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The Effect of Pre-Feeding Protocol with and Without Tactile and Kinaesthetic Stimulation on Oral Motor Ability & Physiological Stability in Preterm Infants

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ABSTRACT

Background: Frequent desaturation due to immature incoordination of suck-swallow-breathing in preterm infants can influence multiple organs such as the heart, lungs and brain, which can then affect growth and development
Premature infant oral motor intervention (PIOMI) has shown the positive effects on feeding progression of the premature infants. The study was done to analyse effect of the combined protocol PIOMI with tactile, Kinaesthetic and respiratory muscle stimulation on achieving oral motor control and physiological stability and evaluate its efficacy against PIOMI.
Methods: A total 72 clinically stable infants admitted in premature care unit, fulfilling inclusion criterion were enrolled. They were allocated in two groups. Infants receiving PIOMI (Control group) and infants receiving the new intervention protocol i.e. PIOMI with M technique, Respiratory muscle stimulation (Experimental group), for 10 minutes each day. Data was collected for oral motor abilities, day of achieving full feeds and pre & post intervention physiological parameters such as Pulse rate & O_2 saturation.
Results: Gestational age at full feeds was 33.65 weeks and 32.60 weeks in control and experimental groups respectively with 'p' value 0.001. The number of days of full feed in experimental group was 5.20 days earlier (p=0.002). Infants from experimental group showed improved mean rank on NNS during first follow up day. More percentage of infants showed the physiological stability.
Conclusions: New intervention protocol i.e. PIOMI with M technique, Respiratory muscle stimulation was well tolerated by preterm infants. This led to achieving better physiological stability during feeding with early achievement of oral feeds.

Keywords: Preterm infants, full feeds, Heart rate, Respiratory muscles, breathing, O_2 saturation, gestational age

INTRODUCTION

Fifteen million infants are born preterm every year globally i.e. 1 per 100 live births in India due to various reasons including feeding & breathing difficulties. The lack of coordination of sucking, swallowing, and respiration can be the major problem in achieving oral feeding along with immature oral feeding ability has severe impact on the normal development of preterm infants and also increased the morbidity in this given population. Frequent desaturation due to immature incoordination of suck-swallow-breathing in preterm infants can influence multiple organs such as the heart, lungs, and brain, which can

then affect growth and development. Most notably in preterm infants, feeding desaturation may even affect pulmonary function during gavage feeding. [(1)]

Once infant recovers from critical phase, its ability to feed orally maintaining, physiologic stability is the main determinant length of hospitalization.

Difficulty with oral feeding with difficulty in maintaining physiological parameters during & after feeding leads to longer hospital stays and higher costs. [(2)]

The ability to feed orally can be defined as the period when infants have the characteristics that enable them to take more than 80% of the prescribed total fluid intake orally in a twenty-four hour period. Infant feeding is a complex process, requiring the precise coordination of Suck-Swallow-Breathe. [(3)]

Respiratory control in the foetus and neonate is quite immature when compared to that of adults. This immaturity involves all facets of respiration including respiratory responses to hypoxia, hypercapnia, an exaggerated apnoeic response to laryngeal stimulation and immature responses to activation of pulmonary afferents. The net result of this immaturity of breathing responses is the vulnerability of neonates and especially preterm infants to apnoea and respiratory pauses. [(4)]

Tactile stimulation, manual or mechanical, has been shown to shorten the duration of apnoea, hypoxia, and or bradycardia or even prevent an apnoea. Automated stimulation, using closed-loop pulsating or vibrating systems, has been shown to be effective in terminating apnoea; Apnoea is one of the most common diagnoses and therefore a major concern in the Neonatal Intensive Care Unit (NICU). [(4,5,6)] Frequent apnoeic spells can lead to serious cerebral injury and affects neurodevelopmental outcome. [(5)]

When lacking ability of self-feeding early intervention proves to be effective in initiation of early oral motor activity. Development of no- nutritive sucking skills can enhance the feeding skills in preterm infants. [(2)]

Various oral motor stimulation programs that are designed often involve tasks such as stroking the peri-oral and intraoral structures in a specific way with a gloved finger for a period of time prior to feeding. [(6,7)] Dr. Brenda Lessen completed a pilot study on the effect of oral stimulation i.e., premature infant oral motor intervention (PIOMI) on feeding progression in preterminfants.5 The PIOMI demonstrates high inter observer reliability (97.57%), inter-user reliability (97.59%), and test-retest reliability (97.58%). Currently this protocol is used with Preterm Infants with feeding difficulties. [(8)] The study done by Dr Karan et al has proved that infants receiving PIOMI reached full independent wati spoon feeds significantly earlier than the infants in control group. [(9)]

