CHAPTER III
MATERIALS AND METHODS

3.1 Introduction 93
3.2 Research approach 93
3.3 Research design 94
3.4 Rationale for research design 94
3.5 Settings of the study 95
3.6 Reference population 95
3.7 Source population 95
3.8 Sampling frame 96
3.9 Study sample 96
3.10 Sampling technique 96
3.11 Sample recruitment and entry criteria 96
3.12 Exclusion criteria 97
3.13 Procedure for randomization 97
3.14 Comparison group 98
3.15 Flow chart 99
3.16 Sample size 99
3.17 Blinding 100
3.18 Follow up procedure 100
3.19 Contamination 103
3.20 Time and duration of the study 103
3.21 Self Instructional Module and Tools used in the study 103
  3.21.1. Preparation 103
  3.21.2. Description of Self Instructional Module 104
  3.21.3. Tools and techniques used in the study 105
  3.21.4. Validity and reliability 107
3.22 Pilot study 108
3.23 Ethical Implications 108
  3.23.1. Ethical clearance 108
  3.23.2. Informed Consent 109
  3.23.3. Right of Withdrawal 109
  3.23.4. Confidentiality 109
3.24 Data collection process 109
  3.24.1. Exposure to independent Variable 110
  3.24.2. Follow up visits 110
3.25 Data management 111
3.26 Data quality 111
3.27 Plan of analysis 112
3.28 Summary 112

Figures and Tables
Fig.3.1. The study Design 94
Flow chart 3.1. Patient recruitment and follow up plan 99
Flow chart 3.2. WWE eligibility & recruitment status 101
Flow chart 3.3. WWoE eligibility & recruitment status 102
Table 3.1. Units of Self Instructional Module 104
CHAPTER III
MATERIALS AND METHODS

3.1. Introduction

The study was done in three phases.

In Phase I – A structured Self Instructional Module (SIM) for Women with Epilepsy titled ‘You and Your baby – conception, labor, and infant care- A self Instructional Module for women with epilepsy’ was developed.

In Phase II – Women with epilepsy in their early pregnancy attending the Kerala Registry of Epilepsy and Pregnancy (KREP) were enrolled as per inclusion and exclusion criteria, interviewed, and then randomised into intervention and control groups. The intervention group was provided with the Self Instructional Module and the control group was provided with an alternate booklet already available in the Department of Neurology. Simultaneously an age, education and parity-matched pairs of women without epilepsy (comparison group) in their early pregnancy were recruited from the antenatal clinic of SAT hospital, based on inclusion and exclusion criteria. A second visit was done during third trimester to collect antenatal data.

In Phase III – Follow up visits were conducted three to four months after delivery to test the effect of Self Instructional module on Women with Epilepsy and to compare the child rearing practices of WWE with that of Women without Epilepsy (WWoE). The maternal and baby outcomes also were compared.

3.2. Research Approach

The present study was an interventional study to assess the effect of Self Instructional Module on the child rearing practices of WWE and to compare their child rearing
practices, and health related outcome with women without epilepsy. An experimental research approach was used in this study.

3.3. Research Design

The research design adopted for the present study was pretest - posttest comparison design. WWE in the study were randomly assigned to an intervention or a control group. The self-instructional module was the intervention. The initial or baseline child rearing knowledge was assessed. The dependent variables measured as outcome included the child rearing knowledge, child rearing practice, maternal and baby outcome. The childrearing knowledge and practices of women with epilepsy as well as maternal and baby outcome were compared with that of women without epilepsy also. The study design is diagrammatically represented in Fig.3.1

<table>
<thead>
<tr>
<th>Study Groups</th>
<th>Pretest</th>
<th>Treatment</th>
<th>Posttest</th>
<th>Compare</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control group (WWE)</td>
<td>O₁</td>
<td>R</td>
<td>O₂</td>
<td>O₁ → O₂</td>
</tr>
<tr>
<td>Intervention group (WWE)</td>
<td>O₁</td>
<td>R</td>
<td>X → O₂</td>
<td>O₁ → O₂</td>
</tr>
<tr>
<td>Comparison group (WWoE)</td>
<td>O₁</td>
<td>M</td>
<td>O₂</td>
<td>O₁ → O₂</td>
</tr>
</tbody>
</table>

In this diagram R = randomization, M=Matching, O₁ = pretest, X = intervention and O₂ = posttest.

