Chapter III
METHODOLOGY

The manner of handling the various details of experiment is extremely important to the success of research. Research methodology involves the systematic procedures by which the researcher starts from the initial identification of the problem to its final conclusion.

This chapter describes the procedures followed in the selection of subjects, selection of variables, selection of tests, competency of the tester, instruments reliability, reliability of the data, orientation to the subjects, training programme, collection of data, administration of the questionnaire, administration of tests, and research design and statistical procedures were discussed.

Selection of Subjects

A total of 40 subjects, between the ages of 40-50, with a mild to moderate degree of self-reported knee pain associated with joint osteoarthritis were volunteered to participate in this study. The selected subjects were divided in to two groups of 20 each namely diet modification group and diet modification with home-based exercise training group. The screening criteria for the subjects included appropriate age, no history of severe cardiovascular risks, liver and kidney disease and also the participants signed an agreement not to start on any new prescribed medication for knee pain during the 12 weeks of intervention, willingness to modify diet and/or incorporate an at-home exercise program, and obligation to make visits to the
Krishnakumar Hospital, Parvathipuram, Nagercoil. Consent form was obtained from the participants and the model was appended in Appendix I.

At the time of pre test before the experimental period, subjects were provided with a verbal and written description of the research work and the researcher answered the questions which were raised by the participants regarding their participation in the present study. The potential subject was assured that their participation is completely voluntary and was then asked to sign an informed consent form. The subjects were randomly assigned to either the dietary modification with home-based exercise training group or the dietary modification with home-based training group for a period of 12 weeks. They were followed up by frequent phone calls and then they made a final visit after the 12 weeks at Krishnakumar Hospital, Parvathipuram, Nagercoil. The exercise program was developed as an easy to follow home program.

Selection of Variables

The knee joint is composed of two distinct articulations located within a single joint capsule. The knee consists of several different tissues (articular cartilage, ligaments, meniscus, bone, synovium, joint capsule, afferent receptors and peri-articular musculature) that allow relatively frictionless, painless movement to occur during gait. The evidence that intermittent mechanical loads within normal physiological limits contribute to normal knee joint function and balance between tissue synthesis and degradation. In contrast, excessive joint loads have led to articular cartilage fissuring subchondral bone remodeling and microfractures, and articular cartilage vascularization. In addition, altered spatial orientation of the tibial and
femoral articular surfaces and/or joint unloading and immobilization have been shown to result in knee joint degeneration. Knee osteoarthritis has been considered an attempt to contain these mechanical problems of the joint.

Knee osteoarthritis occurs in all compartments of the knee joint, including patello-femoral, lateral and medial tibio-femoral surfaces, however medial knee osteoarthritis is more frequently reported and has received a great amount of investigation. The complexity of structural involvement make capturing the disease with any one feature difficult, as has been discussed in the case with isolating knee osteoarthritis structural impairments to articular cartilage degeneration. In addition, impairments to physiological functions of the knee joint and surrounding tissue include the muscular and neurological systems and synovium. Together these impairments to joint structure and function provide a foundation to understand osteoarthritis.

Knee osteoarthritis is a progressive disease that results from failed repair of joint damage that can arise as a result of biomechanical, biochemical and/or genetic factors. While considered progressive, the reparative process can also be successful leading to a functional, painless joint. Therefore, the balance between tissue synthesis and degradation is not constant. It has been discussed that stresses (physical and/or biochemical) can be initiated in any of the synovial joint tissues, including articular cartilage, subchondral bone, ligaments, menisci, periarticular muscles, peripheral nerves, or synovium. This ultimately results in the breakdown of cartilage and bone, leading to symptoms of pain, stiffness and functional disability.
Knee osteoarthritis is a multifaceted disease process that impairs joint structure and function, limits the performance and capacity of weight-bearing activities and ultimately restricts societal participation. The International Classification of Function provides a framework to organize the interrelationship between these levels of human function affected by this disease.

