## CHAPTER III

RESEARCH METHODOLOGY

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CHAPTER III

RESEARCH METHODOLOGY

3.1 Introduction

In this chapter the methodology for the study is presented. The methodology for the research includes the methods of research adopted, the description of setting, population, sample, sampling technique, data collection techniques, development of the tool and standardization of tool, validity and reliability of the tool, pilot study, procedure for data collection, scoring and processing of data, and plan for data analysis. The present study is intended to find out the prevalence of anxiety and depression among pregnant women during pregnancy and postnatal period. The study also explored the effectiveness of childbirth education programme in reducing pregnancy-specific anxiety.

3.2 Methods Adopted

3.2.1 Research Approach

To accomplish the objectives of the study, the investigator selected a combination of descriptive and experimental research. The present study was done in two phases. Descriptive research involves collecting data in order to test the hypotheses or to answer questions concerning the current status of the subject of the study (Gay, 1990). Among the different descriptive approaches that are used in research, prospective cohort approach of explorative survey was selected for the first phase of the study.

A quasi-experimental two-group pretest - posttest design was used in the second phase of the study to test the effectiveness of the planned childbirth education programme on pregnancy-specific anxiety and labour outcomes.
3.2.2 Research Design

The term research design refers to the structural framework of the study. It serves as a blueprint for the conduct of the study by maximizing control over factors that could interfere with the desired outcome of the study.

**Phase I** : The research design adopted for Phase I of the study was prospective cohort approach of explorative survey. Five hundred pregnant women were surveyed in prospective cohort study to find out the prevalence of anxiety and depression using standardized structured tools such as STAI, BDI. Pregnancy-specific anxiety was measures using PSAI. The knowledge of five aspects of antenatal care was assessed by structured interview schedule using Knowledge Questionnaires. Labour Outcome Checklist was used to find out labour outcomes by record analysis. The same mothers were followed and reassessed for anxiety and depression with same tool during postnatal period too.

**Phase II (a)** : Development of Planned Childbirth Education Program.

**Phase II (b)** : Testing the effectiveness of childbirth education programme.

The research design adopted for Phase II of the study was Quassi-experimental two group pretest-posttest design.

According to Campbell and Stanley (1972), this is one of the most widely used experimental designs in educational research.
In the second phase of the study hundred nulliparous pregnant women in their third trimester of pregnancy were selected and they were randomly allocated to control and experimental groups with 50 members in each group.

Pretest was conducted among these 100 pregnant women to assess general anxiety, depression and pregnancy-specific anxiety using STAI, BDI and PSAI. Their knowledge related to five aspects of antenatal care was measured by structured interview schedule using Knowledge Questionnaires.

Planned Childbirth Education Program was administered to selected 50 nulliparous pregnant women who were in the experimental group. The control group of 50 nulliparous pregnant women was not exposed to intervention except the routine care. Post test was done for all 100 samples before delivery. The effectiveness of the program was judged by the difference between pretest and posttest scores of experimental and control groups. Labour outcomes of 100 subjects were also noted with the Checklist. The same mothers were followed and their postnatal anxiety and depression levels were also measured using the same tools. The whole research design is given as schematic representation in figure 3.1 and 3.2.
Figure 3.1 Schematic Representation of Research Design Phase I
Figure 3.2 Schematic Representation of Research Design Phase II
3.3 Population

Regardless of technique to be used in selecting a sample, the first step is defining the population, which is the group in which the Investigator would like to generalize the result. The population denotes the entire groups of subjects under the study. A majority of pregnant women except the elite group have their antenatal check-up and deliveries conducted in the government hospitals of Kerala. In the present study, the population refers to all pregnant women attending the government hospitals in Kerala.

3.4 Research Setting

In consultation with the Research Guide the Investigator selected the government Victoria Hospital, Kollam, which is one of the largest government maternity hospitals in Kerala State as the setting of the study. The study was conducted among pregnant women attending this hospital in Kollam during the data collection period. Annual delivery statistics revealed 2400 -3000 deliveries per year with average monthly deliveries of 200 to 250. Detailed statistical data showed that 70 to 75% deliveries were normal deliveries. The average outpatient attendance at the antenatal clinic was 60-75 pregnant women per day. So feasibility of the sample was assured.

3.5 Sample and Sampling Technique

Selection of the sample is a very important step in conducting any research study. A representative sample based on the inclusion and exclusion criteria mentioned below is used for the study selected by the Investigator.

