CHAPTER – 4

4.1 Introduction:

This chapter includes a detailed description of the research methodology, participants selected to participate in the study and the outcomes used in the study. The measurements obtained and the statistical procedures used in the analysis of the data were also discussed.

Advertisement: Participants were recruited by sending pamphlets and circulars to the various departments of C.U.Shah medical college, local hospitals and clinics in Surendranagar.

4.2 Research Methodology:

4.2.1 Research design : Experimental design. (Interventional Study)

4.2.2 Sample design : Simple Random sampling. (Probable sampling) – Computer generated table (Annexure-6)

4.2.3 Study Population : Patients coming to C.U. Shah Physiotherapy Out patient department with the clinical diagnosis of Low Back Pain during the period of April 2009 to March 2011 (2 years).

4.2.4 Sample size : N=330, Acc to prevalence – (Annexure-5)

4.2.5 Sample Allocation: After the participants were assessed, those fulfilling the inclusion and exclusion criteria for the study were allocated into group 1, 2 or 3.

  Group 1 = (n=110)
  Group-2 = (n=110)
  Group-3 = (n=110)

4.2.6 Study Setting : C.U.Shah Physiotherapy College OPD, Surendranagar, Gujarat, India-363001.

4.2.7 Study duration : Two years (April 2009 to March 2011)
4.2.8 Selection Criteria:

4.2.8.1 Inclusion Criteria:

- Age 18 years and older (Younger than 18 years of age would need parental consent and this age group reports peak incidence of LBP in adults.),
- Untreated low back pain for more than ≥ 3 months,
- Both Genders (Males and Females),
- Uncomplicated chronic low back pain and Lumbago,
- Sciatica (Proximal to Knee joint) without neurologic deficit,
- The participants with pain rating scale on the Visual Analog Scale (VAS) greater than 3 and less than 8. This improves the sample homogeneity,
- The participants with Functional Disability on the Roland and Morris Disability Questionnaire Score (RMDQ) greater than 20% and less than 80%. This improves the sample homogeneity.

4.2.8.2 Exclusion Criteria:

Age less than 18 years and over 70 years old. (This represents a pediatric population that has not been carefully studied in the spinal manipulation literature.) Low back pain onset less than 3 months prior to baseline evaluation, Patients who have received physical therapy or any other manual therapy for low back pain within the past 3 months, Roland and Morris Disability score greater than 80% disability and/or Visual Analog scale Score greater than 8/10. This cohort of patients typically has severe symptoms that may indicate underlying serious pathology, which may not be suitable for manipulative therapy, Roland and Morris Disability score less than 20% disability and/or Visual Analog Scale Score less than 4/10. This cohort of patients typically has a low level of pain and disability that might resolve through natural history, without any clinical intervention. Spondylolisthesis, Spondylolysis, Spondylitis, Hypertrophic spondyloarthrosis. Degenerative disk disease (Spondylisis) and Spinal stenosis. Joint instability, Significant trauma, Acute fractures, Unstable fractures and intra spinal lesions. Gross radiologic deformity, Scoliosis greater than 20 degrees, Severe unremitting (non-mechanical) worsening of pain. Pain referred from pelvic
structures. Signs or symptoms suggestive of severe neurological deficit such as lower extremity sensory loss, motor weakness, atrophy, abnormal reflexes, paresthesia distal to the knee, strong nerve root tension signs, bowel or bladder dysfunction. Cauda Equina Syndrome - (sudden onset major bladder or bowel symptoms, perineal numbness), Nerve root compression (by tumor) and Radiculopathy (Distal to Knee joint), Herniation of the nucleus pulposus with an extruded free fragment, Straight leg raising less than 30 degrees Restriction of motion in two or more non continuous planes, Weight loss, fever, history of cancer/HIV, Use of IV drugs, Prolonged history of steroid use, Prior history of lumbar spine surgery, Malignancies of the spinal cord or vertebral column, Inflammatory joint disease (Rheumatoid arthritis) Ankylosing spondylitis, Bone or joint infection(Spine) (Osteomyelitis, Tuberculosis of the bone), Metabolic bone disease (Osteoporosis, Acute gout, Paget's disease), Congenital bleeding disorders, Hemophilia, Blood dyscrasia, Moderate to advanced spinal osteoarthritis, hip osteoarthritis, Hypertension, Severe over weight (BMI ≥ 32), Pregnancy and breastfeeding, Psychological disturbance/Severe Psychiatric Disease, Any other severe Systemic Diseases (Cardiac, Pulmonary, Neurologic, Orthopedic, Renal, GI, Skin diseases), Involvement in litigation for a health problem, or suspicion of noncompliance, indicated by a failure to attend a baseline visit before randomization. Patients with contraindications to spinal adjustment or mobilization.

