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Original Research Paper

Nursing Science

EVALUATION OF COMPARATIVE EFFICACY OF ERGONOMICALLY DEVELOPED BREAST FEEDING SUPPORTIVE DEVICE REGARDING SAFE AND COMFORTABLE FEEDING AMONG THE PRIMIPARA MOTHERS ADMITTED IN SELECTED HOSPITALS - A RANDOMIZED CONTROLLED TRIAL

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KEYWORDS :

INTRODUCTION

Every mother can Breast feed; Wanting to is enough,

The first 1000 days (from the conception up to the child's second year) provides a unique days of opportunity for optimum child mile stone and also establishes the opportunity for good health for life long.[1]Breast-feedingwiththe comfortable feeding experience technique, frequency, duration, Principal condition of ideal nutrition for infants is exclusive breast feeding up to 6months of age and continued breast-feeding along with appropriate complementary foods or weaning up to2yearsofage[2] Globally, India has the peak under-five mortality (0·9 million deaths in 2016)[3], attributable to an array of co -factors such as low economic status, poor sanitation and water ,poor healthcare facilities and lack of knowledge about Exclusive breast feeding[4,5]. From 2005 and 2016, past many studies from India reported an increased in Exclusive breast feeding prevalence by 9.0% (from 46.0 to 55.0%).[6]Moreever, national data often mask significantly variations across the regions. For example, the result from discrete sub-national studies have shown that Exclusive breast feeding varied widely in India, ranging from 36.0% in Meghalaya to 77.0% in Chhattisgarh[7]. Informal settlements have also reported from similarly, studies broader and lower findings, from 11.4% and 63.0% .[8]

Rationale

In the literature the benefits of breastfeeding are already widely described and cover children, women and families. Moreover, it is noticed that most women start breastfeeding, but interrupt it early. It is estimated that only 34.8% of the children receive breast milk exclusively during the first six months of life, Studies have shown that early weaning is a worldwide event and.2 In Brazil, the prevalence of exclusive breastfeeding (BSE) in under six months in the Brazilian capitals was 41% and the Federal District.[9]

The arrival of the first child includes feelings of fear and insecurity that, associated with not having experience in breastfeeding, exacerbate the idea of being wrong or even unable to provide good nutrition for the child, Another fact related to early weaning is primiparity, which may be a factor that negatively influences breastfeeding self-efficacy.[1]

Inconsistent findings leave uncertainty about the impression of pacifier use of proper and effective breastfeeding technique. Effective technique included positioning, latch, sucking, and milk transfer. Self-reported questionnaires are used for obtained the Data on breastfeeding problems and pacifier. The study population included 570 mothers and baby pairs with full information on breastfeeding technique and pacifier use. The duration of exclusive breastfeeding was the primary outcome .Finding of the study was, One-half of the mothers showed ineffective breastfeeding technique at the first\ observation, most frequently ineffective and latch (52%) position (61%). In the unadjusted analysis, only milk and sucking transfer were related with breastfeeding duration. Observation of breastfeeding technique may help mothers in the stage of when they are establishing breastfeeding to skip early and later problems, but breastfeeding technique is not that much approximate in predicting breastfeeding duration[11] If good attachment and positioning can be achieved at the first and early feeds, most difficulties of breastfeeding can be avoided altogether. Most difficulties of breastfeeding can be less altogether. Most of studies have been done to explore factors affecting breastfeeding practice in general; moreover, there is a meagerness of evidence that assesses factors affecting positioning and attachment during breastfeeding, specifically cross-sectional study was conducted by using observational checklist adopted from the WHO breastfeeding observation form. Studies finding says that there was poorer positioning among Primipara mothers (47.1%) than multipara mothers (28.7%). A poor attachment was also more apparent among primipara mothers than the multipara, Study concluded that younger mothers (<20 years old), the Primipara, and those who have illiterate deserve more attention, support, and direction to make sure that they can achieve attachment and proper positioning during breastfeeding at the first and early feeds.[12]

Nursing professionals with the knowledge and skills are necessary for clinical management and breastfeeding counseling helps to the success of breastfeeding. Nurses' performance and proper care in order to increase women's confidence to breastfeed there be a facilitator of this process.[13]

Identified Knowledge Gap

- Most commonly and widely used technique of breastfeeding is the traditional method, they are associated with problems and challenges for primipara mothers like pain and discomfort
- There are many comfort devices are available in market but they do not fullfill all the ergonomic criteria.
- There is lack of knowledge gap among primipara mothers due to raising number of nuclear family and lack of adequate family and social support to impart training to them
- Therefore there is need to improve the knowledge attitude and practice of breast feeding behaviour among primipara mothers, as well as they were adjunctive support system, by ergonomically design supportive device that will promote breast feeding behaviour among primipara mothers.

