CHAPTER III

METHODOLOGY

3.1 RESEARCH DESIGN

The research design adopted was randomized controlled trial. The aim of the study was to determine the effectiveness of an epilepsy education program on Knowledge, Self management and Quality of Life among patients with epilepsy.

Table 1. Schematic representation of the research design

<table>
<thead>
<tr>
<th>Group</th>
<th>Pre-test</th>
<th>Intervention</th>
<th>First reinforcement</th>
<th>Posttest I</th>
<th>Second reinforcement</th>
<th>Posttest II</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1st day</td>
<td>15th day</td>
<td>45th day</td>
<td>90th day</td>
<td>135th day</td>
<td>180th day</td>
</tr>
<tr>
<td>Study</td>
<td>O₁</td>
<td>X°</td>
<td>√</td>
<td>O₂</td>
<td>√</td>
<td>O₃</td>
</tr>
<tr>
<td>Control</td>
<td>O₁</td>
<td>*</td>
<td>*</td>
<td>O₂</td>
<td>*</td>
<td>O₃°</td>
</tr>
</tbody>
</table>

Key

R : Randomization of patients with epilepsy to the study and control groups

* : Routine care including medications and follow up at the Neurology OPD of Sri Ramachandra Hospital received by PWE both in the study and control groups throughout the study.

O₁ : Pretest on Knowledge, Self management and Quality of Life on the first day
X : Intervention-Epilepsy Education Programme

° : Issue of booklet to PWE in the study group on the 15\textsuperscript{th} day and for the control group on the 180\textsuperscript{th} day after the second posttest.

√ : Reinforcement and clarification of the teaching on epilepsy was carried out on the 45\textsuperscript{th} day and again on the 135\textsuperscript{th} day for the study group after telephonic reminders.

O\textsubscript{2} : First posttest on the 90\textsuperscript{th} day for both the study and control groups on Knowledge, Self-management and Quality of Life.

O\textsubscript{3} : Second posttest on the 180\textsuperscript{th} day for both the study and control group on Knowledge, Self-management and Quality of Life.

3.1.1 INTERVENTION

Based on the inclusion criteria the subjects were randomly assigned to either the study or control groups.

The patients in the study and control groups were assessed for their Knowledge, Self management and Quality of Life on the first day. On the 15\textsuperscript{th} day the study group received the Epilepsy Education Program that included explanation, discussion and clarification about epilepsy, causes, stages of a seizure, family’s role, common diagnostic measures, medications and their effects, foods to be included facts about epilepsy, activities that a person can do and the activities that are to be avoided, special consideration in women using the epilepsy information booklet which was later handed over to the patients. The session lasted for about 25 minutes. Group teaching was given for a group of 3 to 5 patients. The first reinforcement was
given on the 45\textsuperscript{th} day along with clarification of individual patient’s doubts, following which the posttest I was done on the 90\textsuperscript{th} day for both the groups.

After the first posttest the \textbf{second reinforcement} was given on the 135\textsuperscript{th} day along with the routine care that included check-up and medications. Follow-up was encouraged by telephonic reminders. The posttest II was carried out on the 180\textsuperscript{th} day for both the study group and control groups.

Both the study group and control group patients received the seizure diary every month and were asked to note the occurrence of seizures, missed medication, menstrual cycle for women, headache or stress, food allergies, alcohol intake and any specific factors that was felt by the PWE as triggers that could be associated with the episode of a seizure. The time of occurrence of seizures were also asked to be noted along with the help of the family members. During each visit the patients were reinforced to maintain the seizure diary.

\textbf{3.1.2 CONTROL}

Patients with epilepsy who attended the neurology OPD were randomly assigned to the control group. They received the routine care which included regular consultations and medications from the physician. The pretest, posttest I and II were carried out for the control group. Instructions were given to the control group on maintenance of the seizure diary which was collected from them every month. After the posttest II they received epilepsy education and the Epilepsy Information Booklet.
3.1.3 RANDOMIZATION

Informed written consent was obtained and patients were randomly assigned to the study and control groups based on the computer generated random allocation list (Appendix-C).