4.3 Out Come Measures:

4.3.1 Primary Outcome measures:

4.3.1.1 Pain Intensity ; 10 cm Visual Analog Scale. (VAS)

4.3.1.2 Range of Motion ; Modified Modified Schober Test. (MMST)

4.3.1.3 Functional Disability ; Roland & Morris Disability Questionnaire (RMDQ)

4.3.2 Secondary Outcome measures:

4.3.2.1 Depression Level ; Physical Health Questionnaire-9 (PHQ-9)

4.3.2.2 Quality of Life ; Health Related Quality of Life – 4 (HRQOL-4)
4.3.1.1 Visual analog scale:

A widely used subjective measure of pain intensity is the Visual Analogue Scale (VAS). It consists of a 100 mm line reproduced on a piece of paper, with one end labeled "no pain" and the other labeled "the pain is as bad as it could be". The patient is asked to mark a spot on the line which corresponds to the best estimate of his/her own pain level at the time.

The level of pain intensity is measured as the distance in millimeters from the absence point to the patient's mark. It can be used as a relative measure in monitoring pain levels, or it can be used as discrete value.

10 centimeters

No Pain The pain is as bad it Could be

In general, this method of clinical pain assessment has been shown to be reliable and valid.\textsuperscript{300,301} The VAS is used to compare pain intensity in the same patient at different times or in groups of patients receiving different treatments. Huskisson\textsuperscript{300} states the VAS has a greater capacity to detect a change in response to a stimulus such as a treatment, than the simple verbal descriptive scale.

It has also been noted that the VAS is particularly reliable when used to measure current pain intensity.\textsuperscript{301} Other advantages attributed to the VAS include: simplicity, universality,\textsuperscript{300} and that it can usually be subjected to parametric statistical analyses.\textsuperscript{302}

Validity of the VAS has been challenged by Carlsson who states that patients seem to differ considerably in their ability to use the VAS reliably. Price\textsuperscript{302} concluded that validity of VAS measures may be dependent on the instructions given to respondents. This is based on the fact that estimation of pain intensity with VAS requires perceptual ability.

Other sources of error which should be considered with the use of VAS are: photocopying which makes the line longer\textsuperscript{300} and measurement of the VAS line and interpretation of where the subject has made the mark.
4.3.1.2 Modified Modified Schober Method:

Evaluation of patients with low back pain (LBP) frequently includes measurement of trunk range of motion. Many clinical techniques have been described for measuring trunk motion. These include the use of radiographs, inclinometers, spondylometers, fingertip-to-floor methods, goniometers, plumb lines, and tape measures. Each of these techniques has disadvantages, such as cost, exposure to radiation, need for specialized equipment, and questionable reliability. One method of measuring spinal range of motion (ROM) is with the use of a tape measure.\textsuperscript{303}

Modified Modified Schober Test (MMST): This technique was described by \textit{van Adrichem and van der Korst}.\textsuperscript{304}

The MMS technique was selected for several reasons. First, the landmarks in the modified Schober technique\textsuperscript{305} require the identification of the lumbosacral junction and a mark 5 cm below this landmark to include lumbosacral motion and to minimize skin movement. Distance 5 cm below the lumbosacral junction is difficult to accurately identify as it lies in the upper part of the natal cleft on most individuals. The use of the PSISs as the inferior landmark in the MMS technique has several advantages. A mark placed midway between the PSISs is at the second sacral level.\textsuperscript{306} This mark is on the sacrum, which is an inflexible bone, and no motion would be expected to be gained by using an additional mark below this level. This landmark is also easily identifiable and eliminated the need for an additional landmark 5 cm below this landmark.

