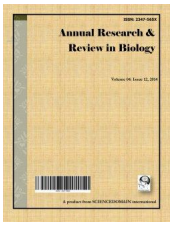

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# Effect of Spinal Manipulation on Specific Changes in Segmental Instability, Pain Sensitivity and Health-Related Quality of Life among Patients with Chronic Non-specific Low Back Pain- A Randomized Clinical Trial

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***Authors' contributions***

*This work was carried out in collaboration between all authors. Author KKS wrote the protocol, performed the statistical analysis, wrote the first draft of the manuscript and managed the literature searches. Author JS designed the study and prepared the final draft of manuscript. Author UM, the guide, managed the analyses of the study. All authors read and approved the final manuscript.*

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## ABSTRACT

**Purpose:** Chronic non-specific low back pain (cNSLBP) is quite common as seen every day in clinics. Therefore, we assessed the effectiveness of spinal manipulation (High-Velocity Low-Amplitude Thrust) on segmental instability, pain sensitivity, and quality of life among patients with chronic non-specific low back pain.
**Subjects and Methods:** This study is a randomized clinical trial with 100 patients aged between 18 and 60 years suffering from non-specific low back pain for at least 3 months of duration. 50 subjects

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were randomly assigned to group A received spinal manipulation and 50 subjects to group B received core stability exercises. After 15 days, scores were measured for segmental instability (centre of foot pressure) by win track platform, pain sensitivity (pain pressure threshold) by digital algometer and health-related quality of life by EuroQol questionnaire.

**Results:** After treatment, spinal manipulation and core stability exercises had improved segmental instability, increased pressure threshold, and enhanced health-related quality of life. However, significantly better improvement noticed in segmental instability, pressure pain threshold, and quality of life by spinal manipulation compared to core stability exercises.

**Conclusion:** The present study indicates that spinal manipulation is more effective than core stability exercises in chronic non-specific low back pain.

*Keywords: Chronic non-specific low back pain; spinal manipulation; segmental instability; quality of life.*

## ABBREVIATIONS

*cNSLBP : Chronic non-specific low back pain, SM: spinal manipulation,*
*HVLAT : High-Velocity Low-Amplitude Thrust,*
*PPT : pressure pain threshold,*
*LBP : low back pain,*
*QoL : Quality of life.*

## 1. INTRODUCTION

Chronic Non Specific Low Back Pain (cNSLBP) is a universal problem that nearly everyone has at various stages in their lifetime. The prevalence of cNSLBP has been explored in various systematic studies. Anderson explored that the lifetime incidence of cNSLBP is more than 70% and 1-year prevalence ranges starting 15% to 45 % with point prevalence averaging 30% [1]. Hoy (2010) anticipated in his systematic review that point prevalence of LBP ranged from 1.0% to 58.1% with a mean of 18.1% and 1-year prevalence ranged from 0.8% to 82.5% with a mean of 38.1% [2]. LBP is more ordinary between the ages of 25 and 64 years [3], however, it may happen in many age groups. The incidence of LBP peaks among age group of 35 and 55[4]. This is measured to reproduce the workforce and high incidence in age between 30 and 50[5,6]. In Indian rate of cLBP has been explored to be 23.09% and has a lifetime prevalence of 60% to 80%. LBP affects men and women equally and generally between the ages of 30 to 50 years [7].

cLBP is defined as pain situated in lower costal margin, on the inferior gluteal folds and has persisted for more than 3 months. Patients abide by physical disabilities and psychological distress along with pain [8]. Accurate causes of low back pain are odd and accounting for less than 15% of all back pain [9]. About 85% of patients with isolated low back pain cannot be specified an exact pathoanatomical diagnosis [10]. Non-specific low back pain is described in a recent review of national guidelines as a diagnosis of exclusion, where pain caused by a suspected or confirmed serious pathological (red flag) conditions such as tumor, infection or fracture or presenting as a radicular syndrome. The review states some guidelines (Australian and New Zealand guidelines) of non-specific low back pain and radicular syndrome [11]. Nonspecific LBP has been defined as tension, soreness, and stiffness in the lower back region for which it is not possible to identify a specific cause of the pain [12]. It commonly leads to a loss of function and limitation in activities and contribution in social life.

