"EFFECT OF OROMOTOR STIMULATION ON PROGRESSION TO FULL ORAL FEEDING IN PRETERM INFANTS: ONE YEAR HOSPITAL BASED CASE-CONTROL STUDY"

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This is to certify that the dissertation entitled **"EFFECT OF OROMOTOR STIMULATION ON PROGRESSION TO FULL ORAL FEEDING IN PRETERM INFANTS: ONE YEAR HOSPITAL BASED CASE-CONTROL STUDY"** is a bonafide and genuine research work carried out by **REG NO. BM0119006**

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LIST OF ABBREVIATIONS

BOMI	-	Beckman Oral Motor Intervention
CDH	-	Congenital Diaphragmatic Hernia
CPAP	-	Continuous Positive Airway Pressure
CPG	-	Central Pattern Generator
ECG	-	Electrocardiogram
EDD	-	Estimated Date of Delivery
Fi02	-	Fraction of Inspired Oxygen
HIE	-	Hypoxic Ischemic Encephalopathy
IVH	-	Intra-ventricular haemorrhage
KMC	-	Kangaroo Mother Care
LBW	-	Low Birth Weight
LGA	-	Large for Gestational Age
LMIC	-	Low-and middle- income countries
LMP	-	Last Menstrual Period
LOHS	-	Length of hospital stay
NG tube	-	Nasogastric tube
NICU	-	Neonatal Intensive Care Unit
NNS	-	Non- nutritive sucking
PDA	-	Patent Ductus Arteriosus
PIOMI	-	Premature Infant Oral motor intervention
POG	-	Period of gestation
sCPG	-	Suck Central Pattern Generator
SGA	-	Small for Gestational Age
WHO	-	World Heath Organisation

ABSTRACT

Background and objectives

One of the limiting factors for early discharge in preterm infants is their inability to feed sufficiently to achieve consistent weight gain. Feeding difficulty is one of the most significant issue faced by preterm infants. These are due to problems in their cardiorespiratory and central nervous system as well as the incomplete development of their oral structure. Difficulty in oral feeding leads to longer hospital stays and higher costs. There is a need for evidence based interventions that facilitate development of oral motor skills, leading to improved oral feeding, thus shortening hospital stays and lowering costs. The purpose of this study was to test the newly developed Premature Infant Oromotor Intervention (PIOMI), to determine whether the pre-feeding intervention would result in a shorter transition time from gavage to full oral feedings, weight gain and a shorter length of hospital stay.

Materials and methods

This observational study was conducted from January 2020 to August 2021 in the Department of Pediatrics, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi. A total of 106 preterm newborns with gestation between 30-34 weeks were enrolled. Maternal and newborn data was collected in a structured proforma. Subjects were randomly allocated to intervention and control group. In the intervention group, five minute oral stimulations were performed based on Premature Infant Oral Motor Intervention (PIOMI) by the nursing staff or mother on a daily basis (three times a day), 20 minutes before feeding for seven days. On the other hand, the control group received routine NICU care. Then the groups were compared in terms of transition duration from gavage to full oral feeds, length of hospital stay and weight gain. The data was analysed using R version 4.1.1 statistical software. Chi-square test, Welch's t- test and Mann –Whitney tests were used.

Results

During the study period 106 babies were enrolled but 103 babies were included in the analysis, out of which 56 babies in intervention group and 47 babies in the control group. Mean gestational age in intervention group is 31.8 weeks and in control group is 31.6 weeks. There is no significant difference in the mean gestation age, gender and birth weight between intervention and control groups. The mean transition duration from gavage to full oral feeds is significantly less in intervention group (5.55±1.67 days) compared to control group (10.53±5.16 days). The mean length of hospital stay is significantly less in intervention group (15.98±5.5 days) compared to control group (20.51±7.81days). 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.

Conclusion

Oromotor stimulation program shortened the transition time from gavage to full oral feed, length of hospital stay and improved weekly weight gain. Therefore, these interventions could be performed for all stable preterm infants admitted to NICU to enhance feeding skills.

Keywords:

Preterm, Oromotor stimulation, Weight gain, Hospital stay.

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INTRODUCTION

According to WHO, The term "preterm newborn" refers to a baby born before the 37th week of pregnancy[1]. Premature birth affects 15 million newborns each year. There is a 9.6% prevalence of premature birth globally. In India, 3.5 million babies are born premature out of a total 27 million births[2].

The survival of preterm neonates has dramatically improved by advancement in newborn intensive care. Successful oral feeding is one of the final requirements in their care prior to discharge. The functional immaturity of several systems causes a variety of clinical problems, oral feeding difficulties are generally prevalent in premature newborns[3].

They need to be admitted to the neonatal intensive care for few days to several months before they learn to coordinate sucking, swallowing, and breathing to attain safe and effective oral feedings, since the digestive, respiratory, central nervous systems of preterm are underdeveloped[4]. Coordinated suck-swallow-breathing patterns becomes more complete with increasing fetal age until 34 weeks. Therefore, infants with higher gestational age will have better sucking skills.

The lack of coordinated sucking, swallowing and breathing is the primary barrier to oral feeding in neonates with gestational age less than 34 weeks. Oral feeding in these neonates can cause transient bradycardia, desaturation, apnea and aspiration. Neonates less than 32 weeks are not able to have an independent oral feeding and they are fed by tubes. Long-term gavage feedings can result in a lack of desire to breastfeed[5]. Infants who experience these problems often requires long term hospitalization ,which can lead to stress in families, especially mothers, and increase in financial burden[6].

Feeding difficulties can also occur due to immaturity of the oromotor systems, which has a negative impact on the weight gain and health status of the infant. Preterm infants after achieving their physiological stability still exhibit greater challenge in transition from nasogastric tube to full oral feeding[7]. Since oral nutrition problems cause long term hospitalization and high costs, some interventions are required to improve the development of oromotor skills, improve oral feeding in neonates 34 weeks and lower, and reduce the costs and length of hospitalization.

Caregivers, who work in the Neonatal intensive care units (NICU) may use variety of oromotor stimulation techniques to improve oral feeding in preterm infants[8]. Non-nutritive Sucking (NNS) and prefeeding oromotor stimulations are the best commonly used techinques. To enhance the oral feed acceptability of premature infants, Premature Infant Oral Motor Intervention (PIOMI) was designed by Dr. Brenda Lessen based on the Beckman's Oral Motor Intervention (BOMI). Oral sensorimotor interventions have been a major focus as they provide a direct, targeted input to the oral structures involved in feeding. Oromotor stimulation programmes have proven advantageous in developing oral feeding skills in preterm neonates due to the fact that centrally generated oromotor patterns produced by the suck Central Pattern Generator (sCPG) can be entrained to an applied orocutaneous stimulus, which serves to induce synchronous patterned neural activity along trigeminal primary afferents and leminiscal pathways[9].

The use of perioral prefeeding stimulation, provides touch pressure throughout feeding time, increases the volume intake[10], and sensorimotor intervention accelerates the feeding efficiency, with consequent decrease of the hospital stay and costs[11].

Oromotor stimulation program given to preterm infants can reduce transition period from gavage to full oral feeding by improving sucking abilities, developing neural networks that are active during suck pattern generation which helps in patterned orocutaneous stimulation .The buccal fat pads are mass of adipose tissues which helps to enhance sucking capacities of masticatory muscles during infancy. Its function in infants is to provide help for sucking and enhancing capacities of buccinators and other muscles of mastication.

In neonates, feeding is one of the important function. To gain weight in preterm low birth weight infants, effective feeding is an important criteria. Sensorimotor intervention can improves oral feeding. Oromotor stimulation is a prominent emphasis because it provides tailored input to oral structures that are engaged in feeding.

Oromotor stimulation is simple, safe, easy and cost effective intervention. In india there is scarcity of literature on oromotor stimulation programme by the mother. Therefore, the present study intends to assess the impact of oromotor stimulation on progression to full oral feeds, weight gain and length of hospital stay in premature infants.

OBJECTIVES

PRIMARY

1. To assess the impact of oromotor stimulation on transition time from gavage to full oral feeds (spoon / paladai) in preterm neonates.

SECONDARY

To assess the impact of oromotor stimulation on

1. Length of hospital stay.
2. Weekly weight gain.

REVIEW OF LITERATURE

Incidence & prevalence

Preterm or premature babies are those born before the 37th week of gestation, according to the World Health Organization (WHO). Every year an estimated of 15 million babies are born premature worldwide, accounting for 9.6% prevalence globally. The incidence of preterm birth in India is estimated to be 11-14%. This accounts for annual incidence of 3-4 million preterm live birth in india[12].

Problems in prematurity

Prematurity is one of the important factor that causes neonatal complications and hampers normal development. During the transition from intrauterine to extrauterine life, infant health problems are specific. In 2017, 2.5 million newborn deaths occurred globally, accounting for 47 % deaths in children younger than five years. Slightly more than a third of these deaths resulted from preterm related causes[13]. Many complications can occur in premature babies, including respiratory distress syndrome, chronic lung illness, intestinal injuries, weakened immune systems,feeding difficulties, and cardiovascular abnormalities.

