CHAPTER 3

MATERIALS AND METHODS

The present research study is conducted in two phases. In Phase I, an exploratory survey was done to explore childbirth preparedness and childbirth experiences. In Phase II, a randomized control trial with multiple observations was conducted to estimate the efficacy of comprehensive childbirth preparation package (CCBPP) and maternal-neonatal outcomes.

Methodology Phase I

Research approach and design

Qualitative approach and exploratory phenomenological design were used in Phase I of the study to explore childbirth preparedness and childbirth experiences.

Research setting

Study was conducted in Dadri Community Health Center, Noida, Gautam Buddha Nagar, Uttar Pradesh. According to Niti Aayog Health Index (2019), Uttar Pradesh is the worst performing state in terms of health care.[119] Registrar General of India (2017–2019) released bulletin stated that maternal mortality ratio of Uttar Pradesh was 167 per 100,000 live births.[120] Dadri Community Health Center covers 135 villages in 559.96 sq km with a population of 3,50,000. Present study setting was selected based on the need of the population and convenience of the investigator. The community health center is equipped to provide 24 hours and 7 days delivery services,emergency obstetric care including caesarean section and newborn care. The total number of

normal deliveries in average approximately is 600 per month and total number of antenatal OPD is 1,800 per month.

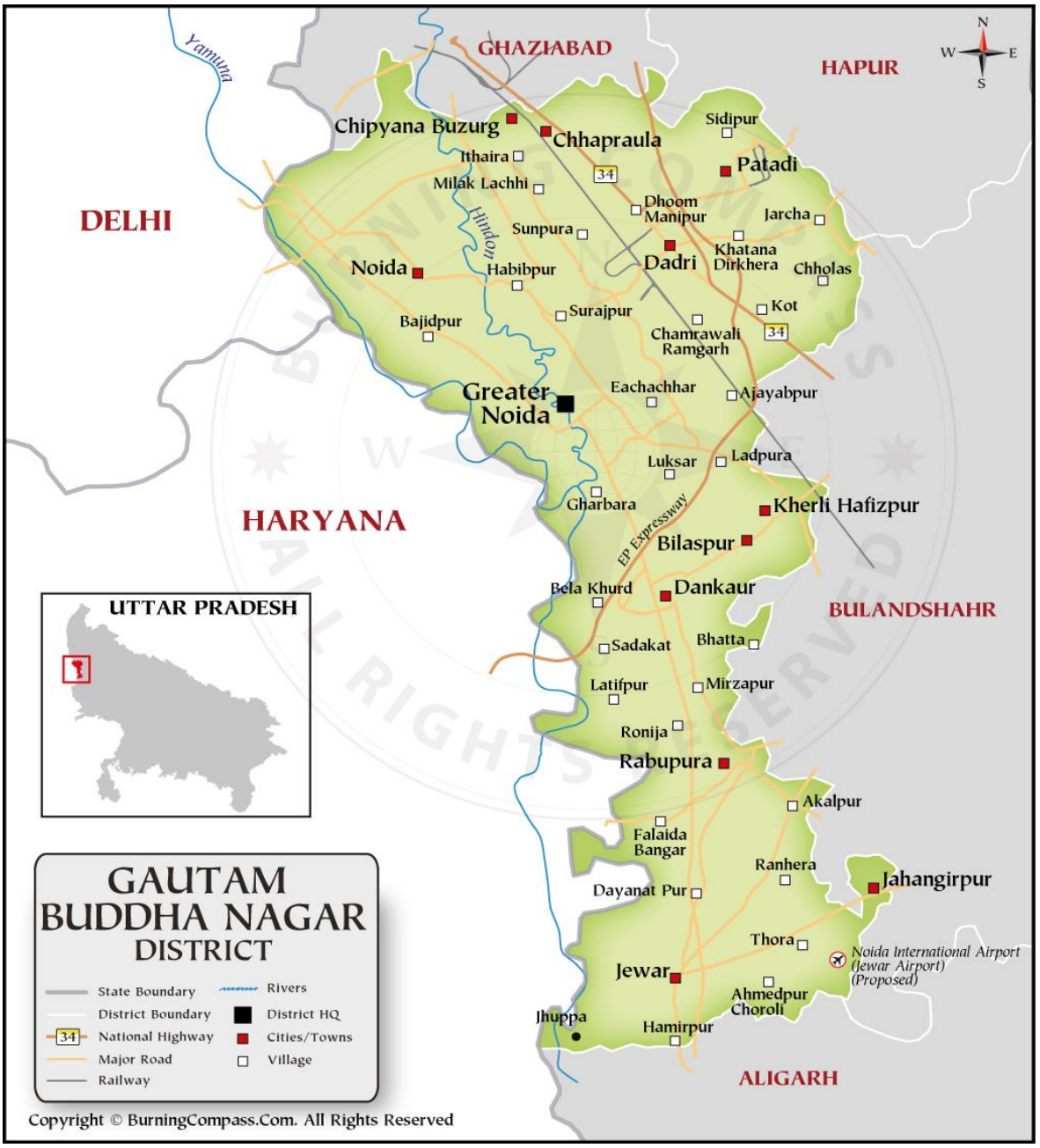


Figure 2. Map of Noida, Gautam Buddha Nagar District, Uttar Pradesh

Population and sample

In order to explore the childbirth preparedness, 15 primigravidae between 24–34 weeks of gestation willing to participate were chosen by purposive sampling technique. Primigravidae who were more than 35 years of age, mentally challenged or suffering from any mental illness, having history of abortion, having complications like mal-presentations, eclampsia, or gestational diabetes, were excluded.

For exploring the childbirth experiences 10 primiparous women in 3rd day of delivery were selected by purposive sampling technique. Those who were suffering from delayed stress disorder, postpartum psychosis, and depression or any complication during childbirth like caesarean section, or instrumental delivery, were excluded.

Data collection method

In-depth interview was used to collect information on childbirth preparedness and childbirth experiences were collected from primigravidae. Participants were asked open ended questions to explore their childbirth preparedness, expectation, and experiences. Basedon responses leading questions were asked. In case a gap was identified in the information, further data collection was done till data saturation was attained.

Data analysis method

