Chapter - III

RESEARCH METHODOLOGY

Research Methodology for this study includes the research approach, research design, research setting, population, sample, data collection instrument, pilot study, procedure for data collection and the plan for data analysis.

Research Approach

Keeping the objectives in mind, i.e. evaluation of the effectiveness of early initiation, education on breastfeeding on certain bio-psycho-physiological parameters of mothers and babies, knowledge and practices on breastfeeding, establishing cause and effect relationship, an experimental approach was adopted.

Research Design

Research design adopted for the study was Concurrent Parallel Study Design, which is one of the designs of Randomized Control Trial.
FIGURE - 2: SCHEMATIC DIAGRAM OF CONCURRENT PARALLEL STUDY DESIGN

Random Assignment of Subjects

Intervention Group
- Education on Breastfeeding
- Early Initiation of Breastfeeding

Observation

Control Group
- Routine Care

Observation

COMPARE OUTCOMES

Assessment for Mothers
- Lochial discharge
- Fundal height
- After pains
- Amount of breastmilk secretion
- Attachment with baby
- Knowledge and practice on breastfeeding

Assessment for babies
- Feeding behaviour
- Weight loss
- Urination
- Elimination
- Hours of Sleep
RESEARCH SETTING

Location

The study was conducted in the labour ward, RMMCH, Annamalai University, Chidambaram which is about 235 kms away from Chennai, situated in Tamilnadu, India. Annamalai University at Annamalainagar, is a renowned autonomous university since 1923, famous for its academic excellence in almost all faculties.

Study Setting

Rajah Muthiah Medical College & Hospital (RMMCH) is a 1110 bedded rural-based teaching hospital, providing tertiary level care, serving mostly less educated, low income group of population from nearby towns and villages. Health services are provided free of cost and only nominal charges are collected.

Study Area

Labour ward is the busiest ward in RMMCH. It has 13 delivery tables and a waiting room for antenatal mothers who are in labour. The postnatal cubicle is adjacent and has 30 beds, where mothers and newborns are taken care. It also has an Intensive Care Unit (ICU) which takes care of high risk mothers. Neonatal
Intensive care Unit (NICU) is situated adjacent, which takes care of the high risk newborns, where facilities for immediate transport, specialized equipments and skilled care by neonatologists are available round the clock.

**Study Period**

Data collection was done from March 2005 to May 2005.

**Population**

All pregnant mothers with normal obstetrical history, at term gestation, admitted in labour ward.

**Sample**

**Inclusion Criteria**

- Mothers who have normal obstetrical parameters.
- Mothers who are at term gestation and delivered normal babies
- Mothers who are not in labour
- Mothers who have normal obstetrical parameters upto 3 days postpartum
- Mothers who can understand and speak Tamil language
- Mothers who are willing to participate in the study.
Exclusion Criteria

- Mothers with less than 38 weeks of gestation
- High risk mothers
- Mothers who develop major complications during first 3 days post-partum.
- Mothers who have babies with abnormal parameters

Sampling technique

Simple random sampling technique was used. Keeping this in mind the investigator randomly assigned designated days, for both groups. The designated days for the intervention groups were Mondays, Wednesdays and Fridays and for the control group the designated days were Tuesdays, Thursdays, and Saturdays. Everyday an average of 12-15 mothers are admitted in the labour ward of which 7 to 8 mothers undergo normal delivery.

The first two to three mothers, delivering on the randomly assigned designated days, fulfilling the needed criteria, were selected for control or intervention groups.

Assessment was done for 2 to 3 mothers who deliver on that particular day. When number of assessed mothers in a particular
group was saturated (n=75), then assessment was carried on for mothers for the required group only, to make it to 75. Thus, the number of samples came to 75 for each of the groups.

**Case**

A case is defined as an antenatal mother, who fulfilled the needed criteria and to whom education on breastfeeding was given, assistance offered for early initiation of breastfeeding within ½ to 1 hour of delivery by the investigator and post test was applied.

**Control**

A control is defined as an antenatal mother who fulfilled the needed criteria, and to whom routine care was given and post test was applied.

