CHAPTER 4

METHODOLOGY

Study is conducted in two different phases. Phase I being the pilot study and phase II is the Randomized clinical study. The study was approved by Institutional Ethical committee, Saveetha University on 25th February 2008 (Enclosed: Appendix E).

4.1 PHASE I-PILOT STUDY

The pilot study was performed prior to data collection. The goal of the pilot study was to standardize the procedure of the study and to estimate the sample size.

Study Design: Experimental study design, Sampling-Quota sampling

The first objective of the pilot study was to know the percentage of 1 RM to be selected for inducing delayed onset muscle soreness (DOMS) and to know their recovery from DOMS. In the pilot study, 9 college athletes were selected, and they were divided in to 3 groups, each group having 3 participants. 70 % of 1 RM for group A, and 80 % of 1 RM for group B, and 90 % of 1 RM for group C have been taken to induce DOMS experimentally. Participants were then given a VAS scale with specific instructions on how to record information regarding their level of pain after developing soreness.

RESULTS:

![Figure 4.1 Pain at 24 & 96 hours after inducing DOMS in 3 different eccentric loading protocols](image)

Figure 4.1 Pain at 24 & 96 hours after inducing DOMS in 3 different eccentric loading protocols
From the results (Fig 3.1) it was found that group B (80% of 1 RM) recovered faster when compared to group C. Group A did not develop the symptoms of DOMS. Group C took much time for pain recovery. Pain by VAS scale is the outcome measure taken at 24 hours and after 96 hours. From the results of the pilot study it was found that 80 % of 1 RM was enough to induce DOMS experimentally when compared to 70% and 90% of 1 RM. Thus the pilot report concludes the effectiveness of the standardization of the procedure.

The second objective of the pilot study was to estimate the sample size. Twenty four subjects participated in the study. DOMS were induced to all the participants and they are randomly allocated into three groups (8 subjects in each group). Group A received (Ultrasound) Group B received (Exercises) and Group C (Control) received no treatment. Participants were then given a VAS scale with specific instructions on how to record information regarding their level of pain after developing soreness.

**RESULTS:**

![Figure 4.2 Pain at 24 & 72 hours after inducing DOMS in 3 different groups](image)

<table>
<thead>
<tr>
<th>Groups</th>
<th>24 hours</th>
<th>72 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>Phonophoresis</td>
<td>5.12</td>
<td>0.5</td>
</tr>
<tr>
<td>Exercises</td>
<td>5.05</td>
<td>0.62</td>
</tr>
<tr>
<td>Control</td>
<td>5.27</td>
<td>0.23</td>
</tr>
<tr>
<td>Anova f Value</td>
<td>0.45</td>
<td>115.26</td>
</tr>
<tr>
<td>P value</td>
<td>0.641(^{Ns})</td>
<td>0.000(^{***})</td>
</tr>
</tbody>
</table>
From the pilot study mean and standard deviation, the sample size was estimated using the formula,

\[ n = \frac{z^2 \cdot \varepsilon^2 \cdot \sigma^2}{\varepsilon^2 \cdot \mu^2} \]

Where, \( \sigma \) : Standard deviation
\( \varepsilon \) : Relative precision
\( \mu \) : Mean
1- \( \alpha/2 \) : Desired Confidence level

by a power analysis with 90% power and a 1-tailed level of significance of P <.05 based on data from the pilot study.

4.2 METHODOLOGY FOR PHASE II STUDY

STUDY DESIGN: Randomized clinical trial

SAMPLING: Quota sampling technique was used and all the subjects were randomized equally into four groups, each group having forty subjects.

SAMPLE SIZE-One Hundred and sixty college athletes.

STUDY PERIOD: The study was conducted for a total period of two years and eight months.

STUDY CENTER: The whole study was conducted in Saveetha University.

SUBJECTS:

One hundred and sixty collegiate recreational athlete subjects in the age group 18-25 years who were not under any training protocols and with no history of upper arm injury were recruited. During the experimental period, subjects were requested not to take any medication, change their diet, or perform any strenuous exercise. All subjects were informed about the meaning of the study.
4.3 INDUCTION OF DELAYED ONSET MUSCLE SORENESS

All the subjects were induced delayed onset muscle soreness (DOMS) by an eccentric loading protocol with a barbell (Tiidus and Ianuzzo, 1983)

**Eccentric Loading Protocol**

**1 RM Calculation**

The subject was asked to lift a fixed weight in his hand from a fully extended to a fully flexed position in standing position. The amount of weight was determined by subject's perception. Initially 1 Repetitive maximum (RM) was calculated by using the formula

\[
\text{[Number of repetitions + 1]} \times \frac{\text{Weight used}}{30}
\]

80% of 1 RM was calculated and used for inducing DOMS. Concentric contractions were followed by eccentric contractions for 7 seconds. Assistance was given for
concentric contractions and no assistance given for eccentric contractions and all the subjects were verbally encouraged. The subjects were instructed to perform 4 sets, 1 set consisting of 10 repetitions, with a rest period of 3-5 minutes between each set. After inducing DOMS the subjects were divided into one of four treatment groups.

