMITATION AND SCOPE OF THE STUDY

- Ours is the only study which looked for the impact of abdominal massage on transition time to achieve full oral feeds, where as other studies looked for various other outcomes like frequency of vomiting, abdominal circumference, volume of milk intake, gastric residual volume, thus making the comparison difficult.
- Abdominal massage is a simple cost effective procedure where mother also can be involved, to provide intervention, which increases bonding between mothers and their babies.
- As the study included limited population from single center, results cannot be extrapolated to the whole population. A study with a large sample size from different geographical areas should be conducted to have reliable results.
- There is a scope for testing the safety and efficacy of abdominal massaging in high risk neonates with lower gestation, as our study was done on stable preterm babies.
- It will be interesting to test whether abdominal massage intervention can be continued following hospital discharge, by planning home-based follow up intervention to assess the efficacy on feeding related issues.

CONCLUSION

One of the most important problems encountered in a premature neonate is feeding difficulty. Our study supports the practice of five minute abdominal massage, two times a day for seven days in preterm infants to improve their feeding tolerance. Implementation of the abdominal massage therapy shortened the transition time from gavage to full oral feed, duration of hospital stay and improved weekly weight gain. Therefore, this simple, cost effective intervention can be performed on all stable preterm neonates admitted to NICU to impact feeding tolerance.

SUMMARY

Observational study was conducted from January 2023 to December 2023 in the Department of Paediatrics, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi.

The salient findings of the study are summarized below :

- During the study period, 92 babies were enrolled, of which only 88 were included in the analysis. Forty four babies were allocated to the intervention group and the remaining 44 to the control group.
- In our study, 43.20% of babies were female and the remaining 56.80% were male in the intervention group. In the control group, 47.7% were female and the remaining 52.3% were male.
- Majority of the enrolled participants were > 32 weeks of gestation in both the groups i.e, 77.3% in intervention group, 84.1% in control group. Mean gestational age in the intervention group is 32.93 weeks and in the control group 32.61 weeks.
- In our study , 4.5% of the neonates were < 1000 grams, 36.4% were between 1001 to 1500 grams and 59.1% were > 1500 grams. Mean birth weight in the intervention and control group was 1564.18 grams and 1522.5 grams respectively.
- There was no significant difference in the mean gestation age and birth weight between intervention and control groups.

- Mean transition time from gavage to full oral feeds in intervention group is significantly low (5.37 days) compared to control group (8.19 days) and is also true for individual gestational age and birth weight groups.
- Mean duration of hospital stay is 14.81 days in intervention group which is significantly less compared to 19.16 days in control group. Also, statistically significant differences are observed across gestational age and birth weight categories.
- In our study, there was significant weight gain in intervention group compared to control group in the 2nd, 3rd, and 4th week.

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ANNEXURE I - CONSENT FORM

CONSENT FOR PARTICIPATION IN RESEARCH

**“EFFECT OF ABDOMINAL MASSAGING ON PROGRESSION TO FULL
ORAL FEEDING IN PRETERM INFANTS - ONE YEAR HOSPITAL BASED
OBSERVATIONAL STUDY”**

Principal Investigator : REG NO. BM0121014

Guide : Dr . _____

Co Guide : Dr . _____

Objective:

Primary :

- To determine the effect of abdominal massaging in preterm infants on transition time from gavage to full oral feeds (spoon / paladai feeds).

Secondary :

- To determine the effect of abdominal massaging in preterm infants on :
 1. Weekly weight gain.
 2. Length of hospital stay.

Name of the Participant :

You are hereby requested to involve your preterm newborn baby in the above-mentioned research to be conducted at KLES Dr Prabhakar Kore Hospital and Medical Research Centre, Belgaum from January 2023 to December 2023 by me.

Introduction:

Prematurity is associated with an underdeveloped gastrointestinal system leading to feeding intolerance in infants. Feeding is one of the important functions of a neonate. Effective feeding is important for weight gain in preterm infants. To enhance feeding tolerance various intervention techniques have been tried and found to be beneficial. The main purpose of this study is to determine the efficacy of abdominal massaging as measured by transition time from gavage to full oral (spoon/paladai) feeds, weekly weight gain, and duration of hospital stay.

Voluntary participation in the study :

Participation of your preterm newborn baby in this study is your voluntary decision. Whether to participate or not participate will not affect your current or future relationship with KLES Dr Prabhakar Kore Hospital and Medical Research Centre, Belgaum. You are free to discontinue participation in the study at any time for any reason and you will not be paid any reimbursement for participation in the research.