3.4. Rationale for Research Design

Experimental method is the best method for establishing cause and effect relationship between the independent variable and dependent variable. It is also the best approach to testing the effectiveness of an intervention. This is appropriate for determining differences between groups. Randomization is very essential in a true experimental study. In clinical studies randomized controlled double blind trials are used for this purpose.
The pretest posttest comparison design with randomization enables changes to be measured. Random assignment into intervention and control group ensures comparability between the groups. Threats to internal validity like learning, maturation and experimenter effects are equally distributed in both the groups, while matching and random assignments have ensured initial equality of the groups, thus adding to the internal validity.

3.5. Settings of the study

The study was conducted in the Kerala Registry of Epilepsy and Pregnancy, which is functioning at the R. Madhavan Nayar Centre for Comprehensive Epilepsy care, Department of Neurology at the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum. The comparison group of women without epilepsy was selected from the antenatal clinic of Sree Avittam Thirunal Hospital, the Women and Children hospital of Medical College, Trivandrum, a premier centre that caters to a large proportion of pregnant women from southern Kerala. Both the study centres were tertiary level referral speciality government hospitals.

3.6. Reference Population

The reference population for this study includes all women with epilepsy who are mothers or potential mothers. The Kerala Registry of Epilepsy and Pregnancy (KREP) is the only Registry in India where WWE who are mothers or potential mothers are being registered and followed up systematically. The registry is functioning in a reputed national institute and majority of WWE were being referred to this registry by obstetricians and neurologists all over the state of Kerala and nearby areas of Tamil Nadu.

3.7. Source Population

The source population consisted of all WWE attending the Kerla Registry of Epilepsy and Pregnancy, R. Madhavan Nayar Centre for Comprehensive Epilepsy care,
Department of Neurology at the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum. The Neurology Department of this Institute of National Importance offers special care to the WWE through the Kerala Registry of Epilepsy and Pregnancy from the year 1998 onwards. Although any woman with epilepsy in the childbearing age can register here, most of the registered women belonged to Kerala state and nearby districts of Tamil Nadu. They are referred here from preconception period onwards for registering in the KREP.

3.8. Sampling frame

The sampling frame consisted of WWE registered in the KREP in the 48 months between April 2003 and March 2005. Out of a sampling frame of N= 252, hundred consecutive samples who met the inclusion criteria were randomized into intervention and control group in a double blind manner.

3.9. Study Sample

The study sample consisted of all WWE mentioned in the sampling frame, meeting all the inclusion criteria and who have given consent to enrol themselves in the study and for follow up visits till the end of pregnancy and/or till the baby is three to four months old.

3.10. Sampling technique

Randomised experimental designs are the gold standard of research. Being an experimental study, random sampling technique was used. A double blind technique was used to avoid even the investigator bias.

3.11. Sample recruitment and inclusion criteria

Face to face recruitment was used.

1. WWE who were registered in the Kerala Registry of Epilepsy and pregnancy and were in the first trimester of pregnancy.
2. WWE who were able to read Malayalam since the booklets were in Malayalam.

