DOI: 10.7860/JCDR/2026/88610.23770

Research Protocol

Physiotherapy Section

Targeting the Sacroiliac Joint: A Research Protocol for a Study on Pain, Functional Recovery, and Disability in Lumbar Disc Prolapse

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ABSTRACT

Introduction: Lumbar Prolapse Intervertebral Disc (PIVD) is a major cause of Low Back Pain (LBP) and disability, often associated with radiating symptoms and activity limitations. Altered spinal mechanics and compensatory movement patterns increase stress on the Sacroiliac Joint (SIJ), leading to SIJ Dysfunction (SIJD). The co-existence of SIJD with lumbar disc pathology complicates diagnosis and management due to overlapping clinical features.

Need of the study: Although SIJ mobilisation has shown potential to improve lumbopelvic mechanics, reduce pain, and enhance neuromuscular control, there is limited structured evidence regarding its effectiveness in patients with lumbar PIVD. Additionally, concerns regarding the safety of manual therapy in acute disc pathology necessitate further investigation. Therefore, a systematic evaluation of SIJ mobilisation is essential to establish its role in reducing pain, functional recovery and reducing disability outcomes in this population.

Aim: To investigate the efficacy of SIJ mobilisation on pain, functional recovery and disability in patients with lumbar PIVD.

Materials and Methods: A quasi-experimental design, which requires 35 participants selected through specific inclusion and exclusion criteria. The study will be conducted at a tertiary care hospital in North India from January 2025 to December 2026. The study will provide all participants with SI mobilisation treatment, both posterior-anterior and lumbar extension glides, and core strengthening exercises. The study will use three outcome measures: pain intensity assessment by the Visual Analogue Scale (VAS), functional mobility assessment by the Timed Up and Go (TUG) test, and disability assessment by the Oswestry Disability Index (ODI), which will be measured before the intervention and after its completion. Statistical analysis will be performed using a paired t-test or Wilcoxon signed-rank test based on data normality, with the level of significance set at 0.05.

Keywords: Humans, Intervertebral disc, Low back pain, Pain management

INTRODUCTION

Lumbar Prolapsed Intervertebral Disc (PIVD) functions as a major source of LBP disability. The condition manifests through unilateral radiating pain and impaired ability to perform daily tasks. Altered spinal mechanics, protective movement patterns, and neuromuscular changes in patients with PIVD lead to increased mechanical stress, which causes SIJ dysfunction [1]. The overlap in clinical presentation between SIJD and lumbar disc pathology poses diagnostic and therapeutic challenges for healthcare professionals [2]. The medical condition of SIJD frequently occurs with PIVD because most patients with MRI-confirmed lumbar disc herniation show clinical signs of SIJD, which results in shared symptoms between the two conditions [3].

The association shows how both the lumbar spine and the SIJ, which work together as fundamental components of human movement, create biomechanical links to postural control and load distribution across the lumbopelvic area. The body functions as an integrated system; when one component fails to operate properly, it can disrupt the entire system, leading to persistent discomfort and reduced functional capacity [4]. An evidence-based approach to clinical decision-making in lumbar disc pathology requires careful and judicious application of manual therapy techniques. While spinal and pelvic manipulations may offer benefits in managing specific musculoskeletal conditions, they also carry risks, including potential symptom exacerbation and neurological injury if applied improperly [5].

In patients with acute disc pathology, clinicians must employ specialised techniques due to heightened neural tissue sensitivity and underlying structural impairment. The situation becomes critical for people who experience PIVD because their changed body mechanics, together with their nerve damage, create a greater risk of problems. SIJD shows a strong tendency to occur together with lumbar PIVD, which leads to shared symptoms that make both diagnosis and treatment more difficult. The clinical overlap between these two conditions requires investigators to study how safe and effective SIJ mobilisation treatments function in practice [6]. Low-velocity graded mobilisation techniques directed at the SIJ can safely address lumbopelvic dysfunction through an indirect approach that minimises excessive mechanical stress on the lumbar spine [7]. Investigating SIJ mobilisation will enhance understanding of rehabilitation strategies that are both safe and effective for this patient population, which continues to face significant and underexplored challenges in spinal care.

