CHAPTER – III

METHODOLOGY

3.1 RESEARCH DESIGN

The experimental research approach was applied since the aim of this study was to elicit the effect of the selected stress reduction strategies on anxiety, Self-efficacy and activity level among patients subjected to CABG. Prospective pretest post test experimental design was adopted. The schematic representation is as follows.

\[
\begin{align*}
R & \quad E \quad O_1 \quad X \quad O_2 \\
C & \quad O_1 \quad O_2 \\
R & = \quad \text{Randomization} \\
E & = \quad \text{Experimental Group} \\
C & = \quad \text{Control Group} \\
O_1 & = \quad \text{Pre test observation} \\
O_2 & = \quad \text{Post test observation} \\
X & = \quad \text{Stress reduction strategies namely,} \\
& \quad \quad \quad \bullet \quad \text{Video assisted information} \\
& \quad \quad \quad \bullet \quad \text{Yoga Relaxation Techniques - namely Alternate nostril breathing and Yoga Nidhra.}
\end{align*}
\]

The participants flow through the study has been depicted in the following figure 3.
**Patient selection and recruitment**
Elective OFF PUMP CABG
Both male and female.
40 – 70 years age.

**Baseline testing and Randomization**
Pre operative Day - I
Demographics, Baseline T-Anxiety and S-Anxiety, BP, Pulse rate, Pain scores, Self-efficacy scores, Self-reported activity score

**Control Group**
*Routine protocol* (*n = 78*)
Pre operative counseling
Routine physiotherapy
Health education and brochure

**Experimental Group**
*Routine protocol* (*n = 78*) +
*Stress reduction strategies*
Pre operative counseling
Routine physiotherapy
Health education and brochure
**Video assisted information**
**Yoga relaxation techniques**

### OUTCOME

| Post operative Day 2 – 6 | S-Anxiety scores on post operative day 2,& post operative day 6
Observational score of activities of daily living (MSBI) from postoperative day 2 to day 5
Measurement of BP, Pulse rate, pain intensity score. |
|-------------------------|-------------------------------------------------------------|
| Post operative 6th week | S-Anxiety scores, Self-efficacy scores,
Self-reported activity score.
BP, Pulse rate, respiratory rate. |

**Figure:** 3 Flow chart depicting the methods and procedure.
3.2 SETTING

The Kovai Medical Center and Hospital (KMCH) Coimbatore is a 525 bedded multi specialty hospital. The high-tech cardiac care center consists of a 12 bedded Cardiac post operative ICU, 6 bedded coronary care unit and 40 bedded cardiac wards. The cardiac ward where pre and post operative patients are cared was the setting for this study. The cardiac out patient department was the venue for data collection in the follow up phase.

3.3 POPULATION

Patients subjected to Coronary Artery Bypass Grafting in Kovai Medical Center and Hospital, Coimbatore, South India were the population for the study.

3.4 SAMPLE

The samples were selected from the patients subjected to CABG at KMCH and who fulfilled the selection criteria. Sample size was determined using power analysis and effect size. This study involves comparison of two means. The sample size to get the power of .80 and moderate effect size of 0.05 would be minimum of 126 (Polit & Beck, 2008). To get a comfortable sample size, considering the possibility of drop outs and post operative exclusions researcher decided to enroll 25% excess sample for the study. One hundred and fifty six eligible patients consented to participate in the research during the six months data collection period, out of which 78 patients were assigned to experimental group and 78 patients were assigned to control group randomly.
3.5 SAMPLING TECHNIQUE

Non probability purposive sampling was employed to choose the samples. Those who fulfilled the selection criteria and willing to participate were recruited for the study.

3.6 RANDOMIZATION

Simple random technique was applied to assign the participants to experimental or control Group. Equal number of lots for experimental and control groups were made (n = 156) and kept in a sealed cover. The sealed cover containing lots were picked up from the box by the participants. Based on the lot 78 participants were assigned to experimental group and 78 were assigned to control group. Out of the 78 allotted to control group, two subjects had post operative arrhythmia and one was last to follow up. Among the stress reduction group five did not have the regular practice of yoga. For final data analysis 75 subjects belonging to control group and 73 subjects belonging to the stress reduction group were included.

