Chapter 3

Methodology
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Research design:
The research design used for the study was pre post experimental design.

Sample:
The sampling method used for collection of data was systematic random sampling method.

The sample for the study was selected through camps organised exclusively for patients with low back pain. The camps were organised by Back Pain Research Clinic of Dr.Padiar Memorial Homoeopathic Medical College, Chottanikkara, Ernakulam district.

A total number of 1142 patients with low back pain were registered in the camps. Out of the 1142 patients, 898 patients had met with the inclusion criteria. Out of the 898 patients 518 patients were found to have pathological low back pain. From among the 518 patients with pathological low back pain (Group I) 75 were included in Category I Medicine group. 75 were included in Category II placebo group, 75 were included in Category III combination group. Systematic random sampling method was used for the categorisation. Every third subject
was put into each category till the required number of 75 was completed. Similar procedure was used to categorise 320 patients with somatoform low back pain (Group II).

The patients in Group II were also further classified into three categories based on the type of interventions used. Category I consisted of patients who received homoeopathic medicines alone (Medicine category). Category II consisted of patients who received placebo alone (Placebo category). Category III consisted of patients who received both medicine and placebo in combination (combined group).

Seven patients were dropped out from Group I and 4 patients were dropped out from Group II. Thus the total number of subjects in Group I were 218 and in Group II were 221.

The breakup of final sample is presented in Table 3.1

**Table 3.1 Breakup of the final sample**

<table>
<thead>
<tr>
<th>Groups</th>
<th>Category I Medicine</th>
<th>Category II placebo</th>
<th>Category III combination</th>
<th>Total subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group I pathological</td>
<td>73</td>
<td>70</td>
<td>75</td>
<td>218</td>
</tr>
<tr>
<td>Group II somatoform</td>
<td>73</td>
<td>75</td>
<td>73</td>
<td>221</td>
</tr>
</tbody>
</table>

Total 439.
**Inclusion criteria:**

1. Patients with low back pain who had pain as their primary symptom for more than 6 months

2. Patients with low back pain who were between 30 to 50 years of age.

3. Patients with low back pain who belonged to either sex (male or female) were included under the study.

**Exclusion criteria:**

1. Patients who had red flag signs like malignancy, signs of intense neurological deficit, severe weakness of lower extremities

2. Low back pain patients other than musculoskeletal reasons which are ruled out by physical examination for e.g. genitor urinary diseases, gastro intestinal disease and secondary to systemic diseases

**Procedure**

The sample for the study was selected from the camps organised specially for the purpose of data collection. The camps were organised by Back pain research clinic of Dr Padiar Memorial Homoeopathic Medical College, Chottanikkara. Dr Padiar Memorial Homoeopathic
Medical College is a referral institute for homoeopathic treatment. People from different regions are referred to this hospital for expert opinion and homoeopathic management. The institute can hence be considered to be the most ideal institute for data collection. An advertisement was given in three of the leading newspapers about the three camps organised by the institute. The advertisement was intended to draw the attention of patients with low back pain who could seek treatment in a specialised manner. The intention was also to get a large number of patients from in and around Ernakulam district. Thus the investigator could get a representative sample from various parts of Ernakulam, Alleppey and Kottayam districts.

Every patient who attended the camps was detailed about the research purpose. A fully informed written consent was obtained from every patient before the beginning of intervention.

Case history of all the patients was taken using the case history schedule. The physical examinations were conducted for all the patients with the help of physical examination check list. The tools were administered to the patients individually. The instructions were read out and explained. Doubts were cleared and clarifications were
given to the patients. After conducting the pre tests, interventions were carried out for the six categories of patients for a period of three months. The tools were administered after the completion of three months of intervention. The inventories were collected and checked for their completeness. The completed inventories were scored as per the manuals. The scored data were coded and subjected to statistical analyses.

**Tools used**

1. Personal information data sheet (developed by investigator).
2. Hamilton anxiety rating scale (Hamilton 1959)
3. Beck depression inventory (Beck 1961)
4. PGI General well being measure (Verma & Verma 1989)
5. Oswestry low back pain scale (Fairbank 1980)

**Tool Description**

1. Patient information data sheet was developed by the investigator herself to collect the personal information, socio economic
details and previous history related to low back pain and treatments adopted.