3. WWE who were willing to participate in the study.

3.12. Exclusion Criteria

1. WWE who were in the second or third trimester of pregnancy

2. WWE who were coming for preconception counselling

3. Recruited WWE coming after repeat pregnancy during the study period.

3.13. Procedure for Randomization

Eligible subjects who met all the inclusion criteria were interviewed and randomly assigned to the intervention and control group using computer generated random numbers and assigned booklets using the following method. Computer generated random numbers were assigned to two types of booklets to be given to the enrolled sample. The booklets were (1) the self-instructional module which was specially developed for this study and (2) an alternate health education booklet on Epilepsy which was already available in the Department of Neurology, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum, Kerala. The Self Instructional Module or the alternate booklet was placed inside opaque brown paper envelopes and sealed and assigned random numbers without the knowledge of the investigator and the master code for this was kept locked. This was to avoid any sort of bias from the investigator while giving scores to the WWE in the intervention and the control group. The module and the alternate booklets were randomly assigned numbers and serially arranged from 1 to 100 to be distributed to the enrolled WWE who met the inclusion criteria. Consecutive sampling was used to enrol 100 women with epilepsy (WWE) who met the inclusion criteria. They were randomised 50 each to the intervention group and to the control group. The baseline data was collected before randomisation thus ensuring that subjects would not be biased in any way. Moreover the researcher as well as the subjects was not aware of the group to which each subject belonged, all through out the study.
All enrolled WWE were given a booklet to counteract the Hawthorne effect, which is a threat to internal validity. Moreover, this addressed the ethical issue of not denying educational materials and services to the control group since this alternate booklet on epilepsy also had session on epilepsy and pregnancy (See Flow Chart -3.1).

3.14. Comparison Group

The comparison group enrolled were age, education and parity matched pairs of women without epilepsy. The investigator personally went to the antenatal clinic of Sree Avittam Thirunal Hospital, the Women and Children Hospital of Medical College, Trivandrum, on weekdays and selected samples for comparison group. A preliminary interview was done to select candidates who met the inclusion criteria. The inclusion criteria were:

1. Women who were registered in the antenatal clinic, waiting for antenatal check up. The waiting time could be utilized for the personal interview without causing additional anxiety in the women.
2. Women who were in the first trimester of pregnancy
3. Women who could converse in Malayalam language
4. Women who were willing to participate in the study
5. Women who resided within approximately 5 Kilometre radius from the hospital or who were likely to come for follow up in the same hospital.
3.15. Flow Chart

The flow chart for patient recruitment and follow up was planned as follows.

<table>
<thead>
<tr>
<th>KREP – WWE</th>
<th>Antenatal Clinic of SAT hospital - WWoE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnostic criteria &amp; Exclusion</td>
<td></td>
</tr>
<tr>
<td>Enrolment</td>
<td>Matching</td>
</tr>
<tr>
<td>Demographic data</td>
<td>Demographic data</td>
</tr>
<tr>
<td>Obstetrical data</td>
<td>Obstetrical data</td>
</tr>
<tr>
<td>Knowledge test</td>
<td>Knowledge test</td>
</tr>
<tr>
<td>Randomisation</td>
<td>Randomisation</td>
</tr>
<tr>
<td>INTERVENTION SIM</td>
<td>CONTROL GROUP</td>
</tr>
<tr>
<td>Alternate Booklet</td>
<td>No booklet</td>
</tr>
</tbody>
</table>

Second Visit - 3rd Trimester

<table>
<thead>
<tr>
<th>Antenatal Data</th>
<th>Antenatal Data</th>
<th>Antenatal Data</th>
</tr>
</thead>
</table>

Third Visit - 3-4 months postpartum

<table>
<thead>
<tr>
<th>Knowledge test</th>
<th>Knowledge test</th>
<th>Knowledge test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child Rearing Practice</td>
<td>Child Rearing Practice</td>
<td>Child Rearing Practice</td>
</tr>
<tr>
<td>Maternal outcome</td>
<td>Maternal outcome</td>
<td>Maternal outcome</td>
</tr>
<tr>
<td>Baby outcome</td>
<td>Baby outcome</td>
<td>Baby outcome</td>
</tr>
</tbody>
</table>

Flow Chart. 3.1. Patient recruitment and follow up plan

3.16. Sample Size

The Sample size of WWE was limited to 100 considering the following. The annual attendance in the KREP in the previous year was 120 women with epilepsy. Among this, women in the early pregnancy, eligible to be enrolled in the study would be about 50. In two years time initial enrolment would be over for 100 women with epilepsy and the data collection could be completed in three years time. So time factor and
subject availability were the main determinants in limiting the sample size to 100. Special care was taken to minimize subject attrition through personal rapport. For comparison group an age, education and parity matched pairs of pregnant women without any major illnesses were selected using convenient sampling technique. Seven WWE who had low education did not get matched pairs.

3.17. Blinding

The researcher didn’t know the treatment status of the women in the study group that is whether the subjects belonged to the intervention or control group. The subjects also didn’t know the group to which they belonged.