3.2 VARIABLES OF THE STUDY

Independent variable

The independent variable in this study was the Epilepsy Education Programme.

Dependent variable

The dependent variables in this study were the Knowledge, Self-management and Quality of Life.

3.3 SETTING

The study was conducted at the Neurology OPD of Sri Ramachandra Hospital. On an average the number of patients attending the neurology OPD ranges from 60 to 80, out of which there are 8 to 10 PWE and 1-2 newly diagnosed PWE.

3.4 POPULATION

The target population were patients with epilepsy.
3.5  SAMPLE

Patients with epilepsy attending the Neurology OPD of Sri Ramachandra Hospital who fulfilled the inclusion criteria and gave their acceptance to the informed written consent were included in the study group and control group respectively.

3.6  SAMPLE SIZE

The calculated sample size on the basis of power analysis

- Power 80%
- Sample size 350
- Study group 175
- Control group 175

Table 2. Sample size during the study

<table>
<thead>
<tr>
<th>Study duration</th>
<th>Attrition</th>
<th>Sample size</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Study group</td>
<td>Control group</td>
</tr>
<tr>
<td>No.</td>
<td>Reason</td>
<td>No.</td>
</tr>
<tr>
<td>Pretest</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Posttest I</td>
<td>4</td>
<td>2 outstation 2 irregular follow-up</td>
</tr>
<tr>
<td>Posttest II</td>
<td>2</td>
<td>outstation</td>
</tr>
</tbody>
</table>
The attrition at 90\textsuperscript{th} day for the study group was found to be 4, 2 PWE reported later as they had gone outstation and so were not included and 2 had irregular follow up. In the control group 6 PWE had irregular follow up and hence had to be excluded. On the 180\textsuperscript{th} day 2 PWE in the study group had gone outstation and 2 in the control group of which one did not come due to marriage and another had irregular follow up were excluded. The sample size on the 180\textsuperscript{th} day during Posttest II was 169 for the study group and 167 for the control group.

3.7 SAMPLING CRITERIA

Inclusion criteria

- At least one seizure during the last six months
- Age 21-60 years
- Both gender
- Able to understand and respond to questions in English or Tamil
- Regular follow up at SRH
- Willing to participate

Exclusion criteria

- Cognitive impairment
- Cerebral infections/tumors
- Pregnant women
3.8  SAMPLING TECHNIQUE

Samples were allotted to the study and control groups randomly (Appendix-C)

3.9  DESCRIPTION OF THE TOOL AND RELIABILITY

The tool consists of two parts

Part I:

A.  Demographic variables

This includes variables as age, gender, education, occupation, monthly family income, residence, marital status and type of family.

B.  Social variables

Caregivers relationship, dependence and medical expense management

C.  Clinical variables

Age at onset of epilepsy, duration of epilepsy were obtained from patients response and type of epilepsy as obtained from the patient records. The time of occurrence of seizures was obtained from the patients response.

Part II:

A. Epilepsy Knowledge Scale

The scale consists of two parts with a total of 19 questions. It was developed by Theodor W. May and Margaret Pfafflin and was used in the MOSES trial (2002). The questions are on work that can be done, activities, diagnostic test for epilepsy,
medications, symptoms, job, and sports, if epilepsy is associated with mental illness and driving related questions. Each question has three choices namely yes, no and do not know. The right answer has a score of 1 and the wrong answer has no score, the do not know option is for those individuals who are ambiguous about the answer. (Appendix –E).

**Scoring**

The total score is 19 and for identifying the level of knowledge the scale score was graded into

- Inadequate : <50 %
- Moderately adequate : 51-75 %
- Adequate : >75 %

**Reliability**

The reliability of the tool was determined by the test-retest method and was found to be $r = 0.72$.

