Study Protocol

Protocol for RCT: Effectiveness of Traditional Breast Stimulations as adjuvant Techniques to Breast Milk Expression on Lactational and Maternal Outcomes

Abstract:

Background: Mothers of infants who are dependent on expressed breast milk often find difficulty to express adequate quantity of breast milk to ensure exclusive breast feeding to their babies and it has become a major stress factor among these mothers. Many cost-effective adjuvant techniques are proved to be very useful in improving the quantity and quality of expressed breast milk.

Objective: To determine the effect of two traditional breast stimulation techniques such as warm compress and breast massage as adjuvant to breast milk expression on maternal and lactational outcomes

Methodology: A hospital-based cross over trial will be considered to compare the effects of two interventions such as breast massage and warm compress, adjuvant to breast milk expression method (breast pump) on lactational outcomes (Quantity and quality of expressed breast milk) and maternal outcomes (Nipple pain, anxiety and experience of breast milk expression). The setting of the study will be selected tertiary level hospital of New Delhi. Approval from Institutional the Ethical approval is obtained from Institutional Ethical Committee, DMIMS (DMIMS (DU)/IEC/2017-18/6979) and also from the institutional ethical committee of armed forces medical services hospital of New Delhi where the study will be conducted. The data collected will be entered to an electronic data sheet and analysis will be done using SPSS.

Expected Results:
There will be a positive impact of interventions on locational outcomes such as quantity of expressed breast milk and quality of expressed breast milk.
There will be a positive impact of interventions on maternal outcomes such as nipple pain. Anxiety and breast milk expression experience.
This nurse led interventions will be made as a part of hospital policy to provide routine care to the mothers who are expressing breast milk in hospital settings.

Conclusion: Conclusion will be drawn after the analysis of data collected from the predetermined sample size. The findings of the study will be published in an open access peer reviewed journal.

Keywords: Traditional breast stimulations, Adjuvant techniques, Breast milk expression, lactational outcomes and maternal outcomes

Introduction:

Breast milk is the most ideal and exclusive nutrient for the newborn and is one the key concept of essential newborn care. Exclusive breast feeding has proved to have multiple health benefits and incredible future health outcomes in newborns.

Ensuring exclusive breast feeding in newborn and infants up to 6 months is a venture taken globally by World Alliance for Breastfeeding Action (WABA) World Health Organization (WHO) and United Nations International Children's Emergency Fund (UNICEF). World Health Organisation and the American Academy of Paediatrics (AAP) has given much emphasis on exclusive breast feeding as it promotes healthy living for both mother and baby. These health agencies also recommend that timely support and health education for breast feeding offered to mothers are very essential requirements towards promoting exclusive breast feeding [1.]

It is identified that there is increasing morbidity and mortality rates among non-breastfed infants in developed countries and this supports the fact that exclusive breast feeding has significant benefits even in areas of severe poverty. Infants born as premature are more prone to high morbidity and mortality rates in developing countries and therefore having an inescapable requirement for own mother's milk for their survival. Improved infant survival is positively associated with exclusive feeding of own mother's milk (OMM) [2].

Rationale of study:

Milk expression, defined as the removal of breast milk from a mother's breast without an infant's mouth at her nipple, is a normal component of breastfeeding for many mothers [3].

Certain circumstances demand, newborns to be fed with expressed breast milk as they cannot be fed on breast directly at birth. Therefore, methods of expressing milk needs to be evaluated for ensuring the quantity and quality of expressed breast milk as it is vital for the survival of vulnerable newborns [4]. The mothers of infants who are dependent on expressed breast milk often find difficulty to express adequate quantity of breast milk to ensure exclusive breast feeding to their babies and it has become a major stress factor among these mothers.

Breast feeding at early stage is initiated and promoted by the expression of breast milk either manually or by use of a pump. Ensuring complete evacuation of breast milk by adopting proper techniques for breast milk expression is very important. The hind milk is more viscous because of its high fat content may explain why it's difficult to remove this milk with a standard electric pump alone. But extracting more high-fat hind milk could give babies an

important calorie boosts [5]. If the breast milk expression methods are supplemented with adjuvant techniques, it is thought to have a greater impact on the quantity and quality of expressed human milk.

