Chapter III

PROCEDURE

This chapter explains the following—design of the study; pilot study, selection of subjects, selection of variables, selection of questionnaire and experimental program, collection of data, process of administering questionnaire, experimental treatment and statistical model used for analysing the data.

Considering the present trend, for the above-mentioned problem very little or lack of similar work has been done in this field. Thus, the research scholar has decided to develop a comprehensive exercise and lifestyle modification program for preventing, maintaining and rehabilitating the health and fitness status of old age cardiac patients.

The leading cause of morbidity, cardiac disease, is thought to be attributable largely to the sedentary lifestyle and reduced physical activity. This study has characterized the association between cardiac risk and daily physical activity status. Also, applied tools have been used to identify and characterize the cardiac risk. This has provided
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Design of the Study

Considering the present trend, for the above-mentioned problem very little or lack of similar work has been done in this field. Thus, the research scholar has decided to develop a comprehensive exercise and lifestyle modification program for preventing, maintaining and rehabilitating the health and fitness status of old age cardiac patients.

The leading cause of morbidity, cardiac disease, is thought to be attributable largely to the sedentary lifestyle and reduced physical activity. This study has characterized the association between cardiac risk and daily physical activity status. Also, applied tools have been used to identify and characterize the cardiac risk. This has provided
an important step towards reducing the high CAD morbidity and mortality association with conditions mentioned.

The major objective of this research was to provide a comprehensive program which would be safe, useful, practical and at the same time user friendly as well as affordable for manifest coronary diseases.

**Pilot Study**

On the recommendation of Research Degree Committee, Lakshmibai National Institute of Physical Education, Gwalior, a pilot project was successfully conducted on Ten known Coronary Artery Disease (CAD) patients. The preliminary research work was done to determine the feasibility for experimenting and conducting research work on heart patients at larger scale as well as to find out the viability in terms of cost involvement and subject's availability.
Selection of Subjects

Research scholar had conducted an extensive and detailed survey in hospitals, nursing homes, heart centres and clinics, stadiums and public parks etc., to select the subjects for the purpose of this study.

The purpose of the study was explained to all the subjects and all of them agreed voluntarily to undergo testing and training program.

Subjects were equally divided into control and experimental group respectively. 100 volunteer patients participated in an experimental; research program where subjects were classified into Angina-I and Angina-II category by a cardiologist according to their present complaints and symptoms based on the guidelines of NYHA.

NYHA has classified Angina into IV parts and suggested physical activity level for their patients.

NYHA

The New York Heart Association published a classification of patients with cardiac disease based on clinical severity and prognosis.
<table>
<thead>
<tr>
<th>Class</th>
<th>New York Heart Association Functional Classification</th>
<th>Specific Activity Scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Patients with cardiac disease but without resulting limitations of physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.</td>
<td>Patients can perform to completion any activity requiring $&lt;-7$ metabolic equivalents, e.g., can carry 24lb up eight steps; carry objects that weigh 30lb; do outdoor work (shovel snow, spade soil); do recreational activities (skiing, basketball, squash, handball, jog/walk 5mph).</td>
</tr>
<tr>
<td>II</td>
<td>Patients with cardiac disease resulting with slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.</td>
<td>Patients can perform to completion any activity requiring $&lt;-5$ metabolic equivalents, e.g., have sexual intercourse without stopping, garden, rake, weed, roller skate, dance fox trot, walk at 4mph on level ground, but cannot and do not perform to completion activities requiring $&gt;7$ metabolic equivalents.</td>
</tr>
<tr>
<td>III</td>
<td>Patients with cardiac disease resulting with slight limitation of physical activity. They are comfortable at rest. Less than ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.</td>
<td>Patients can perform to completion any activity requiring $&lt;-2$ metabolic equivalents, e.g., shower without stopping, strip and make bed, clean windows, walk 2.5mph, bowl, play golf, dress without stopping, but cannot and do not perform to completion activities requiring $&gt;-5$ metabolic equivalents.</td>
</tr>
<tr>
<td>IV</td>
<td>Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency or of an anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.</td>
<td>Patients cannot or do not perform to completion any activity requiring $&gt;-2$ metabolic equivalents. Cannot carry out activities listed above (Specific Activity Scale III)(^1)</td>
</tr>
</tbody>
</table>

