CHAPTER III

METHODOLOGY

This chapter deals with the selection of subjects, selection of variables, selection of the tests, Criterion measures preparation of the herbal-medicins, the experimental design, reliability of the data, orientation of the subjects, collection of data, administration of the herbal-medicines and the statistical techniques used for analyzing the obtained data.

SELECTION OF SUBJECTS

For the purpose of the study, 45 athletes who were students of the University of Calicut undergoing professional course in Physical Education were selected as subjects. Only those students who have volunteered themselves for acting as subjects were selected and the age of the subjects ranged between 18 to 25 years. The subjects were informed about the nature of the study and their written consent were also taken before involving them as subjects in this study. The subjects were later randomly assigned to a supplementation group, a placebo group and a control group under double blind condition.

All subjects were residing in the university hostel leading routine lives and were doing the same kind of physical exercise for five days a week. Their average Physical characteristics are shown in table 3.1.
Table 3: The anthropometric data of the subjects selected for the study

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Total (N=45) (Mean)</th>
<th>Supplementation Group (Mean) N=15</th>
<th>Placebo Group (Mean) N=15</th>
<th>Control Group (Mean) N=15</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>22.25</td>
<td>22.48</td>
<td>22.83</td>
<td>22.42</td>
</tr>
<tr>
<td>Weight (Kg)</td>
<td>62.42</td>
<td>63.41</td>
<td>62.20</td>
<td>61.49</td>
</tr>
<tr>
<td>Height (Cm)</td>
<td>172.0</td>
<td>171.27</td>
<td>170.21</td>
<td>172.45</td>
</tr>
<tr>
<td>BMI (Kg/m²)</td>
<td>18.62</td>
<td>17.23</td>
<td>17.69</td>
<td>17.84</td>
</tr>
</tbody>
</table>

The investigation was carried out after seeking necessary permission from the head of the Department of Physical Education, University of Calicut. The Subjects were also informed that they were free to withdraw their consent in case they felt discomfort during the course of their participation in the study.

**SELECTION OF VARIABLES**

The researcher have had a thorough search of the available literature and had discussion with various experts in Ayurveda before the selection of this problem. The feasibility like availability of the medicines, the procedures and the possible outcomes were extensively analyzed before the problem was finalized. After analyzing the various factors associated with the problem, the following variables were selected for this study.
The important Biochemical variables selected such as Hemoglobin, Blood Sugar and Blood Cholesterol are not only closely related to human health and physical performance but also do depend a lot upon the consumption of food items.

Since, Resting Pulse Rate, Respiratory Rate, Breath Holding Time, Vital Capacity and Blood Pressure are certain parameters or rather external signs of Cardio-Respiratory Endurance, they were also selected as variables for this study.

**SELECTION OF THE TESTS**

Standard tests were conducted to measure the various variables of this study. The selected variables and their respective tests and instrument used are presented in table 3:2

**Table 3:2**
The list of selected variables and their respective Test and instrument used

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Variable</th>
<th>Test and Instrument used</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Physical Fitness Variable</strong></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Cardio- Respiratory Endurance</td>
<td>12 minute Run /walk test (Cooper Test)</td>
</tr>
<tr>
<td></td>
<td><strong>Bio chemical Variable</strong></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Hemoglobin</td>
<td>Tested at a standard Medical Lab</td>
</tr>
<tr>
<td>3</td>
<td>Blood Sugar</td>
<td>Tested at a standard Medical Lab</td>
</tr>
<tr>
<td>4</td>
<td>Total Cholesterol</td>
<td>Tested at a standard Medical Lab</td>
</tr>
<tr>
<td></td>
<td><strong>Physiological Variable</strong></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Resting Pulse Rate</td>
<td>Palpation of radial artery at wrist</td>
</tr>
<tr>
<td>6</td>
<td>Respiratory Rate</td>
<td>Observing the raise and fall of the Chest</td>
</tr>
<tr>
<td>7</td>
<td>Systolic Blood Pressure</td>
<td>Sphygmomanometer</td>
</tr>
<tr>
<td>8</td>
<td>Diastolic Blood Pressure</td>
<td>Sphygmomanometer</td>
</tr>
<tr>
<td>9</td>
<td>Breath Holding Time</td>
<td>Observing the duration of holding the breath</td>
</tr>
<tr>
<td>10</td>
<td>Vital Capacity</td>
<td>Spirometer</td>
</tr>
</tbody>
</table>