Even though some cost-effective adjuvant techniques are proved to be very useful in improving the quantity and quality of expressed breast milk, much emphasis is not given till now to the adjuvant techniques to be practised while expressing breast milk in most of our clinical settings. Therefore, more studies need to be undertaken to improve level of evidence for use of cost-effective adjuvant techniques for breast milk expression to improve quality and quantity of breast milk. So, creating much evidence on this aspect is a need of the hour so that the high-risk babies and mothers may get the benefits of this practice as early as possible.

Objective

To determine the effect of two traditional breast stimulation techniques such as warm compress and breast massage as adjuvant to breast milk expression on maternal and lactational outcomes.

Methodology

Type of study**:** Randomized Control trial (Cross over study). Schematic representation of the methodology is depicted in Fig: 1

Site of study: Study will be conducted in the Neonatal Intensive Care Unit of Army Hospital (R&R) New Delhi

Time frame: The study will be conducted from Jan 2021 till adequate number of samples are enrolled in the study

Subjects: All the mothers whose children are admitted to NICU and are fulfilling the exclusion and inclusion criteria will be recruited in the study. Trained Nursing staff and Interns from NICU will deliver the intervention. Milk sample analysis will be done on day 1 in Pre-intervention phase. It will give the baseline values (Control) for comparing milk quality and quantity and will prove the effect of intervention.

Inclusion criteria

- Mother of neonate who is admitted in NICU.
- Mother of neonate who is between 3 to 14 days of post-partum period.
- Mother of neonate who is exclusively fed on expressed breast milk.
- Mothers willing to express breast milk every 3 hourly
- Mother who is not having any postnatal complication.
- Mother who is on routine ante natal and postnatal drugs such as supplements of Iron, folic acid, calcium, analgesics , and routine antibiotics and obstetric drugs as per hospital policy.

Exclusion criteria

- Mothers diagnosed with breast abscess, mastitis breast engorgement, cracked nipple and with the history of any previous breast surgeries.

- Mother taking any special medications such as chemotherapy drugs, ART drugs, immuno suppressants, thyroxine supplements like eltroxin, Insulin and lactation suppression agents or galactagogues

Withdrawal Criteria

- Unwilling to continue the study
- Neonate is advised for Non-nutritive or nutritive suckling
- Not fulfilling study schedule

Sample size

Sample size calculation was done using formula used is based on paired t test

$$n = \left[\frac{(z_{1-\alpha/2} + z_{1-\beta})}{d/s} \right]^2$$

where $z_{1-\alpha/2}$ = 1.96 for 5% level of significance

$z_{1-\beta}$ = 0.84 for 80% power

d/s is the effect size (Cohen effect size) = 0.3%

$$n = \left(\frac{1.96 + 0.84}{0.3} \right)^2 = 88$$

For an effect size of 0.3, 5% level of significance and 80% power, the minimum sample size is 88 (i.e., 44 for A-B and remaining 44 for B - A sequences). An additional 10 samples are added to the sample size calculated inconsideration of dropout. Therefore total 98 samples will be considered 49 samples will be allotted to each group.

Randomization

The participants will be randomly allotted to two different groups to receive two different orders of interventions by sequentially numbered system**.**

Work up of the study subjects

The study will be conducted in three phases: Pre-Intervention phase, Intervention phase and Post- intervention phase (Table 1: Study Schedule)

Pre-Intervention phase

- The researcher will establish IPR with the mother
- Screen mothers for criteria mentioned in the inclusion and exclusion criteria of the study
- The purpose and nature of the study will be explained to the mother fulfilling the exclusion and inclusion criteria and a written participant's consent will be taken
- The sociodemographic data will be collected from the mother
- Clinical data regarding mother and child will be collected from case records.
- The state anxiety level of the mother related to breast milk expression will be assessed by using STAI 5-S by researcher.
- The breast milk expression experience of the mother will be assessed by Breast Milk Expression Experience Measure.