**B. Epilepsy Self-management Scale (ESMS)**

This scale was developed by DiIorio et al. (2004) It has got 38 items divided under five components as

- Information management : 8
- Medication management : 10
- Safety management : 8
Seizure management : 6
Lifestyle Management : 6

Score interpretation

Each item is rated on a five point rating scale with never being 1, rarely 2, sometimes 3, most of the time 4 and always 5. There were twelve negatively worded items for which the score was taken by reverse coding, and then the total score was obtained. The total score ranged from 38 to 190. The higher the score the better the self-management. The average score/ mean is taken for each component as Information management was totaled and divided by the number of items, this gave the mean score. Similarly the mean score for each component was calculated. The mean score of the whole scale was obtained by the sum of all items divided by the total number of items (Appendix F).

Reliability

The reliability of the scale was determined by the test-retest method. The reliability value obtained was $r = 0.81$.

C. Quality of Life in Epilepsy 31

The QoLIE 31 has 31 items. It is a rating scale and the scores range from 0-100. It has the following components:

Seizure Worry 5
Overall Quality of Life 2
Emotional Wellbeing 5
Energy/ Fatigue 4
Cognitive functioning 6
Medication Effects 5
Social functioning 3

The scoring manual gave the scoring for each item which ranged from 0, 20, 40, 60, 80, 100 and the total was taken and divided by the number of items. The total of all items were taken and checked with the profile sheet and the TQoL was arrived at for each subject. The higher score indicated a better QoL (Appendix G).

Reliability

The reliability determined by the test retest method was found to be .77.

D. Seizure Diary

This is a monthly diary maintained by the patient by self or with the help of the caregiver. The seizure diary had the following components as days of the month against which the patient places a tick (✓) for day time or night time seizures along with any specific triggers identified. The total number of seizures as reported by the patients each month was taken into account up to the 180th day (Appendix H).

3.10 VALIDITY

The content validity of the tools was obtained from the international and the national experts in Neurology and Nursing (Appendix-I).
3.11 TRANSLATION OF THE TOOL

The tools were translated from English to Tamil version by language experts and it was back translated. The reliability of the translated version was also determined (Appendix K).

3.12 PILOT STUDY

The pilot study was conducted at the neurology OPD of Sri Ramachandra Hospital. 30 PWE were selected and 15 were assigned randomly to the study group and 15 to the control group respectively. The data were analyzed and the findings showed that it was feasible to conduct the main study.

3.13 DATA COLLECTION PROCEDURE

Ethical permission was obtained for the study (Appendix-A). After obtaining approval from the ethics committee, permission was obtained from the Head of the department of Neurology to collect the data from the PWE attending the neurology OPD at Sri Ramachandra Hospital.

The randomization list was prepared to allocate the patients to either the study or the control groups.

The investigator introduced self to the PWE and explained the procedure; an informed written consent was obtained from the PWE willing to participate in the study after identifying their fit into the inclusion criteria. Data were collected during the OPD hours from 9.00 a.m to 12.30 p.m every day. On the first day following the routine consultation the PWE were assessed for the pretest on Knowledge, Self management and Quality of Life, if the patients were able to read and understand they were asked to mark their responses, for those PWE who had difficulty in understanding how to score explanation was provided and their response was
obtained for each item. The Knowledge scale has 19 items and has only three response as yes, no and do not know. The Self-management scale has 38 items on a 5 point rating scale. The Quality of Life in Epilepsy 31 has 31 items. The responses were obtained for all the items.

After the pretest when the PWE came for their follow-up visit on the 15th day the Epilepsy Education Programme which included explanation, discussion and clarification about the nature of illness and Self-management using epilepsy information booklet (EIB) was taught for a group of 3-5 patients. The duration of teaching was for about 25 minutes as the attention span of an average individual is found to be 20 minutes more so with PWE since the effect of medication as drowsiness and cognitive functions have to be taken into account. Questions were answered after the teaching for 10 to 15 minutes based on the individual patients doubts. Following the teaching the EIB was handed over to the study group participants.