**CRITERION MEASURES**

The criterion measures for the selected variables were

1. Hemoglobin was recorded in grams percentage.(gm%)
2. Blood Sugar was recorded in milligrams of deciliter.(mgs/dl)
3. Total Cholesterol was recorded in milligrams of deciliter. (mgs/dl)

4. Resting Pulse Rate was recorded in numbers.

5. Systolic Blood Pressure was recorded in milligrams of mercury (mm/Hg)

6. Diastolic Blood Pressure was recorded in milligrams of mercury (mm/Hg)

7. Vital Capacity was recorded in litres.

8. Breath Holding Time was recorded in seconds.

9. Respiratory Rate was recorded in numbers.

10. Cardio-Respiratory Endurance was recorded in metres.

**EXPERIMENTAL DESIGN**

The experimental design used for this study is a random group design involving forty five subjects, who were later randomly divided into three groups of fifteen each. One group was the experimental group, one placebo group and the last one the control group. The experiment was carried under double blind condition. The herbal-medicines were prepared and packed under the direct supervision of a registered medical practitioner in Ayurveda,
who only knows which capsule contained the herbal-medicine and which is placebo. Thus, neither the subjects nor the investigator have had any idea of the experimental group and the placebo group in this double blind design and hence the subjects of the experimental group and the placebo group were of the impression that they were all taking herbal-medicines.

**PREPARATION OF THE HERBAL-MEDICINES**

**Preparation of the *Lakshadi Choornam***

“Lajjalu smarase sammyak

*Sapthvaram subavitham*

*Laksham pishtua cha thannire*

*the choornamadhuna lihyath”*

(Iyyar)

One kilogram of “Laksha” (“Lassifer Lacca”) was titrated in one litre juice of “Lajjalu” (mimosapudica) about seven times and was later dried, powdered and packed into capsules.

**Preparation of Placebo**

Normal wheat powder is prepared and packed in capsules.

**ORIENTATION OF THE SUBJECTS**

The investigator explained to the subjects participating in this study, the purpose of the study, the administration of the medicines, the collection of data and their role in this study. No information was given about the placebo
used in this study. The investigator also briefed about the various physical, biochemical and physiological tests used in this study.

**RELIABILITY OF THE DATA**

Reliability of data was ensured by tester’s competency and instrument reliability.

**Tester’s Competency**

All the measurements excluding the biochemical variables in this study were taken by the investigator with the help of assistants. From the research point of view, it is very important to be familiar in using the instrument and hence, the investigator had undergone training under an expert, inorder to ensure the reliability of measurements taken. After a series of practice sessions, the tester’s competency was statistically analyzed and established by using the test retest method. Since the correlation coefficient values were very high, the tester’s competency in taking measurements were accepted. The biochemical variables were tested in a reputed Medical laboratory by qualified lab Technicians and hence the results of biochemical variables were reliable enough for the study. The correlation coefficient values obtained for the various tests for testing the tester’s competency is presented in the table 3:3.