**Hamilton Anxiety Rating Scale**

The Hamilton Anxiety Rating Scale was one of the first rating scales developed to quantify the severity of anxiety symptoms. It is a clinical rating scale. Since HAS’s introduction by Max Hamilton in 1959, it has become a widely used and accepted outcome measure for the evaluation of anxiety in clinical traits. This scale is a 14 item test (anxious mood, tension, fears, insomnia, intellectual impairment, depressed mood, somatic muscular complaints, somatic sensory complaints, cardiovascular symptoms, respiratory symptoms, gastrointestinal symptoms, genito urinary symptoms, autonomic symptoms and behaviour at interview) measuring the severity of anxiety symptoms. The HAS is used to assess the severity of anxiety symptoms present in children and adults. The English version of Hamilton anxiety rating scale has an Internal scale consistency (coefficient alpha) of 0.92 and the test retest reliability of 0.96. The correlation between the computer and clinical Hamilton Anxiety Rating Scale scores was 0.92.
The questionnaire was translated to Malayalam by Dr Razeena Padmam and Dr Subhadra in 2009.

**Procedure**

The questions were translated into Malayalam retaining the meaning of each question. The translated questionnaire was circulated among experts. The questionnaire was further corrected based on the suggestions provided by the experts. The translated questionnaire was administered to 200 patients with low back pain patients who had a history of low back pain for more than 6 months, irrespective of their diagnosis.

**Validity**

As the tool is a true translation of the English version of Hamilton Anxiety Rating Scale can claim both content and face validity.

**Reliability**

The reliability (Cronbach’s alpha) was calculated and was found to be 0.813.

**Scoring**

There are 14 items and each item carried 5 alternatives. Maximum total score obtained is 56. Interpretation is calculated as 18 to 24 mild anxiety, 25-29 as moderate anxiety and above 30 as severe anxiety.
Beck’s Depression inventory

The Beck’s Depression Inventory was created by Aaron T Beck (1961). This consists of a series of questions developed to measure the intensity, severity and depth of depression in patients with psychiatric diagnosis. Its long form consists of 21 questions, each designed to assess a specific symptom common among people with depression.

Individual questions of the BDI assess mood, permission, sense of failure, self dissatisfaction, guilt, punishment, self dislike, self accusation, suicidal ideas, crying, irritability, social withdrawal, body image, work difficulties, insomnia, fatigue, appetite, weight loss, bodily preoccupation and loss of libido. Items 1 to 13 assess symptoms that are psychological in nature, while items 14 to 21 assess more physical symptoms.

Becks depression inventory can be used for both adults and adolescents 13 years of age or older. Beck depression test is a standard measure of depression used mainly in research and for the evaluation of effectiveness of treatments used for depression.

Internal consistency of the BDI ranges from 0.73 to 0.92 with a mean of 0.86. The BDI demonstrates high internal consistency with alpha
coefficients of 0.86 and 0.81 for psychiatric and non psychiatric population respectively. BDI has a split half reliability of 0.93.

BDI has high content validity and validity in differentiating between depressed and non depressed people. BDI items are consistent with six of the nine DSM III categories for the diagnosis of depression. Concurrent validity with clinical ratings of depression using BDI range from 0.62 to 0.66.

Internal consistency has been successfully estimated by over 135 studies in many populations. The BDI has been shown to be valid and reliable, with results corresponding to clinician ratings of depression in more than 90% of all cases.

The questionnaire was translated to Malayalam by Dr Razeena Padmam and Dr Subhadra in 2009.

**Procedure**

A true translation of the questions of the Beck’s Depression Inventory was done. The translated questionnaire was circulated among experts. The questionnaire was further corrected based on the suggestions provided by the experts. The translated questionnaire was administered
to 200 patients with low back pain patients who had a history of low back pain for more than 6 months, irrespective of their diagnosis.

**Validity**
As the tool is a true translation of English version of Beck’s Depression Inventory, the tool can claim both content and face validity.

**Reliability**
The reliability (Cronbach’s alpha) was calculated and was found to be 0.786.

**Scoring**
The sum of all BDI item scores indicates the severity of depression. It consists of 21 items. Each item has 4 possible responses. Each response is assigned a score rating from 0 to 3.

For the general population a score of 5 to 9 is considered normal, 10-18 as mild to moderate, 19-29 as moderate to severe and 30-63 is considered as severe.

**PGI wellbeing Measure**
The instrument was developed by Verma and Verma in 1989. This instrument consists of 20 questions related to personal satisfaction and
well being. The questionnaire was translated to Malayalam by Dr Razeena Padmam and Dr Subhadra in 2009.

**Procedure**

A true translation of the questions of the PGI wellbeing measure was done. The translated questionnaire was circulated among experts. The questionnaire was further corrected based on the suggestions provided by the experts. The translated questionnaire was administered to 200 patients with low back pain patients who had a history of low back pain for more than 6 months, irrespective of their diagnosis.

**Scoring**

The check list consisted of 20 items. Each question had yes or no options. ‘Yes’ option was scored as 1 and ‘No’ option was scored as 0. A score of 20 indicates maximum well being measure.

**Validity**

As the tool is a true translation of English version of well being the tool can claim both content and face validity.