The functional immaturity of several systems causes a variety of clinical problems, and understanding them is important for the management of premature babies. In babies weighing less than 1800g or born before 35 weeks of gestation, the central nervous system's immaturity manifests as inactivity and lethargy, a poor cough reflex, and lack of coordinated sucking and swallowing. Due to a relative lack of vitamin K dependent coagulation factors and enhanced capillary fragility, these preterm neonates are highly susceptible to intraventricular-periventricular haemorrhage and leukomalacia. In babies with a gestational age lesser than 26 weeks, the cuboidal alveolar lining causes inadequate alveolar gas diffusion, and hence the infant may not be viable. If combined with lung surfactant insufficiency, they cause resuscitation problems at birth, which are frequently followed by hyaline membrane disease. In cardiovascular system, the closure of the ductus arteriosus in the circulatory system is delayed in premature newborns. About a third of infants born at 34 weeks or less have clinical signs of patent ductus arteriosus, either with or without congestive heart failure[14].

Feeding is challenging due to the gastrointestinal system's immaturity. Incoordinated sucking, a small stomach capacity, incompetence of the cardio-esophageal junction, and a poor cough reflex are all factors that contribute to regurgitation and aspiration.

Feeding problem in preterm babies

Feeding problems affects 25% of all babies. However prematurely born neonates, are more likely to have feeding issues than term babies. Oral feeding issues affect 30-40% of premature infants. Because of their harmful effects on babies health and quality of life, oral feeding issues in the preterm neonates are a serious public health concern[15].

The survival of preterm neonates have been dramatically improved by advancement in newborn intensive care. Successful oral feeding is one of the final requirements in their care prior to discharge. The functional immaturity of several systems causes a variety of clinical problems, oral feeding difficulties are generally prevalent in premature newborns[3].

They need to be admitted to the neonatal intensive care for few days to several months before they learn to coordinate sucking, swallowing, breathing to attain safe and effective oral feedings. Feeding behaviors are developed before birth. At week 11, the fetus starts jaw movements followed by swallowing and sucking at 13^{th} week[16].The breathing, sucking and swallowing patterns become more complete with an increase in fetal age until 34 week. Therefore infants with higher gestational age will have better sucking skills.

Hypotonia, weakness, and lack of coordination in movements, poor consciousness, irritability, unstructured motor activities, and physiological instability all contribute to feeding issues in babies born before 37 weeks of gestation[16]. The lack of coordinated sucking, swallowing and breathing is the primary barrier to oral feeding in neonates with gestational age less than 34 weeks. As a result, infants under the age of 32 weeks are unable to feed themselves and rely on tube feeds for nutrition. Infants with these issues, frequently require long-term hospitalization, which can cause stress in families particularly mothers, as well as an increase in financial burden[6].

Immaturity of the oromotor systems also contributes to feeding difficulties which has a negative impact on the weight gain and health status of the infant. After establishing physiological stability, a significant number (30%) of preterm babies still face difficulties in transitioning from nasogastric tube to full oral feeding[7]. Since oral nutrition problems cause long term hospitalization and high costs, interventions are required to facilitate the development of oromotor skills to improve oral feeding in infants 34 weeks and lower, and reduce the cost and length of hospitalization.

The suck Central Pattern Generator (sCPG), which contains bilateral internuncial circuits within the pontine and medullary reticular formation, is principally responsible for ororhythmic motor activity. Suck indicates a complex sensorimotor activity that aids in determining the integrity of central nervous system[9].

Fucile et al, conducted a study in 2011 which showed that a comprehensive approach can lessen and/or prevent infant oral feeding issues, easing the cost of care. Early intervention measures are required to help preterm infants establish optimal oral feeding abilities[15]. This is essential for relieving parental anxiety, avoiding long-term hospitalisation, and lowering expenditures. A study by Mousa et al.in 2017 reported that oral feeding requires the coordinated interaction of multiple complex processes like sucking, swallowing, and breathing which are all controlled by cardio-respiratory, neurological, gastrointestinal, behavioural, and musculoskeletal systems[17].

Oral stimulation techniques are often employed in premature infant rehabilitation programmes. It has been proved from various studies that prefeeding oromotor stimulation can results in improvement of sucking, swallowing and respiration. NNS and intra-oral stimulation improves salivary secretions and make swallowing smoother. Perioral stimulation improves oromotor organisation, muscle contractility, and sucking rate, which improves oral intake and minimises fluid loss[18,19].

Following interventions are generally used to facilitate feeding preparedness

1) Oromotor stimulation

2) Non-nutritive sucking (NNS)

3) Oral support.

1. Oral Motor Stimulation

Premature Infant Oral Motor Intervention (PIOMI) was designed by Dr. Brenda Lessen based on the Beckman's Oral Motor Intervention (BOMI). Oral stimulation techniques can help to enhance suck-swallow-breathe coordination, latching, suction strength and endurance, all of which can assist with safe and successful oral feeding. According to study by Calk.P in 2019, using both intra and peri oral pre-feeding stimulation, there was statistically significant results of improved feeding efficiency, shorter duration to reach full oral feedings and weight gain as well as shorter length of hospital stay[20]. It is significant to ensure that preterm infants are physiologically stable and should show hunger signs as well as neurobehavioral states of calm and alertness before starting oral stimulation. After achieving the prior mentioned circumstances, it is recommended to initiate perioral stimulation followed by intra oral stimulation.

According to PIOMI, oromotor stimulation programme is a five minute intervention three times per day, twenty minutes before feeds for seven consecutive days. This intervention consists of following steps- Lip roll, Lip curl or Lip stretch, Gum massage, Stroking of cheeks, lateral borders of tongue and mid blade of tongue followed by suck elicitation. Steps of oromotor intervention is described below (Figure- 1).

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- 1. Steps of premature infant oromotor intervention

2. Non-nutritive Sucking (NNS)

Non-nutritive Sucking (NNS) is any suckling that does not involve the introduction of fluid, as opposed to nutritive suckling that involves the introduction of fluid and the formation of bolus in the mouth and throat[21]. NNS is a self soothing behaviour and its use has been shown to reduce length of hospital stay in preterm infants[22].

NNS may help neonates' behavioural and physiological states, in addition to coordination in sucking, swallowing and breathing, by increasing strength, endurance, and suction. Methods, Implementation and Outcomes of NNS as follows:

a) Methods

- Pay attention to the infant's cues, including as crying, sucking, vigorous movement, and rooting.
- Look for symptoms like sucking on the orogastric tube or waking up for feeding when assessing an infant's readiness to breastfeed.

b) Implementation

- Place the baby in a way that encourages hand-to-mouth activity..
- Place the infant so that he or she may suck on his or her own thumb and fingers. To aid the behaviour, it's essential to induce nesting or a flexed position
- For about five minutes before oral gastric / oral feeds, give preterm infants dummies / pacifiers, since this helps with state organisation and soothing..
- Wait for the neonate to open his or her mouth wide and extend his or her tongue before giving him or her a dummy/pacifier to promote this prefeeding behaviour.

c) Outcomes

- Earlier achievement of nutritive sucking [23].
- Improvement of the mature suck-swallow reflex, resulting in a shorter time to full enteral feeding and increased weight gain[24].
- It promotes initiation of lactation and minimise the length of hospital stay[22].

A study by Lessen BS in 2011 states that a remarkable improvement in suck organization, coordination, strength and endurance when using NNS with a pacifier or finger[25]. NNS in combination with oral stimulation resulted in a significant increase in oral feeding. Fucile et al., in 2011, found the preterm infants who got NNS in addition to oral stimulation seem to be discharged earlier than those who did not receive the same[15].

3. Oral support

Oral support helps in deglutition coordination, reduces fliud loss, and improves cheek and jaw stability[26]. Oral support should be used during oral feeding to provide stability and improve the sucking pattern by placing the middle finger under the chin to apply pressure to the mandible, the thumb and index fingers compressing the cheeks toward the lips, and the fifth digit compressing the floor of the oral cavity under the chin to reinforce the swallowing[27,28](Figure-2). In 1994 a study by Einarsson-Backes et al, on the effect of oral support to improve sucking efficiency in preterm infants reveals a significant increase in volume intake in the oral support group compared to non-oral support group[29].

Figure- 2. Method of giving Oral support

3. **Co-interventions**

Studies by Averdson et al, Asadollahpour, et al.(2015) showed oral stimulation, when used in conjunction with NNS and oral support, resulted in significantly shorter duration of transition to oral feeds and weight gain in preterm infants[30]. Fucile et al., (2011) reported that neonates who received oromotor stimulation along with NNS had higher weight gain and shorter hospital stay than those who received either one intervention or no intervention[15].