**Table 3:3**

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Tests, Methods and Variables</th>
<th>Coefficient of Correlation</th>
</tr>
</thead>
</table>

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*Note: The table contains the data for correlation coefficients of various tests used to assess the competency of the tester.*
<table>
<thead>
<tr>
<th>Instrument Used</th>
<th>Measured</th>
<th>Correlation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Palpation of radial artery at wrist</td>
<td>Pulse Rate</td>
<td>0.90*</td>
</tr>
<tr>
<td>2 Observing the rise and fall of the chest</td>
<td>Respiratory Rate</td>
<td>0.91*</td>
</tr>
<tr>
<td>3 Wet Spirometer</td>
<td>Vital Capacity</td>
<td>0.94*</td>
</tr>
<tr>
<td>4 Observing the total time for holding the breath</td>
<td>Breath Holding Time</td>
<td>0.93*</td>
</tr>
<tr>
<td>5 Sphygmomanometer</td>
<td>Systolic Blood Pressure</td>
<td>0.91*</td>
</tr>
<tr>
<td>6 Sphygmomanometer</td>
<td>Diastolic Blood Pressure</td>
<td>0.92*</td>
</tr>
<tr>
<td>7 Running or walking for 12 minutes</td>
<td>Cardio-Respiratory Endurance</td>
<td>0.94*</td>
</tr>
</tbody>
</table>

* Significant at 0.01 level of Confidence as the required value is 0.77

Since the obtained ‘r’ values were much higher than the required values, the data collected by the tester for the study were ascertained as reliable.

**Instrument reliability**

The instrument Wet Spirometer, Sphygmomanometer, Stop watches etc. for measuring the physiological variables were all having ISI standard and manufactured by reputed companies. Besides, were being used in Research Laboratories. Thus, the instruments used in this study were reliable enough for the purpose of this study.

**COLLECTION OF DATA AND ADMINISTRATION OF THE HERBAL-MEDICINES**
The control group consumed nothing while the experimental and placebo group consumed the Ayurvedic-herbal medicines and the placebo respectively. Besides, both the experimental and placebo groups continued their own routine physical activities for 45 days. The drugs were administered by the investigator himself everyday under the direct supervision of a medical practitioner in Ayurveda and were asked to consume the drugs in front of the investigator and practitioner then and there. The pre-tests were conducted 24 hrs. before the experiment and the post-tests were conducted 24 hrs after the experiment. The dosage of the Ayurvedic-herbal medicines and placebo given to the subjects were decided after seeking expert advice from the medical practitioner.

**Estimation of Biochemical Variables**

**Estimation of Hemoglobin**

The Hemoglobin of the subjects were tested at Kottakal, Aryavaidya Sala Clinical laboratory and the units were recorded in grams%.
Estimation of Total Cholesterol

The Total Cholesterol of the subjects were tested at Kottakal, Aryavaidya Sala Clinical laboratory and the units were recorded in mgs/dl.

Estimation of Blood Glucose

The Total Blood Sugar of the subjects were tested at Kottakal, Aryavaidya Sala Clinical laboratory and the units were recorded in mgs/dl.

Measurement of Physiological Variables

Resting Pulse Rate:–

Purpose:

To calculate the number of heart beat per minute under resting condition.

Procedure:

For assessing the Resting Pulse Rate, a stop watch (1/100th of a second) and a pencil is used. The subject were asked to lie down on a table. The thumb is placed on the carotid artery and the stop watch is switched on. The Resting Pulse Rate for 1 minute were taken three times and the average was taken as the score.
Scoring:

The average number of Pulse Rate per minute was taken as the test score. (Johnson and Nelson, 1986)

**Respiratory Rate:**

*Purpose:*

To calculate the number of breaths per minute under resting condition.

*Procedure:*

Respiratory Rate was measured by counting the rise and fall of the chest for one minute. When the subject became familiar with the room temperature and attained normal breathing, the subject was asked to have a breath normally for one minute. The investigator stood near to the subject observed and recorded the readings by palpating the chest.

**Breath Holding Time:**

*Purpose:*

The objective was to measure the ability of the subjects to hold the breath for a longer time.