3.7 ELIGIBILITY CRITERIA FOR SELECTION OF SAMPLE

a) Inclusion Criteria

♦ Patients subjected to CABG on elective basis for the first time.

♦ Off pump CABG patients irrespective of number of blocks or % of blocks.

♦ Patient with adequate LV function >35% EF.

♦ Both male and female patients subjected to CABG.

♦ Patients in the age group of 40-70 years.

♦ Knows to read and write either Tamil or English.
b) Exclusion Criteria

♦ Patients with unstable angina and those who were confined to bed.
♦ Patients with mental disorders.
♦ Patients with stroke / asthma.
♦ Patient who experienced cardiac arrest or severe arrhythmias post-operatively.

3.8 MANIPULATION - Stress Reduction Strategies

Experimental Interventions include

♦ The video assisted information and
♦ Yoga relaxation techniques.

The Video – "COPE UP WITH CABG EASILY" was developed by the investigator. The video provided information based on the perceived needs of patients and literature. According to Bandura (1994) Self-efficacy expectations are amenable to being shaped during the transition of recovery. Self-efficacy expectations are influenced by direct performance of an activity (mastery), observing others performing the activity (vicarious experience), and verbal persuasion by a credible authority, and by the individual's prepared physiologic state. Based on this conceptual basis video was prepared in an interview format with investigator and video model. Two former CABG patients were allowed to express their feelings and share how they could overcome the stress associated with CABG.

The surgeon and the investigator were considered to be the credible authority to give reliable information, and emphasized the need for changes in the life style.

The Video provided the following information

♦ Orientation to health team members.
Structure and functions of the heart.

A brief explanation about CAD and treatment methods.

Pre operative routines.

Expected immediate post operative aspects of care such as continuous monitoring and pain relief.

Postoperative exercises – pulmonary hygiene, walking, related precaution.

Dietary modification, quitting smoking and alcohol.

Process of transition to normal life style and

Vicarious experience in the form of interview with two former patients who had underwent CABG 5 years and 20 earlier and volunteered to share their experience.

The video was shown to the patients and their relatives after preoperative assessment in their rooms. The video was originally prepared in vernacular language (Tamil) and related translated in English also. The video runs for 20 minutes.

The yoga techniques applied in this study were:

- The Naadi suddhi pranayama otherwise known as alternate nostril Breathing.
- The shavashan or Yoga Nidhra.

Naadi suddhi

This is a slow breathing technique proposed to control the mental tension. The sequence of the steps is as follows:

- Sit comfortably with the spine erect.
- Close right nostril with right thumb.
♦ Inhale slowly, steadily and deeply as long as possible.

♦ Follow the entire course of the breath by feeling the movement of air.

♦ Don't hold the breath inside.

♦ Now release the right nostril and close the left nostril with the little and ring finger of the hand.

♦ Breathe out through the right nostril.

♦ Again breathe in through the right nostril and breathe out through the left nostril.

♦ This forms one round.

♦ Mentally recite peace or om.

♦ Complete "9" Rounds in the morning & "9" rounds in the evening.

Time taken for the practice of this is only five minutes.

Yoga Nidhra

Nidhra refers to sleep. Yoga Nidhra is a sleep like state with retaining ones awareness. Yoga Nidhra is a deep relaxation technique in shavasana or corpse pose. It releases the tension layer by layer. The whole process takes 15 minutes. Patients have to close the eyes throughout this relaxation exercise. Instruct the patient to maintain silence and not to get distracted by other noises or conversation. Yoga Nidhra has to be practiced at same time in the evening after walking exercise and before Nadhi suddhi. With audio instruction patient were instructed to do the yoga nidhra practice.

Yoga Nidhra starts with the relaxation of the physical body or the annamaya khosa by sequentially tensing and relaxing actively the body parts from legs to the
crown. Next the psychic layer or Manomaya khosa is relaxed. In this process with auditory guidance the patient mentally scans the body part by part and relaxes, again from toes to the crown. Next the third layer or pranamaya Khosa is acted upon by observing the spontaneous breath. There is a gradual slowing down of the breath. Then fourth layer the knowledge sheathe or vignayamaya khosa is relaxed by observing the inner peace. For detailed steps of the Yoga Nidhra kindly refer Appendix B.