Possible benefits of participating in the study :

You will not have nor get any benefits by participating in this study. The data gathered will help the population at large.

Possible risks of participating in the study :

There are no risks involved in participating in this study.

Privacy and confidentiality :

The only people who will know that you are a research participant are members of the research team. No information about you or provided by you, during research will be disclosed to others without your written consent. When the results of the research are published or discussed in the conferences, no information will be disclosed that would reveal your identity. Any information obtained in connection with this study that can be identified with you remains confidential and will be disclosed only with your permission.

Financial incentives :

You will not receive any payment for participating in this study.

Queries :

In case of any questions about this study, you may contact **REG NO. BM0121014**, Post Graduate Student, Department of Pediatrics, KLES Academy of Higher Education and Research, Jawaharlal Nehru Medical College, Belgaum.

In case of any questions about this study, you may contact **Dr Harsha Hegde**, Chairperson, JNMC Institutional Ethics Committee on Human Subjects Research, Jawaharlal Nehru Medical College, Belgaum.

STATEMENT OF CONSENT

I hereby voluntarily agree to my newborn baby's participation in the study, **“EFFECT OF ABDOMINAL MASSAGING ON PROGRESSION TO FULL ORAL FEEDING IN PRETERM INFANTS - ONE YEAR HOSPITAL BASED OBSERVATIONAL STUDY”**. I understand that even if I choose to allow my newborn baby to take part in this study, I have the liberty to withdraw at any time. My signature below indicates that I have read or have been told about this entire consent form including the risks and benefits and have had all my questions answered. I will be given a copy of this consent form.

Signature or left thumb impression of the parent : _____

Date : _____

Name : _____

Relation to the subject : _____

Signature or left thumb impression of the witness : _____

Date : _____

Name : _____

Signature of the investigator : _____

Date : _____

Name : _____

ANNEXURE II - PROFORMA

**“EFFECT OF ABDOMINAL MASSAGING ON PROGRESSION TO FULL
ORAL FEEDING IN PRETERM INFANTS - ONE YEAR HOSPITAL
BASED OBSERVATIONAL STUDY”**

Principal Investigator : REG NO. BM0121014

Guide : Dr. _____

Co Guide : Dr. _____

SUBJECT NO : - _____

IP No : _____

MATERNAL INFORMATION :

1) Name :

2) Age :

3) Permanent address :

4) Telephone No. :

5) LMP :

EDD :

Gestational age(weeks) :

NEONATAL INFORMATION:

1) Date of birth : ___/___/_____ 2) Study group : A B

3) Gestational age : _____ week

- 4) Age at enrollment :-
- 5) Sex : Male / Female
- 6) Birth weight (grams) :- _____ gm
- 7) Weight at enrollment :- _____ gm
- 8) Any major congenital anomalies : YES/NO
- 9) Intra ventricular hemorrhage - YES/NO, if YES, Grade - _____
- 10) Necrotizing enterocolitis – YES/NO, if YES, Stage - _____
- 11) Perinatal Asphyxia – YES/NO, if YES, Stage - _____
- 12) Any condition where oral feeding is contraindicated – YES/NO, if YES,

13)		Tube feeds	Tube + spoon feed (partial spoon feeds)	Full spoon feeds
	Day of life			
	Time taken to achieve full oral feeds in days			

14) Day of life	day 7	day 14	day 21	day 28
Weight (gms)				
Weight gain (gms)				

15) Weight at discharge : _____


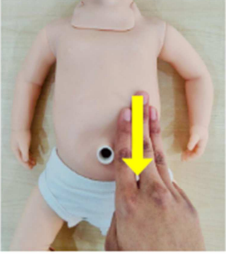

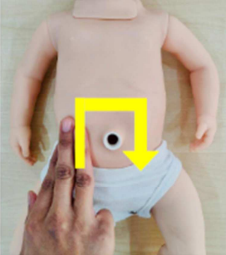

16) Duration of hospital stay : _____ days.

17) Date of discharge :

ABDOMINAL MASSAGE MONITORING CHART

	12:00 PM	4:00 PM	Remarks
Day 1			
Day 2			
Day 3			
Day 4			
Day 5			
Day 6			
Day 7			

STEPS OF ABDOMINAL MASSAGE

STEPS	TECHNIQUE	PHOTOS
1	The massage is given in circular, clockwise motion, with the fingertips around umbilicus for 10 times	
2	Stroke down on left side of baby's tummy (like letter "I") for 10 times	
3	Give a stroke starting from Right to Left of baby and then downwards (like upside down "L") for 10 times	
4	Give a stroke starting from below on baby's right side, up and give stroke horizontally, and then down on left side (as on inverted "U") for 10 times (combinedly this method is known as "I Love U" stroke)	
5	Move fingers around umbilicus, in clockwise motion for 10 times.	

