

## **Chapter 3**

### **Materials & Methods**

This chapter deals with the methodology used for the study. The study was carried out in two phases. In phase I, a cross-sectional survey was done to determine the breastfeeding knowledge, practices and problems related to breastfeeding among the postnatal mothers. The intervention comprehensive breastfeeding promotion program was developed on the basis of this need assessment survey. In phase II, an experimental approach was undertaken to test the effectiveness of the comprehensive breastfeeding promotion program (CBPP) on breastfeeding self-efficacy, practices and outcomes among the primigravid mothers. The methodology of the two phases i.e., phase I and phase II are discussed separately in this chapter.

#### **Methodology of Phase I**

##### **Research Approach & Design**

A cross-sectional survey with exploratory approach was used in Phase I to determine the breastfeeding knowledge, practices and problems related to breastfeeding among the postnatal mothers.

##### **Variables**

The research variables in Phase I were:

- a) Breastfeeding knowledge
- b) Practices related to breastfeeding
- c) Problems related to breastfeeding

## **Setting**

The present study was done in the following four private maternity hospitals of Allahabad district. These hospitals were selected for data collection as they were accessible maternity care centers and the permission granted to carry out the study.

1. Dr. Rekha Srivastava Maternity Hospital: The hospital was 200 bedded and the weekly census for out-patient department was around 300 patients. The delivery rate was 180-200 deliveries per month.

2. Dr. Sangeeta Sharma Clinic – The hospital was 50 bedded and the weekly census for out-patient department was around 70-80 patients. The delivery rate was 90-100 deliveries per month.

3. Saket Maternity Hospital - The hospital was 150 bedded and the weekly census for out-patient department was around 400 patients. The delivery rate was 200 deliveries per month.

4. Allahabad Nursing Home - The hospital was 100 bedded and the weekly census for out-patient department was around 100 patients. The delivery rate was 150 deliveries per month.

## **Population**

The population for the Phase I comprised of postnatal mothers who gave birth to the live babies at full term and within six months postpartum.

## Sample

The samples in Phase I involved the postnatal mothers who gave birth to the live babies at full term and those who attended the immunization clinics of the selected four maternity hospitals up to six months postpartum.

## Sample Size

Based on national data regarding exclusive breastfeeding rate, the sample size for the present study was estimated at the expected prevalence of 40%.<sup>130</sup> On the basis of this data and in order to achieve a statistical significance of 95%, with 80% power ( $\beta$ ) at 5% level of significance and nearly 10% of dropouts, the study sample size for Phase I was considered as 400 mothers.

$$n = \frac{z^2 * \hat{p}(1 - \hat{p})}{\epsilon^2}$$

Where n = Sample size

z = 1.96 for 95% confidence level

p = prevalence from the study<sup>130</sup>

e = acceptable error i.e., 0.05

The most credible sample size needed for **Phase I study is=369**, which is **400** appropriate for the study.

## Sampling Technique

Quota sampling technique was adopted in the study to recruit the sample and 100 postnatal mothers from each of the four maternity hospitals (n=400) were selected.

## **Inclusion Criteria**

The inclusion criteria for the study were postnatal mothers who:

1. had delivered live baby at term.
2. were attending the immunization clinics of the four maternity hospitals.
3. were between the period from birth to 6 months post partum.

## **Exclusion Criteria**

Mothers who were -

1. suffering from conditions like pre-eclampsia, HIV etc that affects the breastfeeding outcomes.
2. diagnosed with fetal congenital anomalies like cleft lip and cleft palate.
3. having any psychiatric illness.

## **Methodology of Phase II**

### **Research Approach & Design**

A quantitative experimental approach was used to see the influence of comprehensive breastfeeding promotion program on breastfeeding self-efficacy, practices and outcomes. The study adopted post-test only control group design. The schematic representation of the study design is presented below:

Group	Intervention	Post intervention assessment		
		Thirdday	At 6 weeks	At 6 months
Experimental Group (n=50)	X	O <sub>1</sub> Breastfeeding self-efficacy, practices and outcomes	O <sub>2</sub> Breastfeeding practices and outcomes	O <sub>3</sub> Breastfeeding practices and outcomes
Control Group (n=50)		O <sub>1</sub> Breastfeeding self-efficacy, practices and outcomes	O <sub>2</sub> Breastfeeding practices and outcomes	O <sub>3</sub> Breastfeeding practices and outcomes

### Variables

The research variables in phase II were:

Independent Variables: Comprehensive Breastfeeding Promotion Program

Dependent Variables: 1) Breastfeeding self-efficacy

2) Breastfeeding practices

3) Breastfeeding outcomes

4) Breastfeeding experiences

### Setting

The Phase II of the study was conducted in Saket Maternity Hospital. This hospital was selected based on the weekly census of around 400 mothers in the out-patient department and the delivery rate was around 200 per month.