Research Question

PHASE I [Pilot Study]

RQ1:

Part A:

Whether the generated structured informational module for

breast feeding is valid and reliable?

Part B:
Whether ergonomically developed Breast feeding supportive device will better than the popular device available in the market for safe, comfortable feeding and emotional outcome among primipara mothers through piloting?

PHASE II [Clinical study]
RQ2:
Part A:
Whether the generated and validated structured informational module for breast feeding significantly efficacious for improving the knowledge, practice and attitude of primipara mothers?

Part B:
Whether ergonomically developed Breast feeding supportive device will improve the practices in overcoming the problems faced by primipara mothers as compared to popular device available in the market?

Generated Hypothesis phase II

H0: The generated structured informational module for breast feeding is not sufficiently efficacious in improving knowledge, practice and attitude among primipara mothers regarding safe and comfortable feeding

H1: The generated structured informational module for breast feeding sufficiently efficacious in improving knowledge, practice and attitude among primipara mothers regarding safe and comfortable feeding

$H0_1$: The ergonomically developed Breast feeding supportive device is not clinically efficacious in improving practice and overcoming the problems faced by primipara mothers as compared to popular device available in the market regarding safe and comfortable feeding.

H2: The ergonomically developed Breast feeding supportive device is clinically efficacious in improving practice and overcoming the problems faced by primipara mothers as compared to popular device available in the market regarding safe and comfortable feeding.

AIMS AND OBJECTIVES
AIM
Phase I:
To evaluate the validate and Reliability of structured informational module of breast feeding for improving KAP regarding safe and comfortable feeding amongst primipara mothers.

Phase II:

a) To evaluate the generated and validated structured informational module for breast feeding significantly efficacious for improving the knowledge, practice and attitude of primipara mothers
b) To evaluate and compare the efficacy of ergonomic developed Breast feeding supportive device in improving the practices in overcoming the problems faced by primipara mothers as compared to popular device available in the market.

OBJECTIVES
Phase I

1. To evaluate and validate Reliability of structured informational module of breast feeding for augmenting Knowledge attitude and practice among primipara mothers regarding safe and comfortable feeding.
2. To evaluate the feasibility of ergonomically developed Breast feeding supportive device through piloting.

Phase II

1. To assess and compare the breast feeding knowledge and Attitude at base line and after intervention using structured tool.
2. To identify the problem faced by primipara mothers related to comfort, emotional and safety and practice.
3. To assess and compare the efficacy of ergonomic developed Breast feeding supportive device in improving practice and overcoming the problems faced by primipara mothers as compared to popular device available in the market regarding safe and comfortable feeding.

Material With Information Regarding Standardization
Data collection Process
After grouping the population in to clusters, selection of Primipara mothers as per inclusion criteria through single blinding method, detail explanation about nature and purpose of the study and the written consent from the subjects will be taken before data collection by the investigator.

Steps involved in a parallel arm trial design
Eligibility of study subject assessed → Recruitment into study after consent → Randomization → Allocation to either test or control group

Mode of Data Collection
The collection of the data by conducting one-on-one interviews with the primipara mothers in hospitals and in their homes.

Structured informational module will be given to assess and compare the breast feeding knowledge and Attitude at base line and after intervention using structured tool.

Collection of Pretest Data:
In order to collect pretest data, on the date of their hospitalization, the primipara mothers of both Interventional and control groups will be given the Personal Information Form, Structured informational module will be given to assess knowledge and Attitude at base line , Nordic musculoskeletal Questionaire Tool.