The experimental group subjects were given a brief introductory class on the basic principles of yoga. An instruction guide along with yoga audio track was given to them. The Yoga Nidhra and the alternate nostril breathing techniques were demonstrated and supervised by the investigator on the day before surgery and from postoperative day 2 to day 5. The time taken to complete one session of Yoga Nidra is 15 minutes and 1 session of alternate nostril breathing is 5 minutes. The audio track prepared by the investigator facilitated the practice of Yoga Nidhra. The experimental subject could master the practice of Yoga relaxation within 2-3 sessions. They were instructed to maintain a log of the daily yoga practice.

3.9 CONTROL

The comparison group which was almost equal in all aspects served as the control group. Randomization technique had resulted in 2 comparable groups with respect to the demographic and clinical characteristics. The routine pre operative and post operative protocols were followed for both the groups. The control group subjects received the preoperative counseling by the surgeons, and nurses. Post operatively the routine physiotherapy and health education were given. On discharge the pamphlet consisting of information on lifestyle modifications was distributed. Except for the experimental interventions groups were essentially similar.
3.10 NEED FOR CONSTRUCTING NEW INSTRUMENTS FOR ASSESSING SELF-EFFICACY AND ACTIVITY LEVEL

The Self-Efficacy scale and Self-Reported Activity Questionnaire

According to Bandura (1977 & 1986) self-efficacy expectations are behavioral specific in that they are focused on beliefs about personal abilities with regard to carrying out a particular behavior such as dieting or exercise. Moreover, because self–efficacy expectations are highly context or situation dependent, measurement tools must be developed with respect to a specific task or activity, and for each particular population (Resnick & Jenkins, 2000). Self-efficacy expectation for a behavior is dynamic in nature. Therefore measures of these needs to be administered at different points. Additionally, it is important in measuring self-efficacy expectations to (a) rate self-efficacy expectations before measuring any other scale that could influence the individual’s self–efficacy expectations (b) include measure of the behavior of interest that corresponds to the items in the self-efficacy scale, and (c) measure self-efficacy expectations only in respondents capable of performing the activity or the measure will be one of wishful thinking rather than a belief in the individual’s ability to perform a behavior realistically (Bandura, 1997,1986).

It was aimed at measuring the Self-efficacy of subjects for various categories of activities and the performance of corresponding activities as part of this investigation. Activities performed other than the ADL keeps changing according to culture and there are variations noted in the activities according to gender. The activities permissible by the CABG patient in their post operative course had to be considered. The scales that assess the functional ability in cardiac population like Seattle angina questionnaire asks about their performance of lawn moving etc which has least relevance in the Indian context. The other available scales for self-efficacy
also assess only one component of activities such as the exercise self-efficacy and not for the range of activities assessed in this study. Recognizing these facts the investigator developed a new tool for assessing the self-efficacy and a questionnaire to assess the performance of the corresponding activities.

The scales were validated by experts in the field of Nursing, medicine, Psychology. Reliability of the tools were established in the pilot run. Both the tools had good reliability also.

3.11. INSTRUMENTATION AND SCORING PROCEDURE:

Instruments used for data collection consisted of the following,

**Part I:** Demographic & Social variables.

**Part II:** Clinical variables Included were the number of vessels blocked, number of grafts, co-existing illnesses such as Diabetes mellitus, Hypertension, Left ventricular ejection fraction, presence of pain or chest discomfort and their level in numeric rating scale, blood pressure and pulse rate.

**Part III:** This part consisted of the State Trait Anxiety Inventory-STAI. It was constructed and standardized by Speilberger, (1966, 1977, and 1991). The scale comprised of two separate self report scales for measuring State Anxiety (S-Anxiety) and Trait Anxiety (T-Anxiety). Both the English and Tamil version of the STAI were used in this study.

**S-Anxiety.** The S-Anxiety was evaluated with the State Trait Anxiety Inventory's STAI Form Y-I. The STAI is widely used standardized scale for measuring the state and trait form of anxiety. This self-reporting instrument consists of 20 short statements. It allows participants to
evaluate how they feel “Right now, at this moment” and rate the intensity of their feeling of anxiety by rating themselves on a 4 point rating scale with following four ratings.