Second, the superior landmark for the MMS technique was identified as a measured distance (15 cm) above the inferior landmark of the line intersecting the line connecting the PSISs, rather than the first lumbar vertebra. This method was proposed to minimize error in identifying the first lumbar vertebra. Van Adrichem and van der Korst\textsuperscript{304} suggested that a 15-cm distance superior to the line intersecting the line connecting the PSISs was an accurate representation of the actual length of the lumbar spine.

The final reason for selection of the MMS technique was to provide common landmarks for the MMS and Double Inclinometer (DI) methods. The MMS method appears to produce reliable measurements of spinal flexion and extension in patients with LBP. MMS measurements are easier and quicker to obtain.
**Procedure:**

1. A set of paper footprints is kept on the floor, with the heels of the footprints about 15 cm apart.

2. Patient position: The patient stands erect, eyes focusing horizontally in front, arms at side, with feet placed on the paper footprints.

3. Skin markings: The therapist stands behind the patient and identifies the posterior superior iliac spines (PSISs) by marking the PSISS with his or her thumbs. Make an ink mark on the midline of the lumbar spines horizontal to the PSIS. Make another mark on the spinous processes 15 cm superior to the PSIS line (to the nearest millimeter). The distance between the superior and inferior skin marks on the spinous processes is 15 cm.

4. Align the tape measure between the two skin marks, with zero at the inferior skin mark and 15 cm at the superior skin mark. Keep the tape measure firmly against the patient's skin while the patient bends forward.

5. Instructions to the patient: "Bend forward as far as you can while keeping your knees straight."

6. Measurement procedure: When the patient has bent forward, the new distance between the superior and inferior skin markings is measured (to the nearest millimeter) with the patient positioned in full lumbar flexion.

7. Instructions to the patient: "You can come back to a comfortable standing position."

8. On the sheet provided, record the measurement. Flexion range of motion is the difference between the initial length between skin markings (15 cm) and the length measured in full forward flexion.

9. Remove all skin marks with rubbing alcohol.

10. What to do if the patient cannot attain or maintain position: Allow 1 minute of rest in the patient's most comfortable position. Try again. If that fails, abort the test. Record "N/A" and indicate the reason for failure.
4.3.1.3 Roland and Morris Disability Questionnaire:

A wide variety of rating systems were used to measure functional outcomes in patients with LBP. Functional status measures are usually classified as generic or disease specific. Disease-specific measures assess symptoms and functional limitations related to a specific disease/condition, so in the back pain patient back related problems are focused. Although many back pain score systems are available, the most used in clinical settings are: RDQ, ODI, QBPDS, WDI, MVAS, LBOS, LBPRS, NASS, and CBPQ.

The Roland and Morris Disability Questionnaire (RDQ) is a health status measure created to assess physical disability from LBP and it is one of the most used in research or clinical settings for monitoring patients. It is constructed by choosing statements from the sickness impact profile (SIP).

The scale consists of 24 yes/no items related specifically to physical functions to specifically assess the disability from LBP. The physical functions considered include walking, bending over, and sitting, lying down, dressing, sleeping, self-care and daily activities. Patients are asked whether the statements apply to them that day (i.e. the last 24 h). In the scale, one point is given for each item. The RDQ score can be obtained by adding up the number of items checked. The final score ranges from 0 (no disability) to 24 (severe disability).

The total scores measured by the RMDQ were divided into three score scales for measuring the degree of disability, taking 0-8 as minimal disability, 9-16 as moderate disability, and 17-24 as significant disability (Kovacs et al., 2002).

The questionnaire is self-administered by the patient, it can be completed in a maximum of 5 min, and an un-weighted score can be calculated in less than 1 min. The questionnaire is simple to complete and easily understood by patients. The RDQ score correlate well with the data obtained from other physical function score systems, such as the QBPDS and the ODI. The RDQ has good construct validity, internal consistency, responsiveness and reliability. On the basis of the validation study conducted by Roland and Morris, the RDQ should be applied for disability assessment when there is the need to detect short-term changes in back pain or short term changes in response to treatment. The RDQ is validated in Guajarati and 36 other languages.
4.3.2.1 Physical Health Questionnaire-9 (PHQ-9):

The PHQ-9 is derived from Primary Mental Disorders (PRIME-MD)\(^ {312} \) which was originally developed to detect five common mental disorders in primary care. It is a self-report questionnaire that assesses the levels of depression on the nine key symptoms (each rated from 0-3) in the past two weeks. Answer of "not at all" "several days" "More than half the days" and "almost every day" scores 0, 1, 2 and 3, respectively.