The management of osteoarthritis like many other chronic diseases cannot be achieved without considering general lifestyle changes. Numerous dietary factors have been noted in observational and laboratory studies to be linked with the cause of osteoarthritis. This includes vitamins A, C, E and D as well as boron (Hunter et al., 2006).

These dietary factors have been to prevent cartilage degradation associated with osteoarthritis through four different mechanisms. This includes protection from oxidative damage, modulation of inflammatory response, facilitating cellular differentiation, and biological actions related with bone and collagen synthesis (Sowers, 2001).

Therapeutic exercises are known to reduce pain, increase muscle strength, increase range of motion, increase endurance and aerobic capacity and improve physical function and quality of life (Singh, 2003; Balint and Szebenyi, 1997). At the joint level, exercise is known to be advantageous in increasing synovial fluid circulation, thereby providing nutrients to the articular cartilage which helps maintain periarticular muscle strength. A two-year clinical trial on home-based exercise in knee osteoarthritis patients showed the exercise arm of the trial had highly significant reduction in pain compared to the control group (Thomas et al., 2003). Hence the
The purpose of this investigation was to explore the effect of diet and physical activity intervention in the management of pain associated with self-reported knee osteoarthritis. Since, the following variables were selected for this study.

**Dependent Variables**
- Weight
- Fat Percentage
- Pain Pattern
- Current Pain Intensity
- High Pain Intensity
- Usual Pain Intensity
- Left Leg Extension
- Right Leg Extension
- Left Leg Flexion
- Right Leg Flexion

**Independent Variables**
- Diet-modification without home-based exercises
- Diet-modification with home-based exercises

**Selection of Tests**

The present study was undertaken primarily to find out the effects of diet modification with and without home based exercise programme on self-reported knee pain osteoarthritis. As per the available literatures (Baker KR, Nelson ME, Felson DT, Layne JE, Sarno R, Roubenoff R., 2001; Cibere J, Kopec JA, Thorne A, Singer J, Canvin J, Robinson DB. 2004; & McAlindon T, Formica M, La Valley M, Lehmer M,
Kabbara K., 2004), the following standardized tests were used to collect relevant data on the selected variables and they are presented in the Table 3.1.

Table 3.1
TESTS SELECTION

<table>
<thead>
<tr>
<th>S. No</th>
<th>Criterion Variables</th>
<th>Test items</th>
<th>Unit of Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Weight</td>
<td>Weighing machine</td>
<td>In kilograms</td>
</tr>
<tr>
<td>2</td>
<td>Fat Percentage</td>
<td>Skin fold Caliper</td>
<td>In percentage</td>
</tr>
<tr>
<td>3</td>
<td>Pain Pattern</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Current Pain Intensity</td>
<td>McGill Pain Questionnaire (Appendix II)</td>
<td>In numbers</td>
</tr>
<tr>
<td>5</td>
<td>High Pain Intensity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Usual Pain Intensity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Left Leg Extension</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Right Leg Extension</td>
<td>Goniometer</td>
<td>In degrees</td>
</tr>
<tr>
<td>9</td>
<td>Left Leg Flexion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Right Leg Flexion</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Tools Used

A medical history questionnaire was completed at the first visit for each of the study participants. This questionnaire was used to further support our prescreening of individuals who were excluded due to certain chronic and acute medical conditions.
The pain assessment questionnaire was conducted at both the initial and the final visit. All the questionnaires have been validated for using with osteoarthritis patients. The pain assessment questionnaire used in this study was a modification of the McGill Pain Questionnaire and SF-36 health survey questionnaire (Melzack R. 1975; & Stein C Mendl G. 1988).

**Competency of the Tester**

The investigator took all the measurements in this study with the assistance of lab technician of Krishnakumar Hospital, Paravathipuram, Nagercoil, Tamilnadu. To ensure that the investigator and assistants were well versed with the technique of conducting tests, they had a number of practice sessions in adopting the correct testing procedure. The tester's reliability was thus established by test and re-test method.