**Data Collection Instrument**

**Description of the Data Collection Instrument**

The data collection instrument was divided in to VI parts which included sections, as described below: (Appendix - I)

- **Part - I** - Personal and Family characteristics of mothers - 13 items
- **Part- II** - Section A : Past Obstetrical data - 8 items
Section B: Present Obstetrical data – 9 items
Section C: Partograph
Section D: Salient Events during delivery including early initiation - 15 items

Part III Assessment of the bio-physiological parameters of post natal mothers.

Part IV Assessment of attachment of mothers with their babies on a 5 point scale.

Part V Assessment of the bio-physiological parameters of newborns.

Part VI Questionnaire to assess the knowledge and practice of mothers on breastfeeding.

ASSESSMENT OF THE BIO-PHYSIOLOGICAL PARAMETERS OF MOTHERS IN PUERPERIUM

Assessment of amount of lochia

This was done by assessing the number of saturated pads changed as reported by mothers on day 1 and day 2.

Symphysis fundal height measurement

After emptying the bladder and keeping the mother in supine position by using the standard inch tape, symphysis fundal height was measured from upper border of the symphysis pubis to the level of fundus of the uterus. The difference between day 2 and day 3 was noted.
Assessment of Intensity of After Pains

Assessment of intensity of After pains was done by asking the mother to show her intensity of After pains on the Numerical Pain Intensity Scale (NPS) and it was noted by the investigator.

Assessment of Amount of breastmilk secretion

Using electronic weighing scale the babies were weighed just before feeding and immediately after feeding and the weight was measured in grams using electronic weighing scale. The difference in weight was noted and the increase in weight in grams was calculated to be equal to millilitres of breastmilk intake. The slightly increased density of breastmilk when compared with water can be balanced with water lost by sweat by the infants during breastfeeding. The procedure was validated by experts and found valid.

ASSESSMENT OF ATTACHMENT OF MOTHERS WITH THEIR BABIES

On the third day of delivery mothers were asked to express, how they feel with their baby which was assesses by suing the attachment scale using a five point Likert type scale.
The above mentioned procedures were validated by experts and was found to be valid.

**ASSESSMENT OF NEWBORN’S BIO-PHYSIOLOGICAL PARAMETERS**

**Assessment of duration of feeding**

The starting and the finishing time of sucking was noted and the difference in time was taken as the duration of feed.

**Assessment of frequency of feeding**

Frequency of feeding was assessed by asking the number of time the babies were suckled by their mothers, per day.

**Assessment of Weight loss of newborns**

Babies were weighed at birth with the electronic weighing scale and the weight loss on the second day was noted using the same weighing scale.

**Assessment of Urination**

Urination was assessed by counting the number of times babies passed urine, per day.

**Assessment of Elimination**

Elimination was assessed by the number of times babies passed meconium, per day.
Assessment of Hours of Sleep

Hours of sleep was assessed by asking the mothers the duration of sleep at different times, during the day and night times and adding it together. The above procedures were validated by experts and found valid.

Assessment of Knowledge and Practice of mothers on breastfeeding

Questionnaire consisted of a set of open ended and closed ended questions, which also included a few items (2) to be assessed by observation. These questions would elicit answers, showing how far the mothers had knowledge about breastfeeding, their practices about breastfeeding. The questionnaire was prepared meticulously based on the literature search and the educational module.

The Questionnaire had 50 questions, which were organized under various sections as shown below:

- Initiation of breastmilk secretion - 3 questions
- Prelacteal feeds - 3 questions
- Exclusive breastfeeding - 3 questions
The questionnaire was scrutinized by experts before data collection, and was found valid.

**Scoring Procedure**

Each correct answer was given a positive score. Weighted score was given as per the expert’s guidance of for important questions. Incorrect answers and ‘do not know’ response were scored as 0. (Zero)

**Interpretation of the score**

The overall score on the questionnaire revealed the level of knowledge of mothers and their practices related to breastfeeding and the score was interpreted as shown below:

- 75-100% Above average
- 50-75% Average
- <50% Below average
DESCRIPTION OF THE INTERVENTION  

Education Module (Appendix – III)  

 Mothers in the intervention group were given education on breastfeeding using the education module which consisted of various aspects of breastfeeding and it was arranged under the following captions.