Combining SIJ mobilisation with core strengthening exercises is expected to improve lumbopelvic stability, promote optimal load distribution, and enhance neuromuscular control, thereby leading to better clinical outcomes in patients with lumbar PIVD. Although existing literature suggests a co-existence of lumbar PIVD and SIJD, there remains a lack of robust, structured evidence regarding the effects of SIJ-targeted interventions on pain, functional capacity, and disability. This gap underscores the need for systematic investigation to generate clinically meaningful insights for physiotherapy practice.

REVIEW OF LITERATURE

Mobilisation is a low-velocity, passive manual therapy technique applied within or at the limit of joint range to restore mobility, alleviate pain, and improve lumbopelvic function [8]. In individuals

with LBP and SIJD, altered biomechanics and impaired neuromuscular control significantly contribute to pain and functional limitations. Manual therapy interventions, particularly SIJ mobilisation, have been explored for their potential to restore movement patterns and improve clinical outcomes; however, variations in study design and population characteristics limit the generalisability of findings.

Gorrell LM et al., in a systematic review of randomised clinical trials, reported that adverse events associated with spinal manipulation are often inconsistently documented, which may lead to underestimation of the true incidence of complications. Although most reported adverse effects are mild and transient, the variability in reporting highlights the need for careful patient selection and cautious clinical application, particularly in populations with underlying spinal pathology and heightened neural sensitivity [5].

Bialosky JE et al., proposed a comprehensive model explaining the mechanisms of manual therapy, suggesting that mobilisation exerts its effects through neurophysiological pathways, including modulation of nociceptive input and central pain processing. The study highlighted improvements in muscle activation and reduction in guarding; however, it primarily focused on theoretical and mechanistic frameworks rather than direct clinical outcomes, limiting its applicability to patient-specific interventions [9].

O'Sullivan P emphasised the role of maladaptive movement patterns and motor control impairments in chronic LBP. The study advocated for interventions targeting movement restoration and lumbopelvic stability, suggesting that mobilisation may enhance functional performance. Nevertheless, the work was largely conceptual and classification-based, lacking experimental validation specifically addressing SIJ mobilisation [10].

A study by Shokri E et al., involved 20 participants with MRI-confirmed lumbar disc herniation accompanied by SIJ hypomobility. All participants underwent Spinal Manipulative Therapy (SMT) directed at both the lumbar spine and SIJ. The intervention comprised five sessions administered over two weeks, utilising High-Velocity, Low-Amplitude (HVLA) thrust techniques delivered by a trained practitioner. The study showed a significant improvement in pain and functional outcomes following spinal manipulation, providing clinical support for manual therapy in this population. However, since manipulation is associated with potential risks such as symptom exacerbation, increased neural irritation, and rare but serious complications, including neurological deficits, its application in disc pathology populations should be interpreted with caution [11].

However, despite these reported benefits, most existing studies have focused on general LBP or isolated SIJD. There is limited structured evidence specifically evaluating the effectiveness and safety of SIJ mobilisation in patients with lumbar PIVD, where altered spinal mechanics and neural sensitivity may influence treatment outcomes. Therefore, the present study aims to address this gap by systematically investigating the effects of SIJ mobilisation on pain, functional recovery, and disability in this specific population.

Objectives

Primary objectives:

- To evaluate the effects of SIJ mobilisation on pain using the VAS scale in patients with lumbar disc prolapse.

Secondary objective:

- To evaluate the effects of SIJ mobilisation on function using the TUG test in patients with lumbar disc prolapse.
- To evaluate the effects of SIJ mobilisation on disability using the ODI questionnaire in patients with lumbar disc prolapse.

Hypotheses

Null hypothesis: There will be no significant effect of SI joint Mobilisation on Pain, functional recovery, and Disability in patients with lumbar disc prolapse.

Alternate hypothesis: There will be a significant effect of SI joint mobilisation on pain, functional recovery, and disability in patients with lumbar disc prolapse.

