CHAPTER - III
METHODOLOGY

This study was designed to determine the effectiveness of nurse-led cardiac rehabilitation on adherence and quality of life among patients with heart failure.

3.1. RESEARCH DESIGN

A quantitative research method was used to determine the effectiveness of nurse led cardiac rehabilitation on adherence and quality of life by adopting a true experimental research design.

<table>
<thead>
<tr>
<th>Group</th>
<th>Pretest measurement</th>
<th>Interventions</th>
<th>Posttest measurements after a study period of</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>1 month (Posttest-1)</td>
</tr>
<tr>
<td>Control Group</td>
<td>01</td>
<td>-</td>
<td>02</td>
</tr>
<tr>
<td>Study Group</td>
<td>01</td>
<td>X</td>
<td>02</td>
</tr>
</tbody>
</table>

Key:

01 : Pretest data on demographic variables, clinical variables, biological parameters, generic quality of life using SF 36 V2, disease specific health related quality of life using Minnesota
living with heart failure, adherence to cardiac rehabilitation using heart failure compliance scale and 6 minute walk test.

02 : Posttest-1 data on generic quality of life using SF 36 V2, disease specific quality of life using Minnesota living with heart failure, adherence to cardiac rehabilitation using heart failure compliance scale and 6 minute walk test one month after discharge.

03 : Posttest-2 data on generic quality of life using SF 36 V2, disease specific quality of life using Minnesota living with heart failure, adherence to cardiac rehabilitation using heart failure compliance scale and 6 minute walk test three months after discharge.

X : Interventions, the structured teaching on cardiac rehabilitation and book-let on “Healthy way to Healthy Heart” and telephone call for reinforcement on cardiac rehabilitation.

INTERVENTIONS

It is a process of providing series of instructions and information regarding cardiac rehabilitation which can be followed by the patient himself towards better outcome.

The structured teaching on cardiac rehabilitation was developed based on the review of literature, experts and investigators experience. The components of structured teaching on cardiac rehabilitation includes; general information on disease condition, diet, exercise, medication, home care instruction smoking
cessation, and lifestyle modification. Power point presentations were used to teach the patient on one to one basis in three different sessions by using a laptop.

Book-let on “Healthy way to Healthy Heart” was provided for the study group on the day of discharge and it contains the information on components of cardiac rehabilitation.

Telephone call was made for every fortnight once till three months after their discharge from the hospital to reinforce the importance of adherence to cardiac rehabilitation. The same book-let was provided for the control group after the posttest-2.

3.2. SETTING OF THE STUDY

This study was conducted at Sri Ramachandra Medical Center situated at Porur, Chennai. This Medical Center has a bed strength of 578 with various specialties like Cardiology, Neurology, Nephrology, Orthopaedics etc. The study was conducted in the Cardiology department which has various units like, Coronary care unit, Cardiothoracic ICU, Cardiology wards and Cardiac care centre. The cardiac wards such as E5, D5 where patients with heart failure were taken care and other cardiology special wards at Sri Ramachandra Medical Center was the setting for this study. The outpatient department of cardiac care centre of Sri Ramachandra Medical Centre receives between 1300-1500 patients per month for treatment and in which 300-400 patients were heart failure patients. The cardiac care center was the venue for collecting posttest-1 and posttest-2 data.
3.3. **POPULATION**

The target population for this study was adult patients diagnosed to have heart failure in Tamilnadu and the patients admitted in the Cardiology department at Sri Ramachandra Medical Centre with the diagnosis of heart failure during the period of data collection.

3.4. **SAMPLE**

The patients diagnosed to have chronic heart failure and have fulfilled the inclusion criteria during the data collection period were recruited for the study.

3.5. **SAMPLE SIZE**

A total of 200 patients with chronic heart failure admitted in the cardiology department at Sri Ramachandra Medical Centre were recruited for the study and randomly assigned to study group and control group equally.