**Reliability**

The split half reliability was calculated and was found to be 0.932.
**Oswestry low back pain scale**

The Oswestry low back pain scale was developed by Fairbank, 1980 (version 1.0). It has 10 sections of questions that evaluate the activities of daily living, which can be drastically influenced by LBP. The sections have been selected from experimental questionnaires that aimed to assess several aspects of daily living. The OSWESTRY LOW BACK PAIN SCALE domains are the following: pain intensity, personal care, lifting, walking, sitting, standing, sleeping, sex life, social life and travelling. Each section contains six statements that are scored from 0 (minimum degree of difficulty in that activity) to 5 (maximum degree of difficulty). If more than one statement is marked in each section, the highest score should be taken. The total score is obtained by summing up the scores of all sections, giving a maximum of 50 points. The final score is expressed as a percentage with the following formula: (total score/ number of questions answered) 100%. The OSWESTRY LOW BACK PAIN SCALE is a functional status outcome measure widely used in the clinical management of spinal disorders. It is validated in English, (Fairbank 1980) and many other languages. The OSWESTRY LOW BACK PAIN SCALE has been
recommended as a back pain–specific measure of disability by researchers in this field (Brox 2003).

The OSWESTRY LOW BACK PAIN SCALE has high internal consistency (Cronbach’s alpha 0.71–0.87) (Fairbank2000) and test–retest reliability (intraclass correlation coefficient 0.84, 95% confidence interval 0.73–0.91). The standard error of measure has been reported to be between 4 and 6. The OSWESTRY LOW BACK PAIN SCALE has adequate content validity, as it covers activities of daily living that are commonly experienced by patients with back pain. The OSWESTRY LOW BACK PAIN SCALE has high internal consistency, with Cronbach’s alpha between 0.71 and 0.87 (Fairbank 2000)

**Physical examination check list (Porter 2003)**

The check list consists of various physical examination procedures which are specific to the musculo skeletal system of low back. It consists of following procedures.

1. Posture
2. Normal alignment
   - Deviations from normal
• Creases in the posterior aspect of the trunk and particularly adjacent to the spine

• Sway back comprises hyperextension of the hips, an anterior pelvic tilt and anterior displacement of the pelvis.

• Flat back consists of a posterior tilt and a flattening of the lumbar lordosis, extension of the hip joint, flexion of the upper thoracic spine and straightening of the lower thoracic spine.

• Kypholordosis is forward poking chin posture, elevation and protraction of the shoulders, rotation and abduction of the scapulae, an increased thoracic kyphosis, anterior rotation of the pelvis and an increased lumbar lordosis.

• Shifted posture commonly arises from disc herniation or acute irritation of a facet joint. Mostly the shift occurs away from the painful side.

3. Active Movements

• Flexion

• Extension

• Side Flexion
4. Passive physiological intervertebral movements (PPIVMs)
   • Overpressure
   • Repeated movements
5. Assessing the sacroiliac joint
   • Sitting flexion (Piedello’s sign)
   • Standing flexion (Stork test)
6. Compression tests
   • Posterior ligaments
   • Anterior ligaments – Faber’s test
7. Neurological Testing
8. Myotomes
9. Reflexes
10. Adverse mechanical tension
    • Passive neck flexion
    • Straight leg raise (SLR) test
    • Prone knee bend (femoral nerve stretch) test
    • Slump test
11. Testing for lumbopelvic stability
12. Palpation
13. Accessory spinal movements
Statistical techniques

The statistical analysis of data was done using SPSS 20. The techniques used were

1. ANCOVA
2. Pearson correlation analysis
3. Wiloxon Signed Rank test

1. ANCOVA was used to find out whether there were significant differences between patients with pathological low back pain and patients with somatoform low back pain patients in pain & functional disability, anxiety, depression and wellbeing after being treated with homoeopathic medicines alone, with placebo alone and with homoeopathic medicine in combination with placebo.

ANCOVA was also used to find out whether there were differences among patients with pathological low back pain in pain & functional disability, anxiety, depression and wellbeing after being treated with homoeopathic medicines alone, with placebo alone and homoeopathic medicine in combination with placebo.
ANCOVA was also used to find out whether there were differences among patients with somatoform low back pain in pain & functional disability, anxiety, depression and wellbeing after being treated with homoeopathic medicines alone, with placebo alone and with homoeopathic medicine in combination with placebo.

2. Pearson correlation analysis was used to find out whether there were any correlations between the selected variables in the 2 categories of patients.

3. Wilcoxon signed rank test was used to analyse whether there was any significant difference in the physical signs before and after being treated with homoeopathic medicines alone, with placebo alone and with homoeopathic medicine in combination with placebo.