**Scoring Procedure:** The anxiety present items are scored as it is and anxieties absent items were reverse scored. The reverse scored items were 1, 2, 5, 8, 10, 11, 15, 16, 19, & 20. Total S-Anxiety scores range from 20 to 80. The summed up scores indicate the S-Anxiety. The more the score the more is the S-Anxiety.

**Trait Anxiety:** Using the Form Y-II of STAI the trait anxiety was measured. In the T-Anxiety scale subjects report how they generally feel by rating themselves on the 4 point frequency scale.


**Scoring Procedure:** The anxiety present items were scored directly. Absent items were reverse scored. The reverse scored items were 21, 23, 26, 27, 30, 33, 34, 36, 39. Anxiety present items were scored directly. Total Trait Anxiety score ranges from 20-80. The higher score indicates higher level of anxiety.

**Part IV:** **Self-Efficacy scale:** To measure the confidence level of the individual in performance of activities of daily living, physical exercises, social and spiritual activities, and leisure time activities investigator developed Self-Efficacy scale was used. It is a five point rating scale with 25 items encompassing. Self-efficacy for four distinct categories of activities.
Subjects rate their level of confidence in the performance of the set of activities on a five point rating scale

1. Not at all confident.
2. Little confident.
4. Moderately confident.
5. Fully confident.

Representative items are given below.
1. Warm up exercise.
2. Brisk walking for 10 minutes.
3. Brisk walking for 20 minutes.

In the Self–efficacy scale

8 items were included to cover the ADL Self-efficacy.
5 items were included to measure the Self-efficacy for physical exercises
8 items covered the Self-efficacy for Social and spiritual activity.
4 items covered the Self-efficacy for leisure activity

**Scoring Procedure:**

The minimum score was 0 and maximum score was 100. The scores for the five options are as follows.

<table>
<thead>
<tr>
<th>Not at all confident</th>
<th>0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Little confident</td>
<td>1</td>
</tr>
<tr>
<td>Some what confident</td>
<td>2</td>
</tr>
<tr>
<td>Moderately confident</td>
<td>3</td>
</tr>
<tr>
<td>Fully confident</td>
<td>4</td>
</tr>
</tbody>
</table>
In case any of the items (1 or 2 items) are not applicable the score was averaged to the other items.

**Part V: Self-reported activity scale:** It is the investigator developed self report measure that measures the actual performance of activities with the degree of difficulty in very similar activities enlisted in the Self-Efficacy scale. Keeping in view that the self-efficacy assessment for specific set of activity should be followed by actual performance, the same set of activities were included in the Activity scale. It consists of 25 items with five point rating scale ranging from fully difficult to not at all difficult.

**Scoring Procedure:** The score ranges from 0-100. The scoring for the options were.

- Fully difficult: 0
- Moderately difficult: 1
- Some what difficult: 2
- Little difficult: 3
- Not at all difficult: 4

If any activity is not applicable due to gender or other consideration the score was averaged.

**Part VI: Modified Scoring for Barthel Index:** It is an observational scale developed by Shah, Vanclay, & Cooper, (1989). It consists of 10 items which measures the level of dependency of patients on various activities of daily living. The score ranges from 0-100. The representative items are Personal hygiene, bathing, Feeding, Toileting,
Stair climbing, Ambulation etc. According to the ability to perform the activity they are scored on a five point rating scale. The ratings are

1. unable to perform.
2. attempts task but unsafe.
3. moderate help required.
4. minimal help required.
5. Fully independent.