3.6. **CRITERIA FOR SELECTION OF SAMPLE.**

3.6.1. **Inclusion Criteria**

1. Adult patients diagnosed to have chronic heart failure (Coronary artery disease, dilated cardiomyopathy and hypertensive heart disease).
2. Ejection fraction (EF) less than 40%
3. New York Heart Association classification (NYHA) of dyspnea grade II & III.
4. Male and female patients aged between 31 - 80 years.

3.6.2. **Exclusion Criteria**

1. Patients posted for cardiac surgery.

2. Patients with associated complications like arrhythmias, peripheral vascular disease, CVA, and end stage renal disease.

3. Patients connected with ventricular assistive devices.

4. Patients with known history of congenital heart disease.

3.7. **SAMPLING TECHNIQUE**

Probability sampling - Simple random sampling using lottery method was adopted to recruit the sample for this study. Samples were randomly assigned to study group or control group. Equal number of lots (100 chits for study group and 100 chits for the control group were made) and kept in a ballot box. The sealed cover containing lots were picked up from the box by the participants. Based on the lot 100 samples were assigned to study group and 100 samples were assigned to control group.

3.8. **DESCRIPTION OF TOOL**

The tool consists of three sections. (Appendix – F)
1. **SECTION - I**

It consists of items regarding background variables of patients with chronic heart failure. It has two parts,

**Part- A. Demographic variables**

It consists of variables such as age, gender, educational status, occupation, marital status, religion, residence, total family income, type of family and tobacco use.

**Part- B. Clinical variables**

It consists of duration of illness, diagnosis, NYHA, EF and co-morbid condition.

2. **SECTION - II**

It consists of questions related to adherence to cardiac rehabilitation; it has four parts such as,

**Part - A. Dutch knowledge on heart failure questionnaire.**

It was constructed and standardized by Martje, H.L.Van der wal, Tiny, Jaarsma,et al., (2003). The structured knowledge questionnaire consists of 15 multiple-choice items on aspects of heart failure for measuring the level of knowledge on heart failure concerning,

1. **Heart failure in general - 4 items**
2. Treatment for heart failure (diet, fluid restriction and activity) - 6 items


The Dutch knowledge on heart failure scale is a self-administered questionnaire. For each item, patient can choose from three options, with one of the options being the correct answer. The minimum possible score is 0 and maximum possible score is 15. Both the English and Tamil version of the tool were used for data collection.

**Scoring and Interpretation**

One score for each right answer and zero score for wrong answer was given. The total score was interpreted as

- Inadequate knowledge      -  0 to 9
- Moderately adequate knowledge - 10 to 12
- Adequate knowledge        - 13 to 15

**Reliability**

The reliability (Cronbach’s Alpha) of this scale was 0.7.

**Part -B. Modified heart failure compliance scale**

To assess the level of adherence, the modified heart failure compliance scale was used. Originally it was constructed and standardized by Martje, H.L.Van der wal., Tiny, Jaarsma., et al., (2003) with 30 items. It was modified by adding 10
more items by the investigator. The modified heart failure compliance scale has eight health behavior components such as, appointment-keeping, medication, sodium restriction, fluid restriction, daily weighing, exercise, smoking cessation and lifestyle modification.

The modified heart failure compliance scale is a self administered questionnaire. It consists of 40 items in a 5 point Likert scale. The tool was used to rate the difficulty in adherence to identify the barriers for adherence and the level of adherence for various health behaviour components. Patients were informed to state how important the health behavior was by using a 5-point scale ranging from,

0. Not at all important
1. Somewhat important
2. Important
3. Very important
4. Highly important

Subsequently, patients were asked to identify whether they had difficulty in complying with the health behavior. Adherence was measured on a 5-point Likert scale such as,

0. None of the time
1. Very seldom
2. About half of the time
3. Most of the time and
4. All of the time
Patients were asked to rate their compliance with the health behavior when they come for follow up to the hospital. Patients were asked to rate their level of difficulty in adherence to health behavior. It was measured on a four point scale,

0. No difficulty
1. A little difficulty
2. Moderate difficulty
3. A lot of difficulty

Patients were also asked to express the barriers for adherence to cardiac rehabilitation.

