CHAPTER III

METHODOLOGY

3.1 RESEARCH DESIGN

A quantitative research method was used to determine the effectiveness of Comprehensive Stroke Education Program on knowledge and quality of life among patients with stroke and knowledge and burden among caregivers by adopting randomized controlled trial.

<table>
<thead>
<tr>
<th>Group</th>
<th>Pretest</th>
<th>Intervention(S)</th>
<th>Posttest</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>I</td>
</tr>
<tr>
<td>Study</td>
<td>(O_1 + O_1)</td>
<td>*X ()</td>
<td>(O_2 + O_2) () (O_3 + O_3) () (O_4 + O_4)</td>
</tr>
<tr>
<td>Control</td>
<td>(O_1 + O_1)</td>
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<td>(O_2 + O_2) () (O_3 + O_3) () (\sqrt{O_4 + O_4})</td>
</tr>
</tbody>
</table>

**Key**

\(R\) : Randomization

\(O_1\) (patient) : Assessment of knowledge on stroke, ADL and generic quality of life as a pretest measure

\(O_1\) (caregiver) : Assessment of knowledge on stroke as a pretest measure
<table>
<thead>
<tr>
<th></th>
<th>Routine care</th>
<th><strong>Comprehensive Stroke Education Program</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>O₂ (patient)</td>
<td>First posttest assessment of knowledge on stroke, ADL, generic and disease specific quality of life on 30(^{th}) day after the discharge</td>
<td></td>
</tr>
<tr>
<td>O₂ (caregiver):</td>
<td>First posttest assessment of knowledge on stroke and burden among caregiver on 30(^{th}) day after the discharge of the patient</td>
<td></td>
</tr>
<tr>
<td>O₃ (patient) :</td>
<td>Second posttest assessment of knowledge on stroke, ADL, generic and disease specific quality of life on 90(^{th}) day after the discharge</td>
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<tr>
<td>O₃ (caregiver):</td>
<td>Second posttest assessment of knowledge on stroke and burden among caregiver on 90(^{th}) day after the discharge of the patient</td>
<td></td>
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<tr>
<td>O₄ (patient) :</td>
<td>Third posttest assessment of knowledge on stroke, ADL, generic and disease specific quality of life on 180(^{th}) day after the discharge</td>
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<tr>
<td>O₄ (caregiver) :</td>
<td>Third posttest assessment of knowledge on stroke and burden among caregiver on 180(^{th}) day after the discharge of the patient</td>
<td></td>
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<td>✓</td>
<td>Issue of booklet to control group dyads</td>
<td></td>
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</tbody>
</table>
3.1.1 **Intervention**

Intervention refers to the Comprehensive Stroke Education Program that was provided by the investigator to the patients with stroke and their caregivers in the study group apart from the routine care. Laptop assisted teaching by lecture method was used to teach the dyads (patient + caregiver) on one to one basis. The teaching module prepared by the investigator and validated by the experts was used to teach the study participants. It consisted of a 40 minute inpatient teaching session each day for three consecutive days for the patients with stroke and their caregivers which included,

**Day 1**: Lecture on structure and function of the brain and general information on stroke and its management. The content included were stroke definition, cause, risk factors, warning signs, investigations, adherence to medication and collaborative management of stroke.

**Day 2**: Lecture on managing swallowing problems, bowel and bladder problems, memory problems, speech and vision problems, prevention of complications such as pressure sore, injury to affected limbs, fall prevention, swelling of affected limbs, post stroke depression and tips for caregivers which was tailored to the needs of the individual patients.

**Day 3**: Lecture on assisting with the personal activities of daily living (bathing, toileting, grooming and feeding), performance of range of joint movement (ROJM) exercise on the patient that included possible movement of shoulder, wrist, elbow, hip, knee and ankle joint followed by performance by the caregiver on the
patient was carried out which improved the confidence of caregiver to work out with joints.

Booklet on “Life after stroke” was provided for the study group participants on the day of discharge and it contained the information on components of Comprehensive Stroke Education Program. Telephone call was made once in every fortnight after the discharge from the hospital till the 180th day, for regular follow up and adherence to medication.