*Equipment:*

A stop watch with calibration of 1/100th of a second, score sheet and a pencil were used to administer the test. (Cooper, 1978)

*Procedure:*
The subject stood at ease and inhaled deeply after which the breath is held for a length of time possible. The index finger of the respondent served as an indicator for the investigator to know the start and end of the recording time. The thumb and the centre finger were used to hold the nose to avoid letting the air through nostrils. The subjects were requested not to let the air out by opening the mouth while recording the Breath Holding Time. The time of holding the breath till the subject let the air out was clocked by using the stop watch to the nearest one tenth of a second and this is taken as this score. (Astrand and Rodahl, 1977)

**Vital Capacity:**

Purpose:

To measure the Vital Capacity of the subjects

Equipment:

The apparatus Wet Spirometer was used to measure the Vital Capacity.

Procedure:

The subject sit at ease and inhale as much as air one can and exhale this air into the mouth piece of the Spirometer, which indicate the Vital Capacity in litres. Care must be taken while blowing so as not to leak any amount of air between the mouth piece of the Spirometer and mouth. (Rayner, 1977)

**Blood pressure:**
Purpose:

To assess the Systolic Pressure and Diastolic Pressure of the subjects.

Equipment:

Sphygmomanometer, stethoscope, scoring sheet and a pencil

Procedure:

The subject was asked to sit comfortably on a chair, with the left arm slightly flexed and whole forearm supported at the heart level on the table. The subject was asked to have the weight of the body on the forearm with the fingers relaxed. The center of the rubber compressor bag was squarely placed over the brachial artery and then the silk cuff was wrapped in such a manner that the end of bandage were tucked in nearly avoiding any racks in wrapping. Later, the systolic and diastolic points were determined from the different sounds made by blood in the artery, as the artery is subjected to various degrees of compression. The sounds were heard by means of stethoscope applied just below the arm band at the bifurcation of the brachial artery.
Scoring:

**Systolic pressure**: Pressure was applied by means of the pressure balls and with the left hand palpating the pulse, the pressure was continued for about a further of 10 mm above the point of pulse disappearance. The stethoscope was applied to the brachial artery together by releasing the pressure in the rubber compressor bag slowly and evenly by means of a slight movement of the release screw of the control valve, care was taken to listen for heart sounds. The first sound was usually clear and easy to distinguish, the first regular beat being heard should be read as the point of systolic pressure.

**Diastolic Pressure**: The process was continued to release the pressure and tone and volume of the sound changed and finally disappeared in a faint murmur. The last sound just before disappearance was the point to read the diastolic pressure. (Johnson and Nelson, 1986)

**Cooper’s Twelve Minutes Run/Walk Test:-**

Purpose:

The purpose of this test was to assess the Cardio-Respiratory Endurance of the subjects.
Facilities and equipment:

The test was administered on a 400 M track. A stop watch with calibration of 1/100 of a second, a whistle, score sheet and pencils were used to administer the test.

Procedure:

Cooper’s twelve minutes run/walk rest was administered with the help of qualified testers. For this test, a 400M track was prepared with marking at every tenth metre. The investigator and the testers served as the lap scorers. The subjects were asked to stand on the starting line drawn at finish line of the 400M track and were given instructions to cover as much distance as possible by running/walking. They were instructed to continue running/walking till the final whistle. The race was started with a whistle and the number of minutes left was announced to the subjects every minute and at the twelfth minutes a whistle was blown a second time and the subjects stopped instantly and stood on the spot. The distance covered by each subject in twelve minutes was recorded to the nearest tenth of a metre.

The distance covered by the subjects was used as a measure of Cardio-Respiratory Endurance (Johnson and Nelson, 1986)

STATISTICAL TECHNIQUES

The data collected from the three groups before and after the treatment were statistically examined for significant difference in means by applying analysis of co-variance (ANCOVA). Later, wherever the F-ratio was found
to be significant, the Scheffe’s post-hoc test was applied so as to test whether actual differences existed among the adjusted post-hoc means. The level of significance was set at 0.05.

The data was analyzed on the computer using the statistical package for social sciences (SPSS) and the level of significance was fixed at 0.05.