Content analysis was done with the gathered information. Overall reading of the transcript, followed by line-line initial coding was done. After code generation themes and sub-themes were developed.

Methodology Phase II

Research approach

In the Phase II, to find the effectiveness of comprehensive childbirth preparation program, quantitative experimental approach.

Research design

Randomized control trial was done for phase II of the study. The layout used for research design was pre-test post-test control group design for childbirth experiences variable and for post-natal outcome of mother and baby, post-test only control group design was used. The schematic representation of the study design is presented below:

Groups	**Variable**	**Design Layout**	**28-34 wks.**	**Intervention**	**15th day**	**3rd day**	**7th day**	**6th wk.**
R_E	Childbirth experiences	Pre-test Post-test design	O1	X	O2	O3		
	Maternal-neonatal outcome	Post-test only			---------	---------	O1	O2
R_C	Childbirth experiences	Pre-test Post-test design	O1	X	O2	O3		
	Maternal-neonatal outcome	Post-test only			---------	---------	O1	O2

*Childbirth experiences: Childbirth preparedness, Childbirth expectation, Childbirth fear, Labor and birth experiences

*Maternal-Neonatal Outcomes: Labor outcome, Postnatal outcome of mother and baby.

Research setting

Phase II of the study was conducted in Dadri Community Health Center, Noida.

Population of the study

Target population comprised of the primigravidae who were in 28–34 weeks of gestation. Accessible population were primigravidae attending the Dadri Community Health Centers.

Sample

Sample size of the study was 100 primigravidae in 28–34 weeks of gestation. It was estimated from a similar study[7] to achieve power 80% (β) at 5% level of significance (α) sample size calculated was 88, with 44 in each group. Sample size estimation was also done through pilot study findings, effect size was calculated to be 0.60, and minimum total sample size required was 90. Assuming 10% of dropouts, investigator selected total 100 sample of primigravidae, with 50 in each group.

Sampling technique

Primigravidae attending antenatal OPD were screened for eligibility criteria. All the primigravidae who met inclusion criteria and were willing to participate were included in the study. Random allocation software was used to prepare sequentially numbered concealed envelopes with the help of a statistician. The primigravidae were allocated to intervention and control groups by concealed randomization. Participants picked the sealed envelope and were accordingly assigned to the respective groups.

Selection criteria of the participants:

Inclusion criteria: **Primigravidae who are:**

1. In 28–34 weeks of pregnancy.
2. Having antenatal registration with selected health center.
3. Willing for delivery and postpartum care in selected health center.
4. Having a smart phone and using WhatsApp.