While spinal manipulation (SM) is suspicious a possibly effective interruption for patients with low back pain, different theories and mechanisms of action for SM are still under conversation [13]. Manual therapists, osteopaths, and chiropractors are well oriented by a biomechanical mechanism where mechanical forces applied to specific vertebral regions may modify segmental biomechanics by releasing trapped meniscoid lesions and adhesions or reducing distortions of the annulus fibrosus [14]. This biomechanical mechanism of action would allow the vertebral segments to progress in a bigger range of motion and would diminish the mechanical pressure on paraspinal muscles, thus reducing pain and distress. However, the mechanisms underlying the effect of SM appear more difficult than a simple biomechanical oriented model and are more achievable to be better explained by a combination of biomechanical and non biomechanical effects [15].

A more recent theoretical premise of segmental instability using a "neutral zone" concept has been proposed by Panjabi. This concept is based on the observation that the load-displacement curve of the typical spinal motion segment is highly nonlinear with high flexibility for motion occurring around the neutral position of the spine and with increased passive resistance to motion nearer to end-ranges of spinal motion [16]. The total range of motion (ROM) of a spinal motion segment, therefore, may be divided into two zones; a neutral zone and an elastic zone. The neutral zone is the initial portion of the ROM during which spinal motion is produced against minimal internal resistance. The elastic portion of the ROM is the portion nearer to the end-range of movement that is produced against substantial internal resistance [17].

Patients with low back pain have altered segmental stability compared to healthy persons. It has been claimed that the reduced proprioceptive perception originated from muscle or joint mechanoreceptors can be a reason of changed segmental instability [18]. One more theory that claims patients with low back pain have impaired quick-fix memory which leads to detain in processing postural control information and improved segmental instability [19].

There is outstanding work screening that forces of the magnitude of SM loads can stimulate proprioceptors in the joints and muscles [20]. The approach is to use SM as a tool to impact proprioceptive input on spinal tissues and detect the effects on sensorimotor function. As a result, the study has given clues to the sensorimotor mechanisms that cause experimental functional deficits associated with LBP as well as the mechanism of action of SM [21].

A plausible contributing factor of chronic low back pain is poor control of trunk and back muscles to the exigencies of day-to-day activities. Core stabilization exercises are focused to address inter-segmental stability by facilitating neuromuscular control in the lumbar spine. Studies have reported that specific stabilization exercises reduces pain and disability in chronic but not in acute low back pain and can be helpful in the treatment of acute low back pain by reducing recurrence rate [22].

Though stabilization exercises have become a major focus in spinal rehabilitation as well as in prophylactic care such as sports injury prevention [23], the therapeutic evidences in terms of postural control variables were not well documented. Further randomized controlled trials already have been reported on the effect of core stability exercises versus conventional physiotherapy treatment regimes on pain characteristics, recurrence and disability scores in cLBP emphasizing patient centered outcomes [24].

It is commonly acknowledged that chronic pain has a pessimistic collision on Quality of Life (QoL). QoL among patients with cLBP is less significant in common population [25,26]. This considerately affects the functional ability and working status of young and adult population [27]. Spinal manipulation (SM) is effective for some persons experiencing LBP; though, the mechanisms are not recognized concerning the role of placebo [28]. SM allied with QoL has been found signifying correlated changes in pain sensitivity and changed central nervous system relay or dispensation of afferent nociceptive input [29].

Therefore the purpose of this randomized clinical trial was to consider a potential mechanism of spinal manipulation by determining its efficacy on the segmental instability, pain sensitivity and health-related quality of life.