**Instruments Reliability**

The weighing machine, skinfold caliper and goniometer, were used in this study were availed from the Krishnakumar Hospital, Paravathipuram, Nagercoil, Tamilnadu. The instruments were purchased from reliable and standardized companies and were considered accurate enough to collect the data for the study.

**Reliability of the Data**

Test and retest method was followed in order to establish the reliability of data by using ten subjects at random. The same personnel under similar conditions tested all the dependent variables selected for the present study twice for the subjects. The intra class co-efficient of correlation was used to find out the reliability of the data and the results are presented in Table 3.2.
TABLE 3.2
INTRA CLASS CO-EFFICIENT OF CORRELATION ON SELECTED VARIABLES

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Variables</th>
<th>'R' Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Weight</td>
<td>0.97*</td>
</tr>
<tr>
<td>2</td>
<td>Fat Percentage</td>
<td>0.94*</td>
</tr>
<tr>
<td>3</td>
<td>Left Leg Extension</td>
<td>0.95*</td>
</tr>
<tr>
<td>4</td>
<td>Right Leg Extension</td>
<td>0.92*</td>
</tr>
<tr>
<td>5</td>
<td>Left Leg Flexion</td>
<td>0.90*</td>
</tr>
<tr>
<td>6</td>
<td>Right Leg Flexion</td>
<td>0.93*</td>
</tr>
</tbody>
</table>

*Significant at 0.05 level of confidence. (Table value required for significance at 0.01 level of confidence is 0.77).

Since the obtained 'R' values were much higher than the required value, the data were accepted as reliable in terms of instrument, tester and the subjects.

Orientations to the Subjects

The investigator explained the purpose of the study to the subjects and their part in the study. For the collection of data, the investigator explained the procedure of testing on selected dependent variables and gave instructions about the procedure to be adopted by them for measuring. The subjects were sufficiently motivated to perform their maximal level during training and testing periods.

Validity and Reliability of the Questionnaires

Many researchers have used these questionnaires for research. The questionnaires used by them were medical history questionnaire and pain assessment
questionnaire. All the questionnaires have been validated for using with osteoarthritis patients. There can be no better evidence to prove the validity of the questionnaire than this. A trial run of the inventory was made to ensure the reliability of the inventory and also to establish time-limit so that the respondents could give their feelings without too much of boring.

Training Programme

Subjects in both groups received individual counseling to modify their dietary intake of fat, cholesterol, and sodium, and to reduce the overall intake of calories.

Additionally, study participants were provided with dietary guidelines for Indians, established by the National Institute of Nutrition (NIN), Hyderabad, India (2010) (Appendix III) to increase their fruit and vegetable intake to increase the intake of antioxidant, vitamins and minerals. Research suggests that increased antioxidants in the diet help to decrease the inflammatory process associated with cartilage degeneration.

Subjects in the dietary modification/exercise regimen group were also be provided with counseling to incorporate an at-home exercise programme to their daily routine. This exercise programme was designed by Qualified fitness therapist and is a modification of an exercise programme recommended by the orthopedic surgeons/rheumatologists focused on knee osteoarthritis.

The exercise program was designed to improve the strength of muscles acting around the knee, the range of motion at the knee joint, and the locomotor function. The participants were encouraged to do the exercise regimen daily with both legs for 30-45 minutes. The exercise programme was self-paced and the participants were
advised to make it more challenging by increasing the number of repetitions of each exercise. The exercise program was taught to the participants in the assessment laboratory by trained graduate students. To help subjects follow the exercise programme at home, they were provided with a supportive device and a schematic presentation of the individual exercises (Appendix IV).

A home based exercise intervention should not be affected the compliance of the subjects. Moreover, a home based exercise program should have helped with compliance to the intervention because time and access are the most common barriers to compliance. The exercise program was self paced and it became progressively more challenging.

All the subjects were followed up by three weekly phone calls to address issues or problems related to the study treatments. These follow-up phone calls were also utilized to evaluate the compliance of study participants. The subjects returned for their final visit approximately 12 weeks after the initial visit. During the final visit, all of the measures obtained at baseline were repeated to evaluate the effect of the treatment.

