CHAPTER III

METHODOLOGY
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In this chapter, the procedure adopted for the selection of subjects, study setting, experimental variables, experimental design, outcome measures, pilot study, reliability, procedure of evaluation, procedure of intervention, collection of data and methods employed for statistical treatment have been described.

SUBJECTS – INCLUSION CRITERIA

One hundred and thirty six subjects selected for the study were players who were having complaints of pain due to any sports related musculoskeletal sub-acute and chronic conditions such as soft tissue injuries, first degree strain, first degree sprain, recurrent injuries & strain, overuse syndromes, altered biomechanics and poor posture. They were University level players involved in Cricket, Volley ball, Badminton, Table Tennis, Football, Long distance running, Sprinting, High jump, Long jump, Triple jump, Swimming, Javelin throw, Discus Throw, Weight Lifting, Hockey, Kho kho, Kabaddi and Basket ball. Players with acute injuries, fracture, dislocation, subluxation, spinal, head, and visceral injuries were not included.

The subjects selected were volunteers both male & female who were aged between 18 years to 32 years and who were playing not less than 1 year in their relevant sports. The subjects were students of R.K Group of Colleges, Rajkot, Gujarat, students of Masterskill University, Kuala Lumpur, Malaysia, students of Magadh University, Bodhgaya, Bihar. The written consent was taken from all the subjects those who were participated in the study.
STUDY SETTING

The Evaluation and Treatment Intervention was done in the following settings;

i) Out Patient Department, R.K. Physiotherapy Centre, Rajkot, Gujarat.

ii) Out Patient Department, R.K. Physiotherapy College Campus, Rajkot, Gujarat.

iii) Out Patient Department, Masterskill College, Kuala Lumpur, Malaysia.

iv) Out Patient Department, Institute of Physiotherapy, Magadh University, Bodhgaya. Bihar.

SELECTION OF VARIABLES

The Dependent variables selected for the study as follows: Pain intensity and Pain relief for Physical component of pain, Pain interference in general activity, walking ability, outside & household work and Recreation & sports for Functional component of pain, Pain interference in mood, concentration, sleep, and interaction with others for Psychological component of pain and Disability index for shoulder, elbow, back, knee and ankle & foot.

The Independent variables selected for the study as follows: TENS Transcutaneous Electrical Nerve Stimulation, IFT Interferential Therapy, PEMF Pulsed Electromagnetic Field therapy.
RESEARCH DESIGN

The type of research was Experimental Research which is single blinded, randomized, controlled study. The experimental design of the study was 4x3 Factorial design with last factor as repeated measures.

In this study 4x3 factorial design was used to analyse the main and interaction effects. Where the main effect and interaction effect was significant (Factor ‘A’ and Factor ‘B’) the Bonferroni Post hoc test was used to find out the paired mean difference. (Anne Ruthestin, 1985)

OUTCOME MEASURES

The Brief Pain Inventory short form which is also known as BPI-sf, modified version is a validated, widely used, self-administered questionnaire developed to assess the severity of pain and the impact of pain on daily functions was used to assess the intensity of different Physical, Functional & Psychological components of pain.

The modified BPI-sf, like the parent scale, is a valid and reliable tool for situations in which pain is assessed daily and minimizes the burden placed on patients to record information necessary for scientific investigations. (Mendoza T et al, 2005)

Disability Index of the subjects was assessed using Constant Shoulder Score, Mayo Elbow Performance Score, Back Pain Functional Scale, Manchester Foot & Ankle Disability Index – Sports Module to objectively analyse the effectiveness of treatment intervention on the components of pain.
PILOT STUDY

A pilot study was conducted to find out the accuracy of measurement tools which were used during the study and the efficiency of the modalities used for the treatment protocol. Eight subjects were randomly allotted to the four treatment groups, the experimental procedures were administered and the data were documented regarding the Physical, Functional & Psychological components of pain and Disability Index scores. The results were correlated with the hypotheses and were checked,

RELIABILITY OF DATA

The reliability of data was assured by establishing the reliability of tests used for evaluation, reliability of instruments used for treatment intervention, investigator’s competency and subjects’ reliability.