Various researchers have conducted studies regarding effect of oromotor stimulation on progression to full oral feeding in preterm infants and the following are some of those studies.

A Randomized controlled study on oromotor stimulation program for preterm infants by **Arora,et al**. enrolled 30 preterm infants between 28-32 weeks, with 16 in intervention group and 14 in control group, reported that neonates in the intervention group achieved full oral feeding earlier than the infants in control group (P=0.001).

Also reported significant weight gain in intervention group compared to control group (P=0.001)[31].

Bala et al, conducted a randomized controlled trial to assess the effect of oromotor stimulation on progression to full oral feeding in preterm infants between 28-34 weeks. Fifty one neonates were included in the study of which 25 were in the intervention group and 26 in control group. Mean duration to reach partial (P=0.006) and full oral feed (P=0.03) were significantly shorter in intervention group than in control group. They also observed that intervention group received partial breast feeding at discharge than control group [32].

A study on prefeeding oromotor stimulation program for preterm infants by **Fucile,et al,** enrolled 16 babies each in intervention and control group. The mean duration to reach to independent full oral feed was significantly early in intervention group compared to control group (P=0.005).Overall intake and rate of milk transfer were significantly greater over time in the intervention group than the control group(p=0.0002).There was no difference in length of hospital stay between the two groups. They concluded that an early oral stimulation program accelerates the transition to full oral feeding in preterm infants[33].

Younesian S et al conducted a study to evaluate impact of oromotor stimulation on feeding performance, weight gain and duration of hospital stay in 20 preterm neonates between 30-32 weeks of gestational age. Study results showed neonates in the intervention group achieved full oral feeding earlier than the control group ($P<0.001$).The length of hospitalization was significantly shorter in the intervention group than in the control group ($P<0.05$). The two groups showed no significant difference in terms of weight gain[34].

In 2010 a study with cross over design on effects of prefeeding oral stimulation on feeding performance in preterm infants by **Yea-shwu Hwang et al,** revealed, infants in the intervention group achieved a more volume intake in the initial five minute of the feeding (p=0.021). There was no difference in weight gain between two groups. They concluded that oral stimulation had a modulating effect on the feeding performance of preterm[35].

Asadollahpour F,et al conducted an observational study on the effects of NNS and prefeeding oromotor stimulation on feeding performances in preterm neonates between 26-32 weeks of gestational age. Results showed infants in the intervention group required shorter duration to reach full oral feeding than the control group (P=<0.05). Weight gain at discharge in intervention group was significantly higher than control group (P=<0.05)[36].

A study on effect of oromotor stimulation on feeding progression in 40 preterm babies with gestational age between 28-32 weeks in the NICU by **Mahmoodi N et al** showed, intervention group required shorter duration to reach independent oral feeding than the control group (P=0.034) and the length of hospitalization was shorter in the intervention group compared to control group (P=0.027)[37].

H.Ghomi, et al, in a randomized controlled study on the effect of premature infant oromotor intervention (PIOMI) on oral feeding in preterm infants. Thirty three neonates were included in the study out of which 17 were in intervention group and 16 in control group. Transition duration from gavage to full oral feeds is earlier in intervention group (P<0.001). Length of hospital stay in intervention group was significantly shorter than control group (P=0.03)[38].

A Randomized controlled trial on the effect of an early oral stimulation program on oral feeding in preterm infants, study enrolled 72 preterm infants less than 34 weeks, with 36 in intervention group and 36 in control group. Results showed that the time to reach full oral feeding was significantly shorter in the intervention group ($P < 0.05$). However, there was no significant difference in respect of length of hospital stay ($P=0.724$), or rate of weight gain [39].

MATERIAL AND METHODS

The study was conducted in the department of pediatrics, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, affiliated to Jawaharlal Nehru Medical College Belagavi, from January 2020 to December 2020. Due to COVID-19 pandemic study period was extended till August 2021.

Study design

Observational study.

Study duration and period

One year and eight months. From January 2020 to August 2021.

Place

KLE'S Dr. Prabhakar Kore Hospital and Medical Research Centre, a teaching hospital affiliated to Jawaharlal Nehru Medical College, Belagavi.

Source of data

Preterm infants admitted to the NICU of KLE'S Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi.

Sample size

$$n = (Z_\beta + Z_{\alpha/2})^2 \, (sd_1^2 + sd_2^2)/(\mu_1 - \mu_2)^2$$

$Z_\beta = 1.24$ for 90% power

$Z_{\alpha/2} = 1.96$ for 95 %confidence & 5 % alpha

$n = (1.96+1.24)^2 \, (4^2+4.8^2)/(16.1-13.6)^2$

$n = (10.24)(16+23.04)/(2.5)^2$

$n = 10.24*39.04/6.25$

$n = 400/6.25 = 63.9 \approx 64$ in each groups.

Total sample size = 128.

Due to COVID -19 Pandemic, sample size was reduced to 103.

Ethical clearance

Prior to commencement, study was approved by the Ethical and Research Committee, Jawaharlal Nehru Medical College, Belagavi.

Selection Criteria

Inclusion Criteria

1) Babies (Inborn & Outborn) born between 30-34 weeks of gestation.
2) Medically stable with no respiratory support (except CPAP with low FiO2).
3) Willing to participate in the study.

Exclusion Criteria

1) Major congenital anomalies (craniofacial malformation, hypo-plastic left heart, neural tube defect, congenital diaphragmatic hernia, intestinal obstruction etc.)
2) Grade 3/4 intraventricular hemorrhage.
3) Necrotising enterocolitis stage 2 and 3.
4) Perinatal asphyxia with HIE stage 2 and 3.
5) Any other conditions where oral feeding is contraindicated.
6) Out born babies with more than three days.
7) Babies who die during the period of intervention due to some other cause.

Informed Consent

All the neonates admitted in the NICU fulfilling the eligibility criteria were enrolled into the study after obtaining written informed consent (Annexure-I) from parents.

Methodology

Eligible neonates were allocated to two study groups. Infants born on even dates are allocated to intervention group (Group A), those born on odd dates to control group (Group B). Both groups received care as per NICU protocol, and in addition Group-A received study intervention.

Oromotor stimulation programme is a five minute intervention that consists of following steps- Lip roll, Lip curl or Lip stretch, Gum massage, Stroking of cheeks , lateral borders of tongue and mid blade of tongue followed by suck elicitation. Mothers were trained to deliver intervention till she is confident. Using all aseptic precautions, Infants allocated to intervention group will be subjected to oromotor stimulation by mother/trained nursing staff. Intervention was given three times per day (10am, 1 pm,4 pm) for five minutes each, during day time and 20 minutes before feeding for seven consecutive days.

Both groups were monitored for the study outcomes like time to achieve full oral feed and other outcomes like weight gain and duration of hospital stay. Length of hospital stay is defined as date that infant admitted to date of discharge from the hospital. Weight was recorded by using digital scale.

A detailed neonatal information like Name, Sex, Date, and time of birth , gestational age (weeks) , birth weight (gms),age at enrollment (days), weight at enrollment (gms), weekly weight gain (gms) were recorded in a structured proforma (Annexure -III).

Intervention : Oromotor stimulation

Premature infant oromotor stimulation is a new intervention that is adopted from Beckman oromotor intervention to improve the ability of preterm neonates to accept oral feeds. Oromotor stimulation consists of following steps , Stroking of cheeks, Lip roll, Lip curl or Lip stretch, Gum massage, Stroking of lateral borders of tongue and mid blade of tongue, followed by suck elicitation. Intervention is delivered for five minutes, three times a day (10:00 am,1:00 pm,4:00pm) for seven consecutive days. Steps of oromotor stimulation are as follows (Table 1).

Technique	Repetitions	Time
Cheek C - Stretch	2X each cheek	30 seconds
Lip Roll	1X each lip	30 seconds
Lip Curl or Lip Stretch	1X each lip	30 seconds
Gum Massage	2X around	30 seconds
Lateral Tongue	1X each side	15 seconds
Midblade Tongue	2X	30 seconds
Elicit a Suck	N/A	<15 seconds
Support of Non-Nutritive Sucking	N/A	2 minutes

Table 1. steps of oromotor stimulation.