## 2. MATERIALS AND METHODS

A consecutive convenient sample of 100 patients with chronic non specific low back pain of those who met the inclusion criteria was taken for the study from Outpatient Department of Physiotherapy, Lovely Professional University, Phagwara, Punjab, India, between July 2015 and October 2016. Prospective patients were screened for eligibility by a physiotherapy specialist after obtaining a signed inform consent of individual willingness to involve in study. To be eligible for inclusion, patients had to have Chronic Non-Specific Low Back Pain (cNSLBP) for no less than 3 months duration and aged between 18 and 60 years [30,31]. The exclusion criteria were injury or surgery of spine, congenital spinal deformity (e.g., spina bifida, scoliosis, ankylosing spondylitis etc), lumbar radiculopathy or presenting neurological deficit, subjects administered epidural injection, and contraindication to manipulation (e.g. vertebral malignancy of lumbar, vertebral-basilar insufficiency, bone infections, fracture of vertebra, osteoporosis). This study was approved

by the University Human Ethical Committee (LPU/IEC/PTY/004).

The patients had been allocated into two equal groups by alternate randomization, each group 50 subjects and both groups received postural correction and ergonomic advice along with treatment for 15days. All participants were assigned 15 treatment visits for 15 days. Fifty subjects were randomly assigned to the group A received SM (High-Velocity Low-Amplitude Thrust-HVLAT) on lumbar region (between L1 and L5 vertebrae) in side lying position with more painful side facing upward. The therapist stands in front of the patient, and then flexes the top leg until there is movement at the selected segment (e.g., L4-L5 inter space) and place the patient's foot in the popliteal fossa of the bottom leg. Next he grasps the patient's bottom shoulder and arm and introduces left trunk side bending and right rotation until motion is felt at the L4-L5 inter space. The therapist's right thumb is then placed on the right side of the L4 spinous process and the patient's arms are positioned around the therapist's right arm. Setup is maintained while the patient is rolled towards the therapist. Finally the therapist's left arm is used to apply a high velocity, low amplitude thrust of the pelvis in an anterior direction.

The side to be manipulated first was the more symptomatic side based on the patient's self report. If the patient cannot specify a more symptomatic side, the therapist may select either side for manipulation. The therapist selected the spinal level towards which to direct the manipulation based on segmental mobility assessment performed in side lying or prone. The therapist chose a segment in the lower lumbar region towards which to direct the manipulation because the lower lumbar spine is more frequently the source of symptoms in patients with LBP and recent research suggests greater benefits from manual therapy techniques directed towards the lower lumbar spine [32]. The therapist will note whether or not a cavitation (i.e., "a pop") was either heard or felt by the therapist or patient after the manipulation is performed. If a cavitation is experienced, the therapist proceeded to instruct the patient in the ROM exercises. If no cavitation is produced, the patient was to be repositioned and the manipulation was attempted again. If no cavitation is experienced, the therapist attempted to manipulate the opposite side. A maximum of two attempts per side was permitted.

Two experienced (not less than 3 years) physiotherapists have administered treatment, each of whom determined the frequency and number of treatment session (for each patient) that lasted 15 to 30 minutes. SM–HVLAT was performed with the patient side lying and two times replicate in each side [33]. 50 subjects of group B received core stability exercises. Two experienced (not less than 3 years) physiotherapists have delivered exercise regimen of 30 minutes duration emphasizing a high number of repetitions (two to three sets of 15 to 30 repetitions for each exercise) and progressive increase in muscle load. The patients were instructed to perform repetitions until they could no longer do so using proper form. For each exercise, the patients started at a level of difficulty that allowed them to complete the minimum number of repetitions 15. They then progressed to the next level of difficulty when they were able to perform the maximum 30 number of repetitions [34]. Core stability exercises were a plank, oblique plank, and superman. The procedure of 1) plank was i) presuppose a frontage sustain situation resting on subjects forearms with shoulders straight over subjects elbows, ii) set straight subject's legs out behind subjects and raise up hips to form a dead-straight line from shoulders to ankles. Subjects should be balanced on forearms and toes, with lower abdomen and back working to keep the body straight. Hold for 1 minute and 15 to 30 repetitions. 2) Oblique Plank i) on the side, balance on the right forearm with shoulder beyond the elbow, ii) with legs out directly to the left pelvis so that balance on forearm and feet. The body should appear in a direct line and feel the oblique muscles down the side trunk working to maintain the position, iii) hold for 1 minute then replicate on another side with total 15 to 30 repetitions. 3) superman-i) balance on the floor on hands and knees. Back should be flat and hips equivalent to the floor, ii) elevate right arm out in front of subject and elevate left leg out after patient maintain it directly, iii) hold for 1 minute and then replicate on the other side with total 15 to 30 repetitions.