MATERIALS AND METHODS

A quasi-experimental study will be conducted at Maharishi Markandeshwar Super Speciality Hospital, a tertiary care centre in North India, from January 2025 to December 2026. The Institutional Ethics Committee at Maharishi Markandeshwar (Deemed to be University) has approved the study under registration number IEC-3101. The trial has been registered with the Clinical Trial Registry India (CTRI) under registration number CTRI/2025/04/084919. Informed consent was obtained from all participants before the study.

Inclusion criteria:

- Participants aged between 30 and 50 years of age;
- Both male and female participants;
- Diagnosed with acute lumbar PIVD with a duration of less than three months;
- Presence of unilateral PIVD, confirmed by Magnetic Resonance Imaging (MRI);
- Types of disc pathology included: paracentral disc bulges, foraminal disc bulges, extraforaminal disc bulges and disc prolapses;
- Presence of unilateral radiating pain;
- No motor or sensory deficits;
- Participants willing to participate.

Exclusion criteria:

- Presence of motor or sensory deficits;
- History of any previous treatment for lumbar PIVD within the past three months.

Sample size calculation:

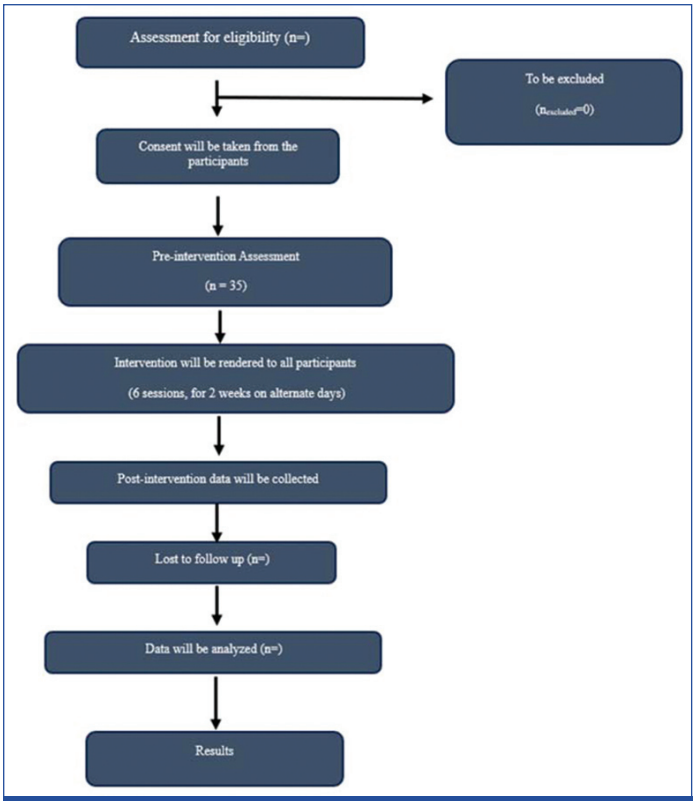
The standard sample size formula: $\{n = (Z\alpha/2 + Z\beta)^2/d^2\}$

Where:

- $Z\alpha/2$ = corresponding to the chosen significance level ($\alpha = 0.05$)
- $Z\beta$ = corresponding to the desired power ($1-\beta = 80\%$)
- d = corresponding to the effect size (Cohen's d)

For pain intensity measured using the VAS, the mean pre-intervention score was 6.492±1.2221, which reduced to 4.975±1.4759 post-intervention, yielding a large effect size of 1.1099 and a required sample size of 12 participants. Functional mobility assessment using the TUG test, with a reduction from 12.75±1.712 seconds at baseline to 11.83±1.586 seconds post-intervention, with a moderate effect size of 0.5566, corresponding to a required sample size of 28 participants. Disability measured using the ODI demonstrated a decrease from a median score of 23.00 (IQR = 5.75) pre-intervention to 11.80 (IQR = 10.77) post-intervention, with a small effect size of 0.2793, resulting in a calculated sample size of 12 participants. After adjusting for an anticipated 20% dropout rate, the final sample size determined using G*Power software was increased from 28 to 35 participants, providing a more precise and statistically robust estimation. The participants enrolled in the pilot study will not be included in the final study.