Reinforcement was carried out as a part of CSEP to the dyads following posttest-I and II by the investigator which was tailored to the need of the individual patients.

3.1.2 Control

The patients and their caregivers in the control group received routine care given by the doctors, nurses and other paramedical personnel in the health care facility. Immediately after posttest III the investigator offered the same booklet on “Life after stroke” to the control group dyads. The data obtained from the control group were utilized to compare with the data of the study group; the effectiveness of CSEP was evaluated. The presence of control group also helped the investigator to overcome the extraneous variables.

3.1.3 Randomization

Patients who were diagnosed to have ischemic and hemorrhagic stroke based on CT- scan findings with mRS (modified Rankin Scale) grade 1 - 4, which
indicates mild to moderate disability after stroke were considered as stroke. A simple random sampling by using a lottery method was adopted to assign the group. Samples were randomly assigned in the presence of the caregivers to the study group or to the control group. Equal number of lots (85 chits for the study group and 85 chits for the control group) were made and kept in a box. Patients and their caregivers who fulfilled the inclusion criteria were allowed to pick their lots from the box. Based on the lot, 85 patients and their caregivers were assigned to the study group and 85 patients and their caregivers were assigned to the control group.

3.2 VARIABLES OF THE STUDY

3.2.1 Independent variable

The independent variable in this study was Comprehensive Stroke Education Program

3.2.2 Dependent variable

The dependent variables in this study were knowledge on stroke, ADL, generic and disease specific quality of life and level of burden.

3.3 SETTING

This study was conducted at Sri Ramachandra Medical Centre (SRMC), Porur, Chennai- 600 116. It is a 1675 bedded multi specialty hospital. The pretest was conducted in neurology wards and the posttest was conducted at neurology OPD of SRMC.
3.4 POPULATION

The accessible population for the study was patients who had stroke and their caregiver admitted in Sri Ramachandra Medical Centre. The target population for the study was patients who were diagnosed to have ischemic and hemorrhagic stroke based on CT-scan findings with mRS (modified Rankin Scale) grade 1-4 score, which indicates mild to moderate disability after stroke were considered as stroke victims and their caregivers at Sri Ramachandra Medical Centre, Porur, Chennai- 116 during the period of data collection.

3.5 SAMPLE

Patients who were diagnosed to have ischemic and hemorrhagic stroke as per CT-scan findings with mRS (modified Rankin Scale) grade 1-4 score and who fulfilled the inclusion criteria were selected. The total number of sample was 170 dyads in that 85 dyads in the study group and 85 dyads in the control group were recruited as samples by lottery method. Informed consent was obtained from the dyads from both the groups.

3.6 SAMPLE SIZE AND ATTRITION

The sample size was 170 dyads (170 patients & 170 caregivers) which was equally divided in to the study group ($n_1 = 85$ patients and $n_2 = 85$ caregivers) and the control group ($n_1 = 85$ patients and $n_2 = 85$ caregivers). Using power analysis, the sample size was estimated as 75 for each group (total = 150), to achieve 80% power at a 5% level of significance, Considering the chance of attrition, an
increase of 10% was done and the obtained value was rounded to 170. 170 patients and 170 caregivers were included for this study.

Table 3.2  Sample size at various duration of the study

<table>
<thead>
<tr>
<th>Duration of the study</th>
<th>Attrition</th>
<th>Sample size</th>
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<tbody>
<tr>
<td></td>
<td>Study group (85 dyads)</td>
<td>Control group (85 dyads)</td>
</tr>
<tr>
<td></td>
<td>Patient (n₁ = 85)</td>
<td>Caregiver (n₂ = 85)</td>
</tr>
<tr>
<td>Pretest</td>
<td>- -</td>
<td>- -</td>
</tr>
<tr>
<td>Posttest-I</td>
<td>- -</td>
<td>2 (family commitment)</td>
</tr>
<tr>
<td>Posttest-II</td>
<td>- 2 (family commitment)</td>
<td>-</td>
</tr>
<tr>
<td>Posttest-III</td>
<td>4 (2-readmission 1-no response 1-financial burden)</td>
<td>4</td>
</tr>
</tbody>
</table>