The following inclusion and exclusion criteria were used for the study.
Inclusion Criteria:

1. Pregnant women attending the antenatal clinic and who are available during the data collection period
2. Those who are willing to participate in the study
3. Pregnant women with singleton normal pregnancy
4. Pregnant women who could speak and read Malayalam
5. Pregnant women at the age of 18 to 35 years
6. Pregnancy achieved without the aid of medical intervention
7. Pregnant women who are mentally and physically stable prior to pregnancy
8. For Phase 1 of the study pregnant women at their 8 to 16 weeks of gestation attending the outpatient department of Victoria Hospital of Kollam District
9. For the second Phase of the study, nulliparous pregnant women who are at their
   a. third trimester (30 – 38 weeks) attending the antenatal clinic of Victoria Hospital of Kollam District
   b. Hospital of Kollam District
10. Pregnant women who expected to deliver after 37 -41 weeks of gestation
11. Pregnant women who were expecting normal delivery

Exclusion Criteria:

1. Pregnant women who are above 35 years and below 18 years
2. Pregnant women with pregnancy complication
3. Pregnant women with a history of mental illness
4. Pregnant woman who develop any complication during the period of study will be excluded
In the first phase of the study, the data collection was done until the completion of the required 500 sample size though started with 700 initial samples. The responses of the remaining pregnant women had to be deleted mainly due to non-completion of the questionnaire in concurrent readings, which in turn, was due to change of consultation, planned operative deliveries for obstetric reasons, and ending of pregnancy within 37 weeks. The data collection was stopped at reaching 500 samples, completing postnatal period data.

The data analysis results of Phase -I revealed prevalence rate of 22% severe pregnancy-specific anxiety during the third trimester, especially that of childbirth anxiety. A 99% prevalence of moderate to severe degree of pregnancy-specific anxiety was noted. A detailed analysis showed that nulliparous pregnant women were more anxious than parous gravid women. So, for the second phase of the study nulliparous pregnant women who were in their third trimester (30–38 weeks) were selected.

The data collection was done until the completion of a sample size of 100 from 120 initial samples. They were selected and assigned to experimental and control groups until completion of 50 samples in each group. For phase II purposive sampling technique was used. The random allocation of the experimental samples was chosen from mothers attending the outpatient department on Monday, Tuesday and Wednesday whereas control group sample was selected on Thursday, Friday and Saturday.

**Ethical Consideration**

The ethical implication of the research that could adversely affect participants and the Organisation, were carefully considered. The appropriate action was taken concerning informed consent, the right to withdraw, the protection of anonymity, potential distress of the patient.
The pilot study and main study were conducted after the approval by Ph.D advisory committee. Data collection permission was obtained from District medical officer of Kollam to collect data from Victoria hospital Kollam. Appendix –A Informed verbal consent was obtained from participants after individual explanation regarding purpose of the study prior to their participation in the research. In addition the participants were asked to sign the consent form Appendix-B which emphasized the voluntary nature of the research and the right to withdraw at any point. Participants were also made aware that they had the opportunity to ask questions at anytime, throughout the study period. When recruited the participants were informed that their responses would be treated with confidentiality. After completion of research tools the researcher ensured that it is securely stored. The overall risk to the participants’ safety was deemed extremely low.

### 3.6 Development of Tools

For collecting the data required for the study of any problem, one may use various devices. The following tools and techniques were used for collecting the data of the present study.

**Data Collection Tools**

**Tool 1** Socio-Personal Proforma Sheet

**Tool 2** Pregnancy-Specific Anxiety Inventory (PSAI) - prepared by the Investigator

**Tool 3** Knowledge Questionnaires - prepared by the Investigator

**Tool 4** Beck Depression Inventory II (BDI-II)

**Tool 5** State Trait Anxiety Inventory (STAI)

**Tool 6** Checklists for Outcome of Labour - Prepared by the Investigator
Intervention Program:

a) Planned Childbirth Education Program - Prepared by the Investigator

b) Video on Childbirth Education - Prepared by the Investigator

3.6.1 Description of the Tools

Tool - 1. Socio-Personal Data Sheet

A General Data Sheet covers the information on background data. The items included were pregnant women’s age, obstetric score such as gravidity, the number of times given birth to live babies, any history of abortion, stillbirth, the period of gestation and trimester, the education and occupation of both the pregnant woman and her husband, birth order, the number of family members, the type of family and any family history of mental illness and sources of information for pregnant women. Husband’s habit of smoking, drinking, and alcoholism also were included.

In addition the satisfaction of the quality of their marital life and their relationship with in-laws were also explored on a five-point rating scale. English and Malayalam version of data sheet are given as Appendix-D and Appendix-O respectively.

Tool - 2. Pregnancy-Specific Anxiety Inventory (PSAI)

A Pregnancy-Specific Anxiety Inventory was prepared after an exhaustive review of literature on related topics. Contact with the pregnant women and the experience with them during intranatal and postnatal periods helped the Investigator in the process of preparation of Pregnancy-Specific Anxiety Inventory. The Investigator acquired firsthand information about anxiety of pregnant women not only from pregnant women who were attending antenatal clinic, admitted to the labor room and underwent laboring process but also from pregnant women who had just delivered and were admitted in postnatal wards.
Informal interviews with pregnant women in all trimesters and postnatal period and with experts in the field of Obstetrics and Maternity Nursing were helpful in the development of the tool. In addition to this, Investigator visited reputable research centers and discussed the content area with many researchers.

Previous Pregnancy-Anxiety Scale and Delivery-Expectancy Inventory used in western countries to assess pregnancy-related anxiety among pregnant women were also reviewed. The Pregnancy-Specific Anxiety Inventory consists of 40 items with a maximum score of 200. After the tools had prepared it was submitted to 10 experts in the field of Obstetrics and Gynecology, Psychiatry, Psychology, Nursing. Modifications were made in the structure and content according to the experts’ suggestions. Thus the face and content validity of the tools was ensured.