3.18. Follow up Procedure

This prospective study was designed to make assessments at first trimester, third trimester, and at three to four months post partum. This time period for comparison of the mother infant dyads was selected because of two reasons. Culturally it is customary for the mothers to take full responsibility of the baby by three months postpartum. This is the usual time when mother and baby returns from her maternal home to husband’s place. Another reason was that this time period coincides with the planned follow up visit of mother infant dyads at the KREP for postpartum maternal and baby evaluation. This period also coincided with the third dose of DPT immunisation when the WWoE and babies could be followed up in the immunisation clinic. Accordingly the women enrolled at first trimester of pregnancy, were followed up till the end of pregnancy, and/or till the baby was three to four months old. The enrolled subjects were provided with an address card with telephone numbers of the investigator with instructions to contact at any time. There were 176 mother infant dyads who completed the one-year follow up study, 88 WWE and 88 WWoE (See Flow charts 3.2 and 3.3).
Kerala Registry of Epilepsy
April 30, 2003 to March 21, 2006
New registrations N = 252

Not considered for recruitment:
Researcher/patient unavailable – 22

Preliminary Screening
N = 230

Inclusion Criteria
N = 108

Exclusion Criteria
N = 8

Approached for consent
N = 100

Enrolled Randomised Intervention/control group

Antenatal Personal Interview 2
N = 92

Postnatal personal interview = 83
Telephonic interview = 5

Final Sample for the Data Analysis
N = 88

Preconception counseling – 60
Advanced pregnancy – 55
Wants MTP – 7
N = 122

Illiterate – 1
Sample Repeat pregnancy – 2
Diagnostic Exclusion – 4
Not having active epilepsy – 1

Abortion/MTP = 5
IUD/stillbirth = 3

Neonatal death = 1
Missed = 3

Flow Chart 3.2 WWoE eligibility & recruitment status
Antenatal Registry
May 2, 2003 to, April 12, 2005
Average new registrations/day = 100

Not considered for recruitment:
Distant native place
Researcher unavailable

Preliminary Screening
N = 150

Inclusion Criteria
N = 150

Exclusion Criteria
N = 10

Approached for consent
N = 140

Enrolled
N = 139

Antenatal Personal Interview - 2
N = 91

Postnatal personal interview = 86
Telephonic interview = 2

Final Sample for the Data Analysis
N = 88

Flow Chart 3.3. WWoE eligibility & recruitment status
3.19. Contamination

Chances of contamination were not present because each woman was handled individually with instructions to open the book packet and read it only after reaching home. Moreover the enrolled subjects came sporadically on different days, from different places, were not relatives or friends.

3.20. Time and duration of the study

The total duration of the study was five years, from 2001 to 2006. The self-instructional module and tool preparation extended for 15 months. The data collection was for three years, started in the month of April 2003 and ended in April 2006.

3.21. Self Instructional Module and Data Collection Instruments used in the study

3.21.1. Preparation

In phase I, literature on child rearing and women with epilepsy was reviewed. In addition subject experts from Nursing, Neurology, Pediatrics and Obstetrics and Gynecology were consulted during the preparatory phase of the self-instructional module for women with epilepsy. The British Epilepsy Association's printed materials for women with epilepsy also served as source material for the preparation of the module. Interviews were conducted with normal mothers attending the study centre and mothers with Epilepsy who were attending the Kerala Registry of Epilepsy and pregnancy, to elicit their problems in child rearing. This served to decide the structure and pattern of the self-instructional module. This also helped in the tool preparation such as item derivation for the knowledge test and child rearing practice scale. Based on these a self-instructional module was prepared in English. Conversion to local language (Malayalam) was done by forward - backward conversion with the help of bilingual experts. The opinion regarding readability and utility of the module was
tested by giving it to mothers with epilepsy. The translated module was pilot tested to correct wording.

3.21.2. Description of Self Instructional Module

The Self Instructional Module (SIM), the booklet prepared and printed for the study purpose, was on antenatal care and child rearing for women with epilepsy and was titled ‘You and Your baby – conception, labour, and infant care- A self Instructional Module for Women with Epilepsy’. The SIM had 2 sections—Section 1 and Section 2 with six units each towards antenatal care and infant care respectively. The units on Antenatal care were: Regular Medical check up, Balanced Diet, Self care, Minor disorders of pregnancy, Towards hospital for delivery, and Postnatal care & contraception. The Infant Care part included: Growth and development, Successful breastfeeding, complementary feeding, Accidents and emergencies, immunization & Protection, and Mother infant bonding & infant stimulation (See Appendix J).