In preterm infants, it was observed that the adverse outcome during feeding is not caused by the apnoea itself but, is associated recurrent hypoxia. Sophie et al stated that using the effective tactile stimulation technique by enabling a direct response can be effective to shorten the apnoea hence reducing hypoxia and bradycardia. [(5)]

When M- technique was used for tactile & kinaesthetic stimulations, it increased the oxygen saturation & showed more positive behavioural cues were observed throughout, at the end, and after the M Technique session. [(10)] If oral motor stimulation given with M-technique & respiratory stimulation, it may help in improving oral motor activity with decreased episodes of apnoea during feeding in preterm infants. The protocol of oral motor stimulation incorporating M-technique & respiratory stimulation is developed considering maintenance of physiological stability & neurodevelopmental mapping in preterm neonates.

A pilot study was done to assess the effect of the newly designed prefeeding stimulation protocol (PIOMI with M-

technique & respiratory muscle stimulation) against PIOMI on achieving full oral feeds & pre & post feeding physiological stability in preterm infants.

METHODS

The study design was experimental, prospective with random allocation of subjects, triple blinded, analytical Study was approved by institutional Ethics committee. Infants were recruited from a premature unit under department of neonatology at a tertiary care hospital in metropolitan city. All Infants admitted in the premature unit. Infants born between 28.0 /7 and 32.0 /7 weeks of gestation, clinically stable as per the medical staff at the time of entry. Infants were on only orogastric or Nasogastric Feeds, or very few needed oxygen per high-flow nasal cannula, for initial 3-4 days, infants with NOMAS score between 18-36 were included. Breast milk of the mother was used, when available. If unavailable, donated human milk from milk bank was used for their feedings. Infants with congenital anomalies, neonatal asphyxia defined by a 5^{th} min Apgar score of 6 or less. Grade III or IV intracranial or intra ventricular haemorrhage, meningitis/sepsis, neonates with mechanical life support, infants with necrotizing enterocolitis (NEC) were excluded. If Infants developed NEC during intervention, they are excluded. A convenient sampling with random allocation was done, in control and experimental group, by using block of 6 subjects, to allow equal distribution in both the groups and thus forming three sets of infants in each block.

As it was the first study to assess effect of new interventions on preterm infants between 28 weeks to 32 weeks, it was considered as a pilot study, so the power of study was not taken into consideration. The sample size decided was 36 in each group, as per the workload in premature care unit and neonatal intensive care unit. Initially thirty-six infants were included in each Group for pilot study. There were drop outs of 4 infants from experimental group & 2 drop outs from control group in the initial phase. Later there were 6 & 5 dropouts from experimental & control groups respectively at the end of study, when full oral feed was achieved. Three of them developed & others took discharge against medical advice.

Intervention was started using two different protocols as per intervention groups. The informed consent was obtained from caregivers and they were explained about the benefits (such as improved feeding ability of infants, stability of vital signs, early discharge etc.) to their infants on participating in the study. They were assured about precautions taken while handling the infant.

All the infants from the two groups received intervention for minimum 8 days or till they received full oral feeds (if oral feeding achieved earlier), thirty minutes prior to feeding. The infants from Control group received PIOMI for 10 minutes, once a day. Infants from experimental Group received M technique consisted of series of massage on trunk and extremities for 3.5minutes followed by PIOMI for 5 minutes + respiratory muscle stimulation 1.5 minutes, once a day.

Intervention was provided by two research assistants (RA), both were given the training for different protocols. For blinding the groups, the curtain was pulled between each isolate in preterm unit. Intervention was given at least once a day by the therapist and this was separated by a minimum of nine hours and a maximum period of 36hours, 24 hours was ideal duration. Variations were considered, as sometimes the infant had been stressed by medical or nursing procedures such as intravenous infusions or temperature instability immediately before the scheduled time of intervention. Sometimes intervention needed to postpone next feeding period, if the therapist has reached late. Negative neuro-behavioural cues were also recorded during the intervention.