## Population

The population for the Phase II comprised of:

Target population: primigravid mothers

Accessible population: primigravid mothers attending selected hospital

## Sample

The samples in Phase II involved the primigravid mothers within the gestational period of 28-34 weeks.

## Sample Size

The sample size for phase II was estimated based on previous study.<sup>128</sup> A sample size calculation was made based on 80% power and 5% level of significance and 10% attrition rate.

$$n = \frac{2[(a + b)^2 \sigma^2]}{(\mu_1 - \mu_2)^2}$$

where n = Size of the sample

$a = Z_{1-\alpha/2} = 1.96$  at 95% confidence interval

$b = Z_{1-\beta/2} = 0.84$  at 80% power

$\sigma$  = pooled standard deviation = 21.6

$\mu_1 - \mu_2$  = difference of mean between two groups = 2.73

Assuming 10% lost to follow-up, a minimum of 50 participants is required in each group. Thus, the most conservative sample size needed for **Phase II study is = 98**, which is **100** appropriate for the study.

## **Sampling Technique**

For Phase II, all the primigravid mothers who were within the gestational period of 28-34 weeks and attended the antenatal clinic of Saket Maternity Hospital were selected for the study. The samples were randomized into control and experimental groups by concealed randomization technique.

## **Inclusion Criteria**

Primigravid mothers who were:

1. within the gestational period of 28 to 34 weeks.
2. having delivery in the same hospital.
3. coming for immunization in the same hospital.
4. having telephonic facility.

## **Exclusion Criteria**

Primigravid mothers who:

1. were suffering from conditions like pre-eclampsia, HIV etc that affects the breastfeeding outcomes.
2. were diagnosed with fetal congenital anomalies like cleft lip and cleft palate.
3. were having any psychiatric illness.

## **Tools for Data Collection**

### ***Phase I***

Tool 1: Structured questionnaire to determine the breastfeeding knowledge, practices and problems related to breastfeeding of the postnatal mothers.

## ***Phase II***

Tool 2: Breastfeeding Self-Efficacy Scale – Short Form to assess the breastfeeding self-efficacy of the mothers on the third day postpartum

Tool 3: Structured questionnaire to assess the breastfeeding practices of the primigravid mothers. It is divided into two sections:

Section A: Bristol Breastfeeding Assessment Scale to assess the observed breastfeeding practices of the primigravid mothers on the third day postpartum.

Section B: Structured questionnaire to assess the self-reported breastfeeding practices of the primigravid mothers on third day, at 6 weeks and at 6 months postpartum.

Tool 4: Structured questionnaire to assess the breastfeeding outcomes of the primigravid mothers on third day, at six weeks and at six months after the birth of the baby.

Tool 5: Structured questionnaire to assess the breastfeeding experiences of the primigravid mothers at 6 months postpartum.

### **Description of Tools**

Tool 1 collects the background information that helps to measure the specific characteristics of the postnatal mothers. It includes age, education, religion, working status, parity, type of family, type of delivery, family support for breastfeeding and breastfeeding status of the postnatal mothers.

Tool 2 evaluates the postpartum mothers' breastfeeding knowledge. The questionnaire has a total of 12 questions that highlighted the mainly three domains of breastfeeding – advantages of breastfeeding, duration of breastfeeding, initiation, and breastfeeding



promotion and techniques. . Scoring was categorized as 0 – 3 = Poor breastfeeding knowledge, 4 - 7 = Fair breastfeeding knowledge, 8 - 12 = Good breastfeeding knowledge.

Tool 3 uses the self-structured questionnaire to assess the practices related to breastfeeding of the postnatal mothers along with open-ended questions to specify the reasons more appropriately.

Tool 4 deals with the problems faced by the postnatal mothers related to breastfeeding. A structured check list was prepared to assess the breastfeeding problems of the mothers up to six months postpartum.

Tool 5 included the background information of the primigravid mothers. It includes age, education, religion, occupation, family type and delivery mode of the primigravid mothers.

