## CHAPTER – 3

**MATERIALS AND METHODS**

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CHAPTER 3: MATERIALS AND METHODS:

3.1: HYPOTHESIS:

PHASE 1:
1.1: Null Hypothesis:
   1.1.1: There is no significant reduction of FEV$_1$ in Patients with Chronic Low Back Pain.
   1.1.2: There is no significant reduction of PEFR in Patients with Chronic Low Back Pain.

1.2: Alternate Hypothesis:
   1.2.1: There is significant reduction of FEV$_1$ in Patients with Chronic Low Back Pain.
   1.2.2: There is significant reduction of PEFR in Patients with Chronic Low Back Pain.

PHASE 2:
2.1: Null Hypothesis:
   2.1.1: There is no significant relationship between Pain, disability and FEV$_1$ in Patients with Chronic Low Back Pain.
   2.1.2: There is no significant relationship between Pain, disability and PEFR in Patients with Chronic Low Back Pain.

2.2: Alternate Hypothesis:
   2.2.1: There is significant relationship between Pain, disability and FEV$_1$ in Patients with Chronic Low Back Pain.
   2.2.2: There is significant relationship between Pain, disability and PEFR in Patients with Chronic Low Back Pain.

PHASE 3:
3.1: Null Hypothesis:
   3.1.1: There is no significant effect of Core Stabilization exercise in reducing the Pain and disability and improving Pulmonary Function - FEV$_1$ & PEFR in Patients with Chronic Low Back Pain.
   3.1.2: There is no significant effect of Yoga in reducing the Pain and disability and improving Pulmonary Function - FEV$_1$ & PEFR in Patients with Chronic Low Back Pain.
3.2: Alternate Hypothesis:

3.2.1: There is a significant effect of Core Stabilization in reducing the Pain and disability and improving Pulmonary Function - FEV$_1$ & PEFR in Patients with Chronic Low Back Pain.

3.2.2: There is a significant effect of Yoga in reducing the Pain and disability and improving Pulmonary Function - FEV$_1$ & PEFR in Patients with Chronic Low Back Pain.

PHASE 4:

4.1: Null Hypothesis:

4.1.1: There is no significant difference between the Core Stabilization exercise and Yoga in reducing the Pain and disability and improving Pulmonary Function - FEV$_1$ & PEFR in Patients with Chronic Low Back Pain.

4.2: Alternate Hypothesis:

4.2.1: There is a significant difference between the Core Stabilization exercise and Yoga in reducing the Pain and disability and improving Pulmonary Function - FEV$_1$ & PEFR in Patients with Chronic Low Back Pain.

3.2: STUDY DESIGN:

Pre-test / Post-test experimental study – A randomized Control Trial

3.3: SETTING:

Department of Physiotherapy, MIP College of Physiotherapy, Yeshwanthrao Chavan Hospital [MIMSR medical College and Hospital], Latur, Maharashtra.

3.4: POPULATION:

Patients attending outpatient physiotherapy clinic with chronic low back pain.

3.5: SAMPLE:

A total number of 216 patients with chronic low back pain who fulfilled the selection criteria’s were included in this study.
3.6: RANDOMIZATION [Sampling]:

Sampling procedure was done by the principal investigator before the baseline assessment. cLBP patients who met the selection criteria were randomized by simple chit method, without any replacement, into 2 groups as Group A [Experimental] and Group B [Control]. Patients in Group – A received core stabilization exercises whereas Group - B patients underwent Yoga as intervention.

3.7: STUDY DURATION [Data Collection]:

2 years

3.8: STUDY DURATION FOR EACH SUBJECT [113, 132, 144, 200]:

9 Weeks

3.9: SELECTION CRITERIA:

3.9.1.:: INCLUSIVE [113, 132, 143]:

➢ Patients with Chronic Low Back Pain for atleast three month of duration.
➢ Both genders are included.
➢ Age between 20 and 50 years.
➢ BMI ≤ 25

3.9.2.:: EXCLUSIVE [113, 116, 143, 144]:

➢ Patients with history of the known pulmonary diseases such as
  o Pulmonary fibrosis,
  o Emphysema,
  o Bronchial asthma,
  o Cardiothoracic surgery,
  o Chronic bronchitis,
  o Lung cancer was excluded.
➢ Patients with specific cause for their back pain such as
  o Spondylolisthesis,
  o Fracture spine,
Spinal surgery
- Trauma
- Spinal abnormalities [Scoliosis, Kyphosis]
- IVDP
- Congenital abnormalities
- Ankylosing Spondylitis
- Hernia / Visceral Problems

➢ Any medical condition like
  - Tumour,
  - Pregnancy;
  - Complex conditions eg., sciatica, spinal stenosis

➢ Patients with medical conditions for which exercise and yoga is contraindicated like
  - Known case of Severe disc disease,
  - Known case of major depression

➢ Also excluded the person who has unstable medical or severe psychiatric issues and dementia.