Table 3.1

Units of Self Instructional Module

<table>
<thead>
<tr>
<th>Section 1</th>
<th>Section 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self Care (Care of You)</td>
<td>Infant Care (Care of your Baby)</td>
</tr>
<tr>
<td>1. Visit your doctors regularly</td>
<td>1. Normal growth and development</td>
</tr>
<tr>
<td>2. Take a balanced diet</td>
<td>2. Successful breast feeding</td>
</tr>
<tr>
<td>3. Attend to yourself</td>
<td>3. Complementary feeding</td>
</tr>
<tr>
<td>5. Going to the hospital for delivery</td>
<td>5. Immunization Schedule</td>
</tr>
<tr>
<td>6. Postnatal care and contraceptives</td>
<td>6. Infant stimulation</td>
</tr>
</tbody>
</table>

Towards the end of each part there were self-tests with answer keys. To increase the readability, tables and pictures were added. A bookmarker with the unit titles and page numbers also was provided along with the SIM.
3.21.3. Tools and techniques used in the study

The main data collection technique was personal interview for which a structured interview schedule was prepared and tested. There were three parts for the interview schedule one meant for the personal interview of each visit (See Appendix C).

Part one was used for the personal interview of the first visit. It consisted of

1. Sociodemographic and obstetric data sheet which included identification data, maternal constitutional variables (age (calculated from date of birth), gravida status, parity, antenatal health, maternal height and weight), and exposure variables (Type of family, Standard of living, Religion, Place of residence, Education & Occupation, and Mass media exposure). Expected date of confinement was calculated from the last menstrual period. Date of marriage was asked to calculate age at marriage. Age, education, and occupation of the husband also were asked.

2. Standard of Living Index – This is a composite index, modified version of NFHS data for measuring the economic status of household, developed by Roy et al., 1999. The index indicates living conditions and household amenities such as type of house, source of lighting, source of drinking water, type of fuel used for cooking, type of toilet and ownership of consumer durables such as car, scooter, television, washing machine, sewing machine, radio, bicycle, and fan, as reported by the women (Appendix H).

3. Epilepsy data sheet for WWE – included questions on type of epilepsy, seizure type and pattern, antiepileptic drug therapy and drug compliance.

4. The Child Rearing Knowledge (CRK) test used to assess maternal knowledge on child rearing had 20 multiple choice questions on infant care divided into four domains: Feeding (6 items), Growth and development (4 items), Cleaning and protection (7 items) and Infant stimulation (3 items). Each question had five choices including one right choice, three wrong choices and a ‘don’t know’ choice to avoid the chance
of guessing. The right choice was given a score of two and other choices were scored as zero. This was used as pretest and had a total weightage of 40 points. It took around 15 minutes for completion.

5. Height and weight record wherein the height and weight of the enrolled subjects were measured using standard height and weight recording machine available in the setting. This was used to calculate Body Mass Index (BMI).

Part II of the interview schedule was used for the second visit. It consisted of

1. Antenatal care and other illness data sheet (See Appendix G - Antenatal Health Index).
2. Epilepsy data sheet for WWE – included questions on seizure pattern, antiepileptic therapy and drug compliance.