The scores on the questionnaire range from 0 to 27: Score 0-4 none, 5-9 mild depression, 10-14 moderate depression, 15-19 moderately severe depression, 20-27 severe depression respectively. A score of 10 or higher is indicative of moderate or severe depression and is used to consider major depressive disorder present.\(^ {313} \) The score can also be used as a measure of depression severity.\(^ {313} \) For the categorical algorithm, the answers on the questions were dichotomized: 0 (not at all) and 1 (several days) are coded as 0 (symptom absent) and the answers 2 (more than half the days) and 3 (nearly every day) are coded as 1 (symptom present).

Cut point of 10 or greater is considered yellow flag on all 3 measures (drawing attention), while a cut point of 15 is a red flag on all 3 measures (active treatment is probably warranted). The final question on the PHQ is not used in calculating any PHQ score or diagnosis but rather represents the patient's global impression of symptom-related impairment. It may be useful in decisions regarding initiation of or adjustments to treatment since it is strongly associated with both psychiatric symptom severity as well as multiple measures of health-related quality of life.

Because of its briefness as well as easy operation and scoring, the PHQ-9 is quickly applied in a wide range of scientific research and clinical practice. It shows as a screening scale for depression in various musculo skeletal disorders, and it has a good reliability and validity. In addition, studies have shown that the PHQ-9 is superior to the HADS in the diagnosis of depressive disorders.\(^ {314} \) Further, as a screening tool, it also shows good validity.\(^ {315} \) The PHQ-9 is also very sensitive to changes of depression after treatment on patients with depressive disorder.\(^ {316} \) Currently, the PHQ-9 is the only self-administered depression scale that are effective in both of screening disease severity and result measurement.\(^ {316} \) Therefore, in the United States, the PHQ-9 is recommended as a routine depression scale by primary health care institutions.
4.3.2.2 Health Related Quality of Life-4 (HRQOL-4):

Low Back Pain is widely accepted as one of the most important determinants of quality of life because of its widespread adverse health effects, including diminishing mental health and well-being; and impairing the individual’s ability to perform daily activities. With the epidemiologic transition in the leading causes of death from infectious disease and acute illness to chronic disease health-related quality of life (HRQOL) is now recognized as an important measurement in public health as well as in clinical research and some other health-related disciplines.

The Centers for Disease Control and Prevention (CDC) has developed a brief set of HRQOL items. CDC HRQOL-4 scale has been shown to perform well in individuals with musculoskeletal pain. The CDC HRQOL assumes that HRQOL is a fundamentally subjective construct whose core features (physical and mental health appraisal) are expressed through patients’ judgments of their general health and the number of days within the past month when they felt physically unhealthy, mentally unhealthy, and limited their activities because of their health. These responses are elicited by four questions that comprise the core module of the CDC HRQOL.

In the CDC HRQOL-4, the first question asks respondents to rate their general health on a scale from excellent to poor. We dichotomized these responses as either “fair/poor” or “good/very good/excellent.” The other 3 questions ask about respondents’ assessment of their health in the previous 30 days:

1. “How many days was your physical health, which includes physical illness or injury, not good?” (Physical distress),

2. “How many days was your mental health, which includes stress, depression, and problems with emotions, not good?” (Mental distress),

3. “How many days did poor physical or mental health keeps you from doing your usual activities, such as self-care, work, or recreation?” (Activity limitation).

We dichotomized these 3 HRQOL variables in terms of their frequency in the previous 30 days (≥14 being frequent or <14 being infrequent). We used the 14-day minimum period because clinicians and clinical researchers often use this period as a marker for clinical depression and anxiety disorders, and longer duration of symptoms is associated with a higher level of activity limitation.
With respect to patient acceptability, the four items of the CDC HRQOL-4 can be completed more quickly (less than 1 minute) than SF-36 (10–15 minutes). The CDC HRQOL-4 does not require complicated scoring algorithms to derive a quality-of-life profile. Because the CDC HRQOL-4 has continuous, cardinal, and bounded (range, 0–30 days) mathematical properties, its metric is concrete and intuitive.