A pilot study was done among 100 pregnant women so the feasibility of the study was assured except the intrapartum period assessment of anxiety and depression.

**Description of Pregnancy-Specific Anxiety**

Pregnancy-Specific Anxiety Inventory (PSAI) consists of 40 items distributed under four headings. PSAI elicits the intensity of woman’s anxiety of related to pregnancy and childbirth. The same tool was used to measure pregnancy-specific anxiety among nulliparous pregnant women during third trimester before and after the childbirth education program.

The Pregnancy-Specific Anxiety Inventory is on a five-point scale and it measures four main areas of pregnancy and childbirth anxiety. The first part deals with Anxiety about Being Pregnant (ABP). The second part is related to Anxiety of Childbirth (ACB). The third part deals with Anxiety about Breastfeeding (ABF) and the fourth part deals with the Anxiety about Newborn Care (ANB). Each item was measured on a five-point scale.
for the intensity of anxiety. Numerical values were assigned to indicate the degree of severity of anxiety ranging from “1” no anxiety to “5” very severe anxiety. The values 1, 2, 3, 4, and 5 denote level of anxiety like “no anxiety, little anxiety, moderate anxiety, severe anxiety and very severe anxiety” respectively for each of the statements. The highest possible score is 200.

The first part of PSAI is Anxiety about Being Pregnant (ABP), with 16 items to explore anxiety related to pregnancy status mainly diet, drugs, the chance of abortion, exercise, check up, minor disorders, travel, investigations, body image, obesity, fetal growth and anomaly, fetal mental growth, relationship with partner and family relationships and the job-related fears.

The second part of the pregnancy-specific anxiety scale is Anxiety about Childbirth (ACB), consisting of 10 items covering the due date of delivery, labour pain, type of delivery, cooperation from midwives and healthcare personnel, examinations during intranatal period, anticipated risks to the foetus and the mother during birthing process, the birth weight of newborn and concerns of self body image.

The third area covers eight questions related to Anxiety about Breastfeeding (ABF) including initiation, effective establishment of exclusive breastfeeding, and the technique of feeding and continuing breast feeding for 1-2 years, worries about breast pain and nipple problems while feeding and also concern about the beauty of the breast.

The fourth part is Anxiety about Newborn Care (ANB) with 6 questions. This part consists of questions related to bathing the new born, dealing with minor disorders of the newborn, types of newborn foods to be given, questions about whom to hand over the baby when going out or to work, concerns about whether others will care for the newborn very well and about how to care for the first child while being fully engaged with new baby.
English and Malayalam versions of final form of structured pregnancy-specific anxiety inventory are given in Appendix- E and Appendix- P respectively. Four areas and the items in the PSAI with the corresponding number of questions and maximum score are presented in Table 3.1

**Table 3.1: Number of Items and Maximum Possible Score for PSAI**

<table>
<thead>
<tr>
<th>Areas</th>
<th>Number of Items</th>
<th>Maximum Possible score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anxiety about Being Pregnant (ABP)</td>
<td>16</td>
<td>80</td>
</tr>
<tr>
<td>Anxiety about Childbirth (ACB)</td>
<td>10</td>
<td>50</td>
</tr>
<tr>
<td>Anxiety about Breastfeeding (ABF)</td>
<td>8</td>
<td>40</td>
</tr>
<tr>
<td>Anxiety about Newborn Care (ANB)</td>
<td>6</td>
<td>30</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>40</strong></td>
<td><strong>200</strong></td>
</tr>
</tbody>
</table>

The total score of 200 is considered as the maximum scores of PSAI. In consultation with statistician for this study, PSAI scores of < 50% considered as mild anxiety, 50-70% as moderate anxiety and above 70% scores as severe anxiety.

**3.6.2 Standardization of Pregnancy-Specific Anxiety Inventory (PSAI)**

**Item Analysis:**

The second tryout of the tool was done to check the item analysis and to establish its reliability. The preliminary scale was with 60 items. As a first step in doing item analysis, Pregnancy-Specific Anxiety Inventory was administered to a representative sample of 100 pregnant women, similar to the population under study who were not included in the sample selected for the study. The subjects were ranked on the basis of the
Research Methodology

total scores in a draft scale. The upper and lower one thirds of the subjects were selected as the high and low scoring groups, respectively.

The t value of the items of low scoring and high scoring groups were computed and ranked. 20 items were deleted and the final Pregnancy-Specific Anxiety Inventory contained 40 items.

**Split Half Method**

The reliability coefficient of the PSAI was calculated using split half method. A random sample of 100 response sheets was selected. The scores obtained for each item of 100 pregnant women for odd and even items were grouped separately. Thus for every individual a pair of scores was obtained. The reliability of the tool was established by using “Guttmans’ split half method” followed by Spearman – Brown prophecy formula.

The reliability of the tool was established and the reliability coefficient obtained was 0.76. The 0.76 value of show that the PSAI scale is a reliable instrument.