➢ Regarding the intervention those who did any kind of back exercise or yoga in the previous 6 months were excluded.

3.10: PROCEDURE:

After informing about the objective and scope, procedures, risks and benefits of the research, all participants gave their signed written consent. Participation was voluntary and withdrawal from this study was permitted at any time. All procedures were carried out in accordance with the Declaration of Helenski. Research was approved by the Research and Recognition as well as Ethical committee of both the university and the study center. All the patients underwent a standardized interview regarding their medical history, pain history, occupation, and duration of the symptoms.

The study sample comprised of 230 patients with history of chronic low back pain. Out of these 230 subjects 216 successfully completed the intervention at the end of 9 weeks. In this, experimental group [EG] and control group [CG] has 109 and 107 patients respectively. Mean age, weight, height, duration of CLBP was recorded. The subjects were matched and randomly assigned into 2 groups; each group performed the assigned exercise
for 30 mins, 2 sessions [Morning & Evening] every alternate day for 9 weeks based on the
guidelines from the previous research works [113,114,143,144]. All the participants were
instructed not to do any other physical exercise, other than the specified prescribed one
during the study period. The outcomes measures were measured before intervention [Pre-
test], 3 weeks [Post-test-1], 6 weeks [Post-test-2] and 9 weeks [Post-test-3] after the
interventions and recorded for statistical analysis.

3.11: INTERVENTION:

3.11.1 Experimental Group:
Core Stabilization exercises [CSE] are done for 9 weeks in total. It is divided into 3
stages with 3 weeks per stage. Each exercise was repeated 10 times with 10 seconds
hold. All the patients were instructed to do warm up for 5 min before the CSE and 5
min cool down exercises after CSE. Simple stretching, active movements and
normal walking is administered for this warm up and cool down phase. Patients were
instructed not to do any kind of breathing exercise throughout the research period.

<table>
<thead>
<tr>
<th>CORE STABILIZATION EXERCISES</th>
</tr>
</thead>
<tbody>
<tr>
<td>STAGE - 1: [0-3 weeks]</td>
</tr>
<tr>
<td>Warm-Up for 5 mins.</td>
</tr>
</tbody>
</table>

1. **Supine Abdominal Draw In:**
   Lie flat on your back. Feet on the floor, knees
   bend to 60 degree. Gentle draw lower stomach
to the spine. Keep breathing.
   ![Photo 1: Supine abdominal Draw In]

2. **Abdominal Draw In with knee to chest:**
   Lie flat on your back. Feet on the floor, knees
   bend to 60 degree. Draw one knee to the chest
   while maintaining abdominal draw in. Keep
   breathing. Repeat for both legs.
   ![Photo 2: Abdominal Draw In with knee to chest]
### STAGE - 2: [3 - 6 weeks]

#### Cool Down for 5 mins.

#### Warm-Up for 5 mins.

Repeat Exercise 1 – 4 for 10 times.