In this respect, the CDC HRQOL-4 has advantages over other quality-of-life instruments that have been described as difficult to interpret and of limited practical value. The CDC HRQOL-4’s unit of analysis is time referenced (30 days) and therefore lends itself to the study of health-related quality of life, regarded as an inherently time related phenomenon.\textsuperscript{322}

The concepts assessed by the CDC HRQOL-4 scale are believed to be universal, however, and are therefore capable of being adapted for use in other cultures and languages. The CDC HRQOL-4 which has been shown by international studies to be both valid (content, construct and criterion) and reliable, was chosen because of its shortness and apparent usefulness in the clinical population.\textsuperscript{323}

Studies have also established the construct validity of the CDC HRQOL-4 for use in general non institutionalized adult populations. One study found the measure of activity limitation days to be a valid global indicator of disability in general adult populations.\textsuperscript{324}

A self-administered version of the CDC HRQOL-4 measures had good construct and concurrent validity based on reported health conditions, physical exams, and other measures.\textsuperscript{325}

The CDC HRQOL-4 measures had acceptable test-retest reliability and strong internal validity.\textsuperscript{326} The core CDC HRQOL-4 measures are the briefest validated set of generic HRQOL measures.

The measures provide a cost-effective and less burdensome alternative or complement to longer HRQOL measures. A CDC-funded validation study concluded that the CDC-HRQOL modules are a reasonable alternative to the SF-36.\textsuperscript{327}

Measures such as the CDC HRQOL-4 may offer clinicians and researchers an important tool for capturing patients’ experience, informing decision-making, strengthening patient–provider relations, and enhancing the delivery of care.
4.4 Program Schedule:

Patients were recruited from all the departments of C.U.Shah Medical College, Surendranagar, and from the local hospitals and clinics in Surendranagar area.

The study was done in two phases. In the first phase the reliability and validity of the Guajarati version of Roland and Morris Disability Questionnaire (RMDQ) and Physical Health Questionnaire – 9 (PHQ-9) was checked. In the second phase the effectiveness of Spinal Manipulation, Low Level Laser Therapy and Conventional Exercises were analyzed and compared.

4.4.1 PHASE – I:

Patients and Setting:

Thirty (n = 30) consecutive outpatients during the period of Jan 2009 to Feb 2009 with non specific chronic low back pain of at least 3-months duration were included in the study. All patients had been previously investigated by physical and neurological examination, spine x-rays and laboratory tests to identify the non-mechanical/medical causes of low back pain. Patients with the suspicion of non-mechanical/medical low back pain and patients having neurological deficit were not included in the study. All patients, after giving their consent to participate, were assessed by the same observer.

The assessments included level of pain on a Visual Analog Scale, lumbar flexibility measured by Modified Modified Schober test (MMST), functional disability by RMDQ and Depression level by PHQ-9. RMDQ and PHQ-9 was self-completed by the patients. Patients were asked to attend for a further assessment three days later.

Assessment of Reliability and Validity:

Reliability is concerned with the consistency of the instrument. Validity is concerned with whether the instrument measures the characteristic it purports to measure. Two common forms of reliability for a self-completed questionnaire in a yes/no format, such as the present instrument, are internal consistency and the intra-class correlation coefficient, (ICC) both of which are evaluated in this study. Increasingly, two forms of validity should also be considered; ‘internal’ validity where attention is given to the
integrity of the defined construct, and external validity which is concerned with expected associations with other key variables. Internal validity in the current study is assessed by fit of the data to the one parameter Item Response Theory (Rasch) Model. The Rasch measurement model assumes that the data from an instrument are one-dimensional and thus the model can be used to test whether the items in the scale do belong to a single underlying construct. Testing the fit of the data to the Rasch model is equivalent to a test of the theoretical construct validity and adequacy of the scale.

Fit is assessed by two mean square (MNSQ) fit statistics. These statistics are derived for every item and, taken together; provide information on the consistency of the responses to each item. The outlier-sensitive MNSQ fit statistic (OUTFIT) is more sensitive to abnormal responses to items far from the person's ability level, for example, those from a very able person responding to a very easy item. This statistic is weighted to derive an information-weighted statistic (INFIT). As the influence of outliers is reduced, the INFIT is able to provide information about the more central responses, that is, individuals' responses to items at the same difficulty level as their ability level.