**Tool – 3: Interview Schedule using Knowledge Questionnaires**

A structured Knowledge Questionnaire was developed to measure the subject’s knowledge regarding five aspects of antenatal care. The steps adopted for the selection of items and the preparation of Knowledge Questionnaire were as follows:

- Review of research and non-research literature was made in the areas related to the selected five aspects of antenatal care and antenatal care as a whole.
- Experts’ opinion and suggestions were taken in determining the important areas to be included in the interview schedule.
- Informal discussions with pregnant women during the investigator’s exposure to the clinical field helped to develop the items.
Description of Structured Knowledge Questionnaire

A blueprint with 75 knowledge items covering all five areas was developed. The final form of the structured questionnaire consists of 66 questions that are grouped under five different sections as in the case of pregnancy-specific anxiety inventory. The sections pertain to their knowledge of antenatal Checkup (KC) with 10 questions, knowledge regarding diet during pregnancy (KD) with 10 questions, and knowledge regarding prevention of minor disorders of pregnancy (KM) with 10 questions, knowledge regarding breastfeeding (KBF) with 11 questions and knowledge regarding preparation for childbirth (KCB) with 25 questions.

The knowledge of antenatal care was assessed by a structured interview. The respondents were instructed to respond to all right answers and a tick mark done in the respective place provided against each item. Each item had one or more than one correct response and the score one point was allotted to each correct answer. The Knowledge questionnaire was prepared after a thorough review of related literature and discussion with the Supervising teacher, experts and pregnant women. The questionnaire was also field-tested and certain modifications were made in the structure and content before printing out the final format. English and Malayalam versions of knowledge questionnaire are given in Appendix- I 1, 2, 3, 4, 5. Appendix-S 1, 2, 3, 4, 5.

Four areas in the Knowledge Questionnaire with the corresponding number of questions and maximum score are presented in Table 3. 2.
Table 3.2: Five Areas in the Knowledge Questionnaire with the Corresponding Number of Questions and Maximum Possible Score

<table>
<thead>
<tr>
<th>Knowledge Areas</th>
<th>Number of Items</th>
<th>Maximum Possible Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diet During Pregnancy (KD)</td>
<td>10</td>
<td>35</td>
</tr>
<tr>
<td>Items</td>
<td>Marks</td>
<td></td>
</tr>
<tr>
<td>Questions 2, 9</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Questions 6</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Questions 5</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Questions 4, 8</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Questions 1, 3, 7, 10</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Antenatal Check Up (KC)</td>
<td>10</td>
<td>30</td>
</tr>
<tr>
<td>Items</td>
<td>Marks</td>
<td></td>
</tr>
<tr>
<td>Questions 3, 9</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Questions 7, 8</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Questions 2, 5</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Questions 6, 10</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Questions 1, 4</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Minor Disorders of Pregnancy (KM)</td>
<td>10</td>
<td>40</td>
</tr>
<tr>
<td>Items</td>
<td>Marks</td>
<td></td>
</tr>
<tr>
<td>Questions 2, 3, 4, 5, 9</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Questions 8</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Questions 1, 6, 7</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Questions 10</td>
<td>6</td>
<td></td>
</tr>
</tbody>
</table>
### Breastfeeding (KBF)

<table>
<thead>
<tr>
<th>Items</th>
<th>Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Questions 1, 2, 3, 7, 9, 10</td>
<td>1</td>
</tr>
<tr>
<td>Questions 4, 5</td>
<td>2</td>
</tr>
<tr>
<td>Questions 6, 11</td>
<td>3</td>
</tr>
<tr>
<td>Questions 8</td>
<td>4</td>
</tr>
</tbody>
</table>

### Preparation for Childbirth (KCB)

<table>
<thead>
<tr>
<th>Items</th>
<th>Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Questions 1, 4, 5, 7, 9, 13, 23</td>
<td>1</td>
</tr>
<tr>
<td>Questions 6, 8, 10, 12, 14, 16, 20, 21</td>
<td>2</td>
</tr>
<tr>
<td>Questions 3, 11, 17, 22, 24</td>
<td>3</td>
</tr>
<tr>
<td>Questions 2, 15, 18</td>
<td>4</td>
</tr>
<tr>
<td>Questions 19, 25</td>
<td>5</td>
</tr>
</tbody>
</table>

### Total Knowledge Score (T Know)

<table>
<thead>
<tr>
<th>Items</th>
<th>Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Questions 1, 2, 3, 7, 9, 10</td>
<td>1</td>
</tr>
<tr>
<td>Questions 4, 5</td>
<td>2</td>
</tr>
<tr>
<td>Questions 6, 11</td>
<td>3</td>
</tr>
<tr>
<td>Questions 8</td>
<td>4</td>
</tr>
</tbody>
</table>

The knowledge scores were also grouped as poor, moderate and good depending on the scores. In consultation with statistician, a scoring of <40% was considered as poor, 40-70% as moderate and >70% as good knowledge levels.

### Content Validity

The content validity of the knowledge questionnaire with its 66 items was determined by giving the questionnaire to the same experts. Out of a total 75 items, 62 items had 100 percentage agreements for the content. Alternative responses were given for four (4) items and were modified.