**Collection of Data**

The investigator screened potential subjects by conducting a short medical history questionnaire. The questionnaire helped to identify subjects who were interested and met the inclusion criteria of age, health status, and knee pain status. The subjects were then asked to come to the Krishnakumar Hospital, Paravathipuram, Nagercoil, Tamilnadu. All measurements and questionnaires were conducted in the Krishnakumar Hospital, Paravathipuram, Nagercoil, Tamilnadu.
Administration of Tests

1. Weight

Test objective

To measure weight of the subject

Equipment

Weighing machine, pencil and score sheet were used.

Procedure

The subject stood on the weighing machine with barefoot and with ideal clothes. At the time of measuring the heels were on the weighing scale without elevating it, and the body was erect in position after the stop of the scale vibration the reading was taken and the subjects stepped away from the weighing machine.

Scoring

The reading was taken nearest to the one kilogram.

2. Percentage Body Fat

Purpose

To measure the percentage of body fat.

Equipments

Skinfold calipers, scorecard and pencils.

Procedure

Measure the vertical pinch of the skinfolds at abdomen, chest and thigh as explained below and repeat the entire procedure three times.
**Abdomen**

A mark was made 2 cm or 1" to the right side of the umbilicus. The vertical pinch is made at the marked site, and the calipers placed just below the pinch.

**Chest**

The pinch is taken at a point between the axilla and nipple as high as possible on the anterior axillary fold.

**Thigh**

The mid-point of the anterior (front) surface of the thigh, midway between patella (knee cap) and inguinal fold (crease at top of thigh). A vertical pinch is taken.

**Scoring**

Record the medium of the three scores for the skinfolds at three sites and percent body fat was calculated by using the following formula as explained below.

\[(BD)=1.10938-0.0008267(X_2)+0.00000016(X_2)^2-0.00022574(X_4)\]

Where,

\[X_2 = \text{Sum of chest, abdomen and thigh skinfolds,}\]

\[X_4 = \text{Age in years}\]

**Body Density to Percent Body Fat**

Percent Body fat= \((495/\text{Body Density})-450\)
3. Knee Flexion

Purpose

To assess the range of knee flexion in a supine position

Equipment required

Goniometer with extended arms and a firm table

Procedure

The subjects were asked to lie down to supine position or reclined with hip and knee in neutral rotation, trunk and pelvis stabilized by body weight and position. Goniometer Axis was positioned at lateral epicondyle of the femur, the proximal arm was placed parallel to the long axis of the femur and pointing at the greater trochanter and the distal arm placed parallel to the long axis of the fibula and pointing at the lateral malleolus. The subject flexed the hip and knee as the heel moves toward the buttock.
Scoring

Measure the maximum angle of knee flexion toward the buttock. The measurement unit is in degrees.

4. Knee Extension

Purpose

To assess the range of knee extension

Equipment required

Goniometer with extended arms and a firm table

Procedure

The subjects were asked to lie down to supine with hips and knees in neutral rotation; distal leg on bolster, trunk and pelvis stabilized by body weight and position. Goniometer Axis was positioned at lateral epicondyle of the femur, the proximal arm was placed parallel to the long axis of the femur and pointing at the greater trochanter and the distal arm placed parallel to the long axis of the fibula and pointing at the lateral malleolus.

The subject lies down in supine, head back and arms across the chest. The hip is passively flexed until the thigh is vertical. The subjects were asked to maintain this thigh position throughout the test, with the opposite leg in a fully extended position. The foot of the leg being tested is kept relaxed, while the leg is actively straightened until the point when the thigh begins to move from the vertical position. The knee angle at this point is recorded.
Scoring

Measure the minimum angle of knee flexion with the thigh in the vertical position. The measurement unit is degrees.