- Random allocation of mothers to group by computer generated simple random number table.
- The schedule or sequence of the intervention will be explained to mother in accordance with the group to which she is allocated.

Intervention phase

A cross over design will be adopted to obtain baseline and intervention data. The sample will be equally divided using random methods in to two groups. Each group will be receiving different order of interventions on two consecutive days. The baseline data will be collected during the previous session3 hours prior to the intervention sessions. A washing period of 12 hours will be ensured between interventions to prevent the residual effect and also to minimize the effect of diurnal variations in milk production.

Intervention A: Breast massage

A breast massaging technique is devised by the researcher after extensive reviews of various techniques practised across the world. This technique basically designed by focusing more on its feasibility and easy adaptability in clinical setting especially in Neonatal Intensive Care Units. The cultural acceptability of Indian mothers along with safety of the technique is kept in view and given emphasise. The steps of procedure are validated by 12 subject experts and the observations made were rectified and the final steps were refined.

The total procedure of breast massage will be performed in four steps viz massage of base of the breast, massage of glandular breast tissue, stroking areola for nipple stimulation and gentle shaking breast against gravity. Each step will be performed on each breast one after the other the total time required for the procedure is 10 minutes.

Intervention B-Warm compress

The researcher has done extensive literature reviews and identified an easy adaptable method for moist heat application especially in Neonatal care settings. Total 10 minutes of moist heat application was given simultaneously to both breast using a thick sponge cloth dipped in warm water at a temperature of 41^0C- 42^0C after wringing out excessive water. The warm application will be applied all over the breast tissue except areolar tissue and sponge cloth will be replaced frequently in every 3 minutes. The temperature of the water will be maintained with the help of a lotion thermometer throughout the procedure.

Post-Intervention phase

The interventions will be followed by breast milk expression by a standardised hospital grade double electrical breast pump (Ameda elite ^{TM}) applied to both breasts simultaneously which is set in vacuum pressure (232mmH g) and number of cycles (60 per minute) for a duration of 20 minutes. A standard measure will be used to quantify the breast milk volume in ML during each session. The volume will be again measured using separate sterile syringes with Measurements in ML and the average value will be recorded by outcome assessors.

The esterified fat in the milk will be estimated using creamatocrit method using a haematocrit centrifuge (Rami 12 C with capacity of 16000 RPM). Two standard glass capillary tube measuring 75X1.5MMoutsidediameter was filled with 75-µL aliquots of fresh breast milk, sealed one end with clay will be then centrifuged in a haematocrit centrifuge at 12,000 revolutions/min for 15 minutes. The tubes will be immediately removed after centrifuge and will be placed vertically with the cream layer in the upper part to prevent cream layer setting

irregularly along sides of the capillary tube. Then the total length of the column and the length of the cream layer will be read with the help of a vernier callipers in both the tubes separately. The upper meniscus will be read for the cream layer since it is opaque in nature and the liquid fat layer present above the cream layer will also be included with the cream. The reading of the cream layer (fig 1) will be to the nearest 0.05mm and will be expressed as a percentage of the length of the total milk column in the tube. The average value of the readings from the two capillaries will be taken in to account. The creamatocrit percentage will be then correlated with esterified fat content and converted into g/l using the equation, Fat(g/l) = (5.37 x creamatocrit %) + 5.28 [6].

The state anxiety level of the mother related to breast milk expression will be assessed by STAI 5-S.

The breast milk expression experience of the mother will be assessed by Breast Milk Expression Experience Measure.

Blinding

The blinding will be done to the outcome assessors to avoid detection bias as the intervention will be done by the researcher and the measurements of volume and fat in expressed breast milk will be done by the NICU staff and internship students (who will be taught the methods of measurements and inter-rater reliability will be established) who are not being disclosed about the type intervention/treatment given to the sample.

Outcome measures:

1. Primary outcome: Primary outcome includes the effect of two traditional breast stimulations as adjuvant techniques to breast milk expression on quantity and quality of expressed breast milk
2. Secondary outcome:

- To assess the effect of two traditional breast stimulation techniques on nipple pain experienced by mother during breast milk expression
- To assess the anxiety experienced by mothers regarding breast milk expression before commencement of these nurse led interventions and after completion of these nurse led interventions
- To assess the experience of mothers about breast milk expression before commencement of these nurse led interventions and after completion of these nurse led interventions.