**Scoring and Interpretation**

Patients were grouped either adherent if they had been complying with health behaviour always/most of the time or non adherent if they had been complying with health behavior half of the time, seldom or never. Patients were considered overall adherent when they were compliant with 6 or more of the eight specific health behavior recommendations. Patients were considered non adherent when they were compliant with 5 or less of the eight specific recommendations.

**Reliability**

Test–retest reliability was evaluated. The intraclass correlation coefficient of the scale was 0.79.
Part -C. Six Minute Walk Test (ATS Statement, 2002)

Six minute walk test is one of the indicators of exercise capacity (ATS statement, 2002). Patients were asked to walk for 6 minute in a track. The track has 30 meter distance and the distance was measured using measuring tape. Every 3 meter distance was marked by red color adhesive tape. Again patients were asked to walk one month and 3 months after discharge during their follow up.

Scoring and Interpretation

Increase in walk-time and distance indicates improved exercise tolerance. Higher the exercise tolerance, better the cardiac functioning.

Reliability

Test-retest reliability at baseline (intraclass correlation coefficient [ICC] = 0.90).

Part- D. Biophysiological Parameters

Consist of body mass index, systolic and diastolic blood pressure, lipid profile such as LDL, HDL, Triglyceride, hemoglobin, random blood sugar, serum electrolytes such as sodium and potassium.

3. SECTION - III

It comprises of the following tools on Quality of life questionnaire
Part - A. Short form 36 V2 Questionnaire.

It was constructed and standardized by John, E. Ware. et al., (2000). The SF-36 is a multi-purpose, 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 physical and mental health summary measures and a preference based healthy utility index. The reliability of the eight scales and two summary measures has been estimated using both internal consistency and test retest methods.

The tool comprises of 36 items self report scales in a 5 point likert scale. These cover the ability to function and complete everyday activities, including physical activities and social activities. The scales also capture well-being, such as, energy or fatigue and mental health.

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 mental health including depression, anxiety, behavioural-emotional control, and general positive affect).

Physical component summary includes physical functioning, role physical, body pain, and general health. Mental component summary includes vitality, social functioning, role emotional and mental health.

**Scoring and Interpretation**

SF-36 V2 scores were converted to a scale of 0 to 100, a higher score indicating a better quality of life and lower the score indicates poor quality of life.

**Reliability**

Reliability estimates for physical and mental summary scores was 0.90.
Part -B Minnesota living with heart failure Questionnaire (MLHF).

It was constructed and standardized by Rector, T.S., et al. 1987. The Minnesota living with heart failure questionnaire was developed at the University of Minnesota, Minneapolis.

It has 21 items that cover heart failure related physical, psychological and social impairments. The patient’s perception of such impairments is assessed on a scale ranging from no (score of 0) to very much (score of 5). The disease specific health related quality of life questionnaire consists of three dimensions.

1. Physical dimensions score (8 items)
2. Emotional dimensions score (5 items)
3. Global (All 21 items)

Scoring and Interpretation

It has 21 items on disease specific health related quality of life with a rating scale range from 0 – 5. The total score is obtained by adding the scores for all 21 items (range, 0-105); the higher the score, the worse the quality of life and lower the score the better the quality of life.

Reliability

Test–retest reproducibility $r= 0.87$. Internal consistency: Chronbachs Alpha for all items $=0.92$. 

3.9. **CONTENT VALIDITY AND RELIABILITY OF THE TOOL**

All the sections of the tool was validated by various experts from the fields of Nursing, Cardiology, Epidemiology, Dietitians and Research (Appendix - B). In the heart failure compliance scale 10 items were newly added and consensus were obtained from the experts. Thus, the final tool was approved by the team of experts with regard to suitability and appropriateness of tool.

The reliability of the each section of tool was shown in each section. Apart from this, permission to use the tools as well as software for SF 36 V2 questionnaire to analyze the date was sought from the author. (Appendix – C)

3.10. **TRANSLATION OF THE TOOL**

The research tools used in the study were translated from English version to Tamil by the experts, to suit the samples and semantic equivalence was obtained by translating Tamil version to English version by other set of experts. The reliability of the translated version was established and it was same as the original version.