Statistical Analysis

Descriptive statistics including means, standard deviations, minimum and maximum were determined for all variables. Distributions of the response variables were examined to determine if statistical tests of hypothesis based on the assumption of normality are appropriate, or whether transformed data or non-parametric tests should be used. An paired t-test was performed on all the data to compare the improvement following 12 weeks of both the interventions. After satisfying the assumption of normality, a univariate analysis of covariance (ANCOVA) was used to compare the baseline values of body weight and fat percentage were compared for the two groups. The baseline values of pain and range of motion were compared to the after treatment values between the two groups. All the data are reported as mean +/- standard deviation, with p<0.05 regarded as significant

No attempt was made to equate the groups in any manner. Hence, to make adjustments for difference in the initial means and test the adjusted posttest means for significant differences, the analysis of covariance (ANCOVA) was used (Broota, 1989).

Justifications for Using One-Way ANCOVA

One-way univariate analysis of covariance (ANCOVA) was used to determine how each dependent variable was influenced by independent variables while controlling for a covariate (pre-test) (Hari, Anderson, Tatham, and Black., 1998).
Analysis of covariance adjusts the mean of each dependent variable to what they would be if all groups started out equally on the covariate. In this study, pretest scores of selected variables have been shown to correlate with the posttest scores, thus they were considered as appropriate covariates.

**Assumptions for ANCOVA**

A preliminary analysis was conducted to determine whether the prerequisite assumptions of ANCOVA were met before preceding the univariate analysis. Thus, the assumption of equality of variance (homogeneity), and the homogeneity of regression slopes were examined.

Levene’s test of equality of error variances on selected variables was calculated and presented in table 3.3.

**Table 3.3**

**LEVENE’S TEST OF EQUALITY OF ERROR VARIANCES ON SELECTED VARIABLES AMONG GROUPS**

<table>
<thead>
<tr>
<th>Variables</th>
<th>F- Ratio</th>
<th>df1</th>
<th>df2</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight</td>
<td>2.076</td>
<td>1</td>
<td>38</td>
<td>0.158</td>
</tr>
<tr>
<td>Fat Percentage</td>
<td>0.013</td>
<td>1</td>
<td>38</td>
<td>0.911</td>
</tr>
<tr>
<td>Pain Pattern</td>
<td>1.478</td>
<td>1</td>
<td>38</td>
<td>0.232</td>
</tr>
<tr>
<td>Current Pain Intensity</td>
<td>2.653</td>
<td>1</td>
<td>38</td>
<td>0.112</td>
</tr>
<tr>
<td>High Pain Intensity</td>
<td>0.003</td>
<td>1</td>
<td>38</td>
<td>0.96</td>
</tr>
<tr>
<td>Usual Pain Intensity</td>
<td>0.304</td>
<td>1</td>
<td>38</td>
<td>0.585</td>
</tr>
<tr>
<td>Left Extension</td>
<td>10.513</td>
<td>1</td>
<td>38</td>
<td>0.002</td>
</tr>
<tr>
<td>Right Extension</td>
<td>1.428</td>
<td>1</td>
<td>38</td>
<td>0.24</td>
</tr>
<tr>
<td>Left Flexion</td>
<td>2.214</td>
<td>1</td>
<td>38</td>
<td>0.145</td>
</tr>
<tr>
<td>Right Flexion</td>
<td>0.419</td>
<td>1</td>
<td>38</td>
<td>0.521</td>
</tr>
</tbody>
</table>

(The table value required for 0.05 level of significance with df 1 & 38 is 4.10).
Homogeneity of variances is a term that is used to indicate that groups have the similar variances. Thus, in Levene’s test of equality of error variances table, the obtained F-values of the selected dependent variables were lesser than the critical value of 0.05, indicates that the variance of each group was not significantly different from one another.

Therefore, the homogeneity of variance of comparing the two groups regardless of the ability level for each of the dependent variables indicated that homogeneity of variance has been met for all the selected dependent variables. Hence it was concluded that the assumption of homogeneity of variance has been met for computing univariate ANCOVA.
The test of significance of the regression of post test (dependent variable) on pre test (covariate) were analysed and presented in table 3.4.