For both the groups assessment was done at day of enrolment, and follow-up

was done at 4th, 8th day of the therapy using all the outcome measures (dependent variables) viz i.e., Non-nutritive sucking ordinal score (NNS), days of full feeds, length of hospital stay and pre -post intervention pulse rate & O_2 saturation In the study, the HR and oxygen saturation levels were monitored with the aid of a pulse oximeter .The principle investigator was blinded for the type of intervention used for the patient. Confounding factors such as feeding protocol by nursing staff experienced in preterm infant feeding and inexperienced parent feeder were not recorded. There were three instances throughout this study protocol was terminated because of adverse behavioural cues from the infant. Infants recovered after 2-3 minutes on discontinuing intervention. Later they were diagnosed as NEC and discontinued from the study.

Statistical Analysis

SPSS-PC 16.0 (IBM, Somers, New York) was used for all analysis. Preliminary data analysis was done using descriptive statistics. The α was set at 0.05 (1-tailed). Demographics were also recorded to analyse the group differences for, ordinal data i.e., age of enrolment, days for full feeds, length of hospital stay was analysed using ANOVA. The nominal data were tested with chi square x^2 values. Data was compared using Kruskal Wallis score. Scores on pulse rate & O_2 saturation was analysed on contingency tables or using cross tabs.

Thirty-six preterm infants were enrolled in each group, 4 mothers took discharge against medical advice from control group. Two infants from experimental group and one infant from control group developed NEC on day 3 of enrolment, so their data was excluded from initial analysis. Later, three mothers took early discharge against medical advice. Thus total 60 infants were analysed at end of the study. Thirty infants from control group & thirty from experimental group were included on last day analysis.

RESULTS

Table1: Gestational age of infants, age at enrolment, full feeds and days of full feed, days of hospital stay

Dependant variables	Groups	N	Mean	Std Deviation	Std Error	95%confidence Interval for mean		F	Sig
						Lower Bound	Upper Bound		
Gestational Age	Control	36	30.47	1.05	0.18	30.11	30.82	2.809	0.065
	Experimental	32	29.93	1.57	0.28	29.37	30.40		
Enrollment Age	Control	36	31.57	0.89	0.15	31.27	31.87	0.707	0.495
	Experimental	32	31.31	0.97	0.17	39.96	31.66		
Age of Full feed	Control	31	33.65	1.47	0.26	33.11	34.1	9.686	0.001
	Experimental	30	32.60	1.08	0.19	32.21	32.99		
Days for Full Feed	Control	30	14.23	8.02	1.46	11.23	17.22	8.875	0.002
	Experimental	30	9.03	3.76	0.87	7.90	10.70		
Duration of Hospital Stay	Control	30	21.60	10.83	1.98	17.56	25.64	6.041	0.005
	Experimental	30	15.17	7.31	1.33	12.44	17.90		

'p'significant if ≤0.05
Control Group-Infants receiving PIOMI
Experimental group-Infant receiving PIOMI+M-technique+Respiratory stimulation

Table 1 shows both the groups has gestational age between 28 weeks to 31 weeks. Enrolment was done at 32 weeks PMA. There was significant difference in age of achieving full oral feeds (i.e. at least 8 oral feeds in 24 hours)The infants receiving new protocol achieved full oral feeds 6.05 days earlier than infants receiving PIOMI('p '≤0.002). There was statistically significant ('p'≤0.005) reduction duration of hospital stay in infants receiving new protocol by 3.52 days.

Then data was compared to study the feeding ability, using Non-nutritive sucking ordinal scale (NNS).

Table 2: the comparison of scores on Non-nutritive sucking ordinal score

Dependant Variable		Control group	Experimental Group	Chi square Value	Asymp Sig
Baseline NNS	Median Score	2	2	2.38	0.304
	Mean Rank	56	52.06		
Day 4 NNS	Median Score	3	3	5.135	0.077
	Mean rank	43.43	58.59		
Day 8 NNS	Median Score	3	4	4.738	0.094
	Mean Rank	45.62	49.02		

'p' significant if $p \leq 0.05$
NNS-Non-nutritive sucking ordinal scale (NNS)
Control Group-Infants receiving PIOMI
Experimental group-Infant receiving PIOMI+M-technique+Respiratory stimulation

As the maximum score in NNS is 6, mean rank was considered for comparison. The Non-Nutritive sucking ordinal score showed difference in the mean rank, but not marked difference. At first follow-up the mean rank difference in two groups was more, but in second follow-up it was negligible. This may show, though the infants achieved full oral feeds or shown the progress in shifting from gavage to full oral feeds, the maturation of suck consistency may need further intervention.