The monthly seizure diary was handed over to the patients both in the study and control groups with instructions as how to mark the occurrence of seizures: night time / day time with the help of their family members, any specific triggers identified as missed medication, sleeplessness, stress, headache, food allergies, menstrual cycle, alcohol intake and any other factors that could be identified by the patients. They were asked to bring the seizure diary after a month to identify the changes if any.

The study and control group participants received telephonic reminders and the first reinforcement was given to the study group on what was taught in the EIB and also specific patient queries related to medication and management were answered. The first reinforcement was carried out on the 45th day during that time the seizure diary was collected from them. The control group received the routine care.
The posttest I on Knowledge, Self-management and Quality of Life was conducted on the 90th day for both the study and control groups which included assessment of the Knowledge, Self-management and the Quality of Life. The seizure diary was collected for both the groups at the end of each month.

The second reinforcement was carried out for the study group on the 135th day and the control group received routine care.

The posttest II on Knowledge, Self management and Quality of Life was carried out for both the study and control groups on the 180th day. The PWE in the control group received the education and the EIB at the end of the posttest II.
Figure 2: DATA COLLECTION PROCEDURE

STUDY GROUP
1st day  
n=175

15th day  
INTERVENTION  
Epilepsy Education Program

45th day: I  
reinforcement

90th day (n=171)  
Attrition: 4  
(2 outstation  
2 irregular follow-up)

135th day: II  
reinforcement

180th day  
(n=169)  
Attrition: 2 outstation

Control Group
1st day  
n=175

15th day  
Routine Care

Pretest  
Knowledge, Self-management  
& Quality of Life

Posttest I  
Knowledge, Self-management,  
& Quality of Life

90th day (n=169)  
Attrition: 6  
(irregular follow-up)

Posttest II  
Knowledge, Self-management  
& Quality of Life

180th day (n=167)  
Attrition: 2  
(1 marriage  
1 irregular follow-up)  
Information booklet on epilepsy
3.14 STATISTICAL METHODS USED

The statistical methods used were descriptive and inferential statistics.

Descriptive statistics as frequency, percentage were used for demographic variables as age, gender, education, occupation, monthly income, marital status, type of family, accompanied by caregiver; social variables as caregiver relationship, dependence, medical expenses taken care of by; clinical variables as age at onset, duration of epilepsy, type of epilepsy, and time of occurrence of seizures.

Frequency, percentage, mean and standard deviation was used for Knowledge, Self-management and Quality of Life.

Homogeneity of the samples was identified by the chi-square test.

Paired ‘t’ test for within groups and independent ‘t’ test and RMANOVA for between groups comparison of Knowledge, Self-management and Quality of Life.

Stratified analysis was done to compare the level of Knowledge, Self-management and Quality of Life with that of the type of epilepsy.

Pearsons correlation, Chi- Square and ANOVA were used for analysis.
Table 3. Statistical methods used in the study

<table>
<thead>
<tr>
<th>Statistics</th>
<th>Type</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Descriptive</td>
<td>Frequency</td>
<td>Background variables</td>
</tr>
<tr>
<td></td>
<td>Percentage</td>
<td>Knowledge, Self-management and Quality of Life.</td>
</tr>
<tr>
<td></td>
<td>Mean</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Standard deviation</td>
<td></td>
</tr>
<tr>
<td>Inferential</td>
<td>Paired ‘t’ test</td>
<td>Within groups Knowledge, Self-management and Quality of Life.</td>
</tr>
<tr>
<td></td>
<td>Independent ‘t’ test</td>
<td>Comparison of Knowledge, Self-management and Quality of Life between groups and at different points of time.</td>
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<td></td>
<td>RMANOVA</td>
<td></td>
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<tr>
<td></td>
<td>Pearson’s correlation</td>
<td>Relationship between Knowledge, Self-management and Quality of Life</td>
</tr>
<tr>
<td></td>
<td>Chi- square and ANOVA</td>
<td>Association between Knowledge, Self-management, Quality of Life and selected background variables.</td>
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</tbody>
</table>