At 90th day, during posttest-II two caregivers from study group and two caregivers from control group did not accompany the patients for the follow up visit due to their family commitment; because of this reason they were excluded from the study. At 180th day during posttest-III in study group two subjects got readmitted, one did not respond to calls and one did not come for follow-up due to financial burden; due to these reasons they were excluded as dyads. At 180th day during posttest-III in control group three subjects got readmitted, one did not respond to calls and one did not come for follow-up due to financial burden due to these reasons they were excluded as dyads. Totally at the end of posttest-III 81 patients
and 79 caregivers were followed up whereas in control group 80 patients and 78 caregivers were assessed.

3.7 SAMPLING CRITERIA

3.7.1 For the patient - Inclusion criteria

Patients who were

1. Between the age of 30 to 60 years
2. Both male and female
3. Modified Rankin grade of 1-4
4. Conscious, alert and oriented to time, place and person
5. Accompanied by caregiver
6. Able to speak either Tamil and/or English

3.7.2 For the patient - Exclusion criteria

Patients who were

1. Not willing to participate
2. Having problems with communication other than stuttering
3. Diagnosed to have complete blindness

3.7.3 For the caregivers - Inclusion criteria

Caregivers who were

1. Between the age of 20 to 65 years
2. Both male and female
3. Able to meet their ADL on their own
4. Willing to provide care to the patient after the discharge till 180 days and above
5. Able to speak Tamil &/or English
3.7.4 For the caregivers - Exclusion criteria

1. Not willing to participate as dyad

3.8 DESCRIPTION OF THE INSTRUMENT

Section I: It consisted of three parts.

Part A: Demographic variables of the patient: It consisted of patient age, gender, education, occupation, marital status, residence, monthly income and type of family.

Part B: Clinical variables of the patient: It consisted of risk factors of stroke, subtype of stroke and neurological deficit.

Part C: Background variables of the caregivers: It consisted of age, gender, education, occupation, marital status and relationship with the patient and prior experience as caregiver.

Section II: Comprehensive stroke education program outcome which consist of five parts

Part A: Stroke Knowledge Test (SKT)

It was developed by Karen Sullivan & Natalie Dunton (2001) which has 20 multiple choice each question had four choices out of which only one was the correct answer. SKT consisted of questions regarding risk factors, signs and symptoms and management of stroke. The responses were elicited by the investigator.
i. **Scoring and interpretation**

Maximum score is 20 and minimum score is zero. The correct responses were coded as 1 and incorrect as ‘0’. According to the score it was interpreted as 0-9 inadequate knowledge, 10 - 15 moderately adequate knowledge, and 16 - 20 adequate knowledge.

ii. **Reliability**

The reliability of the tool was established by test - retest method and the obtained reliability value for SKT was $r = 0.83$.

**Part B: Barthel Index (BI)**

The Barthel Index (BI) was first introduced by Mahoney and Barthel (1965). It consisted of 10 items that measured a person's activities of daily living and mobility. The items included feeding, moving from wheelchair to bed and return, grooming, transferring to and from a toilet, bathing, walking on level surface, going up and down stairs, dressing, continence of bowels and bladder. The scores for each of the items are summed to create a total score.

i. **Scoring and Interpretation**

Total of 10 activities are scored, and the values are then added to give a total score ranging from 0 (totally dependent) to 100 (completely independent). Lower scores indicate greater dependency. The BI can be interpreted as follows:
- Score of 80 - 100, independent
- Score of 60 - 79, need minimal help with ADL
- Score of 40 - 59, partially dependent
- Score of 20 - 39, very dependent
- Score of < 20, totally dependent.

ii. Reliability

Calculated inter-rater reliability coefficient score was $r = 0.89$.