Further Results of Pulse rate status was analysed to evaluate effect of interventions on stability of vitals, since it is important aspect in effective feeding .The pre & post intervention values of Pulse rate of subjects were analysed.

Pre & Post intervention Pulse rate was divided in two categories as,
If Score is--- Category 1 --→ if pulse rate difference post intervention is ≤18 = stable
Category 2--→ if pulse rate difference post intervention is > 18 = at risk. [(11)] (Susannah Fleming, 2011)

Since the data was categorical, Data was further analysed using Cross tabulation table/Contingency table

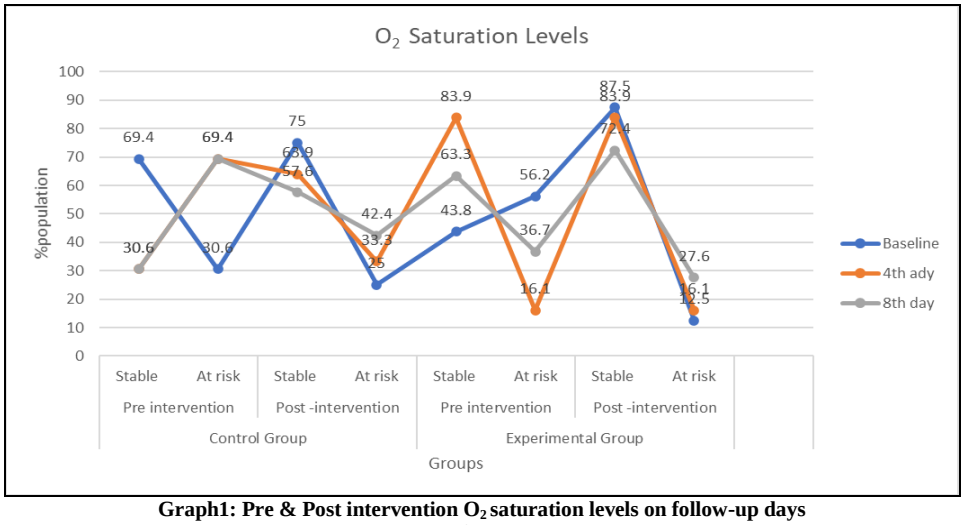
Table 3: shows comparison of pre & post intervention difference in pulse rate

Follow Up	Percentage of Subjects	Control Group		Experimental Group		Chi-square value	Asym Sig	Linear by linear Association
		Pre & post intervention Difference in Pulse rate		Pre & post intervention Difference in Pulse rate				
		Stable	At Risk	Stable	At Risk			
Baseline	Count	29	7	31	1	4.233	0.12	0.079
	%of population within group	80.6%	19.4%	96.9%	3.1%			
4th Day	Count	27	9	30	2	4.540	0.103	0.034
	%of population within group	75.0%	25.0%	93.8%	6.2%			
8th day	Count	23	11	29	3	5.618	0.060	0.020
	%of population within group	67.6%	32.4%	90.6%	9.4%			

'p' significant if ≤0.05
Control Group-Infants receiving PIOMI
Experimental group-Infant receiving PIOMI+M-technique+Respiratory stimulation

From table3 it is observed that both the interventions led to stability in pulse rate in more percentage of population as compared to previous follow -ups & showed statistically significant association in stabilisation of pulse rate, indicating the graded protocol can show similar effects on pulse rate. But in control group more percentage of infants showed at risk pulse rate post intervention is more than in the experimental group.

Further the physiological stability was assessed by monitoring Pre & postintervention O_2 saturation.
Category 1- If O_2 levels -→(86-95) =Stable
Category 2- If O_2 levels → (≤84) & (97-100) = At risk. [(12)]



Graph1: Pre & Post intervention O_2 saturation levels on follow-up days
Control Group-Infants receiving PIOMI
Experimental group-Infant receiving PIOMI+M-technique+Respiratory stimulation

From Graph 1 it was observed that when O_2 saturation was observed in pre & post intervention on day one i.e. baseline score & day 4 score there was significant difference in percentage of population, which achieved respiratory stability after intervention. On day 8 both the groups showed good improvement, so there was no significant difference in percentage of population. Thus infants from control group could achieve respiratory stability, but percentage of population at risk remained at higher level as compared to experimental group.