3.11. **PILOT STUDY**

Permission from the Director, Cardiac Care Centre, Sri Ramachandra Medical Centre was obtained to conduct the study. Informed consent from the patients with heart failure was obtained to include in the study. Total number of 40 samples were selected randomly in cardiology wards of the Sri Ramachandra Medical Centre and the subjects were randomly assigned to control and study
group equally. The pretest data were collected from the control and the study groups. Control group subjects received routine care and whereas the study groups received routine care and were exposed to the structured teaching on components of cardiac rehabilitation. On the day of discharge, booklet was provided only to the study group. Posttest was conducted during their follow-up visit after discharge.

The pilot study findings revealed that, it was feasible to collect the data from the study samples. The pilot study report was presented to research advisory committee and the same was approved by the committee. The research advisory committee approved the pilot study and permitted to proceed with the main study.

3.12. DATA COLLECTION METHOD

Patients with chronic heart failure admitted in the cardiology ward, fulfilling the inclusion criteria were approached and obtained consent after an adequate explanation about the study (Appendix - E). Data collection was focused on demographic and clinical variables, assessment of knowledge on heart failure, adherence to cardiac rehabilitation and the level quality of life both generic and disease specific health related quality of life using structured questionnaire for self reporting.

The study group attended structured teaching on cardiac rehabilitation on a one to one basis with power point presentation for 3 days.

Day 1 - general information on disease condition, medication

Day 2 - fluid & salt restricted diet, exercise and weight management
Day 3 - home care instruction, smoking cessation and lifestyle modification.

At the time of discharge a book-let on Healthy way to Healthy Heart was provided to the study group.

Both the groups were insisted for regular follow up after a period of one month, three months after the discharge and as and when required as per the protocol. The investigator obtained phone numbers of study group for reinforcement over telephone on treatment adherence, exercise regimen, and lifestyle modification periodically.

After one month and three months of discharge the data were collected to assess the level of adherence, level of knowledge, quality of life, six minute walk test and the biophysiological parameters.

3.13. ATTRITION OF SAMPLES

After the first follow-up, three patients from both the groups died due to complications and hence there were three attrition in both the groups. A total number of 97 samples participated in the study at the end of the third month for the second posttest.

3.14. STATISTICAL ANALYSIS

The collected data were coded and analyzed using the descriptive and inferential statistics.
<table>
<thead>
<tr>
<th>Methods</th>
<th>Types</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Descriptive statistics</td>
<td>Frequency, percentage, mean, standard deviation</td>
<td>To describe the background variables. To assess the level of knowledge, adherence score, 6 minute walking distance, quality of life score and biophysiological parameters in both the groups.</td>
</tr>
<tr>
<td>Inferential statistics</td>
<td>Paired 't'-test/ Wilcoxon signed ranks test</td>
<td>To identify the effect of structured teaching program on level of knowledge, adherence, quality of life, 6 MWT and biophysiological parameters within the group.</td>
</tr>
<tr>
<td></td>
<td>Independent 't'-test/ Mann-Whitney Test</td>
<td>To compare the level of knowledge, adherence, quality of life, 6 MWT and biophysiological parameters between the study and control groups.</td>
</tr>
<tr>
<td></td>
<td>Chi-square test</td>
<td>To identify the association between the level of knowledge, adherence, quality of life, 6 MWT with background variables.</td>
</tr>
<tr>
<td></td>
<td>Pearson’s correlation</td>
<td>To correlate between the adherence with quality of life in both the groups.</td>
</tr>
<tr>
<td></td>
<td>Repeated Measures of ANOVA</td>
<td>To compare the effect of intervention between pre test and Posttest -1, and Posttest -2 intervals in both the groups.</td>
</tr>
<tr>
<td></td>
<td>Regression Analysis (Linear, Logistic)</td>
<td>To study the pattern of relationship between adherence and quality of life with background variables.</td>
</tr>
</tbody>
</table>