Part C: Short form 36 V2 Questionnaire

SF 36 V2 is used to assess the generic quality of life of the patients. It was measured and standardized by John, E. Ware, et al. (2000). The SF-36 is a multipurpose, short form health survey with only 36 questions. It yields an 8-scale profile of functional health and well-being scores as well as psychometrically based health utility index. The reliability of the eight scale and two summary measures have been estimated using both internal consistency and test-retest methods.

It is a self-reported measure scale comprising of 36 items in a 5 point Likert scale. It measures the ability to function and complete everyday activities, including physical activities and social activities.

The SF-36 is a generic multidimensional instrument consisting of eight multi-item components representing,
1. Physical functioning (PF; the extent to which health limits physical activities, such as self-care, walking, climbing stairs)

2. Role functioning-physical (RP; the extent to which physical health interferes with work or other daily activities)

3. Bodily pain (BP the intensity of pain and the effect of pain on normal work, both inside and outside the home)

4. General health perceptions (GH; personal evaluations of current health, health outlook and resistance to illness)

5. Vitality (VT; feeling full of energy rather than tired and worn out)

6. Social functioning (SF; the extent to which physical health or emotional problems interfere with normal social activities)

7. Role functioning-emotional (RE; the extent to which emotional problems interfere with work or daily activities); and

8. Mental health (MH; general health including depression, anxiety, behavioral- emotional control and general positive affect).

i. Scoring and Interpretation

Physical component summary includes physical functioning, role physical, body pain, and general health. Mental component summary includes vitality, social functioning, and role emotional and mental health. SF-36 V2 scores were converted to a scale of 0 to 100; a higher score indicating a better quality of life and lower score indicates poor quality of life.
ii. Reliability

Reliability estimated for physical and mental summary score was $r = 0.90$.

Part D: SSQOL (Stroke Specific Quality of Life)

The Stroke Specific Quality Of Life scale (SSQOL) is a patient-centered outcome measure intended to provide an assessment of health-related quality of life specific to patients with stroke. The SSQOL was published and validated in 1999 by Williams, Weinberger, Harris, and Clark. It is a self-report scale containing 49 items in 12 domains: mobility (6 items), energy (3 items), upper extremity function (5 items), work/productivity (3 items), mood (5 items), self-care (5 items), social roles (5 items), family roles (3 items), vision (3 items), language (5 items), thinking (3 items), and personality (3 items). It takes approximately 10-15 minutes to complete the SSQOL scale. Each item shall be scored in a five point Likert scale.

i. Scoring and Interpretation

The scoring is as follows, strongly agree-5, moderately agree-4, neither agree nor disagree-3, moderately disagree -2, strongly disagree-1.

Higher scores indicate better functioning. The SSQOL yields both domain scores and an overall SSQOL summary score.

ii. Reliability

Using test retest method, the reliability of the tool was estimated. The obtained reliability value for SS-QOL was $r = 0.87$. 
Part E: Burden Assessment Scale (BAS)

It is used to calculate the burden experienced by caregivers caring for a loved one. It was developed by Rhonda J.V. Montgomery and it has 22 items related to feelings regarding caring for relative, sense of responsibility, feelings due to impairment and relationship with family and friends in a five point Likert scale.

i. Scoring and Interpretation

Each item is self-reported and scored as never - 0, rarely - 1, sometimes - 2, frequently - 3 and always - 4. Minimum score is ‘0’ and maximum score 88 which is interpreted as 0 - 20 no or minimal burden, 21 - 40 mild to moderate burden, 41 - 60 moderate to severe burden, 61- 88 severe burden.

ii. Reliability

The reliability of the tool was calculated by inter-rater assessment and it was found to be 0.84.

3.9 VALIDITY

The content validity of the tools (Appendix G, Page No. xi) was obtained from international and national experts from the fields of Nursing and Neurology (Appendix H, Page No. xii).
3.10 PILOT STUDY

Permission from the Head of the Department, Department of Neurology of SRMC was obtained to conduct the study. Informed consent from the patients with stroke and their caregivers was obtained to include in the study. A total of 30 dyads were selected randomly in neurology ward of SRMC and the subjects were assigned randomly by lottery method to the study (n =15 patients, n =15 caregivers) and control groups (n =15 patients, n =15 caregivers). The obtained data were analyzed and the findings ensured the feasibility to conduct the main study.