100 subjects participated in this research study. The investigators also collected demographic data such as age, body mass, height, contact details, clinical data, and assessed health-related quality of life measured by EuroQol questionnaire, a spacious established questionnaire for health-related quality of life. EuroQoL questionnaire-5D-3L has 5 dimensions and 3 levels. The EQ-5D-3L evocative system

comprises the following 5 dimensions; mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 3 levels: no problems-0; some problems-1; extreme problems-2. This information can be used as a quantitative measure of health as judged by the individual respondents. The instructions for the EQ-5D-3L task has been changed and simplified [35].

Pressure pain threshold measured (by digital algometer DA-112 made India) at lumbar levels L1 to L5 bilaterally. Pressure pain threshold is defined as the amount of pressure corresponding to when the sensation of pressure changes to a perception of pain. The investigators asked the patient to lie down on the table with pillow support. This device consists of a round probe (1 $cm^2$) vertically to the patient's skin and pressure was applied at a rate of 5 Newton/second. The patients were asked to say "stop" when the sensation of pressure or uneasiness feeling of pain. The mean of 3 trials was calculated and used for the analysis. A 30-second resting period was allowed between each trial [36,37]. The reliability of digital algometer has been found to be high (ICC=0.93; 95%), confidence interval (CI: 0.89-0.96).

The capability to maintain balance in an upright standing posture was supervised using a Win Track platform (Win-Track, Medicapteurs, $n^0$-12k0022, Made in France), which measures the segmental instability (i.e., the movement of the center of foot pressure) in the anterior-posterior (X) and side-to-side (Y) directions. The participant stood quietly on either a solid platform (i.e., directly on the force plate) for a period of 30 seconds with bare feet. The first 30 seconds of data were recorded at a sample rate of 1200 Hz using monitor data acquisition software (WinTrack Software) [38,39].

Stance Positions: Each participant has to have stance positions with eyes open to allow for assessment of postural sway with and without visual input. The order of stance position testing was on bipedal stance. For the eyes-open testing participants were instructed to fix their vision on a large red dot placed at eye level about four meters in front of the force platform. All stance conditions were fulfilled with participants in bare feet.

Primary outcome that were studied centre of foot pressure for segmental instability, pressure threshold for pain sensitivity, and Euro QoL questionnaire health-related quality of life. The test-retest reliability and validity have been found to be sufficient for use in subjects with non specific low back pain. Scores of centre of foot pressure analysis, pressure threshold, and health-related quality of life were measured immediately before the first treatment and subsequently at 15 days after the treatment.

Data were obtainable as mean (standard deviation). All arithmetic analysis was accomplished by SPSS software (version 16.0) for SPSS, Chicago, IL, USA. Within-group differences and their individual 95% confidence interval values were premeditated by paired t-tests. The between-group variation and their individual 95% confidence interval premeditated using unpaired t tests. Significance was set at $p \leq .05$ for all analyses because we were attempting to prove an inspection made in prior studies.

## 3. RESULTS

Patient's enrollment and inclusion were conducted between July 2015 & October 2016. Patient's demographic characteristics at baseline given a detailed below in Table 1. A total of 100 patients were measured for the enclosure. The mean (SD) age for group A and B was 23.38±5.71 and 25.00±7.13 respectively while the BMI was 21.62±3.11 and 23.81±2.96 for group A and B respectively. Age and BMI did not show significant difference in both groups (Table 1).