Nine items having 55-60 percent agreement were deleted before pretesting. After the content validity was determined, the tool was translated to Malayalam by language expert.
Pre-testing

The Malayalam version of the Questionnaires was pre-tested on 100 pregnant women similar to those who would be included in the final study. Informed consent was obtained before tryout. This piloting was done to determine the clarity of items, the presence of ambiguous items, and the difficulty in understanding the scientific terms and to ensure the feasibility and, finally the time taken to complete the interview. The total time taken was 10-15 minutes. Item variance was computed to identify the difficulty level of the item. According to Garrett (1981) the proportion of passing an item is an index of item difficulty. If ‘p’is high, for example, 90 percent, it indicates that the item is easy and if ‘p’ is only 10 percent the item is difficult. Since the subjects had no exposure to teaching related to preparation for childbirth it was assumed that their knowledge would be low. For example questions with poor response related to these topics especially questions like “what are the stages of labour?, what are the different relaxation techniques ?”. The Investigator felt that it was important to know the level of the pregnant women’s knowledge of these items. So these items were not deleted. It was arbitrarily decided to retain items having p value more than 15 %.

Reliability

The reliability of the Knowledge questionnaire was determined by interviewing 100 pregnant women similar to the study population. The reliability coefficient was calculated using split half method. The value obtained was 0.823 which indicates that the tool was reliable.

Tool – 4 Beck Depression Inventory BDI -II

The Beck Depression Inventory (BDI-II) was created by Dr. Aaron T. Beck. The original version of BDI was introduced by Beck and Beck in 1961 and revised in 1978 as
BDI-IA. The second edition of BDI-II was published in 1996. Both original and revised versions were found to be highly correlated. The BDI-II (Beck et al, 1996) is the most widely accepted measure of depressive distress. BDI-II is widely used as an assessment tool by healthcare professionals and researchers in a variety of settings.

The Beck Depression Inventory II is a 21-item multiple-choice self-report inventory test which assesses the existence and degree of depression in adolescents and adults as per DSM-IV, 1994. Each item is a list of four statements arranged in increasing severity about a particular symptom of depression. There are seven options to indicate either an increase or decrease of appetite and sleep. BDI-II consists of items relating to depressive symptoms such as sadness, crying, hopelessness and pessimism, guilt, self dislike, self blame, agitation, suicidal thoughts, insomnia, fatigue, loss of interest in activities, worthlessness, weight loss, and lack of interest in sex.

There is a four-point scale for each item ranging from 0-3. Numerical values of 0, 1, 2 and 3 are assigned to each statement to indicate the degree of severity. The highest possible score from the instrument is 63. A total score of 13 is considered minimal depression, 14-19 score mild depression, 20-28 moderate depression, and 29-63 severe depression. Average reliability coefficient reported from previous studies is 0.86. The same tool was used in local studies by other researchers too.

Beck’s Depression Inventory (BDI) is widely used as an assessment tool by healthcare professionals and researchers in a variety of settings. The BDI was adapted for Turkish use among pregnant women by Hisli (1988). The tool's Cronbach Alpha Internal Consistency coefficient is 0.95. This tool was reported to be used in the screening of depression in pregnancy and validated for use in pregnancy by Holcomb et al., (1996). The BDI has been used in other studies investigating depression in pregnancy. (Ponirakis et
A search on PubMed returns 3,209 peer-reviewed articles that have used the instrument in measurement of depression. English and Malayalam versions of BDI are given in Appendix- F and Appendix - Q

**Table 3.3: Number of Items and Maximum Possible Score for BDI**

<table>
<thead>
<tr>
<th>Tool</th>
<th>Number of Items</th>
<th>Maximum Possible score</th>
</tr>
</thead>
<tbody>
<tr>
<td>BDI</td>
<td>21</td>
<td>63</td>
</tr>
</tbody>
</table>

**Tool 4. State Trait Anxiety Inventory (STAI)**

Maternal state and trait anxiety were measured using Spielberger State-Trait Anxiety Inventory. State Trait Anxiety Inventory (STAI) Spielberger et al., (1970) is a reliable and valid tool that has been used with both clinical and non-clinical populations. The measure comprises separate self-report scales for assessing state and trait anxiety. The state anxiety scale consists of 20 items that evaluate how a person presently feels (or the current feelings of tension, anxiety, and nervousness), while trait anxiety scale evaluates how the subject generally feels with respect to 20 statements. State anxiety is conceptualized as transitory emotional state, whereas trait-anxiety refers to relatively stable individual differences in proneness to anxiety. Adaptation of Spielberger State-Trait Anxiety Inventory by Mohandas and Kumar (1994), Mahatma Gandhi University was used in this study. This inventory also contains 20 state and 20 trait questions and was filled on each occasion.

**Reliability:** This standardized tool was tested in the locality by many researchers. Split-half reliability was 0.89 for State anxiety and 0.79 for Trait anxiety.
Validity: The correlation coefficient obtained for State inventory was 0.84 and for Trait inventory was 0.86. Face validity was also assured by item analysis. Cronbach’s alpha, in the previous study was >0.88 for state anxiety and >0.83 for trait anxiety.