MNSQ values between **0.6 and 1.4** are taken to reflect adequate fit to the model for this sample size. Values above 1.4 indicate unexpected responses to the item, and may reflect poorly understood items, or those that do not belong to the same construct. Values below 0.6 indicate items where the response is more deterministic, in that there is less variation than expected. Once the internal validity of the scale has been confirmed, external validity can be considered. In this study it has been examined by construct validity through convergent validity of the instrument with measure of pain and spinal mobility.

4.4.2 PHASE – II:

At the initial consultation, the subjects were randomly assigned to their groups, subjects were explained outlining the research procedure, which was personally explained to them through Information Form. (Annexure-1) Each subjects signed consent form (Annexure-2) allowing the researcher to begin the research with the subjects understanding that they were able to withdraw from the study at any stage. Each patient underwent a complete low back pain evaluation form (Annexure-3).
Figure 8: Study Flow chart

Enrollment
N = 520

Randomization
n = 330 subjects

Group-1
n = 110 subjects
After 4 weeks
109 (99.09%)
After 8 weeks
107 (97.27%)
After 6 months
102 (92.72%)

Group-2
n = 110 subjects
After 4 weeks
109 (99.09%)
After 8 weeks
106 (96.36%)
After 6 months
101 (91.81%)

Group-3
n = 110 subjects
After 4 weeks
108 (98.18%)
After 8 weeks
105 (95.45%)
After 6 months
101 (91.81%)

Subject Allocation

FOLLOW UP

Final Analysis

n = 108 Excluded.
n = 56 Did not meet inclusion criteria.
n = 26 Not willing to participate.

n = 110 subjects Analyzed
n = 110 subjects Analyzed
n = 110 subjects Analyzed
Self reported measures included the Guajarati version of Roland and Morris Disability Questionnaire (RMDQ) (Annexure-7), Physical Health Questionnaire-9 (PHQ-9) (Annexure-8) and Health related Quality of Life-4 (HRQOL-4) (Annexure-9) was used to measure the functional disability, depression level, and Health related Quality of life of the participants.

Separate sets of questionnaires are used at baseline, 4th week after treatment, and 8th week, and 6 month follow-up assessments. No information and questionnaire scores on previous assessments were disclosed to participants throughout the treatment in order to reduce bias and entered in the data collection form. (Annexure-4)

330 Patients who were willing to participate in the study and fulfill the inclusion and exclusion criteria were included in the study and they were randomly divided (110 + 110 + 110) into three Groups (1 & 2 & 3). Fig-8

Group-3 (n=110): Conventional Exercises.

The assessment and scoring was blinded to each patient until data collection was completed. Participants were advised to abstain from use of other forms of heat and ice therapy, massage therapy, herbal and holistic therapies, sauna, spa baths, steam rooms, and therapeutic showers while participating in this study.

4.4.2.1: Materials Used:
Laser Instrument and its Accessories
Goggles
Treatment Couch, Pillows
Sphygmomanometer
Marker
Inch Tape, Weigh machine
Evaluation Form
RMDQ, PHQ-9, HRQOL-4 Questionnaire
Data collection Form
Figure 9: Materials used in the study:

Figure 10: Laser instrument and its accessories:
Figure 11: Subject receiving Lumbar spine manipulation:

Figure 12: Subject receiving Low level Laser therapy for lumbar spine:
Figure 13: Subject receiving Conventional Exercises:

**Spinal Flexion Exercises:**
- Supine lying – Abdomen Contraction
- Abdomen curlup – with knee extension
- Abdomen curlup – with knee flexion
- Abdomen curlup – with spine rotation

**Spinal Extension Exercises:**
- Prone lying – Spine extension
- Quadruped position – with arm raise
- Spine extension – with leg raise
- Spine extension – with arm and leg raise
4.4.3.1 Description of interventions:

4.4.3.1.1 Spinal Manipulation:331,332

Physical therapists. Physical therapist participating in this study had, on average, about eight to ten years of professional experience in the area of orthopedic, sports medicine and manual therapy. The therapist was not considered suitable to perform these maneuvers until he/she could perform each one correctly in two attempts or less.