Part III of the interview schedule was used for the third visit. It included

1. Maternal Outcome Scale (MOS)- A four point Rating scale of maternal health based on reported feelings of health and well-being as personal, family and maternal life. Maternal outcome scale has 15 items (3 items were dichotomous) and a composite score of 39 (Personal life = 18, Family life= 13, Maternal life =8) (See Appendix F).
2. Baby Outcome Scale (BOS) - a scale of 15 items which included natal outcome (7 items, score =15), and postnatal outcome (8 items, score = 12). A standard paediatric weighing machine was used to check the weight of the baby of WWE. Recorded weight available from the baby records were used in the case of WWoE, since most of the post partum interviews were made in the respondent’s home (See Appendix E).
3. Child Rearing Practice Scale (CRPS). This consisted of 23 items with a total score of 33, divided into four subscales, that covered the four major child rearing domains related to early infancy and related practices. These were: Feeding (7 items, = 14), Growth and development (1 item, score = 1), Cleaning and Protection (hygiene –
4 items, score = 7, infection prevention – 4 items, score = 4, prevention of accidents and injuries – 3 items, score = 3), and Infant stimulation (4 items, score = 4). Out of the twenty three maternal behaviours in the CRPS, three were rated on a 4-point scale (12 scores) and 19 were dichotomous Yes/No questions with one score each (19 scores) and a negative item with a score of two adding to a CRP score of 33. The total CRP score was calculated as the sum total of the four subscale scores. Higher scores indicated better child rearing practices. The CRP Scale required 20 minutes for completion (See Appendix D).

4. Visual Analogue Scale (VAS) – This 11-point Visual Analogue Scale showed a Ladder of child rearing capability wherein the mother could depict her parenting capability. The bottom step denoted total incapability to look after the baby (score 0) and top step denoted complete ability to look after the baby (score 10).

5. Maternal Involvement Scale (MIS) – A 5-point observation checklist on maternal involvement in caring the baby. Direct observation was used to collect this information.

6. Child Rearing Knowledge (CRK) Test was repeated as posttest.

7. Epilepsy data sheet for WWE – included questions on seizure pattern, antiepileptic drug therapy and drug compliance during post partum period.

8. A structured Opinionnaire to determine the utility of the SIM/alternate booklet on epilepsy was part of the interview schedule for the WWE.

9. Medical Records and KREP Records also were consulted.

3.21.4. Validity and Reliability

A panel of subject experts from Nursing, Neurology, Pediatrics and Obstetrics and Gynecology reviewed the Self Instructional Module for content validity. Subject experts reviewed the interview schedule including the knowledge test and child rearing practice scale for content validity. Twenty-five women without epilepsy were chosen for testing the reliability of the knowledge test by test - retest method at an interval of two weeks.
The reliability was tested for the 20 individual items of the knowledge test using Kappa coefficient. All the individual items except item 11 and 12 were found to have adequate agreement between the two test scores (the measurement of agreement Kappa ranged from 0.51 to 1). Accordingly these two questions were modified. The total knowledge scores and sub scores data were analysed for correlation using Pearson’s correlation coefficient and Spearman’s rank order correlation coefficient. A significant Pearson’s correlation indicated that total scores were consistent over time ($r = 0.891$). The sub scores on feeding (6 items), growth and development (4 items), cleaning and protection (7 items), and infant stimulation (3 items) were found to have reliability of 0.906, 0.758, 0.836, and 0.89 respectively using Pearson’s correlation.

3.22. Pilot Study

A pilot study was done to test the feasibility of the study. Twenty normal mothers who were having infants were taken and a pilot study was done. The difficulties encountered in data collection during the follow up of normal women were discussed and it was decided to include women from nearby area of the community so that follow up could be planned as home visits if needed. Each one of the women were given explanation as to what was expected of them and gained their consent and confidence. All the women approached for pilot study were willing to participate in the study and this increased the enthusiasm of the investigator. The pilot study helped in modifying and finalizing the items for the child rearing practice scale.

3.23. Ethical Implications

3.23.1. Ethical clearance

Ethical clearance was obtained from the study centre, Medical College, Thiruvananthapuram, before actual data collection.
3.23.2. Informed consent

The researcher explained the details of the study to each of the women prior to enrolment and their informed written consent was obtained for participation, and follow up visits using separate consent forms (See Appendices - A and B).

3.23.3. Right of withdrawal

This was included as part of the consent form and also mentioned that it would not interfere with the normal care obtained from the registry.

3.23.4. Confidentiality

No information leading to identification of the patient or family members was to be disclosed to anyone and the results would be utilized only for research purposes.

3.24. Data Collection Process

Phase II of the study was of enrolling subjects in the study. The participants signed consent forms after getting an explanation of the purpose, the time commitment, the need and means for second and third visits. The investigator conducted all the face-to-face interviews.