Scoring: The range of possible scores of STAI varies from minimum score of twenty to maximum score of 80 in both State and Trait subscales. Clients respond to each STAI item by rating themselves on a four-point scale as described below:

State Anxiety                           Trait Anxiety

1. Not at all                            1. Almost never
2. Somewhat                              2. Sometimes
3. Moderately so                         3. Often
4. Very much so                          4. Almost always

<table>
<thead>
<tr>
<th>Areas</th>
<th>Number of Items</th>
<th>Maximum Possible score</th>
</tr>
</thead>
<tbody>
<tr>
<td>State Anxiety</td>
<td>20</td>
<td>80</td>
</tr>
<tr>
<td>Trait Anxiety</td>
<td>20</td>
<td>80</td>
</tr>
</tbody>
</table>

**Total Score** | **40** | **160** |

Mohandas and Kumar (1994)

The total score of 160 is considered as the maximum scores for STAI and in this study STAI score of < 50% is considered as mild anxiety, 50-70% as moderate anxiety and above 70% scores as severe anxiety. English and Malayalam versions of STAI are given in Appendix- G and Appendix-R.
Tool. 6: Checklist for Outcome of Labour

Development and Description of Checklist for Outcome of labour

The Investigator made an extensive review of all related literature and websites available and had discussion with experts and reviewed labour records available in the different government hospitals of Kerala State, especially of Kollam Victoria Hospital. The checklist was prepared based on the checklist developed by Noronha (2005). Modifications were done on the items listed by the Investigator. This structured Labour Outcome checklist consisted of 15 items.

The items developed were mainly related to the expected complications that are usually observed in pregnant women with anxiety and depression.

The presence or absence was indicated with a ‘yes’ column and a ‘no’ column. Check-list also contained all possible options to mark a tick against the appropriate options of individual pregnant women’s labour outcome. The data were collected primarily through record analysis. The final form of Checklist is given in Appendix-H

Pregnant women: Duration of labour, type of delivery, indications for assisted delivery, Caesarean section planned or not and its indication, the presence of maternal injury and its type or episiotomy, postpartum bleeding

Baby: Gestational age at birth by week, birth weight, Apgar score, resuscitation used, gestational age of the baby at birth by size, congenital anomalies, birth injuries.

Content Validity: To ensure content validity of the tool, the draft tool was given to the same experts. They were asked to give their suggestions in terms of relevance, accuracy and appropriateness. There were suggestions by two experts to modify the item on Apgar score to ask for whether the baby cried immediately at birth and whether any still birth.
Pre-testing: After obtaining formal administrative approval from the concerned authority, the tool was pre-tested to check for the clarity of items and feasibility.

Record analysis of ten postnatal women was done. The average time taken for assessment was 5-10 minutes.

Reliability: The reliability of the tool was tested on 30 postnatal women. The inter-rater reliability was determined by having another expert make the record analysis. Of the 15 items, 13 items had 100% agreement between two. Two items had 93.33 % agreement. The reliability coefficient was computed by Pearson’s coefficient of correlation formula and it was 0.883.

3.7 Development of Planned Childbirth Education Program

In order to minimize anxiety in pregnant women, an intervention program was found essential. The investigator therefore developed an Intervention Program for minimizing anxiety in pregnant women. The details of the program are given below.

a) Development of the Planned Childbirth Education Program

The Planned Childbirth Education Program was developed for first-time pregnant women. The following steps were adopted:

1. Preparation of the first draft on the Planned Childbirth Education

2. Development of criteria checklist

3. Content validation of Planned Childbirth Education

4. Preparation of the final draft of planned Childbirth Education
1. **Preparation of the First Draft on Planned Childbirth Education**

The first stage of the Planned Childbirth Education was prepared on the basis of literature available on the topic. Keeping in mind the objectives to be achieved and learner’s capacity to absorb and understand information, the content was made simple, clear and comprehensive. The Planned Childbirth Education program was meticulously prepared after an exhaustive review of literature on related topics and experts’ review. Contacts with few pregnant women cleared the way the for development of the Planned Childbirth Education program. The investigator reviewed the available videos prepared in western countries and videos prepared by private drug companies and developed childbirth education video compatible to the cultural background of Kerala. After the preparation of planned childbirth education program it was submitted to 10 experts in the field of Obstetrics and Gynecology, Nursing, Mental health doctors. Modifications were made in to structure and content according to the experts’ suggestions. Hence the face validity and content validity of the tool was ensured.

The areas covered in the Planned Childbirth Education were:

1. Anatomy of the female reproductive tract
2. The Process and stages of Labour
3. The Premonitory signs and true signs of labour
4. Signs and symptoms to distinguish false labour
5. Preparation for labour
6. Usual investigations and examinations done in labour room
7. Measures to reduce labour pain
8. Relaxation techniques useful during the first and the second stages of labour

9. Tips to reduce anxiety and stress during labour

2. Development of Criteria Checklist

The criteria checklist was developed by the Investigator along with experts’ advice. The criteria checklist consisted of items under the heading, formation of objectives, selection of content, organization of content, presentation, language and audio-visual aids.