Exclusion criteria: **Primigravidae who are:**

1. Above 35 years of age
2. Having history of habitual abortion
3. Having complications like mal-presentations, eclampsia, and gestational diabetes mellitus
4. Suffering from delayed stress disorder, postpartum psychosis, and depression
5. Mentally challenged and suffering from psychiatric illness

Variables of the study

1. **Independent variable:** Comprehensive childbirth preparation package.
2. **Dependent variables:**
    a. Childbirth experiences
    b. Maternal-neonatal outcomes.

3. **Extraneous variables:** It includes age, education of women, education of husband, husband's occupation, occupation of women, annual income of family, marital status, type of family, travel time to health facility, mode of transport to commute to the health facility, planned/unplanned pregnancy, number of antenatal visits, and period of gestation.

Tools for data collection

The research tools used for measuring variables are presented in Table 2.

Table 2: List of tools and measured variables

Sl. No.	Variables	Tools
1	Socio-demographic data	Structured background characteristic questionnaire
2	Childbirth planning and knowledge	Structured childbirth preparedness questionnaire
3	Childbirth expectation	Childbirth expectation questionnaire
4	Childbirth Fear	Wijma delivery expectance/experiencequestionnaire (W-DEQ)
5	Labor and birth experience	Childbirth experience questionnaire
6	Labor outcome and postnatal outcome of mother and baby	Maternal-neonatal outcome proforma
7	Breastfeeding self-efficacy	Breastfeeding self-efficacy scale

Tool 1: Background characteristics questionnaire

The present tool was developed by the researcher to collect baseline information which included: age, education of the women, education of husband, husband's occupation, occupation of the women, annual income of family, marital status, type of family, travel time to health facility, mode of transport to commute to the health facility, planned/unplanned pregnancy, number of antenatal visits, date of last menstrual period, expected date of delivery, and period of gestation. A total of 17 items were there in the tool. The items did not have any scoring. *(Appendix I)*

Tool 2: Structured childbirth preparedness questionnaire

Childbirth preparedness questionnaire was developed by investigator to measure the level of childbirth preparation among participants. On the basis of extensive review literature, concept analysis and on suggestions of experts the tool was designed *(Appendix II).* The tool comprises of two sections. Section A includes items related to childbirth planning and Section B includes items related to knowledge regarding childbirth process including danger signs and medical interventions (Table 3). The tool was dichotomous with yes and no response. Participants were asked to respond by ticking Yes/No to each statement. Response to items were scored as yes (1 score) and no (0 score). The total items in the tool were 40. Section A of the tool has 14 items and these were further categorized into adequate (8-14) and inadequate (0-7). Section B of the tool comprises of 26 items. It was further categorized into Good (14-28) and Poor (0-13) based on responses given.

Table 3: Blueprint of childbirth preparedness questionnaire

Sl. No.	Domains	No. of items	No. of items	Percentage
1	Section A: Childbirth planning	14	1–14	35%
2	Section B: Knowledge on childbirth process, danger signs and medical interventions	26	15–40	65%
	Total	**40**	**----**	**100%**

Tool 3: Childbirth expectation questionnaire

The questionnaire was constructed by Beaton and Gupton[121] in 1990. The tool composed of total 35 items. It comprises of four sub-scales under dimension of pain and coping, significant others, nursing support, and interventions. The response of items ranges from 1 = "strongly disagree" to 5 = "strongly agree (Table 4). Higher scores indicate positive childbirth expectations. For item numbers 3,4,7,8,9,10,12,14,15,18,20,21,24,25,29,32,33,34, and 35, a reversed scoring was done. The tool, permission, and scoring are attached. *(Appendix III).*

Table 4: Blueprint of the childbirth expectations questionnaire

Sl. No.	Domains	No. of items	Item number	Scores		Percentage
				Max.	Min.	
1	Pain & coping	11	4,5,12,15,16,18, 2,25,29,35	55	11	31.4%
2	Significant others	7	1,9,11,17,27,31, 34.	35	7	20%

3	Nursing support	8	2,3,6,7,8,23,26, 28	40	8	22.8%
4	Interventions	9	10,13,14,19,20, 24,30,32,33	45	9	25.7%
	Total	**35**		**175**	**35**	**100%**

Tool 4: Wijma delivery expectancy/experience questionnaire (W-DEQ) versions A & B