ANNEXURE - III

KEY TO MASTERCHART

- GENDER

M - Male

F - Female

- DURATION OF TRANSITION TIME FROM GAVAGE TO FULL ORAL FEEDS

RT - Ryle's Tube

SF - Spoon Feeds

ANNEXURE IV - MASTER CHART

subject no	IP no	maternal age (yrs)	gender	gestational age (weeks+days)	birth weight (gms)	day of initiation of tube feeds (day of life)	GROUP-A					day of enrollment	length of hospital stay in days	weight at enrollment (gms)	weight on discharge (gms)	weekly weight gain (gms)				
							day of initiation of spoon feeds (RT+spoon) (day of life)	day of initiation of full spoon feeds (day of life)	duration of transition from gavage (RT & RT+SF) to full oral feeds (SF) in days	1st week (day-7)	2nd week (day-14)					3rd week (day-21)	4th week (day-28)	5th week (day-35)		
1	1160321	23	M	33 weeks+5days	1900	1	2	5	4	1	10	1900	1775	-	15 (day-10)					
2	1160456	21	F	32weeks+6days	1300	1	2	7	6	1	19	1300	1360	-	20	40 (day-19)				
3	1164576	23	M	33weeks+5days	1700	1	2	4	3	1	9	1700	1580	-	20 (day-9)					
4	1161989	21	F	30weeks+1day	1400	1	2	5	4	1	27	1400	1580	-	60	60	80 (day-27)			
5	1160574	25	M	32weeks+3days	1460	1	3	6	5	1	16	1460	1570	-	90	50 (d-16)				
6	1161074	26	M	34weeks	1900	1	2	4	3	1	12	1900	1865	-	15 (day-12)					
7	1161452	20	F	33weeks+3days	1390	1	3	6	5	1	17	1390	1435	-	30	55 (day-17)				
8	1195790	27	M	33weeks+4days	1600	1	2	4	3	1	10	1600	1655	20	35 (day-10)					
9	1203479	24	F	32weeks	1410	1	3	6	5	1	15	1410	1445	-	50	25 (day-25)				
10	1200930	32	M	33weeks+5days	2000	1	2	4	3	1	12	2000	2010	-	50 (d-12)					
11	1201482	31	M	33weeks+6days	2000	2	3	6	4	2	11	1990	1920	-	30 (d-11)					
12	1204025	27	F	33weeks+6days	1640	1	3	5	4	1	14	1640	1700	-	90					
13	1204026	27	M	33weeks+6days	1550	1	3	7	6	1	14	1550	1540	-	50					
14	1206163	25	M	33weeks+3days	1510	2	3	6	4	2	10	1510	1560	20	30 (d-10)					
15	10012353	25	M	33weeks+2days	1980	1	2	6	5	1	20	1980	2100	-	60	60 (d-20)				
16	10012452	26	F	33weeks+6days	1200	2	3	7	5	1	13	1200	1180	-	80 (day-13)					
17	10012453	26	F	33weeks+6days	1450	1	3	6	5	1	13	1450	1500	-	80 (day-13)					
18	10012354	25	M	33weeks+2days	1510	2	4	8	6	2	20	1500	1650	20	50	70 (day-20)				
19	10012846	27	M	32weeks+3days	1460	1	2	6	5	1	15	1460	1520	-	90	-				
20	10013391	34	F	30weeks+6day	1130	2	5	14	12	2	30	1120	1340	-	50	70	100	40 (day-30)		
21	10013928	24	M	32weeks+3days	1460	-	-	-	-	-	-	-	-	-	EXPIRED					
22	10013967	34	F	30weeks+5day	930	2	7	15	13	2	35	920	1240	-	55	100	100	120		
23	10014727	31	F	33weeks+1day	1510	1	2	5	4	1	12	1510	1470	-	no weight gain was observed during hospital stay					
24	10015538	28	M	33weeks+4days	1900	1	2	5	4	1	10	1900	1810	-	30 (d-10)					
25	10015536	32	M	33weeks+4days	2000	1	2	4	3	1	8	2000	1900	-	20 (d-8)					
26	10016456	26	F	33weeks+1day	1300	2	3	6	4	2	13	1300	1310	-	50 (day-13)					
27	10020695	23	F	31weeks+1day	990	2	7	12	10	1	24	990	1020	-	30	50	50 (d-24)			
28	10024165	30	M	30weeks+6days	1640	1	2	8	7	1	17	1640	1790	-	90	90 (d-17)				
29	10021258	25	F	33weeks+5days	1900	1	2	5	4	1	9	1900	1785	-	25 (day-9)					
30	10022510	23	M	33weeks+5days	1400	1	3	6	5	1	9	1400	1320	-	10 (d-9)					
31	10024831	22	M	33weeks	1740	1	2	4	3	1	13	1740	1820	10	70 (d-13)					
32	10024693	22	F	32weeks	1840	1	2	4	3	1	14	1840	1880	-	80					
33	10024690	22	M	32weeks	1670	2	3	10	8	2	14	1660	1660	-	60					
34	10026032	24	M	33weeks+3days	1520	-	-	-	-	-	-	-	-	-	EXPIRED					