Tool 6 included Breastfeeding Self-Efficacy Scale- Short Form (BSES-SF). The self-efficacy of mothers in breastfeeding is measured using the standardized Likert scale. Dennis and Faux developed The Breastfeeding Self-Efficacy Scale-Short Form (BSES-SF) in 1999 to assess the confidence of the breastfeeding mothers. The tool is a self-reported Likert scale with 14 items, ranging from 1 (not at all confident) to 5 (extremely confident). Scoring was categorized as 14 – 28 = Poor self-efficacy, 29 – 42 = Moderate self-efficacy, 43 – 56 = Good self-efficacy, 57 – 70 = Very good self-efficacy.

Tool 7 assessed the breastfeeding practices on the third day postpartum. The Bristol Breastfeeding Assessment Scale was used to assess the observed breastfeeding

practices among primigravid mothers. It has four items – Positioning, Attachment, Sucking and Swallowing to measure the breastfeeding pattern of the babies. Scoring was categorized as 0 – 2 = Poor breastfeeding practice, 3 - 5 = Average breastfeeding practice, 6 - 8 = Good breastfeeding practice

Tool 8 included structured questionnaire to assess the breastfeeding outcomes of the primigravid mothers. The structured tool included five items that helps to measure the breastfeeding outcomes of the primigravid postnatal mothers at different intervals of time i.e., on third day, at six weeks and at six months after the birth of the baby.

Tool 9 assessed the breastfeeding experiences of the primigravid mothers. The tool included self-structured questionnaire and data was collected telephonically using quantitative approach at 6 months postpartum.

### **Validity**

The validity was done by the various experts from the doctors of paediatric department, lactation consultants and neonatologists, paediatric nursing department. The specialists were chosen based on their clinical knowledge, experience, and enthusiasm for the study. They were asked to comment on the appropriateness and applicability of the tool's components. As per the suggestions of the experts and the supervisor, the tools were modified and revised. There was 100% agreement for all items in the tool 1. For tool 2, there was 90% agreement for 14 items. 2 items were removed. There was 94% agreement for tool 3 and 80% agreement for tool 4. Tool 7 was divided into three parts with 100% agreement. Tool 9 and tool 10 showed 90% agreement.

## Pretesting of Tools

All the measurement tools were administered to ten primigravid mothers to see the clarity and comprehensiveness of the tools. No difficulties were faced by the mothers. The tools were translated to local language (Hindi) and they were clear and understandable.

## Reliability

The tools reliability was achieved by administering it to 30 postnatal mothers. Equivalence Reliability - Inter-rater and Test-Retest method was adopted in this study for tools reliability. Table 1 describes the type of tool, number of items in each tool, reliability method applied and the coefficient correlation (r).

**Table 1: Reliability coefficient correlation (r) of the tools**

S.No.	Tool	Number of items	Reliability Method	r
1.	Background information of the postnatal mothers	09	-	-
2.	Structured questionnaire to assess the breastfeeding knowledge of the postnatal mothers	12	Test Retest method	0.74
3.	Structured questionnaire to assess the practices related to breastfeeding of the postnatal mothers	10	Test Retest method	0.82
4.	Structured questionnaire to assess the problems of the postnatal mothers related to breastfeeding	14	Test Retest method	0.78
5.	Breastfeeding Self-Efficacy Scale-Short Form (BSES-SF) to assess the breastfeeding self-efficacy of the primigravid mothers	14	Test Retest method	0.82