Optimistic estimates (for between-group difference) designate progress in support of SM; negative estimates specify progress in support of core stability exercises.

Improved in segmental instability (CoFP) of both groups (SM & core stability exercises): the within-group variation was 0.64 points (95% CI; $p<.001$) in SM group and 0.66 points (95% CI; $p<.001$) in core stability exercises group. Similar to the quality of life, there was statistically significance noted in between-group difference of postural instability in patients with cNSLBP (Table 2) (between-group difference 0.02, 95% CI; $p <.001$). Adverse effects were observed in SM group.

Enhanced both groups in provisions of pressure pain threshold; the within-group difference was -43.10 N (95% CI; $p<.001$) in SM group and -18.31 N (95% CI; $p<.001$) in core stability

**Table 1. Demographic characteristics of the patients at baseline**

| Variables | Group A (Spinal Manipulation) | Group B (Core stability Exercise) | *P* value |
|---|---|---|---|
| Age (Year) | 23.38±5.71 | 25.00±7.13 | P<0.213 |
| BMI | 21.62±3.11 | 23.81±2.96 | P<0.583 |

**Table 2. Mean (SD), within-group variation (95% CI), and Mean variation between-group (95% CI) for centre of foot pressure, pressure threshold, and Euro quality of life questionnaire (Euro QoL)**

| Outcome measure | Group | | Unadjusted within-group variation (95% CI) (Baseline Minus post treatment), *p* value | | Between-group adjusted Mean variation (95% CI, *p* value) |
|---|---|---|---|---|---|
| | Group A (Spinal manipulation) | Group B (Core stability exercise) | Group A (Spinal manipulation) | Group B (Core stability exercise) | |
| Center of foot pressure (CoFP) Baseline | 6.93±0.88 | 5.27±0.46 | | | |
| Center of foot pressure (CoFP) After treatment | 6.29±0.85 | 4.61±0.47 | 0.64, *p*<.001 | 0.66, *p* <.001 | 0.02, *p* <.001 |
| Pressure Pain threshold Baseline | 26.89±4.29 | 27.72±4.69 | | | |
| Pressure Pain threshold After treatment | 69.99±7.04 | 46.03±5.62 | -43.10, *p* <.001 | -18.31, *p* <.001 | -24.79, *p* <.001 |
| Euro QoL Baseline | 21.20±1.46 | 21.2400±1.24 | | | |
| Euro QoL After treatment | 8.80±1.29 | 13.62±1.83 | 12.4, *p* <.001 | 7.62, *p* <.001 | 4.78, *p* <.001 |

exercises group. Though, between-group arithmetically considerable differences were discovered (Table 2), the between-group variation for pressure pain threshold (PPT) was -24.79(95%CI; *p* <.001).

Both groups improved in provisions of health-related quality of life (QoL); the within-group variation was 12.4(95% CI; *p*<.001) in SM group A and 7.62 (95% CI; *p*<.001) in core stability exercises group B. Though, numerically meaningful differences were observed in between groups (Table. 2), the difference for QoL was 4.78 (95% CI; *p*<.001).

## 4. DISCUSSION

This study was to investigate the effectiveness of spinal manipulation (SM-HVLAT) on segmental instability, pain sensitivity and health-related quality of life in patients with cNSLBP. For the outcome trial segmental instability (centre of foot pressure), pain sensitivity (pressure threshold) and quality of life were measured by Win Track Platform, digital algometer, and EuroQol questionnaire respectively. Statistically significant improvement was noted in segmental instability, pain sensitivity, and health-related quality of life outcomes.