35	10026394	26	F	30weeks+4day	1280	2	5	13	11	2	26	1270	1450	-	30	80	100 (d-26)	
36	10028975	21	M	31weeks+2days	1380	1	4	11	10	1	15	1380	1440	-	50	10 (d-15)		
37	10030853	37	F	33weeks+4days	1890	1	2	5	4	1	8	1890	1820	-	10 (d-8)			
38	10033467	30	F	33weeks+6days	1600	1	2	4	3	1	10	1600	1640	10	30 (d-10)			
39	10033469	30	F	33weeks+6days	1300	1	3	6	5	1	10	1300	1300	-	20 (d-10)			
40	10033294	27	M	33weeks	1720	1	2	5	4	1	10	1720	1745	-	35 (d-10)			
41	10034431	25	F	33weeks+5days	1920	1	3	8	7	1	16	1920	1875	-	40	35 (d-16)		
42	10034940	29	F	34weeks	1950	1	2	6	5	1	9	1950	1880	-	20 (d-9)			
43	10037023	31	M	32weeks+4days	1120	1	3	8	7	1	20	1120	1300	10	50	120 (d-20)		
44	10037024	31	M	32weeks+4days	1270	1	3	7	6	1	20	1270	1330	-	40	70		
45	10038057	27	M	33weeks+5days	1630	1	2	8	7	7	17	1630	1790	-	90	100 (d-17)		
46	10039569	28	M	33weeks+3days	1520	1	3	5	4	1	8	1520	1560	20	20 (d-8)			