Patient Position: Start with patient side lying near the edge of couch. Flex the patients left hip and knee with the dorsum of the foot can lie behind the right knee. The straight leg is put into light hip flexion sufficient to place the particular inter vertebral joint midway between flexion and extension. The patient’s left arm is then extended at the shoulder and flexed at the elbow to allow the forearm to rest on his / her side.

The patient’s right arm is then placed in an abducted, laterally rotated position with the hand under his / her head and the spine is "locked" in extension. The therapist’s left thumb presses downwards against the left side of the spinous process of the upper vertebra and right middle finger pulls upwards against the right side of the spinous process of the lower vertebra. Patients also undergo basic range-of-motion exercise.333

Technique: Maximum rotary stretch is applied by rocking the patient back and forth with the forearms gradually increasing the stretch and pressure against the spinous process. The manipulation consists of increasing the push through both forearms and sharply increasing the pressure against spinous process. Greater leverage can be achieved by allowing the patient’s top leg to unhook from behind the opposite knee and relax out straight over the edge of the couch. The therapist’s arm and body were used to apply a high-velocity, low-amplitude thrust of the pelvis in an anterior direction.333

Application: The patient was first treated with the more symptomatic side up based on the patient’s self-report. If the patient could not identify a more symptomatic side, the therapist arbitrarily selected a side to manipulate first. To standardize the intervention, target the manipulation to the L4-L5 segment in all patients. After the first manipulation was performed, note whether or not a click was either heard or felt by the
therapist or patient. If a click was noted, the therapist proceeded to instruct the patient in the range-of-motion exercise. If no click was produced, the patient was repositioned and the manipulation was attempted again. If no click was experienced in the second trial, the therapist attempted to manipulate the opposite side. The therapist performed a maximum of 2 attempts per side. If no click was produced after 4 attempts, the therapist proceeded to instruct the patient in the range-of-motion exercise.

The posterior pelvic tilt range-of-motion exercise was completed in the physical therapy clinic immediately after the manipulation. Patients were asked to lie on their back and bend their hips and knees so that their feet were flat on the surface of the table. Patients were then instructed to attempt to flatten their back to the table by slightly “drawing in” their stomach and rotating their hips backwards, without holding their breath. All patients were treated with the identical manipulation technique and range-of-motion exercise, as described above. Manipulation was given three times a week for four weeks. (3 sessions/week/4 weeks) - 12 Sessions.

4.4.3.1.2 Low Level Laser Therapy;

Patient Position:

Patient lies prone on the couch, expose the treatment area by removing the clothes. Keep pillows under the head and the leg for the relaxation of head and lower limb muscles.

Application: Scrub the (Treatment area) lumbar Para spinal muscles with an alcohol-soaked gauze pad. In each session, a series of standardized fields including eight points in the para vertebral region (L2 to S2–S3) were irradiated by a single laser probe in contact mode. Participants were irradiated with the probe emitting a dose of 27 J/cm². The lasers used for treatment were continuous infrared light with wavelengths of 980nm. The energy density of 2-4J/cm² was used to irradiate the tender points of the vertebrae L4, L5 and S1 and the fasciae, sacral ligaments and Ileum and gastronomies muscles. The exposure time was 2 minutes per point. The total exposure time was 30 minutes. The trigger and acupuncture points were irradiated 1-2 J/cm². Patients were treated with laser 3 times a week for 4 weeks.
4.4.3.1.3 Conventional Exercise:

Exercises included strengthening and stretching of the abdominal and back muscles, depending on the clinical findings. They were instructed to refrain from performing specific exercises for the low back other than those assigned for the study and to refrain from performing strenuous activities outside of normal activities of daily living.