The age group between 18 to 60 years [3,7,25,26,30,31] was taken for the consideration in this study due to availability of reported cases to clinic. Though the structure of spine is of different characteristic features in lower and higher age groups but complain and conditions were found similar and included for the study. We noticed that significant improvement has been established in both lower and upper age groups, this could be due to bringing down the stiffness and segmental instability, improving localized tissue vascularity by reducing ischemia and improving good spinal postural stability. All participants were assigned 15 treatment visits for 15 days with an assumption of ensuring the retention of sustained therapeutic effect to have a result of better effectiveness of intervention.

There is high-class procedural evidence to sustain the use of SM in management of patients with cNSLBP. The intervention is also recommended by clinical practice guidelines for

management of low back pain [40] and additional musculoskeletal disorders [41]. In this study, both groups had a marked improvement of segmental instability from baseline till after treatment. Thus, these results contest that a biomechanical approach would clarify the reduction in segmental instability that was practiced by participants. According to most systematic reviews and evidence-based clinical guidelines, both exercise therapy and spinal manipulation are effective treatment options for CLBP [42]. There is evidence to recommend nevertheless the type, dosage, and mode of delivery of both interventions can persuade the outcome [43]. Regarding spinal manipulation, little is known about optimal dosage and provider type (e.g., chiropractor, osteopath, or physiotherapist) that has not been related to any differential effect [44].

Statistically significance was observed in parameters of within-groups and between groups. Patients allocated to SM (HVLAT) group A fairly improved pressure pain threshold as compared to patients allocated to core stability exercise group B. Our conclusions are extremely alike to individuals of a current meta-analysis that investigated changes in pressure threshold following spinal manipulation [45]. This model suggests that a mechanical strength stimulates a flow of neurophysiologic responses in both peripheral and central nervous systems that might elucidate improvement in clinical outcomes, such as pressure pain threshold [46].

There is premium procedural evidence to sustain the use of SM for the management of patients with cNSLBP. This interference also suggested by clinical perform rules for the management of cNSLBP and additional musculoskeletal disorders [47]. In our study, both groups had an improvement of the QoL after treatment. However spinal manipulation was better effective than core stability exercise. This indicates that patients with cNSLBP have a lower QoL than the general population that visit family doctors as seen in other studies [48,49]. Hence, a biomechanical approach has been found effective in improving quality of life. Also core stability exercise revealed significant improvements in distribution of ground reaction forces, use of optimized postural adjustments in the direction of perturbation, 20% absolute risk reduction and flare-up during intervention and 40% absolute risk reduction for resolution of back pain [50]. Core stability exercise is an evolving process, and refinement of the clinical rehabilitation strategies. However, further work is required to refine and validate the approach, particularly with reference to contemporary understanding of the neurobiology of chronic pain [51,52].

There were numerous confines to our study. On limitation the study was with small sample size which could not oversimplify results. We did not include control group, group with both the interventions, interventional short period as well as follow up. Adding the control group the result could be established with a marked differentiation in effectiveness of two therapeutic interventions, as well as an early recovery and much better prognosis would be expected in a study group of both interventions. Raising the numeral of patients would provide to raise the supremacy of this study. Therefore, future studies are needed with large sample size, include control group, group with both the interventions, increase interventional period, and also include follow up.

On recommendation, the better result can be obtained if both the therapeutics are applied together in clinical practice.

## 5. CONCLUSION

The present randomized clinical trial found that spinal manipulation had a statistically significant effect on segmental instability, pain sensitivity and health-related quality of life in patients with cNSLBP. In addition, results supported that SM-HVLAT and core stability exercises were effective in improving the segmental instability, increasing pressure threshold, and health-related quality of life in subjects with cNSLBP.

## ETHICAL APPROVAL

The study was approved by Institutional Ethical Committee (Lovely Professional University). Reference number- LPU/IEC/PTY/004.

## TRIAL REGISTRATION

This trial was registered in clinicaltrials.gov and ID number- NCT03016676.

Available:https://clinicaltrials.gov/ct2/show/study/NCT03016676

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## COMPETING INTERESTS

Authors have declared that no competing interests exist.

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