RELIABILITY OF THE TESTS

Tester’s competency was evaluated together with the reliability of the tests. Reliability of the test was established by test – retest method whereby the consistency of results was obtained by intra – class correlation. The repeated measurement of individuals on the same test was done to determine reliability as it was univariate not a bivariate situation. It is the distribution of a single variable. It makes sense, then to use a univariate statistics like intra – class correlation coefficient.

The data were collected from two subjects in each treatment groups, who were selected randomly and co-efficient correlation was computed for each variable. Thus obtained results were presented in Table I. The very high value of correlation obtained, established the researcher’s competency to administer the tests as well as the reliability of the tests.
<table>
<thead>
<tr>
<th>SL.NO.</th>
<th>TESTED VARIABLES</th>
<th>CO-EFFICIENT OF CORRELATION (N=8) TEST-RETEST SCORES</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Pain intensity</td>
<td>0.98</td>
</tr>
<tr>
<td>2</td>
<td>Pain relief</td>
<td>0.99</td>
</tr>
<tr>
<td>3</td>
<td>Pain interference in general activity</td>
<td>0.97</td>
</tr>
<tr>
<td>4</td>
<td>Pain interference in walking ability</td>
<td>0.98</td>
</tr>
<tr>
<td>5</td>
<td>Pain interference in outside and household work</td>
<td>0.98</td>
</tr>
<tr>
<td>6</td>
<td>Pain interference in recreation and sports</td>
<td>0.97</td>
</tr>
<tr>
<td>7</td>
<td>Pain interference in mood</td>
<td>0.99</td>
</tr>
<tr>
<td>8</td>
<td>Pain interference in concentration</td>
<td>0.98</td>
</tr>
<tr>
<td>9</td>
<td>Pain interference in sleep</td>
<td>0.99</td>
</tr>
<tr>
<td>10</td>
<td>Pain interference in interaction with others</td>
<td>0.97</td>
</tr>
<tr>
<td>11</td>
<td>Disability index</td>
<td>0.98</td>
</tr>
</tbody>
</table>
SUBJECT’S RELIABILITY

The above test, re-test co-efficient of correlation values also illustrated that subject reliability was adequate as the same subjects were used under similar situation by the same investigator and no motivated techniques were used in any circumstances.

TESTER’S RELIABILITY

Tester’s reliability was established by test – retest procedures. For this purpose, two subjects from different treatment groups were selected at random on the selected variables, which were recorded twice under identical situations on different occasions by the researcher. Such obtained scores could be analyzed by using intra – class correlations. This could be tested for significance at 0.05 level of confidence as presented in Table I.

ORIENTATION OF THE SUBJECTS

Before the evaluation and treatment administration, the subjects were oriented about the purpose of the study regarding the evaluation & the treatment procedures. The investigator instructed the subjects how to document the perception of pain in the Numerical Rating scale in the Brief Pain Inventory short form so that there was no confusion regarding the scale. Brief explanation was given regarding the participation in their individualized Disability Index evaluation. In order to gain full cooperation from the subjects, they were explained about the treatment procedure which includes do s & don’ts during treatment, duration & position of subject during treatment.
PROCEDURE OF EVALUATION

All the subjects included in the study were assessed in pre & post treatment phase at regular interval using the following tools and techniques.

The patient evaluation chart of Brief Pain Inventory short form also known as BPI-sf, modified version was used to evaluate the subjects on 1st day, 6th day & 12th day which consist of following sections: Personal Profile, Pain history, Physical component of pain, Functional component of pain, Psychological component of pain.

In the Personal Profile, the personal details of subjects, i.e. Name, Age, Sex, Game Playing and Painful Condition were documented and Patient ID no. was given according to their random allocation of groups.

In the assessment of pain history, location of pain using body chart, quality of pain, onset, duration and variations of pain, relieving & aggravating factors of pain were documented by the therapist.