<table>
<thead>
<tr>
<th>Exercise</th>
<th>Description</th>
</tr>
</thead>
</table>
| **3** | **Abdominal controlled curls:**  
Same position as above. Hands and arms by the side. Slowly curl up to lift your shoulder blade of the ground. When you lower also keep the abdominal in. Breath in when curls up and out when you go down. | ![Photo 3: Abdominal Controlled Curls](image) |
| **4** | **Bridging:** Lye flat on your back. Keep the spine in neutral position. Draw in abdominals. Push down through your feet and lift your bottom up. Breathe in as you lift and out as you lower. | ![Photo 4: Bridging](image) |
| **5** | **Single Leg Bridging:**  
Same as above. Lift one leg straight so that the trunk is straight [Shoulder, hip and knee in same line]. Maintain the abdominal draw in and breathing | ![Photo 5: Single Leg Bridging](image) |
| **6** | **Quadruped Cat and Camel:**  
In quadruped position. CAT – Inhale as you arch the back up and hollow out abdominals with head tucked in.  
CAMEL – Exhale and lower abdominal and move chin upwards. | ![Photo 6: Quadruped – Cat & Camel](image) |
<table>
<thead>
<tr>
<th></th>
<th>Exercise Description</th>
<th>Instruction</th>
<th>Image</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td>Quadruped Opposite arm / leg:</td>
<td>In quadruped position. Keep the spine straight and draw in abdominals, lift the leg and opposite arm straight.</td>
<td><img src="image" alt="Photo 7: Quadruped – Opposite Arm / Leg" /></td>
</tr>
<tr>
<td>8</td>
<td>Prone Cobra:</td>
<td>Lie on your stomach [Prone] with arms on the sides. Lift the head and chest off the table. Hold the gluteus tight and bring both shoulder blades together. Activate the multifidus muscle by training it.</td>
<td><img src="image" alt="Photo 8: Prone Cobra" /></td>
</tr>
<tr>
<td></td>
<td>Cool Down for 5 mins.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>STAGE - 3: [6 - 9 weeks]</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Warm-Up for 5 mins.</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Repeat Exercise 1 – 8 for 10 times.</td>
<td></td>
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<tr>
<td>9</td>
<td>Hundreds Plus:</td>
<td>Supine Lying flat on the floor. Lift both the lower legs off the ground and keep the hip and knees at 90 degree, so that the shin is parallel to the floor. Draw in the abdominals and do curl up by lifting the head and shoulder off the ground with the arms on the side.</td>
<td><img src="image" alt="Photo 9: Hundreds Plus" /></td>
</tr>
<tr>
<td>No.</td>
<td>Exercise</td>
<td>Description</td>
<td></td>
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<td>-----------------------------------------------------------------------------</td>
<td></td>
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<tr>
<td>10</td>
<td><strong>Lunges:</strong></td>
<td>Stand in walk standing position. Keep spine in neutral and draw in abdominals. Put 90% of body weight in the front foot and bend the knees to 90 degree, trunk should be straight. Arms on the side, back heel off the ground.</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td><strong>Front Plank:</strong></td>
<td>Prone lying position. Place the elbow on the floor directly under the shoulder. Support on the elbow and toes, rise up your body. Trunk should be straight.</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td><strong>Side Plank:</strong></td>
<td>Side lying position. Place the elbow on the floor directly under the shoulder. Support on the elbow and toes, rise up your body. Trunk should be straight.</td>
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</tbody>
</table>

**Cool Down for 5 mins.**

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### 3.11.2 YOGA Group:

Yoga Therapy is done for 9 weeks in total which is divided into 3 stages with 3 weeks per stage. Each Yoga posture was repeated 10 times. All the patients were instructed to do warm up for 5 min before the CSE and 5 min cool down exercises after CSE. Simple stretching, active movements and normal walking is administered for this warm up and cool down phase. Patients were instructed not to do any kind of breathing exercise throughout the research period.
<table>
<thead>
<tr>
<th>STAGE - 1: [0 - 3 weeks]</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Warm-Up for 5 mins</strong></td>
</tr>
</tbody>
</table>

1. **Supta Matsyendrasana:**
   - Reclining twist.
   - Lie flat on your back. Bend both the legs. Twist the lower trunk to one side and keep it flat on the floor.

   ![Photo 13: Supta Matsyendrasana](image)

2. **Janyasana:**
   - Knee to chest.
   - Lie down on your back. Inhale and lift one leg. While exhaling bring knee close to chest and press on abdomen with clasped hands. Hold the position with normal breathing.

   ![Photo 14: Janyasana](image)

3. **Pawanmuktasana:**
   - Knee to chest + Head lift.
   - Lie down on your back. Inhale and lift both legs. While exhaling bring both knees close to chest and press on abdomen with clasped hands. Inhale again and as you exhale bring the head up and touch the knees. Hold the position with normal breathing.

   ![Photo 15: Pawanmuktasana](image)

4. **Setu Bandha Sarvangasana:**
   - Bridging.
   - Lie on your back with feet flat on floor. Press the feet and palm on the floor lift the hip and trunk up. Hold and bring it down.