The degree of dependency is categorized as follows:

- 0 – 24 Total dependency
- 25 – 49 Severe
- 50 – 74 Moderate
- 75 – 90 Mild
- 91 – 99 Minimal

### 3.12 RELIABILITY OF THE TOOLS

<table>
<thead>
<tr>
<th>S. No</th>
<th>Name the Instrument</th>
<th>reliability value “r”</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>State trait Anxiety inventory –Form Y -I</td>
<td>0.82</td>
</tr>
<tr>
<td>2.</td>
<td>State trait Anxiety inventory form Y- II</td>
<td>0.83</td>
</tr>
<tr>
<td>3.</td>
<td>Self-efficacy Questionnaire</td>
<td>0.78</td>
</tr>
<tr>
<td>4</td>
<td>Self-reported activity Questionnaire</td>
<td>0.77</td>
</tr>
<tr>
<td>5</td>
<td>Modified Scoring for Barthel Index</td>
<td>0.81</td>
</tr>
</tbody>
</table>

### 3.13 DATA COLLECTION PROCEDURE

The permission to conduct research in KMCH was obtained from concerned authorities. The ethical approval was also obtained. The eligible participants were
identified through perusal of their records. The purpose of the study and their right to participate or withdraw from the study was explained to the patients. Such consenting patients who fulfilled the inclusion criteria were enrolled for the study.

Baseline data on demographic variables were collected the day before surgery using interview technique. Privacy was provided. Ethical principles were adhered to throughout the study. Subjects themselves completed the STAI Form Y1 and Form YII, Self-Efficacy scale and Self-reported activity Questionnaire. Clinical data regarding LVEF, number of grafts coexisting illness were collected from the patient's case sheet. Pain intensity/ chest discomforts were also assessed using numerical pain / Discomfort rating scale and the activity that aggravates pain was also assessed.

The second post operative data collection point was the second post operative day by which time the patients were usually weaned from all ionotrophs. On 2nd post operative day evening and 6th post operative day evening subjects completed the Form Y-I the S-Anxiety Questionnaire alone. Based on the assumption that the T-anxiety is relatively a stable measure it was not assessed in the post operative phase. In 2nd Phase of data collection, data pertaining to the actual performance of ADL was done through non participatory observation technique using MSBI. Two trained research assistants blinded to subject status did collect data using MSBI on 2nd, 3rd, 4th and 5th post operative day. The pulse, respiration and blood pressure measurements were recorded in the evenings of the second to fifth post operative day. For the experimental and control group the same calibrated BP apparatus was used. For the experimental subjects BP was measured 10 minutes after the Yoga relaxation technique. Additional information on the perception about usefulness of the video and yoga was collected as a qualitative data.

CABG patients operated at KMCH mostly prefer third month and sixth month follow up in their native place. Only those who reside around Coimbatore city turn up
for the second and third follow up. Hence the study subjects were not followed up beyond sixth post operative weeks.

3.14 STATISTICAL ANALYSIS

Both Descriptive and inferential statistical methods have been applied to analyze the collected data. Demographic variables in categorical/dichotomous forms were presented in frequencies with their percentages. S-Anxiety, Self-efficacy scores Self-reported activity score, and observed measure of ADL the MSBI scores were represented in mean and standard deviation. Pretest and posttest differences in Quantitative variables namely the S-Anxiety, self-efficacy, self-reported activity and MSBI scores were analyzed using student paired t-test.

Differences between experiment and control group were analyzed using student independent t-test. Repeated visit wise difference between experiment and control group were analyzed using Repeated Measures ANOVA F-test. Relationship between different score was analyzed using Karl Pearson Correlation Coefficient. Levels of scores were analyzed using Pearson chi square test. Association between demographic variables and gain or reduction scores were analyzed using student independent t-test and one way ANOVA F-test.

Simple bar diagram, Multiple bar diagram, Percentage bar diagram, Subdivided bar diagram, Doughnut diagram, Pie diagram, and Scatter diagram with regression estimate, box plot, line graph were used to represent the data. P<0.05 was considered statistically significant.
3.15 PROTECTION OF HUMAN RIGHTS

As a preliminary step, the patients’ charts were screened for eligibility. The eligible patients were invited to participate in the study. They were given a thorough explanation about the purpose of the study and steps of the study. The need to continue the practice of yoga relaxation and to follow the prescribed life style modification was emphasized adequately. Their doubts were clarified. They were reassured that their identity will not be disclosed to any one and the anonymity will be maintained in all research related communications. Throughout the course of the study participants physical comfort and emotional comfort were ensured. Their private space was not intruded at any point of time. The participants were neither provided with any incentive nor charged for acquiring new skills such as yoga relaxation.