Statistical analysis

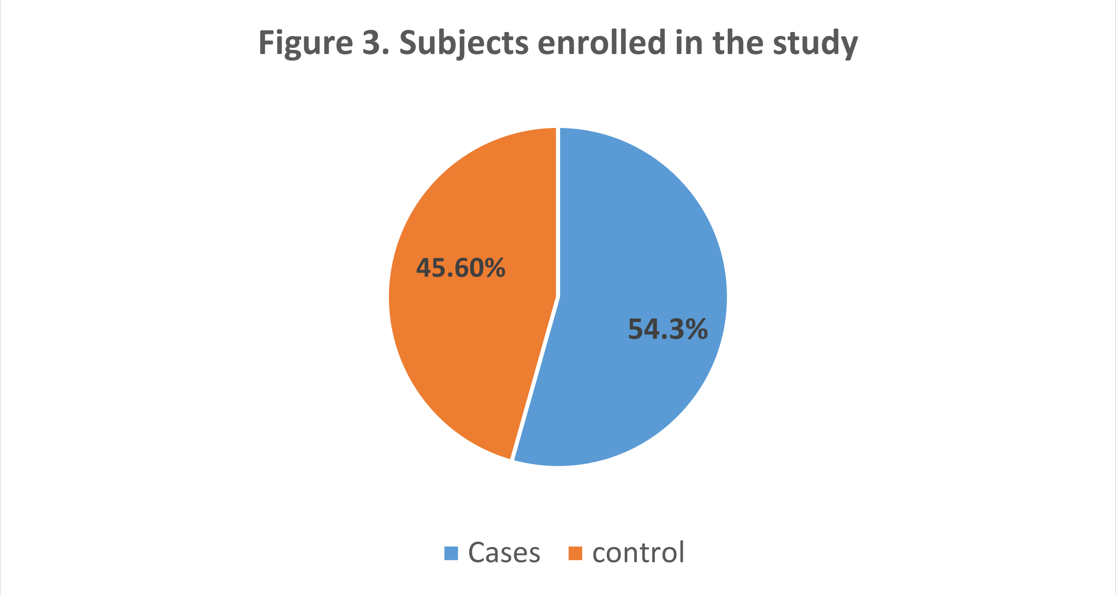
The data was coded and tabulated on excel spreadsheet and master chart was prepared. The data was analyzed using R version 4.1.1 statistical software. To check the association between categorical variables Chi-square test is used. To compare mean between the groups t-test/Welch's t-test is used. To compare the distributions between the groups Mann-Whitney test is used. P value ≤ 0.05 indicates statistical significance.

RESULTS

Table 2 : Subjects enrolled in the study .

Subjects enrolled	106
Intervention (Cases)	56 (54.3%)
Control	47 (45.6%)
Subjects included for analysis	103*

* Died -1, Left against medical advice- 2

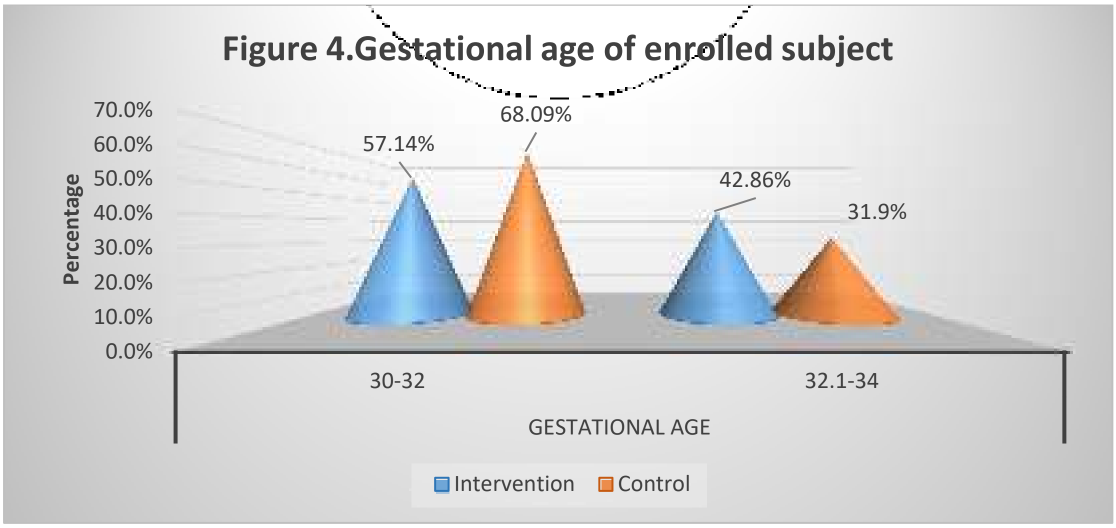


During the study period 103 babies were included for analysis, out of which 54.3% babies in intervention group and 45.6% in the control group.

Table 3: Gestational age of enrolled subjects.

Gestational Age (weeks)	Group		Total (N=103)	p-value
	Intervention (Cases) (n = 56)	Control (n = 47)		
30-32	32 (57.14%)	32 (68.09%)	64 (62.14%)	0.2541
32+1 - 34	24 (42.86%)	15 (31.91%)	39 (37.86%)	
Mean ± SD	31.82±1.17	31.61±0.92	31.76±1.06	0.5448[t]

Abbreviations: t: two sample t-test

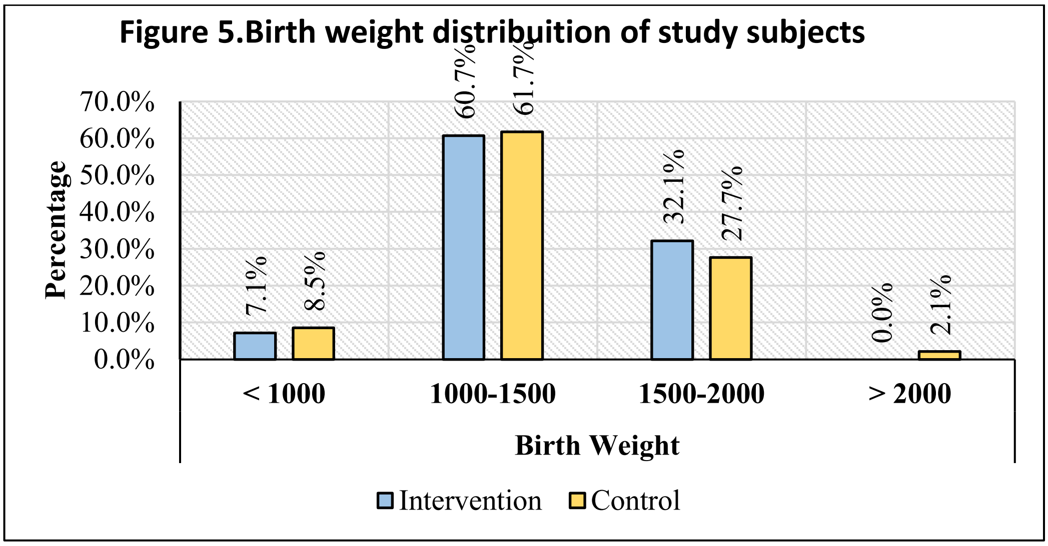


Highest number of cases and controls were noted in the gestational age group of 30-32 weeks ie, 57.14 % and 68.09 % respectively. Mean gestational age in intervention group is 31.8 weeks and in control group is 31.6 weeks. By two sample t test, there is no significant difference between both groups (P=0.5448).

Table 4: Birth weight distribution of study subjects.

Birth Weight (grams)	Group		Total (N=103)	p-value
	Intervention (Cases) (n=56)	Control (n=47)		
< 1000	4 (7.14%)	4 (8.51%)	8 (7.77%)	0.8391^{MC}
1000-1500	34 (60.71%)	29 (61.7%)	63 (61.17%)	
>1500-2000	18 (32.14%)	13 (27.66%)	31 (30.1%)	
> 2000	0 (0%)	1 (2.13%)	1 (0.97%)	
Mean ± SD	1391.14±252.61	1359.47±257.43	1376.69±254.06	0.5312^{t}

Abbreviations: MC: Monte-Carlo's simulation used in Chi-square test, t: two sample t-test.

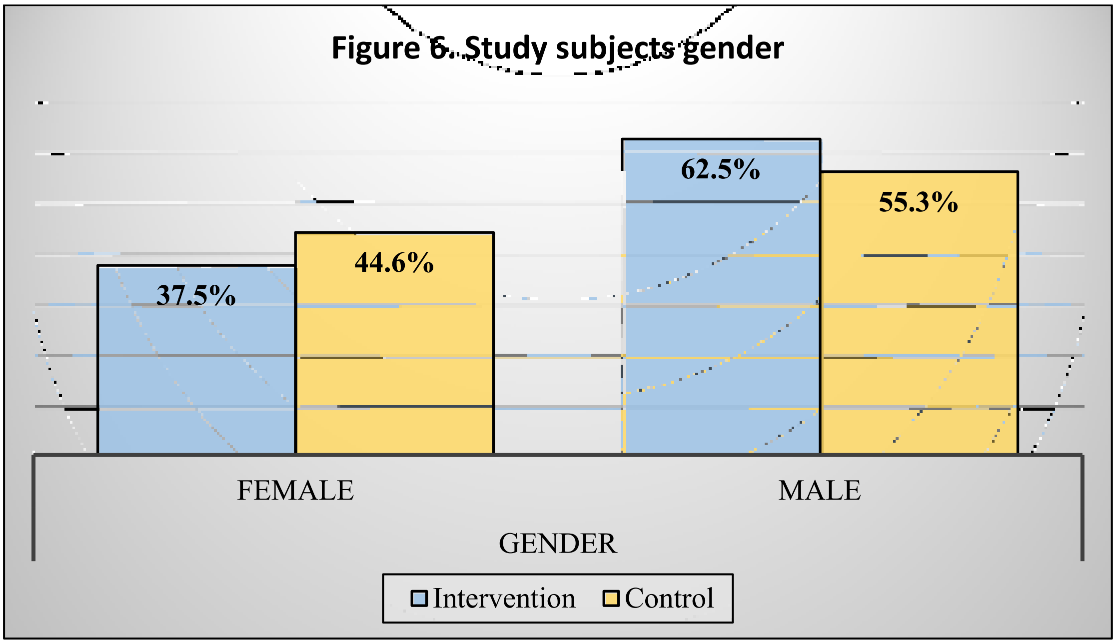


In our study out of 103 babies, 63 babies were between 1000-1500 grams with 53.4% babies in intervention and 46.03% babies in control group. In 1500-2000grams category, 58.06% babies in intervention group and remaining 41.9% in control group. The mean birth weight in intervention group is 1391.14±252.61 grams and 1359.47±257.43 in control group.