   ![Photo 16: Setu Bandha Sarvangasana](image)

**Cool-Down for 5 mins.**

<p>| STAGE - 2: [3 - 6 weeks] |</p>
<table>
<thead>
<tr>
<th>Stage</th>
<th>Exercise Description</th>
</tr>
</thead>
</table>
| 5     | **Uttana Shishosana:**  
Extended puppy pose.  
Come onto all fours. Keep shoulder above the wrist and hip above the knee. Move the hand up. Bring the buttocks half way towards heel. Drop the forehead on the floor to relax the neck. Keep the low back to curve so that it stretches. |
| 6     | **Marjaryasana [Cat Pose]**  
**Bitilasana [Cow Pose]:**  
Begin on all fours position with hands under the shoulder and knees under the hips. Inhale and curl the toes under. Tilt the pelvis towards ceiling and draw the shoulder blades down, keep the neck long. Exhale and point the toes, make the back to round up and tilt the head down. |
| 7     | **Urdhva Mukha Svanasana:**  
Upward facing dog pose. Start lying flat on the floor with your palms faces down. Take your chest off the floor. Let the legs extended straight. |
| 8     | **Salabhasana [Locust Pose]:**  
Lie on the abdomen and the arms are kept on the sides. During inhalation lift both the legs and the upper torso. |

**Cool-Down for 5 mins.**

**STAGE - 3: [6 - 9 weeks]**

**Warm-Up for 5 mins.**
| 9 | **Urdhva Prasarita Padasana:** Upward extended feet pose.  
Lie flat on the back with legs fully extended. Arms kept along the side of the body with palm facing down. Bend both knees so that the thigh touches the abdomen. Stretch the legs towards the ceiling. Extend the arm over the head with palm facing up. |
|---|---|
| 10 | **Virabhadrasana I: Warrior Pose 1:**  
From a standing position, the legs are in a wide stance with the feet aligned and flat on the earth. The back foot is in a 60-degree angle towards the front. The hips are squared. The inner thighs are rotated towards each other. The front knee is bent in a 90-degree angle directly above the ankle. The arms extend up to the sky with the biceps by the ears. The hands can be together or separated and facing each other with the fingers spread wide. The ribcage is lifted and the pelvis tucked. The gaze is forward. |
| 11 | **Chaduranga Dandasana:** Plank.  
From the down dog position, lower your hips so that the body is in a high pushup position with hips kept straight between shoulders and ankles. Engage the abdominals. |
| 12 | **Utkatasana [Chair Pose]:**  
Exhale and bend the knees, squatting down. Reach the hips down and back as if you were going to sit on the edge of a chair, bringing your weight to the heels of the feet. Do not bring the hips lower than the level of the knees. Make sure that the knees are pointing straight ahead. Press the shoulders down and back trying to arch the spine. Relax the shoulders down and back and reach out through the finger tips. Stare at a point on the wall or floor in front of you for balance. Breathe normally. To release: inhale and press down into the feet straightening the legs and inhale the arms up toward the ceiling. Exhale release the arms down. |

**Cool Down for 5 mins.**
For relaxation, Shavasana can be used.

**Shavasana [Corpse Pose]:**

Relaxation. Lie comfortably on your back with the arms separated 45 degrees from the body, palm facing up. Legs apart and allow to roll open. Release all tension from every part of the body.

### 3.12: OUTCOME MEASURES:

#### 3.12.1 Pain:

Visual Analogue Scale.

Pain is measured using a Visual Analogue Scale. VAS is a straight horizontal line with fixed length usually 100mm. the ends are defined as the extreme limits of the pain intensity to be measured, where the left shows no pain and the right is worst pain.

#### 3.12.2 Disability:

Roland Morris Disability Questionnaire [RMDQ]

RMDQ is a self-reported outcome measure for the low back pain. The original version with 24 questions are widely used and a validated measure. The statements are related to the person’s perception of their back pain and its associated disability. It includes items on physical ability / activity [15], sleep / rest [3], psychological [2], household management [2], eating [1] and pain frequency [1]. The score ranges from 0 [no disability] to 24 [maximal disability].