Table 3.4.
TESTING THE SIGNIFICANCE OF THE REGRESSION OF POSTTEST ON PRETEST OF SELECTED VARIABLES

<table>
<thead>
<tr>
<th>Variables</th>
<th>Source of Variance</th>
<th>Sum of Squares</th>
<th>df</th>
<th>Mean Square</th>
<th>F</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight</td>
<td>Regression</td>
<td>1052.052</td>
<td>1</td>
<td>1052.052</td>
<td>181.478</td>
<td>.000a</td>
</tr>
<tr>
<td></td>
<td>Residual</td>
<td>104.348</td>
<td>18</td>
<td>5.797</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fat Percentage</td>
<td>Regression</td>
<td>85.259</td>
<td>1</td>
<td>85.259</td>
<td>253.382</td>
<td>.000a</td>
</tr>
<tr>
<td></td>
<td>Residual</td>
<td>6.057</td>
<td>18</td>
<td>0.336</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain Pattern</td>
<td>Regression</td>
<td>1.064</td>
<td>1</td>
<td>1.064</td>
<td>5.125</td>
<td>.036a</td>
</tr>
<tr>
<td></td>
<td>Residual</td>
<td>3.736</td>
<td>18</td>
<td>0.208</td>
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<td></td>
</tr>
<tr>
<td>High Pain Intensity</td>
<td>Regression</td>
<td>1.366</td>
<td>1</td>
<td>1.366</td>
<td>7.158</td>
<td>.015a</td>
</tr>
<tr>
<td></td>
<td>Residual</td>
<td>3.434</td>
<td>18</td>
<td>0.191</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current Pain Intensity</td>
<td>Regression</td>
<td>1.488</td>
<td>1</td>
<td>1.488</td>
<td>11.842</td>
<td>.003a</td>
</tr>
<tr>
<td></td>
<td>Residual</td>
<td>2.262</td>
<td>18</td>
<td>0.126</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Usual Pain Intensity</td>
<td>Regression</td>
<td>0.2</td>
<td>1</td>
<td>0.2</td>
<td>0.9</td>
<td>.355a</td>
</tr>
<tr>
<td></td>
<td>Residual</td>
<td>4</td>
<td>18</td>
<td>0.222</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left Leg Flexion</td>
<td>Regression</td>
<td>710.26</td>
<td>1</td>
<td>710.26</td>
<td>98.693</td>
<td>.000a</td>
</tr>
<tr>
<td></td>
<td>Residual</td>
<td>129.54</td>
<td>18</td>
<td>7.197</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right Leg Flexion</td>
<td>Regression</td>
<td>609.979</td>
<td>1</td>
<td>609.979</td>
<td>112.242</td>
<td>.000a</td>
</tr>
<tr>
<td></td>
<td>Residual</td>
<td>97.821</td>
<td>18</td>
<td>5.435</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left Leg Extension</td>
<td>Regression</td>
<td>71.175</td>
<td>1</td>
<td>71.175</td>
<td>44.835</td>
<td>.000a</td>
</tr>
<tr>
<td></td>
<td>Residual</td>
<td>28.575</td>
<td>18</td>
<td>1.587</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right Leg Extension</td>
<td>Regression</td>
<td>118.535</td>
<td>1</td>
<td>118.535</td>
<td>96.918</td>
<td>.000a</td>
</tr>
<tr>
<td></td>
<td>Residual</td>
<td>22.015</td>
<td>18</td>
<td>1.223</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Significant at .05 level of confidence
(The table value required for 0.05 level of significance with df 1, 18 is 4.41)
From the table it was observed that regression based method (ANCOVA) predicts the post test scores significantly well from the pretest scores on all the dependent variables. It shows that the pre and post test scores of selected dependent variables were significantly associated. As in regression, it is important that the association between the outcome and the covariate is linear.

After determining the assumptions for computing ANCOVA have been met with the pre data analysis, the univariate ANCOVA statistical output was examined. Then, providing the ANCOVA result was statistically significant, the univariate results were examined for each dependent variable. The results of the descriptive analysis, dependent ‘t’ test and univariate tests on the selected dependent variables are reported in chapter four.