- Anatomy and Physiology of Lactation  
- Role of hormones in initiation of breastmilk secretion  
- Prelacteal feeds  
- Exclusive breastfeeding  
- Maintenance of breastmilk secretion  
- Technique of breastfeeding  
- Ensuring adequacy of breastmilk intake  
- Advantages of breastfeeding for the baby  
- Advantages of breastfeeding of the mother  

 Mothers in the intervention group were given education on the above aspects of breastfeeding, using the education module in a group comprising of 4 mothers, which lasted for 40-45 minutes, using flash cards. The doubts of the mothers were clarified at the end of the session.
Early Initiation of Breastfeeding

Starting the first breastfeeding within $\frac{1}{2}$ to 1 hour of delivery is termed as early initiation of breastfeeding. When the baby was born, immediate newborn care was given, and if apgar was found to be $\geq 7$, the baby was wrapped with a fresh, prewarmed towel, and the mother was helped to suckle the baby within $\frac{1}{2}$ to 1 hour of birth. The intervention was validated by experts and found safe and valid for the conduction of the study.

Content Validity

Seven experts scrutinized the data collection instrument and the intervention module on education and technique for early initiation of breastfeeding to ensure content validity. Expert team included 2 obstetricians, 2 pediatricians, 2 paediatric nursing professors and one bio-statistician. Suggestions given by the experts were incorporated and the tool and intervention were finalized. The final instrument and module were translated into Tamil (local language) and the Tamil translation was retranslated to English for validity of the translated version. The translated instrument was found to be congruent with the original instrument.
Pilot study

A pilot study was conducted in labour ward on 16 mothers to check the practicability and feasibility of the instrument and the instrument was found to be feasible and practicable for the pursuit of the study with a few changes.

Reliability

Test – retest method was used to assess the reliability based on pilot. The obtained Reliability score was 0.85.209

Sample Size Calculation

Sample size was calculated based on pilot study findings. With mean knowledge score of 28.27 for control group and 49.01 for intervention group, the needed sample size was 50, for the power >99%. Hence the sample size was decided as 75 for intervention and 75 for control group.

Sample Size

75 mothers were selected randomly to the intervention group and 75 mothers for the control group.
**Data Collection Procedure**

Permission was obtained from Dean, RMMC, Medical superintendent RMMCH, Professor and Head, the Chiefs of all the Units, Division of Obstetrics & Gynecology, RMMCH, for the conduct of the study. Ethical clearance was obtained from ethical committee.

**Data Collection**

Data Collection was done using the described instrument in the labour ward on antenatal mothers. All antenatal mothers meeting the needed criteria were selected randomly and assigned for control and intervention groups. The researcher introduced herself and explained the study purpose and got written consent from the mothers. The education module was taught to the mothers in the intervention group, using flash cards for 40-45 minutes, in a group of four mothers at a time in a separate room. The researcher remained with the mother during delivery and hands on assistance was given for the early initiation of breast feeding. Mothers in both groups along with their babies were assessed and the needed data were collected upto 3 days postpartum. Questionnaire was
administered to all mothers on the third day after delivery. Education module was taught also to the mothers in control group, at the end of the study. Thus, treatment was made equal to both groups.

**Statistical Analysis**

Means and percentages were used to have a basic idea about the groups. Chi-square test and ‘t’ test was used to compare the groups by selected bio-physiological parameters. Mann Whitney test was used to compare the attachment scores.

Chi-square test and Mann Whitney test was used to associate the response of both groups to the questionnaire on breastfeeding. The ‘t’ test was used to compare both groups on their overall level of knowledge and practice.

Kruskal Wallis test was used to correlate personal, family and obstetrical variables of mothers in control group with their mean knowledge and mean practice scores on selected aspects of breastfeeding.