3.11 DATA COLLECTION PROCEDURE

The study proposal was presented to ethical committee, SRU and was approved (Appendix A, Page No. i). Then permission was obtained from the Head of the Department, Department of Neurology, SRMC, Porur, Chennai- 600 116.

The dyads who fulfilled inclusion criteria were selected by lottery method. Samples were randomly assigned in the presence of the caregivers to the study group or to the control group. Equal number of lots (85 chits for the study group and 85 chits for the control group) were made and kept in a box. Dyads were allowed to pick their lots from the box. Based on the lot, 85 patients and their caregivers were assigned to the study group and 85 patients and their caregivers were assigned to the control group. Throughout the study period (from March 2009
to January 2010) totally 345 patients were assessed for eligibility out of which only 170 dyads who fulfilled the inclusion criteria were included to the study.

Informed consent was obtained from dyads after adequate explanation about the risk and benefits of the study from both the groups. Pretest assessment were taken which focused on demographic variables, clinical variables, knowledge on stroke, ADL and generic QoL using structured questionnaire for the patient and knowledge was assessed for the caregiver by the investigator for both the groups. Knowledge on stroke was assessed by using SKT which was developed by Karen Sullivan & Natalie Dunton (2001) which has 20 multiple choice questions to obtain information regarding risk factors, signs and symptoms and management of stroke. Knowledge on stroke for the dyads was assessed by using SKT. The Barthel Index (BI) was used to measure the patient’s activities of daily living and it was first introduced by Mahoney and Barthel (1965). It consists of 10 items which included feeding, moving from wheelchair to bed and return, grooming, transferring to and from a toilet, bathing, walking on level surface, going up and down the stairs, dressing, continence of bowels and bladder. Short Form - 36 V2 was used to assess the generic quality of life and it was standardized by John, E. Ware, et al. (2000). The SF-36 is a multipurpose, short form health survey with only 36 questions. It yields eight scale which are physical functioning, role functioning - physical, bodily pain, general health perceptions, vitality, social functioning, role functioning- emotional and mental health.
Following pretest, Comprehensive Stroke Education program was implemented to the study group dyads apart from the routine care by laptop assisted teaching by lecture and discussion methods on one to one basis. The teaching module prepared by the investigator and validated by the experts was used to teach the dyads. It consists of a 40 minute inpatient teaching session each day for three consecutive days for the patients with stroke and their caregivers which included,

**Day 1:** Lecture on structure and function of the brain and general information on stroke and its management. The content included were stroke definition, cause, risk factors, warning signs, investigations, adherence to medication and collaborative management of stroke.

**Day 2:** Lecture on managing swallowing problems, bowel and bladder problems, memory problems, speech and vision problems, prevention of complications such as pressure sore, injury to affected limbs, fall prevention, swelling of affected limbs, post stroke depression and tips for caregivers which were tailored to the needs of the individual patients.

**Day 3:** Lecture on assisting with personal activities of daily living (bathing, toileting, grooming and feeding), Performance of Range of joint movement (ROJM) exercise on the patient that included
possible movement of shoulder, wrist, elbow, hip, knee and ankle joint followed by performance by the caregiver on the patient was carried out which improved the confidence of caregiver to work out with joints.

Booklet on “Life after stroke” was provided for the study group participants on the day of discharge and it contained the information on components of Comprehensive Stroke Education Program. Telephone calls were made once in every fortnight till the 180th day after their discharge from the hospital for regular follow up and adherence to medication. Reinforcement was carried out as a part of CSEP following posttest-I and II by the investigator on CSEP which was tailored to the need of the individual patient.

Control group dyads received routine care given by the doctors, nurses and other health care personnel in the health care facility.