\(^1\) [http://www.americanheart.org/cgi/content/full/33/1/245#ABS](http://www.americanheart.org/cgi/content/full/33/1/245#ABS)
Selection of Variables and Tests

The research scholar has reviewed the available scientific literature pertaining to exercise program and lifestyle modification for cardiac patients, physiology of exercise, books, journals, periodicals, magazines, research papers and Internet. According to the series of discussions with the guide, cardiologists, exercise experts, physiotherapists, feasibility criteria and availability of instrument, equipment and the relevance of the variables to the present study following variables and tests were selected.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biochemical Variables</td>
<td></td>
</tr>
<tr>
<td>1. Blood Lipid Profile</td>
<td>Laboratory blood</td>
</tr>
<tr>
<td>(a) Cholesterol</td>
<td>lipid test</td>
</tr>
<tr>
<td>(b) Triglyceride</td>
<td></td>
</tr>
<tr>
<td>(c) HDL</td>
<td></td>
</tr>
<tr>
<td>(d) LDL</td>
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</table>
Physiological Variables

1. TMT  
   (a) Distance  
   (b) Duration  
   (c) Maximum Heart Rate (MHR)

2. Blood Pressure  
   (a) Systolic  
   (b) Diastolic

3. Pulse rate  
   pulse palpation test

Physical Variables

1. Height  
   Height Scale

2. Weight  
   Weighing Scale

3. BMI

Psychological Variables

Level of State and Trait Anxiety  
Spilberger STAI Questionnaire
Administration of Tests

Pre test of all the variables were conducted for both the groups prior to the experimental program. For all the biochemical variables blood lipid profile test and TMT physical and physiological performance test were conducted at various standard clinical laboratories as per the convenience of individual subjects and results pertaining to all the components of lipid variables and TMT were collected at SAAOL Heart Center, New Delhi. The test pertaining to blood pressure, pulse rate, height, weight, and BMI were conducted at SAAOL Heart Center, New Delhi.

Similarly, post tests of all the variables were conducted after six month of training program.

Description and Administration of Questionnaire

Firstly, the researcher has had discussion with the guide, co-guide, experts and reviewed related literatures in the field of psychological research with special reference to stress and its effects. Secondly, availability of reliable and valid questionnaire was also an important consideration in directing one’s ingenuity for the choice of variables.
Considering all these facts the test of state and trait anxiety questionnaire standardised by Spilberger along with Gorsuch and Lushane was selected for this study. It was selected because it was standardised under Indian condition and widely used for research in India.

State and Trait Anxiety Questionnaire:

The State and Trait Anxiety Questionnaire comprises of two forms, i.e., Y^1 & Y^2, former being a measure of situational anxiety and later that of trait anxiety.

In responding to the STAI anxiety scale examiners blackens the number on the standard test from to the right of each 1) Not at all 2) Some What 3) Moderately So 4) Very Much So. In response to the Trait anxiety scale examiners are instructed to indicate how they generally feel by rating the frequency of their feeling of anxiety on the following four-point scale:
1) Almost Never 2) Some Times 3) Often 4) Almost Always

Both the forms in questionnaire contain 40 statements. First 20 statements are related to state anxiety indicates how a person is
feeling right now, at the present moment & and statement from 21 to 40 suggest trait anxiety that is how a person generally feels.

Selection Of Exercise Program

With the aim of developing a comprehensive exercise program with dietary modifications and stress management (lifestyle modification), the scholar had reviewed related literature and consulted with many experts from different fields.