- There is no significant difference in the distribution of birth weight between the groups (P=0.83).

Table 5: Study subjects gender.

Gender	Group		Total (N=103)	p-value
	Intervention (Cases) (n=56)	Control (n=47)		
Female	21 (37.5%)	21 (44.6%)	42 (40.77%)	0.4601
Male	35 (62.5%)	26 (55.3%)	61 (59.22%)	

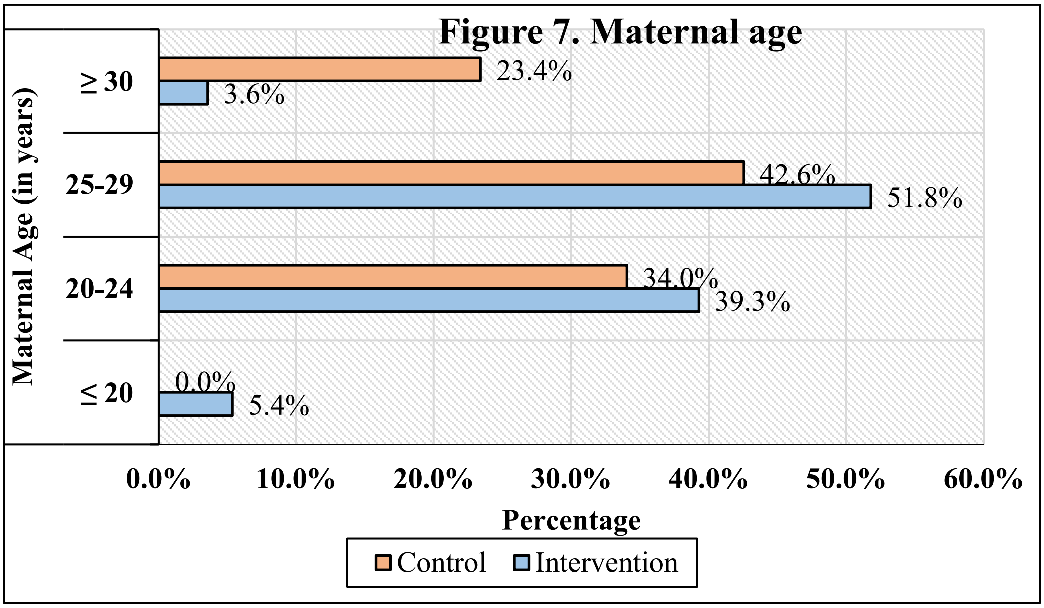


In intervention group, 37.50% of babies were female and remaining 62.5% were male. In control group, 44.6% of babies were female and remaining 55.3% were male. There is no significant difference between intervention and control group (P=0.4601)

Table 6 : Maternal age .

Maternal Age (in years)	Group		Total (N=103)	p-value
	Intervention (Cases) (n=56)	Control (n=47)		
≤ 20	3 (5.36%)	0 (0%)	3 (2.91%)	0.01399^{*MC}
20-24	22 (39.29%)	16 (34.04%)	38 (36.89%)	
25-29	29 (51.79%)	20 (42.55%)	49 (47.57%)	
≥ 30	2 (3.57%)	11 (23.4%)	13 (12.62%)	
Mean ± SD	24.98±2.74	26.98±4.01	25.89±3.51	0.004911^{Wt*}

Abbreviations: MC: Monte-Carlo's simulation used in Chi-square test, Wt: Welch's two sample t-test.



In both intervention and control groups, maximum no. of mothers were in the age group of 25-29 years which was 51.80% and 42.55% respectively followed by in 20-24 years with 39.30% and 34.04% respectively. The mean age in intervention group is 24.98±2.74 years and in control group is 26.74±4 years. There is statistically significant difference between the both intervention and control groups ($P=0.004911^{Wt*}$).

Table 7: Transition duration from gavage to full oral feed and gestational age.

Gestational Age (Weeks)	Transition duration (days)		Total	p-value
	Intervention (Cases)	Control		
30-32	6.09±1.8	10.88±5	8.48±4.44	<0.0001^{Wt*}
32+1 - 34	4.83±1.17	9.8±5.58	6.74±4.28	0.00202^{Wt*}
Overall	5.55±1.67	10.53±5.16	7.83±4.44	<0.0001^{Wt*}

Abbreviations: Wt: Welch's two sample t-test.

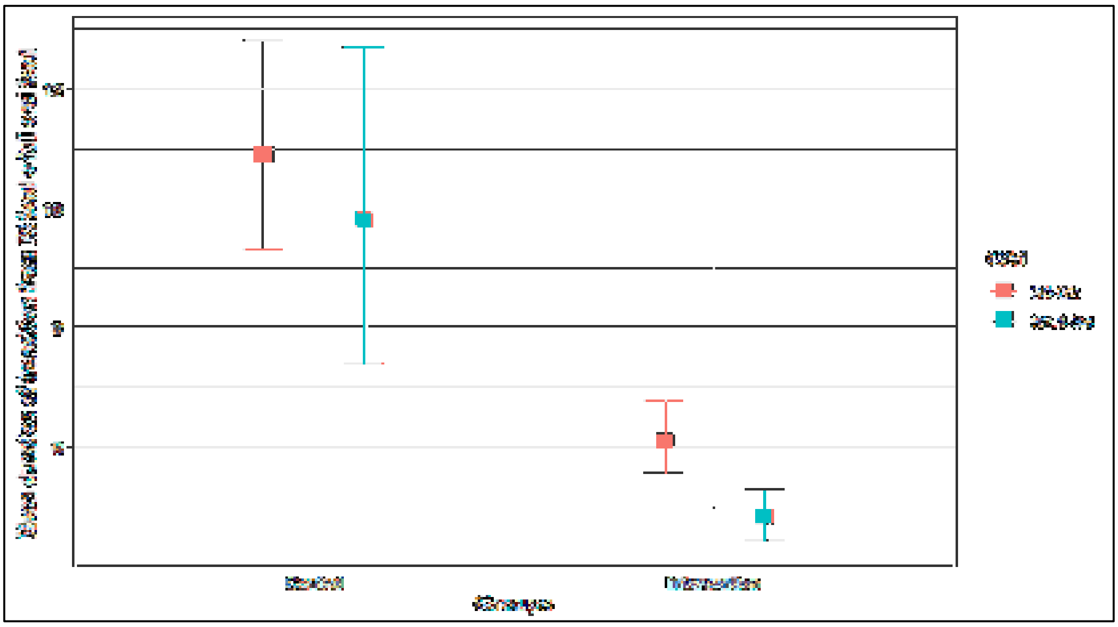


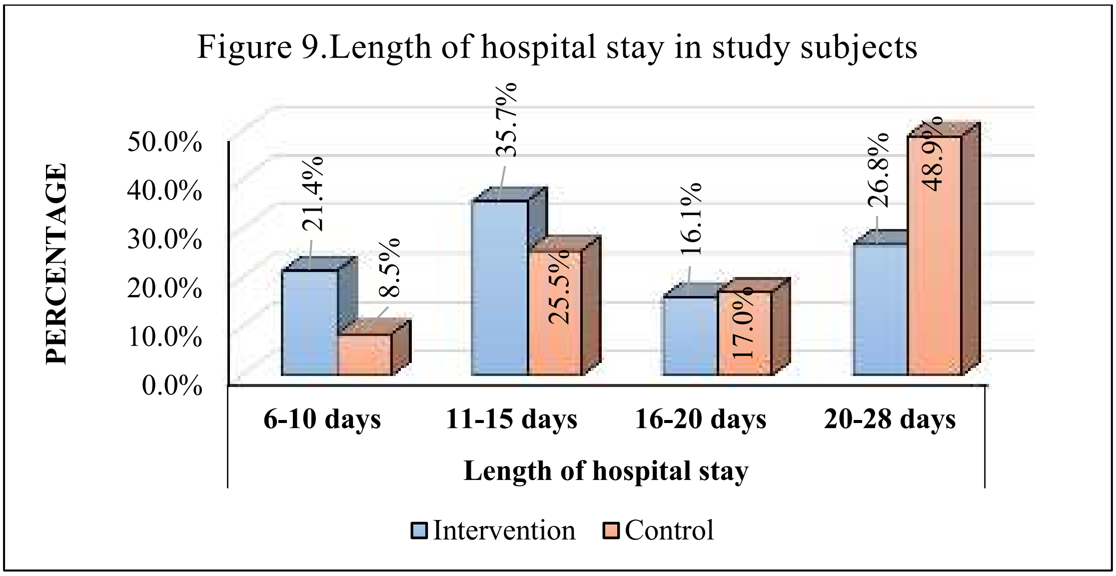
Figure 8. Whisker plot diagram showing transition duration from gavage to full oral feed and gestational age.