Collection of Posttest Data:
For collecting posttest data, the primipara mothers of both Interventional and control groups will visit once in the hospital on the 5th day of their hospitalization and then once a 2ndweek, 4thweek, and then 6th week in their homes During the visits, the mothers were asked to breastfeed their babies. By observing their breast-feeding statuses, Breast-feeding Follow-Up Forms will fill. At the end of the 2ndweek, 4thweek, and then 6th week, the Breast-feeding Self-Efficacy Scale and the Breast-feeding Assessment RULA scale were once again applying at the mothers' home During the home visits, necessary reminders will made to the mothers of the Interventional group, and their questions were answered. The visits made to the homes of the participants of the test group will limit to 30 minutes, whereas they will limit to 10 minutes for the control group.

Immediately after the application of the final tests at the end of the 2ndweek, 4thweek, and then 6th week, the mothers in the control group will provide with an informative booklet.

Nursing interference
5 days starting from their day of hospitalization, the mothers included in the test group will provide training session, In the training session demonstration will be given by the researcher with the use of the breast comfort device and training dummy, at the hours convenient for the mother and their babies, Afterwards, the mothers will ask to practice breast feeding with the dummy and then ask to breast feed their own babies.

At the end of 5 days training, this took about 30 minutes every day

METHODOLOGY/MATERIAL & METHODS IN DETAILS

METHOD: PHASE II

- Settings: Selected Maternity Hospitals at Vidarbha region
- Research Design: Randomized control trial
- Participants: Primipara mothers
- Sampling procedure: Stratified Random sampling technique
- Sample size: 100- Primipara mothers, with 50 for Interventional group and 50 for control group
- Allocation Ratio: Patients will be selected by computer generated random numbers.

Participant-Primipara mothers
Research Approach- Evaluative Approach

Inclusion Criteria-

- Primipara mothers were between the ages of 18 and 35years
- Primipara mothers who have delivered without any complication
- New-born had birth weight is more than 2000g.
- New-born were born at more than 32 weeks of gestational age

Exclusion Criteria-

- Primipara who had seeing or hearing problems
- Primipara who were not ready to open for communication and cooperation
- Those are critically ill.
- The new born with congenital abnormalities

Variables
Outcome Variables-
Physical
Reduction of pain in the shoulder and back

Physiological
Comfort of the mother
Positioning of the mother

Psychological
Improve secretion of breast milk
Safe feeding

Emotional
Early initiation of breast feeding
Bonding between child and mother
Knowledge, attitude and Practice of breast feeding of primipara mothers

Demographic variable– Age, residence, socioeconomic status etc.

Analysis Plan
Statistical analysis will be done by using descriptive and inferential statistics using Chi-square test and z-test for difference between two means and software used in the analysis were SPSS 27.0 version and Graph Pad Prism 7.0 version and $p<0.05$ is considered as level of significance.

Definitions
Effect: The ability to produce proposed outcomes

Breast feeding self-Efficacy (BSE) :
refers to a factor that mediates health behaviors, and expectations about their own abilities to perform behavior, thus self-efficacy for breastfeeding is related to the woman's perception of her ability to breast feed and the belief that she has enough knowledge and decision to breast feed.

Ergonomically developed Breast feeding supportive device:
The pillow used the study was designed for comfortable use during breast feeding. The pillow used the study was designed for comfortable use during breast feeding. Produced with materials that are free of carcinogenic and allergenic substances, the pillow was made of 100% cotton, with a soft light washable cover. In order to prevent infections, the cover of the pillow was changed with a new one before each breast- feeding session.

Comfortable feeding experience Means
World health organization trusted Source and the American Academy of Pediatrics recommend breast milk or formula as the sole source of a baby's food/nutrients during the first 6 months, and encourage breastfeeding for longer; breastfeeding can be done for much more than just feeding your baby Breastfeeding offers opportunities for:

- relaxation
- bonding
- warmth
- cuddles
- relief from pain

Comfort nursing may include different types of sucking in varying duration, including flutter sucking. Remember, comfort nursing just means that the primary goal is not eating a full meal; so many types of sucking motions can achieve this.