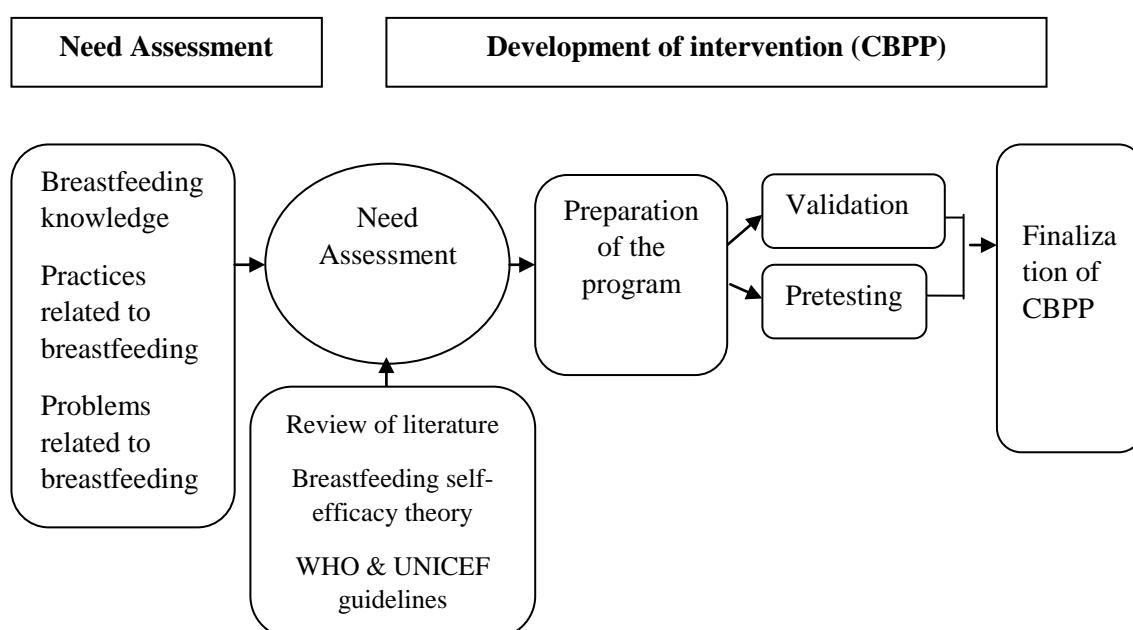
6.	Questionnaire to assess the breastfeeding practices of the primigravid mothers. Section A - Bristol Breastfeeding Assessment Scale to assess the observed breastfeeding practices of the primigravid mothers Section B – Structured questionnaire to assess the breastfeeding practices of the primigravid mothers.	04  13	Inter-rater method  Inter-rater method	0.79  0.77
7.	Structured questionnaire to assess the breastfeeding outcomes of the primigravid mothers	05	Test Retest Method	0.78
8.	Structured questionnaire to assess the breastfeeding experiences of the primigravid mothers	07	Test Retest Method	0.82

### **Development of the Intervention – Comprehensive Breastfeeding Promotion Program (CBPP)**

The intervention was developed based on the assessment of breastfeeding knowledge, practices and problems related to breastfeeding of the postnatal mothers carried out in Phase I of the study. It was found that mothers had average breastfeeding knowledge; their practices related to breastfeeding were also inadequate. The problems faced by the mothers related to breastfeeding were also significant. Extensive review of literature was carried out to develop the program effectively. The program also incorporated breastfeeding self-efficacy theory, WHO and UNICEF guidelines. Thus, the comprehensive breastfeeding promotion program was developed in a systematic manner. The program was validated by experts and pretesting was done among the mothers. The CBPP was a multi-component program designed by the researcher. The

main objective of the program was to improve the breastfeeding self-efficacy, practices and outcomes of the primigravid mothers. It was prepared keeping in mind about the study population. The content was translated into local language Hindi for better understanding of the mothers.

The development of the program has been described in the schematic representation below:



**Figure 2: Schematic representation of the comprehensive breastfeeding promotion program (CBPP)**

To assist mothers in initiating and maintaining breastfeeding practices, educational strategies emphasizing on breastfeeding self-efficacy have been formulated. It has been proved by several researches that maternal satisfaction can help the mother in maintaining breastfeeding exclusivity and continuity.

The breastfeeding self-efficacy theory signifies that self-efficacy is influenced by four variables—personal achievement, vicarious experiences, verbal persuasion, and

physiological and affective states. These four elements are utilized to formulate the breastfeeding promotion program which is discussed below.

1. Verbal persuasion – The mothers were educated on the breastfeeding benefits both to mother and infant, WHO and UNICEF recommendations on breastfeeding – strategies and trends, skin to skin contact benefits, difference between formula and breast milk, importance of colostrums and nutrition of mother while breastfeeding.

2. Vicarious experience – The investigator had used various videos, pictures and demonstrations/re-demonstrations with a baby dummy so as to provide vicarious learning experiences to the primigravid mothers. The program included assessment of breasts, correct breastfeeding techniques, indicators of effective latch, and signs of ineffective latch, strategies to wake up the infant for breastfeeding, early feeding cues, expression and storage of breast milk.

3. Physiological and emotional states – The mothers were discussed about the importance of attachment or bonding between mother and newborn, barriers for early breastfeeding initiation, promoting and protecting breastfeeding within one hour, problems of breastfeeding and some general queries of the mothers that may be frequently asked by them. The program was focused on promoting the mothers' breastfeeding self-efficacy which would in turn help to improve breastfeeding practices and outcomes.