The tool was developed by Klaas and Wijma in 1998 to measure fear of childbirth.[122] Wijma defines childbirth fear as anything that cause fear about labor process, lack of confidence and negative appraisal. The tool has two versions A & B. Version A measures fear during antenatal phase by enquiring women regarding their childbirth expectations and the Version B measures childbirth fear related to postpartum feelings of parous women (*Appendix IV*). It is a self-reported scale of 33 items which is scored on a six-point Likert scale. The score 0 indicates "extremely" and 5 indicates "not at all." The item numbers 2,33,6,7,8,11,12,15,19,20,24,25,27, and 31 was reversely scored. The total score ranges from 0–165. A score lower than 37 indicates mild fear, 38-65 moderate fear, and score of 85 and higher indicates clinical fear. The tool version A & B, permission obtained, and scoring is attached. (*Appendix IV*)

Tool 5: Childbirth experience questionnaire (CEQ)

The tool was developed by Dencker and colleagues in 2010 to measure childbirth experience.[123] It has four dimensions: own capacity, professional support, perceived safety, and participation. Scoring of 19 items was done using a four-point Likert scale, ranging from 1 "totally agree," to 4 "totally disagree." Negative item statements8,9,5, and 3, were reversely scored (Table 5). A visual analog scale was used to assess pain, control, and safety. 0 is no pain and 100 is severe pain. VAS scores have been converted to categorical values. The tool is available for free to use. *(Annexure V)*

Table 5: Blueprint of childbirth experience questionnaire

Sl. No.	Domains	No. of items	Item number	Scores	
				Max.	Min.
1	Own capacity	8	1,2,4,5,6,19,20, 21	32	8
2	Professional support	6	13,14,15,1617	30	5
3	Perceived safety	5	3,7,8,18,22	30	6
4	Participation	3	10,11,12	15	3
	Total			107	22

Tool 6: Maternal-neonatal outcome proforma

The tool was developed by the investigator to assess labor and postnatal outcome of mother and baby on 3rd day, 7th day, and 6th week of delivery *(Appendix VI)*. The proforma was divided into two sections. Section A, labor outcome, was used for data collection on 3rd day of delivery from primigravidae clinical record analysis. Section B, postnatal outcome of mother and baby, was used for collection of data on 7th day and 6th week. Section A includes 8 items and Section B comprises of 4 items.

Tool 7: Breast feeding self-efficacy scale

Dennis & Faux developed this tool to assess breastfeeding self-confidence among parous women.[124] It is a self-administered instrument consisting of 33 items that are scored on five-point Likert scale *(Appendix VII)*. The statement in the scale ranges between 5 (always confident) and 1 (not at all confident). Total scores range from 33 to 165, higher scores reflect greater levels of breastfeeding self-efficacy.

Validity of the tools

Content validity was entrenched with the help of experts in the discipline. The experts were requested to validate the items of the tools for clarity, appropriateness, and relevance of the content. The validators included six nursing experts and one obstetrician. Based on the suggestions of the experts, the tools were finalized.

(Appendix VIII).

Pre-testing of the tools

The pre-testing of the tools was done to determine the clarity of the items, identify the difficulty in understanding the terms and the time required to complete the tools. The tool was administered to five primigravidae. To complete the entire tool the average time taken was thirty minutes. Primigravidae did not face any difficulty in answering and understanding the questions in the tools.

Reliability

Reliability of the tools was established by administering it to 30 primigravidae. The reliability for internal consistency was calculated by Cronbach's alpha and Split half, and for stability the Spearman–Brown rank coefficient was used for childbirth preparedness questionnaire, childbirth expectation questionnaire, Wijma delivery expectancy/experience questionnaire, childbirth experience questionnaire and breast-feeding self-efficacy scale (Table 6). Test-retest was done for maternal-neonatal outcome proforma and it was found to be 1.

Table 6: Reliability of tools

Sl. No.	Tools	Reliability coefficient		
		Split Half	**Spearman–Brown rank**	**Cronbach Alpha**
1.	Structured childbirth preparedness questionnaire	.70	.75	.75
2.	Childbirth expectation questionnaire	.84	.82	.86
3	Wijma delivery expectancy/experience questionnaire (W-DEQ)	.96	.96	.84
4	Childbirth experience questionnaire	.96	.96	.86
5.	Breastfeeding self-efficacy scale	.94	.95	.97

Description of intervention

Comprehensive childbirth preparation refers to a need-based multicomponent education program developed by the investigator for primigravidae to improve their knowledge and confidence about birth process and to reduce childbirth fear and to promote positive childbirth experiences and better maternal-neonatal outcomes.