The check-list had a ‘five response’ column that is, strongly agree, Agree, Partially agree, Disagree and Remarks column for suggestions of experts.

3. Content Validation of Planned Childbirth Education

To determine content validity, the drafts of the Planned Childbirth Education Programme were submitted to 10 experts along with the criteria check-list.

There were 80 percent agreement in the content area. One expert suggested some simplification in the terminology. Suggestions were incorporated. There was a suggestion by experts to give pamphlet at the end of teaching. Suggestions for improving audiovisual aids were executed. The Planned Childbirth Education Programme was finalized with poster, pamphlets and video.

4. Preparation of Final Draft of Planned Childbirth Education

The final draft of Planned Childbirth Education was prepared. Appropriate audiovisual aids were prepared incorporating the suggestions given by experts. English and Malayalam version of Planned Childbirth Education Programme was given in Appendix-J and Appendix-T respectively.

Module on Preparation for childbirth: The hand out module of preparation for Childbirth also developed as a reference for pregnant mothers and distributed to mothers in the
experimental group. English and Malayalam version of module of preparation for Childbirth was given in Appendix-K and Appendix-U respectively.

b) Video on Childbirth Education

The investigator reviewed the available videos prepared in western countries and videos prepared by private drug companies and developed childbirth education video compatible to the cultural background of Kerala. The Investigator narrates the importance of childbirth preparation by stating the advantages of breathing exercises and relaxation techniques. Different stages of labour, breathing and relaxation techniques are explained with appropriate scene. Conclusion by reemphasizing the importance of practicing breathing and relaxation technique by pregnant women to cope with pregnancy fears. Video is 20 minutes in duration. English and Malayalam video as Appendix-L and Appendix-V respectively.

3.8 Pilot Study

A pilot study was conducted among 100 pregnant women attending antenatal clinic of Victoria Hospital Kollam to assess the feasibility of the study. Prior permission was obtained from concerned authorities and also consent was also obtained from pregnant women. After establishing rapport with them, investigator administered STAI, BDI, PSAI, and got them filled in. Then the subjects were interviewed to find out the level of their knowledge regarding selected aspects of antenatal care. The pregnant women reported that the items were clear. The average time taken was 30-35 minutes.

Ten nulliparous pregnant women in their third trimester whose anxiety level was found to be higher were selected and the Planned Childbirth Education Program was administered two times with a gap of one week’s time. Two weeks after the final session, they were requested to fill in the same tool of PSAI used for the pretest. The tools and the
program were found feasible. The ten pregnant women during intranatal period were asked to fill up the STAI, BDI, PSAI but eight of them were reluctant to fill in the form as they reported that they were experiencing so much discomfort and were distressed distracted with labour pain. So intrapartum assessment of anxiety did not seem feasible. When this was discussed with the Guide and experts, they too felt that intrapartum assessment could be limited to record analysis in terms of labour outcome.

The labour records were reviewed for the type of delivery, the length of labour and labour complications such as postpartum hemorrhage, perineal tear, and so on. The outcomes of newborn in terms of the initial cry, gestational age, birth injuries, congenital malformations and the initiation and establishment of effective breast-feeding were also noted from records. Postnatally the pregnant women were able to fill in the STAI, PSAI. BDI-II was administered between two weeks and four weeks postnatally.

3.9 Procedure for Data Collection

Phase I

The Investigator personally contacted Kollam District Medical Officer and sought permission for conducting the study in Government hospital of Kollam District, Victoria Hospital. The most prominent government maternity hospital in Kollam, was selected for the study (Appendix- A). A concurrent permission from Medical Superintendent and Nursing Superintendent also sought prior to the study. Pregnant women in their first trimester (8 –16 weeks) who met the selection criteria and volunteered to participate were invited to participate in the study at the office of their physician in the outpatient department. In order to obtain their sincere co-operation, pregnant women were informed clearly about the purpose and usefulness of the study and they were also assured of confidentiality of data.
The consent was obtained from each pregnant woman indicating their voluntary participation, confidentiality of the data, unconditioned right to withdraw from the study. (Appendix- B Appendix- M). Initially 700 samples were selected and data were collected. The data collection was stopped at reaching 500 samples, completing postnatal period data. The responses of the remaining pregnant women had to be deleted mainly due to non-completion of the questionnaire in concurrent readings, which in turn, was due to change of consultation, planned operative deliveries for obstetric reasons, and ending of pregnancy within 37 weeks.

Investigator introduced herself and explained the purpose of the study. After obtaining informed consent from the clients to participate in the study, an information sheet containing a brief description of the study and telephone number of the Investigator and how to reach Investigator when needed were given to all participants. Their files were tagged with the telephone number of the Investigator. Staff nurses and Ward in-charge nurses who worked in outpatient department, antenatal ward and labour room were informed about the purpose of the study and directed to inform the Investigator when pregnant women report to them for their check-up and further care.