DISCUSSION

Respiration is the last component to be integrated into the coordination of suck-swallow-breathing for successful sucking in preterm infants. It has been shown that even full-term infants had unstable respiration compared to sucking or swallowing during feeding. The stabilization of respiration correlated with postmenopausal age (PMA) rather than postnatal age. The study by Dong showed that respiratory distress inversely correlated with GA and BW and breathing. The respiratory parameters during feeding were unstable and immature in preterm infants. [(1)] Considering this aspect of suck -swallow -breath coordination in preterm infants, the brief tactile respiratory muscle stimulation with kinesthetic stimulation was given in the new protocol. In present study, the pilot study was designed to determine the effect of the new intervention PIOMI with M technique & respiratory muscle stimulation, on preterm infants to enhance oral motor performance, achieving full feeds, length of hospital stay and improving physiological stability in preterm infants.

Results from this study suggest that a 10-minute infant-driven PIOMI with M Technique& respiratory muscle stimulation intervention can help in early achievement of full feeds with no adverse changes in physiological parameters. These results showing the physiological stability are consistent with other supplemental comforting touch studies including therapeutic touch18 and "touch and caressing-tenderin caring" therapies in which HR or oxygen saturations were not adversely affected in very preterm infants. [(13)]

In this study in infants receiving with new protocol with tactile, respiratory & kinesthetics stimulations, the number of days from gavage feedings to oral feedings significantly reduced (6.4 days earlier, with p= 0.002) compared the number of days for the infants who received only. PIOMI intervention. In a study done by Sandra Ficile, it was observed that infants receiving oral stimulation along with tactile & kinaesthetic stimulation can develop good expiration -swallow -expiration cycle than

infants receiving only oral stimulation, which can lead to improved feeding ability without apnea (p≤0.039) [13]

The early achievement of oral feeds with better suck swallow breath coordination, have also resulted in early discharge from the hospital.

In table no 2, the infants in both the groups showed improved ability of non nutritive sucking, but there was not a significant difference in the scores. Both the groups received graded oral stimulations, thus leading to improved ability to feed. In an experimental study when infant received oral motor stimulation with M technique, the infants showed improved ability of non-nutritive sucking on NOMAS score then infant receiving only PIOMI. [14] In another study to analyse association of swallow breath &feeding progression, the results elaborate that the progression of SwBr in Low Risk Preterm infants is influenced by increasing opportunities to practice the skill, or what can be considered "learning". [15] The opportunity provided by graded stimulation in our study has resulted in early achievement of feeding.

As stated by Raynoulds the development of efficient suckle-feeding is dependent on the maturation and coordination of neuronal central pattern generators (CPGs) controlling suck, swallow and breath. This skill is developed on providing opportunities. These same CPGs are activated, to varying degrees, during non-nutritive suck since swallows still occur, although much less frequently than during nutritive feeding. [15] Non-nutritive suck opportunity provided in this study have lead to improved scores in both groups & achievement of nutritive feeding, though the results on NNS are not showing the statistically significant difference Since the sample size is very less & range of score is limited ,the larger sample size may give us predictive results

Apnoea of prematurity (AOP) is one of the most common diagnoses in preterm infants. It is mostly associated with the concomitant hypoxia and bradycardia. The multiple episodes can be seen when preterm infants are started with oral feeds. [13] Considering these complications during oral stimulation, the effect of new intervention on physiological stability during & immediately after feeding was analysed. Depending on the changes in pulse rate pre & post intervention, infants were categorised in two categories Stable & at risk There was significant difference in percentage of infants achieving or maintaining the stability post intervention in infants receiving new protocol than infants receiving PIOMI.(p ≤0.034 & p ≤ 0.020 on 4th day& 8th day of intervention respectively) Dr Sheila Mathai et al has observed that though tactile, kinesthetic stimulations lead to increase in heart rate, but these the changes remain within the stable ranges.[16] In an another review analysing various patterns of kinaesthetic & tactile stimulation, Vinessa stated that various tactile & tactile with kinaesthetic stimulations are effective in improving the physiological stability in preterm infants, graded stimulations in various positions should be administered cautiously.[17,18] In present study the therapist was constantly observing the physiological parameters during intervention.

Another vital parameter O_2 saturation in pre & post intervention on day one i.e. baseline score & day 4 score there was significant difference in percentage of population achieving stability. Only during second follow-up day the infants from both the groups showed good stability post intervention. This can be explained, as infants approaching maturity the control group infants showed stable o_2 saturation levels. Dong et al in their study has also stated that the infants achieve respiratory stability as approach their full term age, [1] Due to early intervention, more percentage of infants from the new intervention group achieved good O_2 saturation, though not the statistically significant difference on second follow up.