The objectives of the CCBPP for primigravidae were to:

1. Improve knowledge on childbirth process
2. Enhance self-confidence about childbirth

3. Create realistic childbirth expectation
4. Reduce childbirth fear
5. Promote positive childbirth experiences
6. Improve maternal-neonatal outcomes

Development of the intervention

In order to develop the intervention, a need-based study was conducted to explore childbirth preparedness and childbirth experiences need among primigravidae and primiparous mothers. Based on the findings of the study, intensive review of literature, personal experiences, and discussion with research guides, content was incorporated in the intervention. As the intervention focusses on improvement of self-efficacy to organize the content of intervention, sources of self-efficacy from Bandura's theory were included. (Figure. 3)

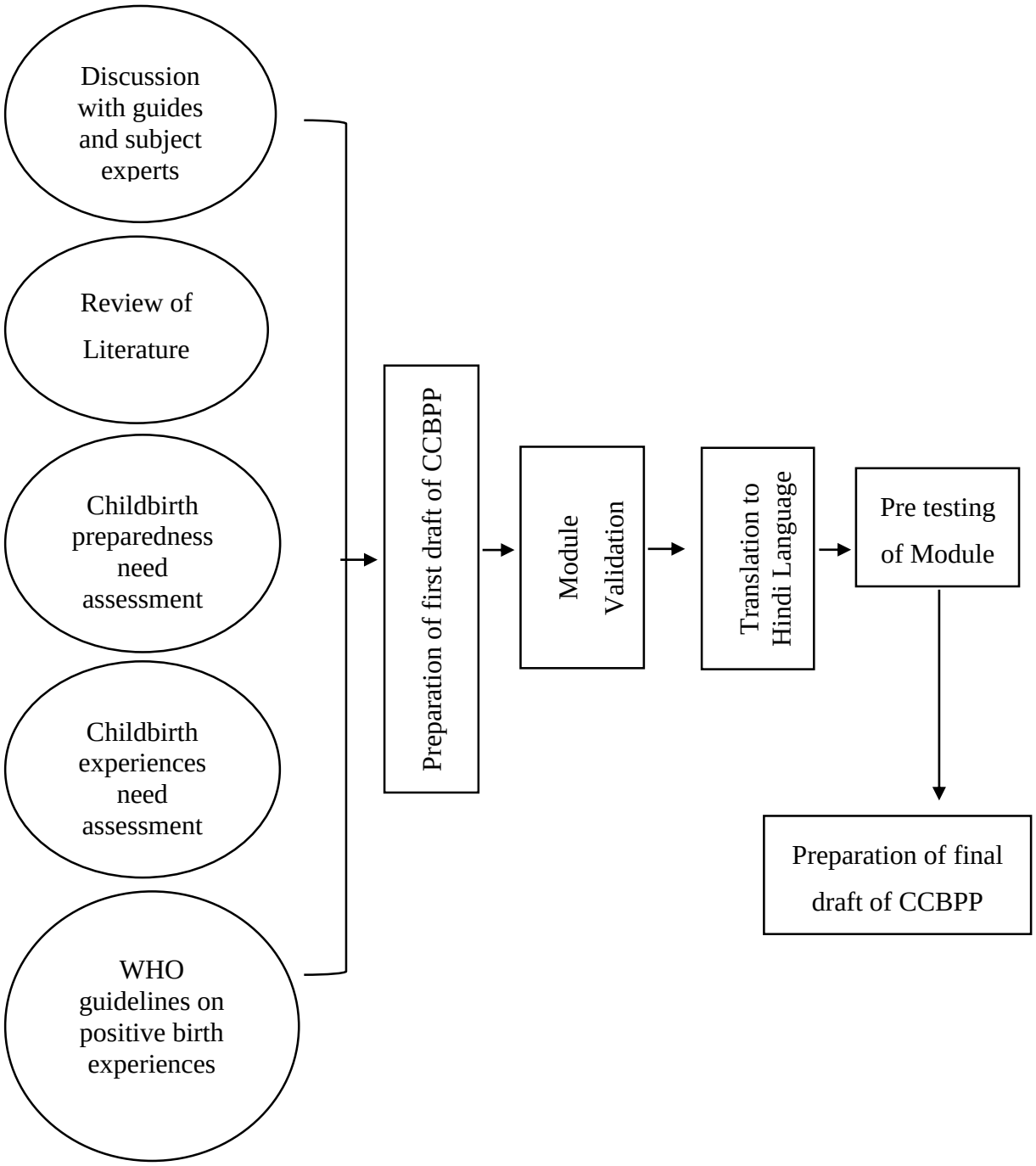


Figure 3. Development of comprehensive childbirth preparation program

The developed intervention was validated by the experts on the content of understandability and adequacy.

Components of CCBPP

The major objective of the intervention is to enhance childbirth self-efficacy. The major sources of self-efficacy proposed by Albert Bandura are modified to develop components of the intervention (Figure 4). Along with the sources of self-efficacy, the component of comprehensive childbirth preparation program is as follows:

1. **Verbal persuasion**

   The component of verbal persuasion explains how our words might increase someone's sense of self-efficacy. Positive childbirth affirmation and counselling were provided to primigravidae to enhance their childbirth self-efficacy.

2. **Education**