The initial data collection took place in the privacy of a nearby waiting area in the antenatal clinic of the SAT hospital or in the waiting area of KREP. The investigator personally conducted the interviews to ensure consistency in the interviewing. The Child Rearing knowledge test in Malayalam was in the form of Multiple Choice items. This was given to them and the questions were read to them on a one to one basis. They were requested to select the best choices. Enough time was given to each person. This increased the clarity that they could see and hear the questions and choices. The correct answers were told to each one of them after the completion of the knowledge test and doubts were clarified. This was done for all the women irrespective of intervention, control or comparison group. The weight and height of the women were measured using standard height and weight recording machine.
3.24.1 Exposure to intervention

The enrolled subjects were given one booklet each. The SIM/alternate booklets on epilepsy were assigned random numbers (1-100) and were arranged serially as described in 3.13. Each enrolled women with epilepsy were randomly assigned after the first interview to receive either the self instructional module (intervention group \( N = 50 \)) or alternate booklet (control group \( N = 50 \)). The booklets were taken out serially from the top starting with number 1. The first enrolled woman received book number 1 and the last woman received book number 100. All the women with epilepsy have received one booklet either the self-instructional module prepared by the Investigator or the alternate booklet on epilepsy, which was already available in the Department of Neurology. The investigator instructed them to read the booklet after reaching home, taking their own time and to contact through telephone in case of doubts, at any time. A contact address card with telephone number was given to each sample for any clarification and to inform their progress in pregnancy. Enrolling of participants continued until 100 samples were completed. This extended from April 2003 to April 2005 for both the groups. The first interview took an average of about 25 minutes.

3.24.2. Follow up visits

Two more follow up interviews were held for the enrolled subjects, one during the last trimester and the last one three to four months post partum when the baby was three to four months old. The second interview, which took place in the third trimester, took an average of five minutes and the post partum interview took an average of 30 minutes. The antenatal data of women who could not be interviewed during third trimester were collected during the post partum visit. These interviews were conducted either at the hospital, or their homes. Majority of the women with epilepsy were followed up in the Kerala Registry of Epilepsy and Pregnancy (KREP) while majority of the women
without epilepsy were followed up in their homes. Nonrespondents were followed up by mailed questionnaire following a telephonic interview and personal request. Five WWE and two WWoE were followed up in this manner. This was made possible due to the trust developed during the first in-person interview. Failure to respond even after telephonic/postal reminders was considered as 'non-response'. There were three nonrespondents among WWE and two nonrespondents among the WWoE group (See Flow charts 3.2 and 3.3 in the chapter 3).

Phase III of the study started with the third interview of the first subject in March 2004 and ended with the last subject in April 2006. During the third interview, at three to four months postpartum, the mothers were interviewed to assess the mother and baby outcome. The Child Rearing Knowledge test was repeated The Child Rearing Practice Scale was used to measure child rearing practice score. The weight of the baby was checked using a standard pediatric weighing machine. The 11-point Visual Analogue Scale on ladder on child rearing capability was shown to the mother to indicate their overall child rearing capability. Maternal behaviour in caring the baby was observed using the observation checklist. The WWE were also asked matters related to seizure control, drug compliance and also the utility of the SIM/alternate booklet on epilepsy. The data collected were cross-validated with the available medical records. This increased the credibility of data.

3.25. Data management

The data collected on interview were recorded on forms and entered in a database to a personal laptop.

3.26. Data Quality

The data were counterchecked for errors with data stored in the KREP records as well as medical records available with the enrolled women.
3.27. Plan of analysis

Data was entered in a database, which was transferred to Microsoft Excel and analyzed using SPSS for Windows version 14.0. For statistical comparisons, Chi-square tests and t-tests were done.

3.28. Summary

This chapter included the research problem, objectives, and various methodological aspects used to achieve the objectives. The significance of the study design selected in answering the research problem, the need to prepare validated reliable tools for the study and the methods adopted were discussed. The procedure for randomization of the WWE into intervention and control group, the double blind nature of the study and the difficulties encountered in getting age, education and parity matched pairs of comparison group of WWoE were explained. The strength of the study was its prospective nature, wherein the data collection extended over a period of three years. The time spent for this was worth since more than 97% of the 193 pregnant women could be followed, each after 1-year, over a period 3 years. Missing samples were only five, three WWE and two WWoE.