### PULMONARY FUNCTION – FEV1 & PEFR:

Among the various pulmonary function parameters, FEV1 and PEFR is selected as these needs the quick recruitment of the transverse abdominis muscle and a stiff spine by the back extensors [66, 77, 81,] and also based on the protocol used in the previous research [66, 77, 81, 86,99].
3.12.3 Forced Expiratory Volume in the first second [Pulmonary Function]:

Spirometer – Welch Allyn – Schiller [SP-1].

Spirometry included different pulmonary tests; in this study we measured FEV1 according to the spirometer manual guidelines with special reference to the recommendations by the American Thoracic Society and European Respiratory Society [166,167].

In our study none of the patients had any chronic or acute pulmonary lung disease. Smoking was not considered important as none of the subjects quite smoking during their treatment. In order to see the effect of a regular physiotherapy programme, none of the patients were given any breathing exercise. Similarly the yoga group subjects were advised not to practice pranayama, a breathing technique.

Advised the patient to sit straight with head slightly extended, in the chair. Allow him to relax for a while. Apply the nose clip firmly. Participants used a nose clip in all tests to avoid any potential air leakage. Breathe in maximally. Hold the mouthpiece between the teeth and then apply the lips for an airtight seal. Breathe out as hard and as fast as possible. Advise the patient to exhale out, until the lungs are empty. Repeat the procedure for 3 times and the best reading is selected. FEV1 is the volume of the air expelled in the first second of a forced expiration.

Calibration:

Calibration of the machine was done by the biomedical department every 6th month.

3.12.4 Peak Expiratory Flow Rate [Pulmonary Function]:

Wright Peak Expiratory Flow Meter - Peak Flow Meter asmaPLAN + [Vitalograph]

PEFR is an inexpensive, accurate and simple test for measuring airway resistance and strength of expiratory muscles. Before starting the procedure, the indicator is moved to the lowest end of the numbered scale. Attach the mouthpiece to the apparatus. Instruct the patient to sit straight and comfortable with slight extension of the neck. Advised the patient to take deep inhalation, the mouth piece is then placed in the patient’s mouth with the lips tightly closing around it. Then the patient has to blowout forcefully and rapidly in single
exhalation to the maximum. Repeat the same procedure for 2 more times. The highest reading is noted and recorded for statistical analysis.

**Caliberation:**

Caliberation of the machine was done by the biomedical department every 6\textsuperscript{th} month.

Photo 26: Measuring PEFR using Wright Peak Expiratory Flow Meter.
3.13: CONSORT CHART

PROCEDURE OF DATA COLLECTION

Ethical Clearance / Approval / Inclusion of Samples for the study

Inclusive / Exclusive Criteria

Potentially Eligible Patients with CLBP [n=230]

Randomly Assigned [n=115]

Experimental Group [n=115]  Control Group [n=115]

Core Stabilisation Exercise for 9 weeks. Drop Outs [n=6]

Post Intervention Samples [n=109]

Drop Outs:
Absence – 4
Fracture – 1
Surgery – 1

Yoga for 9 weeks. Drop Outs [n=8]

Post Intervention Samples [n=107]

Drop Outs:
Absence – 6
Surgery – 1
Pregnancy – 1
3.14: SAMPLE SIZE CALCULATION:

G* power software version 3.1.9.2 [Heinrich-Heine-Universität Düsseldorf, Germany] was used to calculate the sample size. Previous research works on chronic low back pain with interventions such as core stabilisation exercises as well as yoga were used as the reference to calculate the effect size of this study. Assuming the type I error [$\alpha$], effect size of 0.12 (based on the data from research reviews), total sample size of 152 subjects is estimated to achieve a greater power rate of 95%.

The actual sample size of this study $N=216$ has a very less effect size of 0.10 with the greater power rate of 95%.

Table 1: Sample size calculation for the study.

<table>
<thead>
<tr>
<th>F tests - ANOVA: Repeated measures, within-between interaction</th>
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<tr>
<td>Analysis: A priori: Compute required sample size</td>
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<table>
<thead>
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<tbody>
<tr>
<td>Effect size f</td>
<td>0.12</td>
</tr>
<tr>
<td>$\alpha$ error problem</td>
<td>0.05</td>
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<tr>
<td>Power [1-$\beta$ error problem]</td>
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<tr>
<td>Number of groups</td>
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<td>Corr. among rep. measures</td>
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<td>Denominator df</td>
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<td>Total sample size</td>
<td><strong>152</strong></td>
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<td>Actual power</td>
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