   Teaching sessions were provided to primigravidae on nutritional requirements in late trimester, common discomfort and danger signs of the third trimester, daily fetal monitoring, signs and symptoms of labor, common medical interventions performed during labor, care of newborn, and benefits and position of breast feeding.

3. **Realistic expectation**

   Strange and unfamiliar environment increases anxiety and fear. Picturing self in the situation beforehand increases the confidence to face the challenge successfully. Virtual trip to a labor room was provided to primigravidae to make them familiar with labor room procedures, areas, equipment's, and birth positions.

4. Body-mind connect

Guided imagery entails evoking a mental picture that lets us recreate memories. It helps to speculate future experiences. Guided imagery audio clips were provided to primigravidae that entails positive journey of pregnancy, and feeling of a new life in the womb. Demonstration of relaxation and breathing exercises was done and re-demonstration was taken during follow-up session.

5. Symbolic modeling

Successful vaginal delivery videos and sharing of experiences were done to enhance childbirth self-efficacy under the source of symbolic modeling.

The blue print of comprehensive childbirth preparation package is detailed in (Appendix IX). The intervention was carried out in a classroom with a 20-seat capacity. The teaching was delivered as per the teaching plan (Appendix IX). The teaching was participatory and the investigator used teaching methods like lecture, discussion, demonstration, and brain storming. The audio-visual aids used were charts, posters, blackboard, audio-video player, and laptop. Sessions were evaluated by evaluation questions. Question and answers session were kept at the end of sessions to evaluate the immediate knowledge acquired followed by re-demonstration of exercises.