The program was being developed on the guidelines of Dr. Dean Ornish, Cardiologist, USA and under the expert guidance & supervision of Dr. Vivek Pandey & Dr. Bimal Chhajer, MD, SAAOL Heart Center, to ensure maximum utility and safety for the patients.

The basis of constructing this program was to treat the root causes of CAD, which majorly includes high cholesterol & triglyceride, diabetes, inactivity, stress, obesity, high blood pressure, smoking/ tobacco use and non-vegetarian and low fibre high fat diet.

The program was designed, keeping in mind, to eliminate or minimise all major modifiable risk factors. Thus, the concentration was on those exercises, which does not induce angina in heart patients, and at the same time is beneficial to fight with the already increased blood lipid level and other risk factors.
One form of exercise was walking. After reviewing the literature and ongoing programs intensively, and with consultation with cardiologists and exercise experts the duration and intensity was decided.

After administering 20 flexibility exercises, finally 8 exercises (yogasanas) were selected exclusively for heart patients of Angina-I group, which does not increase heart rate more than 10 BPM and considered being safe for Angina-I patients.

These Asanas are:

1. Standing Position
   a. Tadasana
   b. Padhastasana

2. Sitting position
   a. Ardh-matsyendraasana
   b. Yogmudra

3. Supine lying position (on the back)
   a. Uttanpadasana
   b. Merudand asana

4. Prone lying position (on the stomach)
   a. Bhujangasana
   b. Shalbhasana
Out of 8 exercises, 4 exercises (one from each position) were chosen for Angina-II group. These 4 exercises do not increase heart rate more than 5 BPM.

Research scholar based on the literature and practicality on CAD patients designed a set of sequential exercises, called Health Rejuvenating Exercises (HRE). HRE were a set of 20 simple isotonic exercises, which increases heart rate to very minimal and are safe for heart patients. These exercises were selected for the joint-muscle strength and flexibility and as warm-up exercises for next part of the program. They are:

a. For the Eyes- Eye ball rotation
b. For the neck- Neck rotation
c. For the ears- Ears stretch
d. For the face- Palms over face to relax
e. For the shoulders- Shoulder rotation
f. For the chest- Adduction and abduction of Arms
g. For the waist- waist bending and rotation
h. For the thighs and hips- sideways lounging and squats
i. For the Knees- low squats & back bending
j. For the Ankle joints- Ankle rotation
k. For the Toes & Heels- Walking on toes and walking on heels.

Based on the work of Acharya Shri Tulsi and Prabhupad Ji two meditations were selected for the relaxation and peace of mind. In today’s fast world where everyone is under stress, heart patients are at increased risk especially when they are above 55 years.

A meditation called Kayotsarg means, “To drop the body”. The result of “Kayotsarg” is, relaxation of the muscles and reduction of metabolic activities. The physical condition helps in relieving mental tensions. It is an advanced form of Shavasana.

Second one is “Preksha Dhayan” which means “Perception” was selected among many varied meditations.

An expert from Adhyatma Sadhna Kendra, New Delhi, used to give instructions for guided meditation.

Supervision and presence of scholar and cardiologist was always the part of the experimental treatment.

The root cause of high cholesterol and triglyceride is the intake of the same in the diet, so in consultation with consultation with a dietician, a law cholesterol and triglyceride or Very Low Fat Diet (VLFD) (limited intake of milk and complete restriction on egg yolk
and non-vegetarian diet) and zero visible oil in cooking was strictly observed.

Also they were educated about invisible oil in food and caloric calculation to remain within their Recommended Daily Allowance (RDA).

Procedure of Administration of Questionnaire

Self-Evaluation Questionnaire

Purpose:

To assess the stress level and self-image of CAD patients.

Procedure of Administration

To ensure maximum co-operation from the subjects the research scholar had a meeting with CAD patients where the subjects explained and oriented regarding the purpose of the questionnaire.