The investigative identified the study participants every day at registration counter of neurology OPD. The first posttest was conducted for both the groups on the 30th day after the discharge from the hospital, to assess the knowledge on stroke, ADL and generic and disease specific quality of life among patients and knowledge and burden among caregivers at Neurology OPD of SRMC. SSQOL was used to measure the disease specific quality of life which was developed by Williams, Weinberger, Harris, and Clark (1999). It has 49 items in 12 domains: mobility (6
items), energy (3 items), upper extremity function (5 items), work/productivity (3 items), mood (5 items), self-care (5 items), social roles (5 items), family roles (3 items), vision (3 items), language (5 items), thinking (3 items), and personality (3 items). Burden experienced by the caregivers was measured by using Burden Assessment Scale. It was developed by Rhonda, J.V. Montgomery and it has 22 items in a five point Likert scale. After Posttest-I reinforcement on CSEP was rendered to the study group dyad which was tailored to the need of the individual patient.

The second posttest was conducted for both the groups on the 90th day after the discharge from the hospital, to assess the knowledge on stroke, ADL and generic and disease specific quality of life among patients and knowledge and burden among caregivers at Neurology OPD of SRMC. After the Posttest-II reinforcement on CSEP were rendered to study group dyads which was tailored to the need of the individual patient.

The third posttest was conducted for both the groups on 180th day after the discharge from the hospital, to assess the knowledge on stroke, ADL and generic and disease specific quality of life among patients and knowledge and burden among caregivers at Neurology OPD of SRMC. Soon after the Posttest-III, the same booklet on ‘Life after stroke’ was issued to control group dyads.
The posttest was conducted $\pm$ five days from as an average from the expected day of post assessment of the dyads for all the participants. The investigator identified the study participants every day from the registration section of neurology OPD with the patient name and hospital admission number from the discharge summary.

Telephonic call was made to the study group participants for regular follow-up and adherence to medication once in every fortnight from the day of discharge till the 180th day of follow up.
Figure 3.1 Data collection procedure

* Laptop assisted teaching, booklet-‘Life after stroke’ & telephonic reminder once in every fortnight

** Reinforcement following posttest-I

*** Reinforcement following posttest-II

**** Issued booklet - ‘Life after stroke’ to control group dyads
3.12 STATISTICAL METHODS USED

The statistical package for the social sciences, version 17.0 was used to analyze the data of the present study. The statistical methods used to analyze the data of this study were descriptive and inferential. Descriptive statistics were frequency, percentage; mean and standard deviation were used to describe the study variables that included background variables (demographic, clinical and personal variables), Knowledge, ADL, quality of life and burden.

The presence of homogeneity between the study and control groups with relation to their background variables were determined by non-parametric Chi-square test. The effectiveness of CSEP on knowledge, ADL, quality of life and burden was calculated by inferential methods that include Paired t / Wilcoxon signed rank, Independent t / Mann Whitney and Repeated measures ANOVA tests. Paired t / Wilcoxon signed rank was used to compare the pretest data and posttest data within the groups. Independent t / Mann Whitney test was used to compare the data between the groups and repeated measure ANOVA test was carried out to study the effectiveness of CSEP on the dependent variables over a period of time by comparing the data between the groups.
Table 3.3  Statistical tests used for this study

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Method</th>
<th>Test</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Descriptive</td>
<td>Frequency, Percentage, Mean, SD</td>
<td>Assessment of the study variables</td>
</tr>
<tr>
<td>2</td>
<td>Inferential</td>
<td>Non parametric Chi-Square</td>
<td>Determination of homogeneity between groups and to associate the</td>
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<tr>
<td></td>
<td></td>
<td>Paried t / Wilcoxon signed rank</td>
<td>background variables with study variables</td>
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<tr>
<td></td>
<td></td>
<td>Independent t / Mann Whitney</td>
<td>Comparison of data between the groups</td>
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<tr>
<td></td>
<td></td>
<td>Repeated measures ANOVA</td>
<td>Comparison of data between the groups over a period of time</td>
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