subject no	IP no	maternal age (yrs)	gender	gestational age (weeks+days)	birth weight (gms)	day of initiation of tube feeds (day of life)	day of initiation of spoon feeds (RT+spoon) (day of life)	day of initiation of full spoon feeds (day of life)	duration of transition from gavage (RT & RT+SF) to full oral feeds (SF) in days	day of enrollment	length of hospital stay in days	weight at enrollment (gms)	weight on discharge (gms)	weekly weight gain (gms)				
														1st week (day-7)	2nd week (day-14)	3rd week (day-21)	4th week (day-28)	5th week (day-35)
1	1160301	22	M	32weeks+4days	1420	1	3	10	9	1	18	1420	1450	-	40	30 (day-18)		
2	1165789	26	F	30weeks+5days	1500	2	5	14	12	2	28	1480	1410	-	-	20	30	
3	1169846	23	M	33weeks+4days	2000	1	1	2	1	1	11	2000	1990	-	90 (day-11)			
4	1168496	22	F	32weeks+1day	1600	2	3	5	3	2	18	1590	1620	-	80	40 (day-18)		
5	1146777	31	M	30weeks+1day	1280	-	-	-	EXPIRED									
6	1159917	27	F	32weeks+2days	1300	2	4	14	12	2	23	1300	1320	-	60	30	10 (day-23)	
7	1161619	23	F	30weeks+5days	1240	1	3	15	14	1	27	1240	1250	-	-	-	80 (day-27)	
8	1161731	26	M	33weeks+3days	1580	2	4	11	9	2	20	1580	1600	-	10	60 (day-20)		
9	1161590	25	M	32weeks+5days	1470	2	5	10	8	2	17	1470	1420	-	-	20 (day-17)		
10	1179084	23	F	33weeks	1340	2	3	8	6	2	31	1330	1435	-	10	70	50	25 (day-31)
11	1186693	28	M	33weeks+1day	1750	2	6	14	12	2	28	1730	1700	-	-	40	30	
12	1196077	34	M	30weeks+3days	920	2	9	19	17	2	32	920	1125	-	60	80	80	45 (day-32)
13	1197530	36	M	33weeks+6days	1800	1	3	7	6	1	16	1800	1810	-	60	-		
14	1199304	26	M	33weeks+4days	1600	2	3	9	7	2	27	1600	1730	-	60	60	90(day-27)	
15	1199306	26	M	33weeks+4days	1600	1	2	7	6	2	27	1600	1780	-	60	70	100 (day-27)	
16	1200010	31	M	32weeks+4days	1100	1	4	13	12	2	21	1100	1200	-	100	80		
17	1203145	23	F	31weeks+3days	1260	2	6	-										
18	1207148	24	F	33weeks	1700	1	3	10	9	1	20	1700	1730	-	10	80 (day-20)		
19	1207128	32	F	33weeks+5days	2000	1	2	5	4	1	13	2000	1940	-	-			
20	10016619	33	F	33weeks+5days	1550	1	4	8	7	1	15	1550	1540	-	50	-		
21	10018198	40	F	33weeks+1day	1580	1	4	12	11	1	27	1580	1680	-	10	60	80 (day-27)	
22	10018199	40	F	33weeks+1day	1120	2	6	14	12	2	27	1120	1300	-	50	100	90 (day-27)	
23	10018210	21	M	31weeks+4days	1300	1	4	8	7	2	16	1300	1320	-	80	10 (day-16)		
24	10018211	21	M	31weeks+4days	1400	1	2	6	5	2	16	1400	1450	-	60	20 (day-16)		
25	10030834	27	F	33weeks+4days	1900	1	2	5	4	1	14	1900	1840	-	10			
26	10032022	23	M	33weeks+2days	1860	1	3	8	7	1	16	1860	1835	-	30	5 (day-16)		
27	10031146	31	M	32weeks+1day	1600	1	2	7	6	1	10	1600	1575	-	25 (day - 10)			
28	10031849	24	M	30weeks+1day	1040	2	7	13	11	2	31	1035	1100	-	30	40	50	-
29	10032624	32	F	32weeks+5day	1230	1	5	13	12	1	23	1230	1320	-	50	70	20 (day-23)	
30	10032625	32	F	32weeks+5day	1570	1	4	11	10	1	23	1570	1645	-	50	70	15 (day-23)	
31	10033673	26	M	32weeks+1day	1350	2	7	16	14	2	25	1330	1510	-	50	70	100 (day-25)	
32	10033836	29	F	34weeks	1960	1	2	4	3	1	8	1960	1915	-	15 (day-8)			
33	10034328	26	F	32weeks+1day	995	1	10	18	17	1	31	995	1255	-	30	110	130	15 (day-31)

34	10035086	34	M	34weeks	1700	1	3	9	8	1	14	1700	1690	-	70			
35	10035087	34	M	34weeks	1860	1	3	7	6	1	14	1860	1860	-	60			
36	10036522	23	F	32weeks+4day	1600	1	3	7	6	1	13	1600	1610	-	60 (day-13)			
37	10036675	27	F	33weeks+5days	2000	1	2	4	3	1	8	2000	1950	-	-			
38	10037524	25	M	32weeks+3day	1200	1	4	8	7	1	14	1200	1180	-	10			
39	10044614	24	M	32weeks+3day	1100	1	5	13	12	1	20	1100	1200	-	100	80 (day-20)		
40	10041393	23	F	33weeks+4days	1790	1	3	7	6	1	13	1790	1780	-	50 (day-13)			
41	10043544	28	M	32weeks+2day	1660	1	3	9	8	1	15	1660	1645	-	50	5 (day-15)		
42	10045927	23	M	31weeks+6days	1290	1	4	8	7	1	17	1290	1300	-	60	20 (day-17)		
43	10045094	27	M	34weeks	1740	1	2	5	4	1	9	1740	1725	-	25 (day-9)			
44	10045095	27	M	34weeks	1630	1	2	5	4	1	9	1630	1600	-				
45	10045687	28	F	33weeks+5days	1570	1	4	11	10	1	23	1570	1645	-	50	70	15 (day-23)	
46	10046094	29	M	33weeks+4days	1550	1	4	8	7	1	15	1550	1540	-	50	-		