Data management and monitoring

The demographic data of the mother viz Age, Education, Occupation, Occupation of head of the family, Monthly income of the family and maternal and newborn clinical parameters such as Gravida, Parity, period of gestation, Birth weight, Mode of delivery, Day of post-partum, BMI of the mother, Diet of the mother and clinical diagnosis of newborn will be recorded in excel sheets (after coding) when they are enrolled. The baseline anxiety scores of mothers regarding breast milk expression and breast milk expression experience scores(both personal & learning experience) of mothers will be obtained soon after the collection of demographic and clinical data and the same data will be obtained soon after the intervention phase and will be recorded in excel sheets. The nipple pain experienced by the mother will be recorded of one no intervention session in the morning as baseline data and also will be recorded after each intervention sessions. The base line data of volume and the fat content of

expressed breast milk will be obtained in the previous session (3 hours before) of each intervention sessions and will be recorded. The post intervention volume and fat content of expressed breast milk will be obtained after each intervention session and will be recorded in the excel sheet. Investigator will record adverse events and withdrawals for any reason.

Statistical analysis

Descriptive (mean, mean percentage, standard deviation) Inferential, Comparative statistics (student's' test) and co-relational statistics is plan for data analysis.

Ethics and dissemination

Present study approved by the IEC (Institutional Ethics Committee) of DMIMS (DMIMS (DU)/IEC/2017-18/6937) and also by the IEC of Army Hospital (R&R) New Delhi (AH(R&R) IEC Regn: 114/2020). All participants will be asked to read and sign the informed consent. The study results will be disseminated to study participants and published in open access, peer-reviewed publications. All personal data and results will be only accessible to investigator and guide.

Figure and tables:

Figure: 1. Schematic Presentation of Methodology

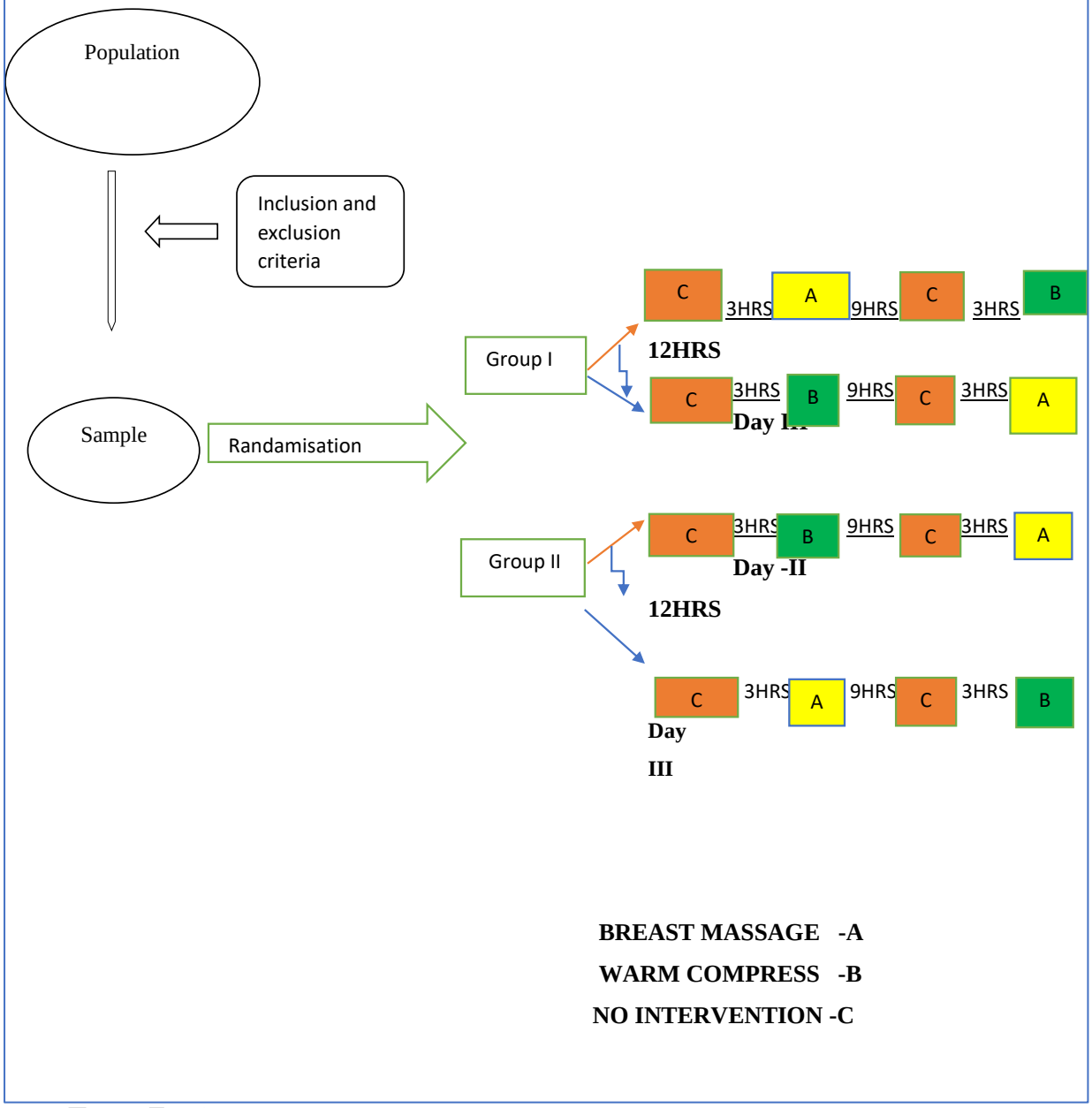

Table No.1. Study Schedule

Day	1st Day	2nd Day	3 rd Day	4th day
Time Point	Visit 1	Visit 2	Visit 3	Visit 4
Written and informed consent and demographic data, maternal and newborn clinical data	X			
Assessment anxiety of mothers related to breastmilk expression	X			X
Assessment breast milk expression	X			X

experience of mothers										
Nipple pain experienced by mother during breast milk expression experience		X				X				
volume of expressed breast milk and fat content before each intervention		X		X		X		X		
Interventions in stipulated order and outcome measurements in terms of volume of expressed breast milk and fat content and nipple pain experienced during breast milk expression			X		X		X		X	

Expected Results:

The study is expected to bring out the positive effect of traditional breast stimulation techniques as adjuvant to breast milk expression on lactational and maternal outcomes among NICU mothers.

Discussion:

There are total nine studies which have examined the effect of traditional breast stimulation techniques such as massage and warm compress on lactational outcomes and maternal outcomes.

Out of seven studies which examined the effect of massage on lactation, two studies throw lights on the fact that various massage techniques like back massage[7], point massage on liver[8] has a positive effect on lactation and its outcomes such as volume of milk expressed, neonatal weight gain, neonatal sleep, maternal satisfaction and comfort.

Other five studies proved that Breast massage[9-13] is very effective in improving the quality and quantity of breast milk expressed or fed by the postnatal women and has improved the maternal comfort and neonatal outcomes

Two quasi experimental studies examined the effect of warmth[14,15] on lactation and its outcome. Both the studies brought out that application of warmth increased the amount of breast milk and is a very convenient method for postnatal mothers to tackle problems of inadequate breast milk supply, breast engorgement and pain. A number of studies on infant and young child feeding were reviewed[16-20].

Traditional techniques of breast stimulations improved lactation outcomes and found to be having positive effect on neonatal outcomes and maternal outcomes. More studies should be conducted on traditional breast stimulation techniques to improve its generalization with large samples across various settings so that breastfeeding practices of the postnatal population can be improved.

Conclusion: The conclusion will be drawn out of inference made out of analysis of data collected.

Trial Registration: Name of Registry- Clinical trial registry- India

Registration No.–CTRI/2020/12/030109

COMPETING INTERESTS DISCLAIMER:

Authors have declared that no competing interests exist. The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

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