Physical, Functional & Psychological components of pain were assessed using a 0 to 10 Numerical Rating Scale which was self administered by the subjects themselves. In the Physical component of pain, worst pain and relief of pain was documented. Interference of pain with general activity, walking ability, outside and household work, recreation and sports were the factors assessed in the Functional component of pain. In the Psychological component of pain assessment, interference of pain with mood, concentration, sleep and interaction with other people were documented.
ASSESSMENT OF PHYSICAL COMPONENT OF PAIN

Numerical Rating Scale was used to record subjective reports of pain. The NRS consisted of a 10-cm horizontal line, anchored with “no pain” at the left end (i.e. threshold intensity) and “pain as bad you can imagine” at the right (i.e. maximally tolerable intensity). The NRS for documenting pain relief consisted of a 10-cm horizontal line, anchored with “no relief” at the left end and “complete relief” at the right end.

ASSESSMENT OF FUNCTIONAL & PSYCHOLOGICAL COMPONENT OF PAIN

The NRS consisted of a 10-cm horizontal line, anchored with “no interference” at the left end (i.e. threshold intensity) and “completely interferes” at the right (i.e. maximally tolerable intensity).

ASSESSMENT OF DISABILITY INDEX

Even though Brief Pain Inventory evaluated the components of pain extensively, subjects were also assessed using the Disability Index for more objective analysis during pretreatment & post treatment i.e. on 1st day and 12th day of treatment session.

Constant Shoulder Score (CSS) designed by Constant CR, Murley AH.(1987) was used to evaluate the subjects with shoulder pain. This consists of 8 parts as follows: pain, activity level, strength of abduction, arm positioning, range of motion of forward flexion, lateral elevation, external rotation, internal rotation. The maximum score obtained will be 100, minimum will be 0 and the interpretation of scores were done as followed: >25 (poor), 25-49 (fair), 50-75 (good), <75 (excellent).
**Mayo Elbow Performance Score (MEPS)** designed by *Mayo Clinic* was used to evaluate subjects with pain in elbow. This consists of 4 parts as follows: Pain Intensity, Motion, Stability, and Function. The maximum score obtained will be 115, minimum will be 15 and the interpretation of scores were done as followed; >60 (poor), 60-74 (fair), 75-89 (good), <90 (excellent).

**Back Pain Function Scale (BPFS)** developed by *Stratford et al* was used to evaluate functional ability in subjects with back pain. This consists of 12 measures related to activity using spine and the responses were graded from 0-unable to perform activity, 1-extreme difficulty, 2-quite a bit of difficulty, 3-moderate difficulty, 4-a little bit of difficulty, 5-no difficulty, the higher the score the greater the subject's functional ability. The maximum score obtained will be 60 and minimum will be 0. The interpretation of scores were done as followed; >15 (poor), 15-29 (fair), 30-45 (good), <45 (excellent).

**Manchester Foot and Ankle Disability Index – Sports Module (FADI)** was designed by *Sheri A. Hale* to provide a quantitative measure of foot and ankle disability and used for subjects having knee & ankle pain. This consists of 8 measures related to activity using Lower extremity. Subjects select the statement, which most closely describes their condition; no difficulty at all (4 points), Slight difficulty (3 points), Moderate difficulty (2 points), Extreme difficulty (1 point), unable to do (0 points). The maximum score obtained will be 32 and minimum will be 0. The interpretation of scores were done as followed; >8 (poor), 8 - 15 (fair), 16 - 24 (good), <24 (excellent).

The scores of condition specific Disability Index was documented on the 1st day before the treatment session and again reassessed and documented after the last day of the treatment session. This was documented to achieve more objective analysis of the subject’s prognosis.
PROCEDURE OF TREATMENT INTERVENTION

After informed consent had been obtained, the subjects were oriented regarding the evaluation and treatment procedure. The total no. of subjects included in the study was 136 (N = 136). All the subjects selected were randomly allocated to one of the four groups as follows:

GROUP A – INTERFERENTIAL THERAPY GROUP (n = 34)

Objective

The purpose was to find out the effect of Interferential therapy in reducing the intensity of all the components of pain and improving the scores of Disability index.