In larger randomized controlled trial on the effect of Gentle Human Touch (GHT)

on physiological stability of preterm infants, Harrison and colleagues did report a decrease in oxygen saturations across the 3 phases of at baseline, during, and after the intervention. They also stated that statistically significant (P =0.001) decrease in oxygen, but it was not clinically significant. In addition, only 19% of the infants in the GHT group had to have one or more GHT sessions terminated early because of a decrease in HR or a decrease in oxygen saturation, but those infants who were lower in gestational age and birth weight and had higher morbidity levels than infants who did not require early termination of the

GHT sessions [19,7] The decrease in oxygen saturation did not occur during follow up days in this study, although infants within this study were slightly younger in PMA compared with the GHT study It is important to note that only two infants in the current study required early termination of intervention, but it was due negative behavioural cues, their O_2 saturation was well maintained.

In a present study the M technique was used for 3.5 minutes with tactile respiratory stimulation for one minute& 30 seconds vibratory stimulations.In a review articleon Chest Physiotherapy for infants the author states that, the gentle rhythmic compression given on chest wall, act simillar as mechanical vibrtory stimulus & helpful in airway clearance.[17] The chest stimulation given during new protocol has resulted in improving oxygen saturation in more percentage of population from the experimental group. In an anther review done by Sophie et.al similar results were observed in four studies. Preventive manual stimulation showed a significant decrease in frequency of apnoea during the stimulation period ($p < 0.01$). When massage stimulation was only administered 5 out of every 15 min. All four studies using a vibratory stimulus reported a significant decrease in apnoeic spells or breathing pauses. [5]

Mechanical tactile stimulation has been evaluated in several studies .It was observed that these stimulations lead to a faster response to stabilise Heart rates & O_2 saturation.[18,19] They have stated in the observation that, the skin contains multiple sensory receptors, which are all most sensitive to a specific frequency range, M technique stimulates appropriate number of nerve receptors. Results in our study imply that the location of stimulation also influences the effect on breathing& feeding coordination, leading to physiological stability.

More recent studies have investigated the effect of vibration as the sole stimulus, which resulted in a significant reduction of apnoea or inter breath intervals and a significant reduction in intermitted hypoxia in all cases. [5] In an another study, after giving mild vibratory stimulus on limbs it is observed that the low-cost neuro-modulatory procedure has the potential to provide a non-invasive intervention to reduce apnoea, bradycardia and intermittent hypoxia in premature neonates. [20]

The combined effect of pre-feeding stimulation with M- technique & respiratory stimulation in new protocol has led to improved oral motor skills, improved feeding, leading to early hospital discharge and improved physiological stability. The newly developed protocol was well tolerated by infants between 28-32 of gestational age. Overall, results from this study suggest that this type of structured and systematic tactile stimulations on perioral & intra oral area with stroking on extremities and vibrations for respiratory muscle stimulation may have a relaxing effect as evidenced by a lower HR, increased SaO_2 with improved sucking skills & early achievement of oral feeds. Although this study does not report morbidity levels more research is needed to determine both the short-and long-term benefits of the new protocol. The results of this study also suggest that, the NICU therapists can provide graded infant driven protocol for achieving good suck -swallow -breath

rhythm & improve physiological stability during breathing. This is easy to learn, and relatively short in duration protocol. In this study the mothers and care givers skills for feeding the infants orally were not considered.

Strengths of this feasibility study that, it guided further the development of a workable and realistic research protocol to design our next phase of study. In addition, logistical problems (e.g., timing of the intervention and coordination of the research team) were identified,

The successful recruitment approaches and data collection methods were refined and data were obtained to aid in determining estimated sample size for future studies.

CONCLUSION

The new protocol PIOMI, M technique & with respiratory muscles stimulation can be implemented for very preterm infants in a level III, NICU from 28 weeks PMA onwards to improve feeding ability & achieve suck-swallow-breath rhythm during feeding without notable adverse effects on physiological parameters. Based on the findings of this feasibility study, our next proposed study is to systematically test the cumulative effect of the new protocol on preterm infant & to determine effects on to brain growth, long-term neurodevelopment. It should be studied further with larger population size and can be considered for multicentric trial.

Another suggestion for, future research is also needed to evaluate the potential impact on parent mental and emotional health and parent-infant bonding, after the new intervention protocol.

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