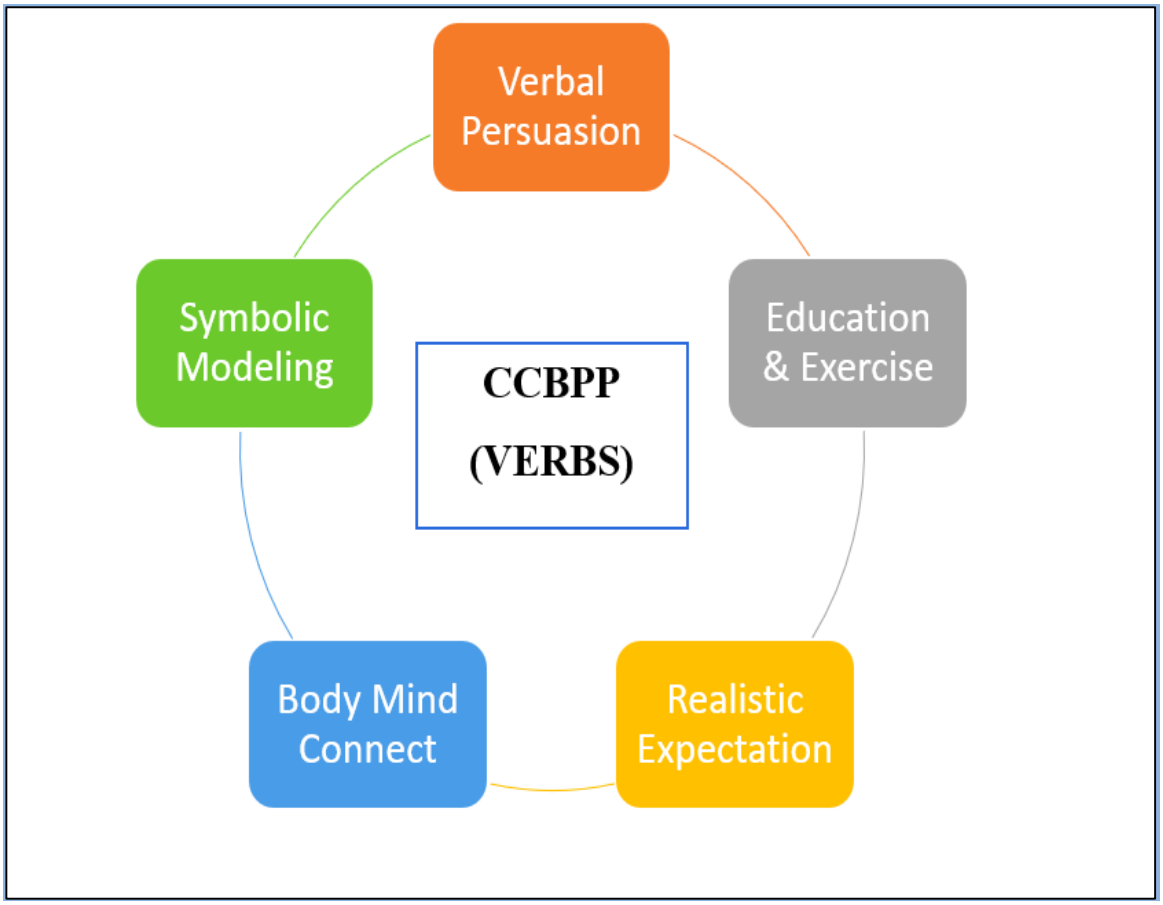


Figure 4. Components of comprehensive of comprehensive childbirth preparation package.

Ethical considerations

1. This research protocol was prepared considering the ethical principles and ICMR guidelines.[125] Ethics committee clearance was obtained from University Ethics Committee with following registration number: SRHU(SRHU/HIMS/E-1/2019/122), *(Appendix X)*
2. Permission was also obtained from Chief Medical Officer, Gautam Buddha Nagar. *(Appendix XI)*
3. Detailed explanation about the study was given to primigravidae by the researcher. Participant information sheet was also given to the primigravidae. *(Appendix XII)*

4. Participation was based on willingness. Participants were allowed to withdraw from the study at any point of time. Confidentiality and anonymity of the information provided by the subjects was assured.

Trial registration

The phase II of the present study was registered in Clinical Trial Registry of India (CTRI) and the trial registration number is: CTRI/2021/01/0308205. *(Appendix XIII)*

Pilot study

In the month of September 2020 to December 2020, pilot rehearsal of the study was done. Thirty primigravidae were included in the study. The study was found to be feasible.

Data collection procedure

After obtaining the ethical and administrative permission data collection was started. The period of data collection was from March 2021 to August 2021. Primigravidae visiting Dadri, community health center was enrolled for study through antenatal register. With the help of the medical officer, the participants were assessed for eligibility. After screening, the nature and duration of intervention was explained to participants and baseline information was collected. Participants were then allocated to experimental and control groups through sequentially numbered concealed random allocation technique. Random allocation software was used for generating sequential numbers and with the help of a colleague opaque concealed envelopes were prepared and participants were asked to pick the envelope and were allocated to different groups. After conducting the pre-test in both the groups, experimental group received comprehensive childbirth preparation package and control group received routine