Intervention

The subjects allotted to this group were treated with Interferential therapy and rest, isometrics, compression with crepe bandage wherever necessary or Support. The electrodes of IFT were applied over the painful area according to the below mentioned dosage.

Position of the Subjects during the Intervention

All the subjects were positioned comfortably and with proper support to relax the corresponding treatment area as follows:

Subjects with pain in shoulder were positioned in supine lying with shoulder 20 deg. abducted and medially rotated supported with pillow.

Subjects with pain in elbow were positioned in supine lying with shoulder 20 deg. abducted and medially rotated and elbow 10 deg. flexed, forearm pronated and supported with pillow.
Subjects with pain in low back were positioned in prone lying, knee 10 deg. flexed and supported with pillow.

Subjects with pain in knee were positioned in supine lying, knee 15 deg. flexed and supported with pillow.

Subjects with pain in ankle were positioned in supine lying, knee 15 deg. flexed and supported with pillow and maintaining lower limb in neutral rotation to keep ankle straight by supporting with a sand bag or pad.

After appropriate positioning the subjects were treated by applying the respective electrodes over the painful area.

**Dosage Parameters for IFT**

- **Electrode Application** – Quadripolar Classical Interference
- **Treatment duration** – 30 minutes
- **Frequency** - 90 – 130 Hz swing pattern
- **PPS** – 125 microsec.
- **Intensity** – comfortable to tolerance

**Total No. of Treatment Sessions**

The treatment was administered for 6 days per week for two consecutive weeks for all the subjects. All the subjects were undergone 12 treatment sessions of electro therapy along with the regular protocol i.e. rest, compression or support and isometrics.
Instructions to the Subjects

All the subjects were instructed to rest and not to overstrain the painful part and advised to follow the instructions such as using crepe bandage or support to the affected part with external aids and doing isometric exercises carefully during the treatment sessions. They were also instructed to maintain the fitness level without straining the painful part.

GROUP B – TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION (n= 34)

Objective

The purpose was to find out the effect of Transcutaneous Electrical Nerve Stimulation in reducing the intensity of all the components of pain and improving the scores of Disability index.

Intervention

The subjects allotted to this group were treated with Transcutaneous Electrical Nerve Stimulation and rest, isometrics, compression with crepe bandage wherever necessary or Support. The electrodes of TENS were applied over the painful area according to the below mentioned dosage.
Position of the Subjects during the Intervention

All the subjects were positioned comfortably and with proper support to relax the corresponding treatment area as follows:

Subjects with pain in shoulder were positioned in supine lying with shoulder 20 deg. abducted and medially rotated supported with pillow.

Subjects with pain in elbow were positioned in supine lying with shoulder 20 deg. abducted and medially rotated and elbow 10 deg. flexed, forearm pronated and supported with pillow.

Subjects with pain in low back were positioned in prone lying, knee 10 deg. flexed and supported with pillow.

Subjects with pain in knee were positioned in supine lying, knee 15 deg. flexed and supported with pillow.

Subjects with pain in ankle were positioned in supine lying, knee 15 deg. flexed and supported with pillow and maintaining lower limb in neutral rotation to keep ankle straight by supporting with a sand bag or pad.

After appropriate positioning the subjects were treated by applying the respective electrodes over the painful area.
Dosage Parameters for TENS

Electrode Application – Quadripolar or Bipolar method

Treatment duration – 40 minutes

Hi TENS Frequency- 100 Hz constant

Pulse Width – 250 microsec.

Intensity – comfortable to tolerance

Total No. of Treatment Sessions

The treatment was administered for 6 days per week for two consecutive weeks for all the subjects. All the subjects were undergone 12 treatment sessions of electro therapy along with the regular protocol i.e. rest, compression or support and isometrics.