In our study, the mean duration for transition to full oral feeds is significantly less in intervention group 5.55±1.67 days compared to control group 10.53±5.16 days for entire cohort (P = <0.0001), and also true for individual gestational age groups.

Table 8 : Length of hospital stay in study subjects.

	Length of Hospital stay (Days)		Overall study group	p-value
	Intervention (Cases)	Control		
Mean ± SD	15.98±5.5	20.51±7.81	18.05±7	0.0006338^{Wt*}

Abbreviations: Wt: Welch's two sample t-test



The mean length of hospital stay (days) is significantly less in intervention group (15.98±5.5) compared to control group (20.51±7.81) (P=0.0006338).

Table 9: Weight of study subjects at different time points.

	Time points	Weight (grams)		Total	p-value
		Intervention (Cases)	Control		
	1st day	1391.14±252.61	1359.47±257.43	1376.69±254.06	<0.0001*T <0.0001*I
	7th day	1343.3±249.55	1302.23±258.11	1324.56±253.07	
	14th day	1403.23±252.32	1349.98±255.93	1375.67±253.83	
	21st day	1475±254.52	1417.04±258.69	1448.55±256.81	
	28th day	1584.11±259.47	1503.06±263.93	1547.13±263.37	

Abbreviations: T: time effect;; I: Interaction of group and time.

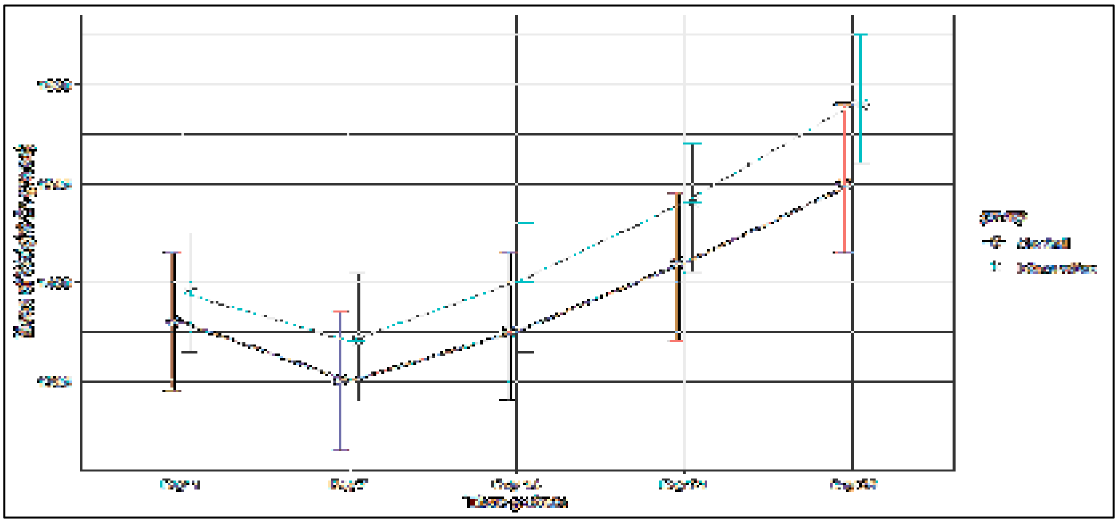


Figure 10. Mean plot diagram showing weight of study subjects at different time points.

In our study, there is significant difference in the mean weight at different time points in both intervention and control groups (P=<0.0001). Also noticed, from post-hoc analysis with Boneferroni adjustment in both control group and intervention group, that there is no difference in the mean weight for day 1 and day 14.

Table 10: Weekly weight gain in study subjects .

Weight gain (in grams)	Group		Total	p-value
	Intervention (Cases)	Control		
At 1st week	-47.84±54.06 -40 (-260, 60)	-57.23±22.6 -60 (-130, 0)	-52.13±42.76 -50 (-260, 60)	0.02763*MW
At 2nd week	57.93±24.32 60 (-50, 90)	47.74±38.03 50 (-80, 150)	51.11±31.32 55 (-80, 150)	0.029098*MW
At 3rd week	77.77±17.4 80 (30, 120)	67.06±24.44 70 (-10, 140)	72.88±21.48 80 (-10, 140)	0.005019*MW
At 4th week	109.11±31.7 110 (70, 320)	86.02±16.85 90 (43, 120)	98.57±28.34 100 (43, 320)	<0.00001*MW

Abbreviations: MW: Mann-Whitney test.

In our study, significant weight loss is observed in both groups during 1st week of life (P=0.02763). There is significant weight gain in intervention group compared to control group in the 2nd, 3rd, and 4th weeks. (P = <0.05).

DISCUSSION

After birth, preterm babies have a variety of challenges, and feeding issues being one of the most common. Preterm babies born before 34 weeks of pregnancy have an uncoordinated suck-swallow-breath pattern and cannot be successfully or securely fed by mouth. Therefore, it's important to see if an oral stimulation programme will help preterm newborns to accelerate their oral feeding rate. The program in our study consist of five minute oral stimulation each time (10:00am, 1:00pm, 4:00pm) for seven consecutive days. Our study evaluated the impact of oromotor stimulation on transition from gavage to full oral (spoon/ paladai) feeds, weight gain and length of hospital stay in premature infant.

During the study period 106 babies were enrolled but only 103 subjects were included in the analysis. Fifty six babies were allocated to intervention group and remaining 47 babies were in control group (Table 2). Initial sample size of our study was 128, but due to COVID- 19 pandemic, sample size was reduced to 103.

In our study there was no significant difference in the mean gestation age, gender and birth weight between intervention group and control group (Table.3, 4 & 5). This Implies that, there is no difference in subject enrolled into intervention and control group.

In our study, the mean duration for transition from gavage to full oral feeds in overall study group is significantly less in intervention group as compared to control group (P=<0.0001) and is also true for individual gestational age group (Table.7). This is in agreement with observation by Bala et al[32], Younesian S et al [34] and Arora et al[31], who reported duration of transition is significantly less in intervention group compared to control group. A study by Calk.P[20] in 2019 reported that the use of both intra and peri-oral prefeeding stimulation resulted in statistically significant shorter duration in intervention group to achieve oral feedings.

In our study, the mean length of hospital stay is significantly less in intervention group as compared to control group (Table. 8). Similarly H. Ghomi, et al[37]. Asadollahpour F, et al[36] and Mahmoodi N et al[16] reported that duration of hospital stay is significantly shorter in intervention group compared to control group. However Arora et al[31], reported no significant change in the length of hospital stay in both the groups. This is probably due to the lower mean gestational age in their study groups compared to the other studies.

We noticed significant difference in the mean weight between intervention group and control group at different time points (P= <0.0001). From post hoc analysis with Boneferroni adjustment in both control group and intervention group, there is no difference in the weight for day 1 and day 14 (Table.9).We couldn't compare this data with others because no studies have reported such analysis.

In our study, we observed significant weight loss in intervention and control groups at 1st week of life (P=0.02763). In comparison to control group, there is significant weight gain in intervention group in the 2nd, 3rd and 4th week (Table.10). Asadollahpour F,et al[36], Mahmoodi N et al[16] and Rocha et al[39], reported significant weekly weight gain in intervention group compared to control.

LIMITATION AND SCOPE OF THE STUDY

- As the study included limited population from single centre, results cannot be extrapolated to the whole population. A study with large sample size from different geographical areas should be conducted to have reliable results.
- Definition of full oral feeds and low Fio_2 have not been defined.
- There is a scope for testing the safety and efficacy of oromotor stimulation in high-risk neonates such as gestation less than 30 weeks or with cardiac issues.
- It is interesting to see whether this Oromotor intervention can be continued after hospital discharge. Home based follow up could be done to assess feeding efficacy at different months.
- Neurodevelopmental assessment can be performed in both the control and intervention groups. If neurodevelopment is better in intervention group, oromotor stimulation programme can be recommended as routine care.