Before the exercise program, the soft tissue flexibility and range of motion of these patients were increased through stretching exercises, with 5–10 minute relaxation periods (warm up). The exercise program was performed 3 days a week with 5 repetitions in 3 sets with 30-second pauses per set to begin with and repetitions were gradually increased until they reached 15. After the basic steps had been covered successfully, patients carried out the exercises in groups of 2 or 3 for the duration of the program. During the exercises the importance of neutral spinal position was repeatedly stressed. The entire program lasted 4 weeks. These are the following events:

**Flexion Exercise:** Supine lying – Abdominal contraction
- Abdominal curl with Knee extension
- Abdominal curl with Knee flexion
- Abdominal curl with Spine rotation

**Extension Exercise:** Prone lying – Spine Extension
- Quadruped position – Arm raise
- Quadruped position – Leg raise
- Quadruped position – Arm and leg raise

All exercises were performed within a limited range of motion, respecting each patient's pain limits. After each session, 10 minutes of stretching of the trained muscle groups were performed using static stretching for 30 seconds for 12 times(cool down).

4.4.3.2 Intervention Frequency:

Participants had twelve visits over a period of four weeks.

4.4.3.3 Measurement Frequency:

All readings and testing were done prior to the interventions at consultation (Baseline) and 4 week, 8 week and 6 month after intervention.
4.5 Statistical Methodology:

4.5.1 Test for Demographic Values:

Frequency tables were computed in the case of the demographic variables. Demographics were compared between the three treatment groups using ANOVA for quantitative normally distributed variables.

4.5.2 Test for Homogeneity: (Normal distribution)

Analysis of variance (ANOVA) test was used to compare the groups (Group-1, Group-2 and Group-3) with regards to Pain Intensity, Range of Motion, Functional disability, Depression level and Health related Quality of life readings between the baseline values. (α = 0.05 level of significance).

Hypothesis Testing: For the above test, the null hypothesis (H0) stated that there was no significant difference between the three groups (Group-1, Group-2 and Group-3) with respect to each of the variables. The alternative hypothesis (H1) stated that there was significant difference between the three groups (Group-1, Group-2 and Group-3) with respect to each of the variables.

Decision Rule: The null hypothesis (H0) is rejected at α level of significance if p < 0.05 where p is the observed level of significance or p-value. Failing this, the null hypothesis (H0) is accepted at the same level of significance (p ≥ 0.05).

4.5.3 Test for Intra Group Comparison: Analysis of Variance (ANOVA) is used to find any significant improvement occurred within each group with regards to Pain Intensity, Range of Motion, Functional disability, Depression level and Health related Quality of life readings, between the baseline value, after 4 weeks, 8weeks, and 6 month.

Hypothesis Testing: For the above test, the null hypothesis (H0) stated that there was no significant difference between the baseline values, after 4 weeks, 8weeks, and 6 month with regards to Pain Intensity, Range of Motion, Functional disability, Depression level and Health related Quality of life. The alternative hypothesis (H1) stated that there was a significant difference between the baseline values, after 4 weeks, 8weeks, and 6 month with regards to Pain Intensity, Range of Motion, Functional disability, Depression level and Health related Quality of life. (α was set at 0.05 level of significance.)
**Decision Rule:** The null hypothesis (H0) is rejected at α level of significance if p < 0.05 where p is the observed level of significance or p-value. Failing this, the null hypothesis (H0) is accepted at the same level of significance (p ≥ 0.05).

**4.5.4 Test for Inter Group Comparison:** Analysis of variance (ANOVA) test was used to compare the groups (Group-1, Group-2 and Group-3) with regards to Pain Intensity, Range of Motion, Functional disability, Depression level and Health related Quality of life readings between the three groups at 4th week, 8th week and 6 month consultations for each variables. (α = 0.05 level of significance). The multiple comparison procedure called the **Benferroni Test** was used as a post-hoc test to determine which group differed from which other group.

**Hypothesis Testing:** For the above test, the null hypothesis (H0) stated that there was no significant difference between the three groups (Group-1, Group-2 and Group-3) with respect to each of the variables. The alternative hypothesis (H1) stated that there was significant difference between the three groups (Group-1, Group-2 and Group-3) with respect to each of the variables.

**Decision Rule:** The null hypothesis (H0) is rejected at α level of significance if p < 0.05 where p is the observed level of significance or p-value. Failing this, the null hypothesis (H0) is accepted at the same level of significance (p ≥ 0.05).

**4.5.5 Test for Correlation:**

Correlation between the variables (Pain Intensity, Range of Motion, Functional disability, Depression level and Health related Quality of life) has been tested through regression analysis method.

SPSS version 16.0 (SPSS Inc., Chicago, Illinois, USA) was used to analyze the data.