The self-evaluation questionnaire was administered to each CAD patient as a pre-test before beginning the experimental program. The researcher, to make the subjects understand about what they exactly required to do, read the directions at a dictation speed. After making them understand the procedure to fill up the questionnaire, they were asked to record the answer for all questions. The subjects were supposed to read the question and mark the very first response
in their mind for that particular question. They were not given much time to think and re-think for an answer. The questionnaires were returned once it was completed. Finally, thorough screening was made to confirm that no question was left unanswered.

**Scoring:**

Each STAI item is given a weighted score of 1-4. A rating of 4 indicates the presence of high level of anxiety. The scoring weights for the anxiety absent items are reversed i.e., responses marked 1,2,3,4 are score 4,3,2,1 respectively. The anxiety absent items for which the scoring weights are reversed on the state anxiety trait anxiety scales are

State-1,2,5,8,10,11,15,16,19,20

Trait- 21,23,26,27,30,33,34,36,39

To obtain scores for the state anxiety and trait anxiety scale, simply add the weighted scores for the inventory items that makes up each scale taking in the account the fact that the scores are reversed for the above items. Scores for both the state and trait anxiety scale can vary from minimum of 20 and maximum of 80 scores.
Procedure of Administration of Experimental Treatment

Total 200 subjects with known CAD (proven blockages either with Tread Mill Test (TMT) or coronary angiogram) in Angina-I and Angina-II group were equally divided into two groups (one experiment and one control group). Each group consisted of 100 subjects.

The experimental group were made aware about the procedure and schedule of the training program, its duration and methodology. They were given education on the selection of treatment tools, its utility and about the effectiveness of the program as well as its results. Subjects were requested to be sincere and offer full cooperation, so that finest outcome could be obtained.

The total training was divided into five segments as follows:

1. Education: A lecture on heart, its structure and list of modifiable and non-modifiable risk factors responsible for CAD and Angina. They were made aware about the common diagnostic tests, treatment options and common medicines. Also the information on plaque building and the role of diet, inactivity, smoking and stress was imparted so that they come to an understanding of how they had developed the disease and their relation to various risk factors.
a. Zero oil Diet: They were taught to consume a Very Low Fat Diet (VLFD) or zero visible oil diet for best results.

b. Stress management: Subjects were also explained about the Type-A and Type-B behaviour and given a (counselling) session on stress management techniques.

2. Walking

3. HRE (Warming Up)

4. Asanas (Flexibility Exercises)

5. Meditation
   a. Kayotsarg
   b. Preksha

Since all the subjects were cardiac patients, they had gone through one or other type of tests, treatment and medicine; they found these lectures very informative and useful.

Before beginning the treatment training all the participants were informed about the best timing to practice is early morning. Ideally the stomach should be empty during the practice, wear loose light and comfortable fitting clothes, quite surrounding and an adequate ventilated room.
They were also instructed not to stop medicine and never try to cross the limits of their capacity. They were also explained about the slow improvement in their capacity and if they feel tired while doing exercises they should take rest.

The exercise program included:

<table>
<thead>
<tr>
<th>Type of Workout</th>
<th>Angina-I Time in (minutes)</th>
<th>Angina-II Time in (minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walk</td>
<td>30 min. (minimum)</td>
<td>20 min. (minimum)</td>
</tr>
<tr>
<td>Kayotsarg</td>
<td>15 min. (minimum)</td>
<td>15 min. (minimum)</td>
</tr>
<tr>
<td>Health Rejuvenating</td>
<td>15 min. (minimum)</td>
<td>15 min. (minimum)</td>
</tr>
<tr>
<td>Exercises (HRE)</td>
<td>8 x 5 reps</td>
<td>4 x 5 reps</td>
</tr>
<tr>
<td>Yogic Exercises</td>
<td>15 min. (minimum)</td>
<td>15 min. (minimum)</td>
</tr>
<tr>
<td>Preksha Meditation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Frequency of the exercise program was 3 days a week in the beginning and was increased gradually. Patients of both groups began to workout all days in a week by the end of the third month.