CONCLUSION

Feeding difficulty is one of the most important problem encounter in a preterm infant. Our study supports the practice of five minute oromotor intervention, three times a day for seven days for preterm infants between 30-34 weeks of gestational age to improves their oromotor skills. Implementation of the oromotor stimulation program shortened the transition time from gavage feed to full oral feed, length of hospital stay and improved weekly weight gain.

Therefore, these interventions could be performed for all stable preterm infants admitted to NICU to enhance feeding skills.

SUMMARY

Observational study was conducted from January 2020 to August 2021 in the Department of Pediatrics, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi. A total of 103 babies with gestational age between 30-34 weeks were included in the analysis. The salient findings of the study are summarized below:

- During the study period 106 babies were enrolled, of which only 103 subjects were included for analysis. Fifty six babies were allocated into intervention group and remaining 47 in control group.

- Highest number of cases and controls were noted in the gestational age group of 30-32 weeks ie, 57.14% and 68.09 % respectively. Mean gestational age in intervention group is 31.8 weeks and in control group 31.6 weeks.

- Sixty three babies were between 1000-1500 grams with 53.4% babies in intervention group and 46.03% in control group. In 1500-2000grams category, out of 31 babies, 58.06% babies in intervention group and 41.9% in control group.

- In our study, 37.50% of babies were females and remaining 62.5 % were male in the intervention group. In control group, 44.6% were female and remaining 55.3% were male.

- We observed, no significant difference in the mean gestation age, gender and birth weight between intervention and control groups.

- Mean duration for transition from gavage to full oral feeds in overall study group is significantly less in intervention group (5.55±1.67 days) compared to control group (10.53±5.16 days) and is also true for individual gestational age groups.

- The mean duration of hospital stay is significantly less in intervention group (15.98±5.5 days) compared to control group (20.51±7.81days).

- In our study, significant weight loss is observed in both groups in the 1st week of life .There is significant weight gain in intervention group than the control group in the 2nd, 3rd, and 4th week.

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ANNEXURE I – CONSENT FORM

CONSENT FOR PARTICIPATION IN RESEARCH

"EFFECT OF OROMOTOR STIMULATION ON PROGRESSION TO FULL ORAL FEEDING IN PRETERM INFANTS- ONE YEAR HOSPITAL BASED CASE-CONTROL STUDY"

Principal Investigator : Dr.
Guide: Dr.

You are hereby requested to involve yourself and your baby in the above said research to be conducted at KLE'S Dr. PrabhakarKore Hospital and Medical Research Centre, Belgaum from January 2020 to December 2020 by me.

Introduction

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

Voluntary participation

You and your baby's participation in this study is your voluntary decision. Whether to participate or not to participate will not affect your current or future relationship with the KLES Dr. PrabhakarKore Hospital and Medical Research Centre, Belgaum.
You are free to discontinue the participation in the study at any time for any reasons. You will not be paid any reimbursement for participation in the research.

Risk and benefits

There is risk of infection but proper aseptic precautions will be taken while giving the intervention. The intervention will help to develop efficient oral feeding leading to weight gain and reduces the hospital stay.

Withdrawal from the study

You can withdraw at any time from the study. There will be no penalty for withdrawal.

Privacy and Confidentiality

The only people who will know that you are a research participant are member 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 connections with this study and that can be identified with you remain confidential and will be disclosed only with your permission.

Financial incentive for participation

You or your baby will not receive any financial assistance for participating in this study.

Queries

If you have any queries you may contact

Dr.

Post Graduate Student

Department of Pediatrics

Jawaharlal Nehru Medical College ,Belagavi-590010

Phone No. 9747667010

Dr.

MBBS,MD (Pediatrics),DM(Neonatology)

Professor, Department of Pediatrics

Jawaharlal Nehru Medical college ,Belagavi-590010

Phone No. 0831-2473777 Ext no. 1451, 4032.

If you have any questions about your rights or research participation you may contact

Dr. Roopa M Bellad

Chairperson of Ethical Committee

JNMC Belgavi-590010

Phone No.9448113403

You will be given a copy of this form for your information and to keep for your records.

STATEMENT OF CONSENT

I hereby voluntarily agree for my and my baby participation in this study. I understand that even if I choose to allow my 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 of the authorized representative/ parent: _______________

Date: _____________

Name: ____

Relation to the Subject: ___________________________________

Signature of the witness: ____________________________

Date: _____________

Name: ____

Signature of investigator: ____________________________

Date: _____________

Name: ____

ANNEXURES II: INSTITUTIONAL ETHICAL CLEARANCE

K.L.E. ACADEMY OF HIGHER EDUCATION AND RESEARCH
[illegible]
[illegible]

JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)

Website: [illegible]
E-Mail: [illegible]

Phone: [illegible] Office: 2471350
Principal: [illegible]
Fax No.: [illegible] 2470759

Ref: MDC/DOME/ 206

Date: 24/12/2019

To,

PG student in Pediatrics,
J.N Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled "EFFECT OF OROMOTOR STIMULATION ON PROGRESSION TO FULL ORAL FEEDING IN PRETERM INFANTS – ONE YEAR HOSPITAL BASED CASE CONTROL STUDY", is ethical and justified. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

(Dr. Aparna Dalal)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N Medical College, Belagavi.

(Dr. Roopa M Bellad)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N Medical College, Belagavi.

ANNEXURE III – PROFORMA

"EFFECT OF OROMOTOR STIMULATION ON PROGRESSION TO FULL ORAL FEEDING IN PRETERM INFANTS- ONE YEAR HOSPITAL BASED CASE-CONTROL STUDY"

Principal Investigator: Dr.

Guide:Dr.

SUBJECT NO.:-______________ IP No :- ____________

MATERNAL INFORMATION

1) Name:
2) Age:
3) IP No. :
4) Permanent address:
5) Telephone No.:
6) LMP: EDD: Gestational age(weeks):

NEONATAL INFORMATION:

1) Date of birth: __/ __ / __ 2) Study group : A ☐ B ☐

3) Gestational age (weeks): ____ weeks

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) Necrotising enterocolitis – YES /NO if YES, Grade - -------

11) Perinatal Asphyxia - YES / NO if YES, Stage - -------

12) Any condition where oral feeding is contraindicated – YES/NO if YES, ---- -----------

13).		Partial spoon feed (days)	Full spoon feed (days)
	Transition from gavage to full oral feed.		

14).	1 st week	2 nd week	3 rd week	4 th week
Weight (kg)				
Weight gain				

15) Duration of hospital stay :- __________days.

Date :

Place:

Oromotor stimulation monitoring chart :

	10:00 AM	1:00PM	4:00PM	Remarks
Day 1				
Day 2				
Day 3				
Day 4				
Day 5				
Day 6				
Day 7				

STEPS OF OROMOTOR STIMULATION:

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.	