The comprehensive breastfeeding promotion program was offered to all those primigravid mothers who were within the gestational period of 28 to 34 weeks. The entire program was covered in two sessions of 1-2 weeks apart followed by one follow-up session. Various audio-visual aids like power point presentation, charts, flip

charts and online videos and teaching-learning activities were carried out to help the mothers in gaining confidence in breastfeeding their infants.

### **Ethical Consideration**

1. The institutional ethics committee, Swami Rama Himalayan University, granted the ethical approval for conducting this research. (Registration No.ECR/483/Inst/UK/2013/RR-16,Dt.23.8.2017)
2. The written consent was obtained from every participant before the study was commenced.
3. The subjects were assured that each participant's anonymity would be preserved.
4. The data were kept confidential.
5. The participants were allowed to discontinue from the study whenever they wanted and assured of no harm.

### **Pilot Study**

40 postnatal mothers participated in the pilot trial for Phase I to assess the feasibility of the investigation using the convenience sampling technique. The postnatal mothers were assessed on the basis of their breastfeeding knowledge, practices and problems of the postnatal mothers related to breastfeeding using various structured tools.

For Phase II, the pilot study was conducted among 20 primigravid mothers. Mothers were divided into experimental (n = 10) and control (n = 10) groups at random. The samples in the experimental group received routine care and comprehensive breastfeeding promotion program whereas the control group was offered only routine care. Both the groups were followed postnatally and the three different variables i.e.,

breastfeeding self-efficacy; practices and outcomes were assessed on third day postpartum and at 6 weeks. The study was determined to be practical.

### **Procedure for Data Collection**

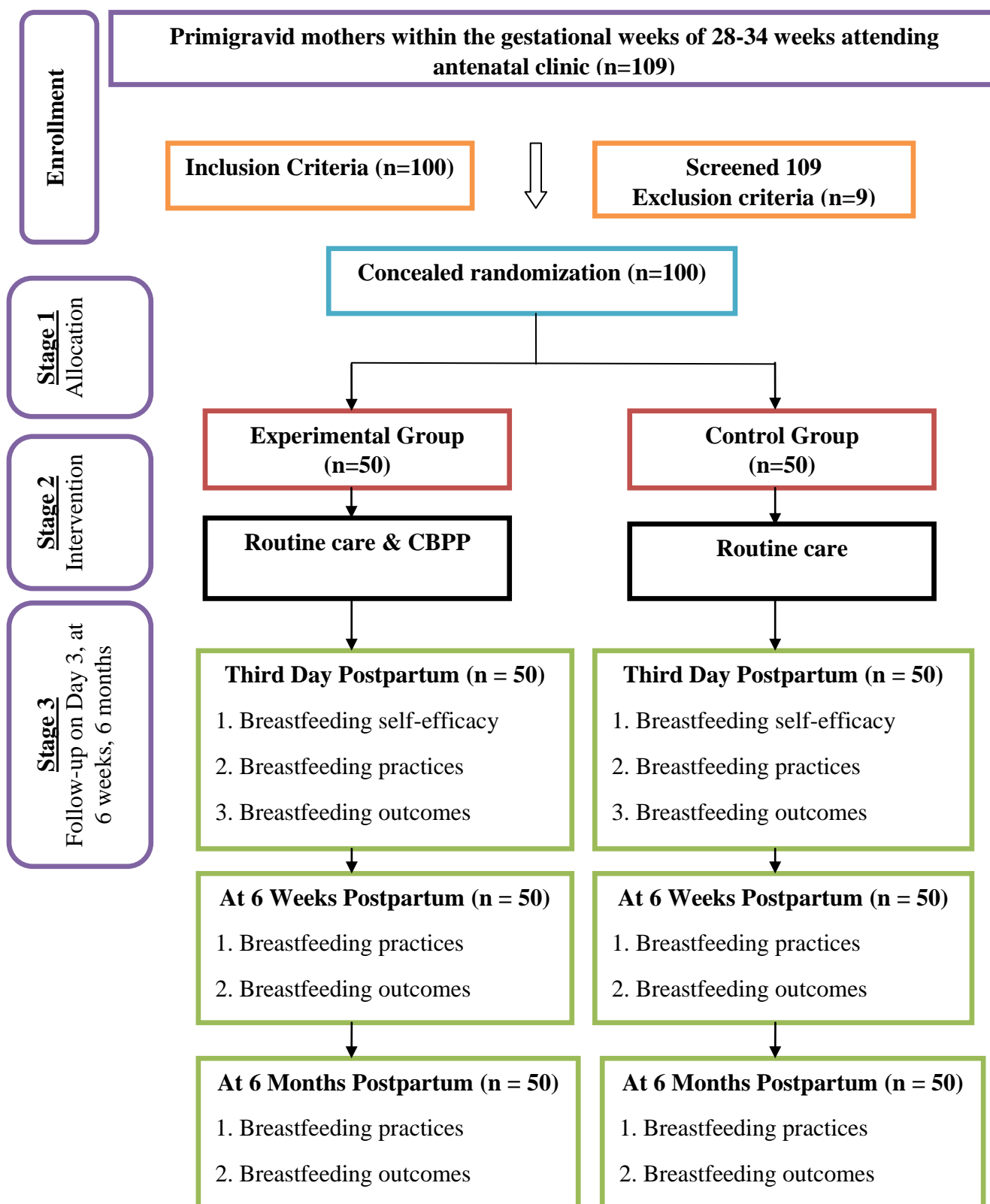
Two stages of the data collection process have been covered:

**Phase I** - A formal request for permission to carry out the research investigation was made from various Medical Directors of different maternity hospitals in Allahabad. The information was gathered in 2021 between July and September. The data was collected from the immunization clinics of four different hospitals – Allahabad Nursing Home, Dr Rekha Srivastava Maternity Hospital, Saket Maternity Hospital and Dr. Sharma Maternity Hospital. 100 postnatal mothers who meet the inclusion criteria were chosen from each facility. The mothers were told of the study's objectives, and their written informed consent was obtained. The breastfeeding knowledge, practices and problems of the postnatal mothers related to breastfeeding were assessed using various structured tools.

**Phase II** – After obtaining administrative permission, the data was collected from November 2021 to August 2022 from Saket Maternity Hospital, Allahabad. 100 primigravid mothers (50 mothers were in experimental group and 50 mothers were in control group) who were within the gestational period of 28 to 34 weeks were selected from the antenatal clinic following the concealed random assignment technique. Double blind method was used to recruit the samples. The samples in the experimental group received comprehensive breastfeeding promotion program in two different sessions along with routine care. The entire program was covered in two sessions of 1-2 weeks apart followed by one follow-up session. The control



group mothers received the routine care. Both the groups were followed postnatally and the breastfeeding self-efficacy, practices and outcomes were assessed on third day postpartum, at 6 weeks and at 6 months.



**Figure 3: Schematic Representation of the study based on CONSORT diagram**

## **Plan for Data Analysis**

Based on the goals of the study and the hypotheses to be tested, descriptive and inferential statistics were used to analyze the data.

### **Phase I**

**Section 1** – To collect the background information, the data were reported in percentage and frequency form.

**Section 2** – To assess the breastfeeding knowledge of the postnatal mothers, the data were represented as mean, standard deviation, range and mean percentage.

**Section 3** – To determine the practices of the postnatal mothers related to breastfeeding, the data were reported in the frequency and percentage form.

**Section 4** - To assess the problems of the postnatal mothers related to breastfeeding, data were reported in the frequency and percentage form.

### **Phase II**

**Section 5** – To compare the background information of both the groups, chi-square test was used to determine the association between the baseline data.

**Section 6** – To compare the breastfeeding self-efficacy of the two groups, Mann Whitney U test was used to determine the significant difference between the groups.

**Section 7** – To compare the breastfeeding practices at different intervals of time, Mann Whitney U test, chi-square test and Fisher's exact test were used to determine the significant difference between the groups.

**Section 8** - To compare the breastfeeding outcomes at different intervals of time, data were reported in the frequency and percentage form to determine the significant difference between the groups.

**Section 9** - To compare the breastfeeding experiences, data were reported in the frequency and percentage form to determine the significant difference between the groups.

### **Summary**

There were two phases to the study's execution. In phase I, a cross-sectional survey was done to evaluate postpartum mothers' breastfeeding knowledge, practices, and problems. The intervention comprehensive breastfeeding promotion program was developed on the basis of this need assessment survey. In phase II, an experimental approach was adopted to see the influence of comprehensive breastfeeding promotion program (CBPP) on breastfeeding self-efficacy, practices and outcomes among the primigravid mothers.