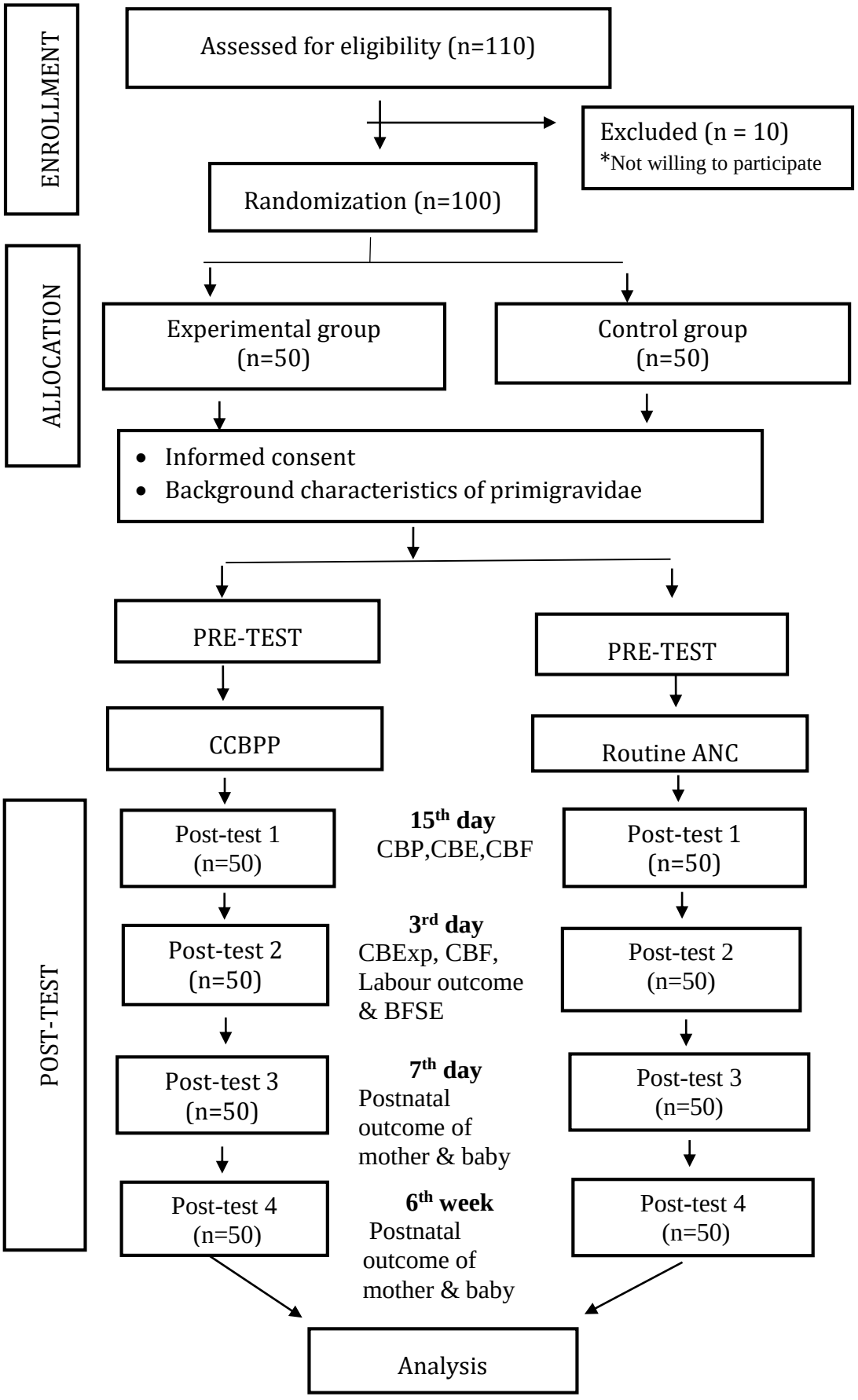
antenatal care. Pre-test was conducted to assess childbirth preparedness, childbirth expectation and childbirth fear. CCBPP was delivered to experimental group once a week for three weeks and control group received routine antenatal care. Post-test was conducted for primigravidae in both group at 15th day of intervention to assess childbirth preparedness, childbirth expectation and childbirth fear, 3rd day to assess childbirth experiences, childbirth fear, labour outcome and breast-feeding self-efficacy, 7th day and 6th week of delivery postnatal outcome of mother and baby was assessed between groups.

Plan for data analysis

The analysis for the data was done as per objectives of the study. Descriptive statistics i.e., frequency and percentage were used to describe childbirth planning and knowledge (childbirth preparedness). Inferential statistics was used to identify the efficacy of intervention i.e., independent 't' test, and Chi square was used to meet the objectives.

Chapter summary

Methodologically the entire study was divided into two phases. The design for the first phase was exploratory phenomenological design and for the second phase was randomized controlled trial design. Further this chapter discussed setting, population, sample and sampling technique, description of tools, their validity and reliability. It also discussed about the development of intervention, pilot study, procedure of data collection and plan of data analysis.



Schematic representation of Data Collection Procedure