The very first component of the program was walking. Participants had to walk within their comfortable limits. Duration, intensity, speed/pace of walking was individualised according to
individual patient condition and body response. They were taught to check their pulse rate and to calculate Target Heart Rate (THR) so that they remain in their THR zone. They were also explained the talk test to keep their speed at optimum and safe.

Angina-I group was given the walk for a minimum of 30 minutes according to their THR, whereas Angina-II group walked for minimum 20 minutes according to their THR.

Next was HRE (Health Rejuvenating Exercises). Subjects were taught HRE, which are simple isotonic exercises, including rotation of joint, bending and stretching exercises. Participants had to perform HRE according to their own performance capacity.

HRE was followed by a meditation called 'Kayotsarg' meant for five minutes relaxation period. The subjects performed the meditation under the supervision of an expert in the presence of the scholar.

Kayotsarg was followed by yogasanas (flexibility exercises). Eight exercises were given to Angina-I patients over the period of three months. Only two standing stretching exercises (Upward stretching & forward bending toe touch) were introduced by third week and by fifth week two sitting exercises (Sasankasana, sitting with knees folded and forward bending arms straight up and forehead
on the ground & seated waist twisting) were being introduced and practised. By the seventh week 4 exercises, two in supine lying position (uttanpadasana & straight leg raises (both legs)) and two in prone lying (Snake pose and straight one leg raise) position respectively.

For Angina-II group, flexibility exercises were introduced after the completion of first month. They were given only one exercise in each position introduced gradually over a period of two weeks and practised.

Preksha meditation was given at the end of the exercise session by an expert under the supervision of scholar and cardiologist for a minimum of 15 minutes for the relaxation and for the management of physical as well as all other stresses.

Control group was kept undisturbed without any specific instructions or exercise program. They were kept free to follow their Doctor's usual instructions with no supervision.

At the end of the sixth month, all the subjects, in experimental as well as control group were asked to get their TMT and blood lipid profile repeated for the post test. At the same time they were again given the questionnaire to check their attitude towards life, stress level etc. The data was collected.
A team of professionals (Doctors, attendants, research scholar) from SAAOL Heart Center supervised each exercise session. The staffs were alert to changes that would suggest the need for modification of an individual’s fitness plan.

This clearly monitored program helped to evaluate each person’s functional work capacity so that an effective exercise regiment was prescribed. Research scholar along with a competent doctor closely monitored all exercise sessions. The SAAOL cardiac support group provided additional support. Health lectures were also scheduled throughout the training program.

This ongoing maintenance program was designed to offer social and professional support and encouraged continuation of other healthy habits for the rest of the life.

Participants completed various individualized physiological tests, state and trait anxiety questionnaire including an interview on general health and lifestyle & overall well-being after the program. Research scholar along with cardiologist, meditation experts & other health professionals conducted test and compared results to normal standards and then to control group. Findings are presented in details, along with a recommended comprehensive exercise program, appropriate safeguards and one’s risk factor analysis for heart disease.
Collection of Data

The data pertaining to selected variables were collected before administration of experimental program by a pre-test and at the end of six month of experimental program the post test for both the groups. All the data of selected variable was collected in SAAOL Heart Center, New Delhi, and selected diagnostic labs of India. Data pertaining to state and trait anxiety was collected by administering the questionnaire.

All collected data were subjected to statistical analysis relevant to purpose of the study.

Statistical Procedure

In order to assess the effectiveness, a six-month comprehensive exercise and/or intensive lifestyle modification program was undertaken. The differences between pre-test and post-test means of experimental and control groups and t-ratio (test of significance) were applied for all the selected variables.

Further, to find out the effect between pre-test and post-test on same variables among control and experimental groups after a period of six months, the Analysis of Co-variance (ANCOVA) was applied.