The Investigator interviewed each pregnant woman for 10-15 minutes using the structured interview schedule (tool-3- Knowledge Questionnaire) to assess their knowledge of selected aspects of antenatal care also collected socio-personal variable using socio-personal data sheet. Anxiety scale (STAI) and Depression scale (BDI-II) were distributed to pregnant women for self-reporting to measure their anxiety and depression levels. It took 10 to 15 minutes to fill in these tools. The Pregnancy-specific anxiety Inventory (PSAI) was also distributed to them for self-rating to assess their pregnancy-specific anxiety, which took 8-10 minutes.
The same pregnant women were followed up throughout their pregnancy and postpartum period. During their second trimester (20–28 weeks) and third trimester (30–38 weeks), they were subjected to the same assessment using the same tools, except for knowledge of the selected aspects of antenatal care. Each woman was assessed every time with an interval gap period of 10-12 weeks.

These pregnant women’s labour outcomes were noted from their labor records using the Checklists for Outcome of Labour. Postnatally before discharge, STAI and Pregnancy-Specific Anxiety level were measured. Between 2<sup>nd</sup> and 4<sup>th</sup> weeks, BDI -II was also reassessed.

**Phase II**

After analyzing the data the Investigator found that the nulliparous pregnant women were more anxious than the parous women especially during third trimester. 120 first time pregnant women in their third trimester of pregnancy (30–38 weeks of gestation), who met the inclusion criteria attending outpatient department of Victoria Hospital Kollam were selected for the second phase of the study. The data were collected until the completion of 100 as final samples for the study with 50 equal samples in each group. The purpose of the study was explained and consent was taken personally. They were interviewed for knowledge of five selected aspects of antenatal care, and their socio-demographic data using the same tool used in phase I.

Whole samples were pretested with same tools STAI, PSAI and BDI -II. After pretest 50 nulliparous pregnant women randomly allocated from 100 samples of expectant mothers, were exposed to childbirth Education, and they formed the experimental group. The experimental samples were chosen from mothers attending outpatient department on Monday, Tuesday and Wednesday. Classes were taken in small groups as well as on
individual basis. Depending on the availability of the sample on an average 2-4 nulliparous pregnant women in a group were given childbirth education. Investigator assured that each of them was exposed to two sessions of childbirth education classes on a weekly schedule. After two weeks gap the posttest was conducted between 37-41 weeks prior to delivery using the same Pregnancy-Specific Anxiety Inventory and the women were interviewed for their knowledge regarding selected five aspects of antenatal care.

These mothers’ labour outcomes were noted from labor records. They were followed after delivery before discharge from the hospital for pregnancy-specific anxiety level and general anxiety. BDI was reassessed at 2 – 4 weeks after delivery during their follow up in the postnatal or immunization clinic. The 50 nulliparous pregnant women in control group selected from mothers attending outpatient department on Thursday, Friday and Saturday, were also post-tested in the same way without exposure to the childbirth education programme. Their labour outcomes were also noted from their labour records. Postnatal period data were also collected from control group. The Investigator expressed her thanks for their participation and co-operation. The data collection period was from June 2004 to July 2005.

3.10 Statistical Techniques Used for Data Analysis

The data were analyzed based on the objectives and hypotheses by employing appropriate statistical methods using SPSS version 16. The following statistical techniques were used for this purpose:

a) Computation of frequencies, percentages, arithmetic mean and standard deviation

b) Karl Pearson’s product-moment coefficient of correlation.

c) Chi-square test
d) General Lineal Model- Repeated Measures

e) Independent group ‘t’ test

The statistical test employed for analyzing data consisted of frequency and percentage to determine the prevalence of anxiety and depression and Chi-square to test the significance of association between socio-personal variables and level of pregnant women’s knowledge of selected aspects of antenatal care. Pearson’s correlation was computed to find out linear relationship of anxiety and depression with level pregnant women’s knowledge of regarding selected aspects of antenatal care.

General Linear Model (GLM )-Repeated Measures is a procedure used to model dependent variables measured at multiple times using analysis of variance. GLM-Repeated Measures model can test the main effect on repeated measures between subjects (grouping) factors, main effects of within subjects factors like measurement times, interaction effects between factors, covariates effects, and also effects of interaction between covariate and between-subjects factors. GLM- Repeated Measures model test was used to test main effect within and between subjects, interaction effects between factors, covariates effects and effects of interaction between covariates and between subjects. This test is used to identify association between socio-personal variables with anxiety and depression at different time period of pregnancy and postpartum period.

The same GLM- Repeated Measures model was used in Phase II of the study to compare the levels of anxiety of pregnant women in experimental and control groups before and after planned childbirth education. Percentages and frequencies are calculated to compare the outcome of labour and to determine the incidence of postnatal depression in experimental group. The independent ‘t’ test were used to find out difference between experimental and control groups post test scores.
3.11 Summary

This chapter dealt with the research methodology, which is of prospective cohort survey-cum quasi-experimental two-group pre-test post-test design. It also described the population and settings. Descriptions of the development of three tools prepared by the Investigator and the two standardized tools were given. A Planned Childbirth Education Program (PCBP) was prepared and presented. The hand out module of Childbirth Education also developed as a reference for pregnant mothers. The developed video of the childbirth education also described. The procedure of data collection was presented with details of survey and the experimental phase. The techniques used for analysis of data were described.