GROUP A INTERVENTION GROUI												
SL.NO	IP.NO	MATERNAL AGE (yrs)	GENDER*	GESTATIONAL AGE	BIRTH WEIGHT (g)	Duration of transition from Rt feed to full oral feed (Spoon feeds in days)	Length of hospital stay	weight on Day 1 (g)	weight on Day 7 (g)	weight on Day 14 (g)	weight on Day 21 (g)	weight on day 28 (g)
1	981306	23	M	34 weeks	1710	5	21	1710	1450	1400	1430	1530
2	983982	28	M	31 weeks	1980	6	15	1980	1860	1900	1980	2080
3	993075	25	F	32 weeks	1300	5	14	1300	1260	1310	1410	1500
4	993076	25	F	32 weeks	1240	5	14	1240	1200	1280	1340	1450
5	1001500	28	M	30 weeks+3 days	1400	5	17	1400	1320	1380	1440	1540
6	1001348	30	M	30 weeks+ 5 days	1810	5	17	1810	1720	1800	1890	1980
7	1004335	24	M	30 weeks	1370	8	21	1370	1270	1350	1380	1460
8	1004336	24	F	30 weeks	1410	7	21	1410	1340	1420	1510	1610
9	1008838	24	M	33 weeks +2 days	1390	5	14	1390	1350	1380	1450	1530
10	1009100	28	M	32 weeks	1880	6	18	1880	1790	1820	1910	2010
11	1009519	21	M	31weeks+2 days	1610	7	15	1610	1590	1640	1720	1840
12	101550	25	M	30 weeks+5 days	1120	6	21	1120	1130	1180	1300	1410
13	1014109	36	M	32weeks+2 days	850	8	31	850	910	920	990	1120
14	1016693	24	F	30 weeks	750	14	24	750	620	680	750	880
15	1016690	24	F	30 weeks	990	8	24	990	890	920	970	1060
16	1019220	28	M	32weeks+3 days	1460	5	15	1460	1430	1520	1620	1730
17	1020444	20	M	30weeks+1 day	1400	6	21	1400	1300	1350	1410	1520
18	1020445	20	M	30weeks+1 day	1200	6	21	1200	1230	1290	1340	1440
19	1021330	25	M	31weeks	1280	7	25	1280	1240	1270	1350	1460
20	1022423	19	M	33 weeks	1460	5	7	1460	1470	1540	1610	1720
21	1022562	26	M	32 weeks	1510	5	14	1510	1460	1500	1580	1690
22	1022254	24	M	30 weeks	1050	7	21	1050	990	1030	1100	1210
23	1022562	24	M	32 weeks	1510	6	19	1510	1480	1520	1600	1710
24	1023191	28	F	32 weeks+ 5days	1300	5	10	1300	1280	1320	1380	1470
25	1024226	25	M	32 weeks	1270	6	20	1270	1220	1260	1330	1430
26	1025111	26	M	32 weeks+5 days	1410	6	14	1410	1330	1390	1450	1560
27	1025246	24	M	32 weeks+4 days	1270	6	17	1270	1210	1260	1360	1480
28	1025467	25	M	33 weeks +4 days	1400	6	17	1400	1230	1240	1320	1440
29	1025466	25	M	33 weeks+4 days	1200	6	17	1200	1100	1180	1270	1380
30	1026908	23	F	33 weeks + 5 days	1900	4	9	1900	1760	1800	1880	1950
31	1027199	27	F	33 weeks	1510	5	9	1510	1530	1580	1650	1750
32	1027430	26	M	33 weeks	1450	5	14	1450	1420	1500	1590	1700
33	1028539	26	F	32 weeks+6 days	1400	5	8	1400	1310	1350	1410	1500
34	1030100	24	F	32 weeks	1410	5	15	1410	1370	1420	1490	1580
35	1030185	25	F	32 weeks+4 days	1520	4	14	1520	1480	1560	1640	1740
36	1031976	25	M	30 weeks	1150	7	21	1150	1090	1160	1250	1370
37	1032734	24	F	30 weeks	1000	8	24	1000	950	1000	1100	1230
38	1033614	24	M	32 weeks	1490	5	14	1490	1420	1480	1550	1640
39	1038566	21	F	32 weeks	1730	5	14	1730	1730	1800	1880	2200
40	1040188	23	F	33 weeks	1350	6	15	1350	1320	1390	1450	1530
41	1040610	25	M	32 weeks	1490	6	14	1490	1450	1530	1620	1730
42	1040611	25	M	32 weeks	1640	5	14	1640	1610	1700	1810	1930
43	1044008	26	M	30weeks+2 days	914	6	30	914	865	925	1030	1130
44	1047275	24	F	33 weeks	1510	4	12	1510	1470	1470	1530	1620
45	1049620	25	M	32 weeks+4 days	1600	3	7	1600	1620	1680	1760	1860

*M-Male

F-Female

46	1049605	26	M	32 weeks+1 day	1380	5	9	1380	1380	1430	1520	1630
47	1051973	25	M	32 weeks+2 days	1700	4	7	1700	1740	1800	1880	2000
48	1053811	24	F	31 week+4 days	1200	5	14	1200	1160	1240	1330	1430
49	1055275	28	F	32 week +1 day	1620	4	14	1620	1580	1650	1730	1830
50	1057151	24	M	32 weeks	1550	4	10	1550	1520	1590	1670	1790
51	1059312	22	M	30weeks+2 days	1150	5	21	1150	1120	1170	1250	1360
52	1060145	21	F	31weeks+4days	1240	4	14	1240	1200	1260	1350	1480
53	1064216	24	F	32 weeks+2 days	1560	3	10	1560	1540	1600	1690	1810
54	1064283	26	F	30weeks+1 day	1250	5	17	1250	1220	1280	1350	1460
55	1065423	29	F	33weeks	1240	4	10	1240	1260	1330	1420	1530
56	1065422	29	M	33weeks	1420	3	10	1420	1440	1500	1580	1690

*M-Male
F-Female

	GROUP B (CONTROL GROUP											
1	975682	27	M	32 weeks +2 days	1100	12	20	1100	1020	1120	1200	1300
2	978120	32	M	30 weeks +6 days	1530	13	31	1530	1470	1390	1380	1430
3	978349	23	F	30 weeks +6 days	1240	14	31	1240	1180	1180	1170	1250
4	979138	31	F	31 weeks+5 days	1260	9	16	1260	1190	1340	1440	1530
5	980868	26	M	33 weeks	994	17	28	994	970	1000	1140	1260
6	993550	22	F	31 weeks	1120	12	28	1120	1060	1110	1210	1300
7	993734	37	M	32 weeks+3 days	838	26	34	838	808	828	870	990
8	1002627	24	F	31 weeks+5 days	1050	11	31	1050	970	1000	1040	1100
9	1009680	25	F	30 weeks +6 days	815	28	42	815	739	789	879	949
10	1010077	26	F	30 weeks +6 days	1280	15	30	1280	1150	1160	1210	1260
11	1012989	36	F	30 weeks +6 days	808	25	37	808	718	852	912	955
12	1014614	32	F	31 weeks+3 days	1080	11	28	1080	1070	1100	1130	1230
13	1015500	31	M	32 weeks+5 days	1420	8	20	1420	1330	1410	1500	1580
14	1015454	25	M	31 weeks +5 days	1550	7	16	1550	1490	1540	1600	1670
15	1015455	25	M	31 weeks+5 days	1470	7	16	1470	1390	1430	1500	1580
16	1018325	29	M	31 weeks	1380	11	17	1380	1320	1400	1460	1550
17	1020228	25	M	30 weeks	1050	16	30	1050	1000	1030	1100	1160
18	1020380	34	F	33 weeks	1580	10	21	1580	1530	1540	1600	1680
19	1020379	34	M	33 weeks	1470	10	21	1470	1420	1480	1550	1620
20	1020486	26	M	32 weeks	1360	11	14	1360	1310	1330	1380	1450
21	1021099	38	F	30 weeks	1160	16	28	1160	1090	1090	1140	1210
22	1021641	28	F	32 weeks+1 day	1340	10	14	1340	1300	1360	1430	1510
23	1023492	26	M	32weeks +3 days	1420	9	14	1420	1380	1420	1470	1540
24	1024338	26	M	33weeks	1400	9	15	1400	1330	1390	1450	1530
25	1024560	23	M	30 weeks	LEFT	AGAINST	MEDICAL	ADVICE				
26	1024561	23	F	30 weeks	LEFT	AGAINST	MEDICAL	ADVICE				
27	1027966	26	M	33weeks	1400	8	15	1400	1330	1390	1460	1560
28	1028333	24	M	32 weeks	1420	9	21	1420	1370	1440	1500	1590
29	1028335	24	M	32 weeks	1310	12	22	1310	1270	1340	1400	1480
30	1028334	24	F	32 weeks	1330	9	21	1330	1290	1350	1420	1520
31	1028870	23	M	31 weeks		EXPIRED						
32	1029034	25	F	33 weeks	1600	8	14	1600	1520	1590	1650	1740
33	1029567	24	M	32 weeks	1500	9	14	1500	1420	1490	1550	1640
34	1030100	24	F	32 weeks	1300	6	15	1300	1230	1310	1390	1490
35	1021200	22	F	30 weeks +5 days	1110	9	25	1110	1050	1050	1130	1210
36	1031945	26	F	33 weeks	1500	8	14	1500	1420	1500	1580	1670
37	1035219	23	F	30 weeks	1570	12	21	1570	1510	1560	1640	1740

38	1039073	24	F	32 weeks	1640	9	14	1640	1590	1660	1740	1830
39	1042270	25	M	31 weeks	1810	8	17	1810	1760	1820	1900	2000
40	1042787	24	M	32 weeks	2000	7	10	2000	1940	1940	2010	2100
41	1044334	24	M	32 weeks	1760	8	14	1760	1710	1780	1840	1930
42	1049863	29	M	31 weeks	1710	7	21	1710	1640	1660	1740	1840
43	1049862	29	M	31 weeks	1720	6	21	1720	1660	1650	1740	1850
44	1051760	30	F	32 weeks+3 days	1200	4	11	1200	1170	1180	1240	1330
45	1052162	24	M	32 weeks +5 days	1420	3	8	1420	1420	1480	1550	1640
46	1054150	30	F	30weeks+1 day	1340	9	25	1340	1300	1370	1450	1550
47	1054521	26	M	30weeks+5 days	1310	8	17	1310	1260	1320	1400	1500
48	1059362	24	F	32 weeks+2 days	1400	5	10	1400	1380	1430	1510	1610
49	1059497	25	M	32weeks	1600	5	10	1600	1550	1610	1680	1780
50	1060612	24	M	30weeks+1day	1230	9	22	1230	1180	1240	1320	1410

*M-Male
F-Female