### 4.4 TREATMENT PROTOCOLS

Treatments were administered at 24, 48, 72, and 96 hours post exercise. The following protocols outline the treatment that subjects received in their respective groups.

<table>
<thead>
<tr>
<th>Groups</th>
<th>Treatment procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group I-Cryotherapy</td>
<td>Ice massage was given by a method of direct application with ice bag technique for duration of ten to fifteen minutes after 24, 48, 72 and 96 hours.</td>
</tr>
<tr>
<td>Group II-Phonophoresis</td>
<td>Phonophoresis (Phyaction 190i ultrasound), Intensity of 0.8 watts/cm² for a duration of 8 minutes given after 24, 48, 72 and 96 hours.</td>
</tr>
<tr>
<td>Group III-Exercise</td>
<td>The individuals performed mild full ROM elbow flexion and extension exercises, with only the gravitational pull on the hand and arm providing resistance. The repetitions were performed continuously during a 20-second period and then rested for 40 seconds. This exercise/rest interval was continued for a total treatment time of 15 minutes.</td>
</tr>
<tr>
<td>Group IV-Control</td>
<td>No therapy was administered. Rest advised for them.</td>
</tr>
</tbody>
</table>

### 4.5 POST TEST MEASUREMENTS

**Dependent variables**

Maximum isometric voluntary contraction (MIVC) of elbow flexors by modified hand held dynamometer, Plasma Creatine kinase (CK) and Lactate dehydrogenase (LDH)
activity were measured from blood samples taken from Cubital veins. Pain assessment
was made from VAS scale. All measurements were taken at the baseline, 24, 48, 72
and 96 hours after inducing delayed onset muscle soreness (DOMS).

4.6 DATA COLLECTION

4.6.1 Serum CK and LDH levels

The analysis is done in Erba Chem 5 plus v2 instrument, Blood samples of 2 ml were
collected from all the subjects using a disposable syringe and the serum separated.
Than 50 micro liters of serum added to1 ml of CK reagent, and incubated at 37 degree
Celsius for 100 seconds in an incubator. Similarly 50 micro liters of serum added to 1
ml of LDH reagent, and incubated at 37 degree Celsius for 1 minute in an incubator.

Test has been done by using the kits from Agappe diagnosis following the standard
protocol and readings displayed in the instrument were noted. This procedure was
done at baseline, 24, 48, 72 and 96 hours and the values were noted.

4.6.2 Maximum Isometric Voluntary Contraction (MIVC)

The dynamometer is a modified Wika pressure gauge (Ploeg, 1984) the pressure
range is 0-300 Newton (N). The meter is equipped with a maximum indicating pointer
with a resetting knob and a curved applicator.

SUBJECT POSITION- Shoulder at neutral, elbow flexed at 90°, Forearm supinated.
Dynamometer placement- elbow just proximal to styloid process. Stabilization of
subject- Superior aspect of shoulder or arm.
Measurement technique and test procedure

At least one practice trial was given to the participants to familiarize them with the feel of pushing against the dynamometer. The participants then performed the action actively until they performed it correctly. Participants were asked to build their force gradually to a maximum voluntary effort over a self-determined 2-second period. They then maintain maximum effort for 5 additional seconds during which dynamometer was held stationary against the limb segment. A rest period lasting 1 or 2 minutes was provided before a second (repeat) measure of an action was taken. Peak force values were recorded for each trial from the digital readout on the dynamometer. The test was repeated three times and an average measure was taken.

4.6.3 Pain measurement

The VAS consists of a 10-cm line with the two endpoints labeled with verbal descriptors. The patient is required to place a mark on the 10 cm line at a point that corresponds to the level of pain intensity he or she presently feels (Turk and Melzack, 1992). VAS consists of a 10 cm line with descriptors at each end. At the left end there was the number zero with the descriptor "no soreness at all", and at the right end there was the number ten with the descriptor "soreness as bad as it could be". Each subject placed an x dong a 10 cm line to describe the amount of muscle soreness he/she was presently experiencing. Data was collected at baseline and at 96 hours.

The Outcome measurements Creatine Kinase (CK), Lactate Dehydrogenase (LDH), Pain measurement, and Maximum Isometric voluntary contraction (MIVC) were taken at the baseline before inducing DOMS, and taken at 24, 48, 72 and 96 hours after inducing delayed onset muscle soreness (DOMS).
One way ANOVA was done to find out the difference between the groups in each outcome measure, and repeated measures ANOVA was done to find out the overall changes within the group.