Study Type And Sample Size Calculation
Sampling Procedure
Sample Size-
100- Primipara mothers, with 50 for interventional group and 50 for control group

$$n = \frac{Z^2 p(1-p)}{e^2}$$

Where

- Z^2 is the level of significance at 5% i.e.
- 95% Confidence interval = 1.96
- P = Proportion of mother's sustained exclusive breastfeeding = 85.7% = 0.857
- e = error of margin = 10% = 0.10
- $n = \frac{1.96^2 \times 0.857 \times (1-0.857)}{0.10^2}$
- n = 47.07, 50
- 50 Mothers needed in each group
- Study Reference: SibelKukukoglu et al
- Formula reference: Cochran W . A. et al (1977)
- Statistical tests: Chi-square Test, Students t-test
- Software Used: SPSS 27.0 version, Graph pad Prism 7.0 version
- Study Design: Case-Control Study:
- Level of Study: Level III
- **Sample**- Primipara mothers
- **Sampling Technique**- Stratified Random sampling technique

Methods With Justification
Ergonomics In Feeding Pillow As An Intervention
The mother's body posture during breast feeding is very important. Furthermore, remaining in a constant physical position is associated with chronic musculoskeletal disorders (MSDs), including back, knee, and neck disorders, which in turns seem to negatively affect breast feeding. Having aches and pains become common place during or after breastfeeding. This may be a sign that you need to modify your breastfeeding position to help reduce the pain.[19]

Posture

- Breastfeeding mothers can, especially in the early days, be exposed to prolonged periods in the seated, lying or reclined position.
- When we are static, the muscles are contracting but there

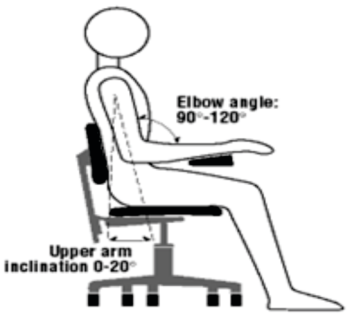
is minimal movement. The muscles are using energy and making lactic acid as a by-product.

- Too long in the one position decreases the rate of circulation around the body, reducing the removal of waste products from the muscles, reducing the provision of oxygen and nutrients to the muscles, increasing the risk of inflammation and strain on the muscles and tendons, causing discomfort.
- Adverse postures can also impact milk flow and latch quality, contributing to breast and nipple discomfort.
- The posture of the mother when breastfeeding is important, So Breastfeeding using sling or pillow has proven a significant effect in the maintenance of good body posture to reduce the pain on the back and also enhance the latching

Benefits Of Ergonomically Developed Breast Feeding Supportive Device During Breast Feedingat Different Positions

Sitting position

In this position, the participant was advised to sit upright and use feeding device which supports, the body in angle of elbow and body will be 90-120^0, upper arm inclination will be around 0-20^0.



The participants are not advised to feed the infant while leaning forward or backward(flexion or extension of the trunk). If the participant bends forward, this posture exerts pressure on the back and neck muscles. If her trunkle and back, the breast is farther from the infant and it is difficult for the infant to continue feeding, rather, encourage the mother to bring the baby up to her breast in a semi-reclined breastfeeding position. Look for symmetry, and remember that a neutral position should be relaxing and comfortable.

Cradle position/ Cross cradle position

In this situation, light pressure is exerted on the mother's neck, shoulders, arm ,and back muscles. To avoid this pressure and discomfort on the neck, shoulders, arm and back muscle feeding pillow have been provided with inserted pouch which hold the baby in the position where the hands of the mother can be kept free. The devices may assist mother with arm, elbow and shoulder support along with baby. Even if the mother's hands are off the pouch baby can access the nipple with comfortable position within the pouch, provided the pouch designed with a material which allows adequate ventilation to baby and also with consideration on privacy of the mother in all circumstances under usage.

Lying position (lying on the side)

In this situation, it is recommended that the mother puts several pillows under her head, back and between her knees to make feeding easier, with help of this device mothers can feed comfortably her infant, it reduce strains associated with holding baby to the breast

1) Which enables the mother to feed the baby in a very comfortable position. It ensures 100% baby support, ventilation and ergonomic design. The item is a wearable jacket which the mother can wear over the dress, provided mother is wearing feeding enabled inners.

It helps the mothers to have light pressure is exerted on the mother's neck, shoulders, arm, and back muscles because the infant weight is balanced on the feeding device

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