Instructions to the Subjects

All the subjects were instructed to rest and not to overstrain the painful part and advised to follow the instructions such as using crepe bandage or support to the affected part with external aids and doing isometric exercises carefully during the treatment sessions. They were also instructed to maintain the fitness level without straining the painful part.
GROUP C – PULSED ELECTR MAGNETIC FIELD THERAPY (n = 34)

Objective

The purpose was to find out the effect of Pulsed Electro Magnetic Field Therapy in reducing the intensity of all the components of pain and improving the scores of Disability index.

Intervention

The subjects allotted to this group were treated with Pulsed Electro Magnetic Field Therapy and rest, isometrics, compression with crepe bandage wherever necessary or Support. The electrodes of PEMF were applied over the painful area according to the below mentioned dosage.

Position of the Subjects during the Intervention

All the subjects were positioned comfortably and with proper support to relax the corresponding treatment area as follows:

Subjects with pain in shoulder were positioned in supine lying with shoulder 20 deg. abducted and medially rotated supported with pillow.

Subjects with pain in elbow were positioned in supine lying with shoulder 20 deg. abducted and medially rotated and elbow 10 deg. flexed, forearm pronated and supported with pillow.

Subjects with pain in low back were positioned in prone lying, knee 10 deg. flexed and supported with pillow.
Subjects with pain in knee were positioned in supine lying, knee 15 deg. flexed and supported with pillow.

Subjects with pain in ankle were positioned in supine lying, knee 15 deg. flexed and supported with pillow and maintaining lower limb in neutral rotation to keep ankle straight by supporting with a sand bag or pad.

After appropriate positioning the subjects were treated by applying the respective electrodes over the painful area.

**Dosage Parameters for PEMF**

- Electrode Application – Quadripolar or Bipolar method
- Treatment duration – 30 minutes
- Unidirectional quasirectangular waveform with strength about 20 Gauss
- Frequency – 30 Hz
- Intensity – 400 microT

**Total No. of Treatment Sessions**

The treatment was administered for 6 days per week for two consecutive weeks for all the subjects. All the subjects were undergone 12 treatment sessions of electro therapy along with the regular protocol i.e. rest, compression or support and isometrics.
Instructions to the Subjects

All the subjects were instructed to rest and not to overstrain the painful part and advised to follow the instructions such as using crepe bandage or support to the affected part with external aids and doing isometric exercises carefully during the treatment sessions. They were also instructed to maintain the fitness level without straining the painful part.

GROUP D – Control group (n = 34)

Objective

The purpose was to find out the effect of Common Protocol alone without any electrotherapy treatment in reducing the intensity of all the components of pain and improving the scores of Disability index.

Intervention

The subjects allotted to this group were treated with no Electrotherapy modality and only with rest, isometrics, and compression with crepe bandage wherever necessary or Support.

Total No. of Treatment Sessions

The treatment was administered for 6 days per week for two consecutive weeks for all the subjects. All the subjects were undergone 12 treatment sessions of common protocol alone i.e. rest, compression or support and isometrics.
Instructions to the Subjects

All the subjects were instructed to rest and not to overstrain the painful part and advised to follow the instructions such as using crepe bandage or support to the affected part with external aids and doing isometric exercises carefully during the treatment sessions. They were also instructed to maintain the fitness level without straining the painful part.

STATISTICAL TECHNIQUES

The collected data on the selected variables scored as pretest before the treatment, post test 1 on 6\textsuperscript{th} day during treatment and post test 2 on 12\textsuperscript{th} day after the treatment intervention were analyzed using 4x3 Factorial Analysis of Variance as recommended by Ann Ruthestin (1985).

The collected data on the selected variables scored as pretest before the treatment and post test scores on 12\textsuperscript{th} day after the treatment intervention were analyzed using Factorial Analysis of Covariance as recommended by Clarke and Clarke (1972).

In all the cases 0.05 level was fixed as level of significance which was considered as appropriate. Bonferroni's post hoc test was calculated to find out the significance of mean difference when the obtained 'F' value was greater than the required value to be significant.