This study comprises three main phases: enrollment (T0), post-enrollment {pre-intervention (T1), and post-intervention (T2)}. During the enrollment phase, eligibility screening, informed consent, and medical history will be obtained by the co-author. The post-enrollment phase will involve baseline assessments of the pre-defined outcome measures [Table/Fig-1].



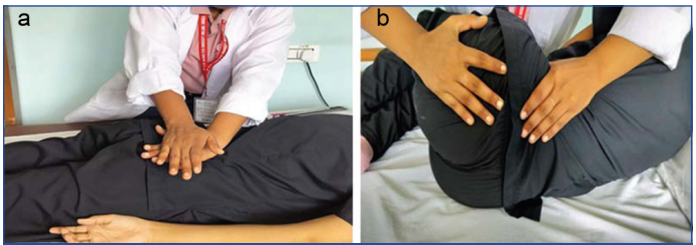
[Table/Fig-1]: Study flow chart.

Participant recruitment will use stratified random sampling methods to achieve balanced representation of different demographic and clinical attributes. The eligible participants will be divided into groups based on their predefined age (30-40 years and 41-50 years) and gender (male/female) characteristics. Within each stratum, participants will be selected using computer-generated random numbers through the software Research Randomiser (version 4.0), which helps minimise selection bias. The random selection procedure will be carried out by an independent researcher not involved in the intervention delivery or outcome assessment. As this is a single-group study, no allocation into different intervention groups will be performed, and all selected participants will receive the same intervention protocol. The approach improves external validity.

The physiotherapy intervention will consist of two primary components [Table/Fig-2] and will be administered by the primary author, AS, for all the eligible participants. The first step involves SIJ mobilisation, with Maitland's rhythmic mobilisation techniques. The practice will use two techniques: posterior-anterior glides [Table/Fig-3a] and glides in the direction of lumbar extension [Table/Fig-3b].

Intervention's name	Frequency/Duration
(1)- Sacroiliac Joint (SIJ) Mobilisation • Posterior-anterior glide. • Glide in the lumbar extension direction	30 glides in three sets with a 30-second rest in between, repeated for two weeks on alternate days.
(2)- Core Strengthening Exercises • Small arc pelvic bridging. • Adductors ball squeeze. • Abductor resistance band strengthening.	10 repetitions with a 10-second hold each.

[Table/Fig-2]: Physiotherapy intervention protocol for SIJD with lumbar PIVD.



[Table/Fig-3]: a) Posterior-anterior glides; b) glides in the direction of lumbar extension.

Participants will undergo six treatment sessions, which will occur every other day during the two weeks. The program will maintain participant engagement through telephone sessions scheduled for off-days, and the SK author will conduct routine follow-up, which will be documented in a diary. The patient will receive standard medical treatment when their pain increases because they will no longer be part of the study. The patient will receive a complete assessment of their results after they finish their treatment. The author SP will examine the data and follow-up results to evaluate how effective the intervention will be. The patient will begin traditional conservative treatment after six intervention sessions fail to resolve their symptoms.

Outcomes

1. VAS is a widely used unidimensional measure of pain intensity, particularly in clinical and research settings involving musculoskeletal disorders. Each participant will be provided with a 10 cm horizontal line anchored by "no pain" at 0 cm and "worst imaginable pain" at 10 cm. Participants will be instructed to mark a point on the line that best represents the intensity of their current LBP at the time of assessment, following standardised instructions to ensure consistency. The score will be calculated by measuring the distance in centimetres from the "no pain" anchor to the participant's mark using a ruler, yielding a continuous value ranging from 0 to 10, with higher scores indicating greater pain intensity. For interpretation, scores of 0-3 cm will be considered mild pain, 4-6 cm moderate pain, and 7-10 cm severe pain. The VAS demonstrates excellent reliability, with an Intraclass Correlation Coefficient (ICC) of 0.97 (95% CI: 0.96-0.98) [12].
2. The TUG test is a simple, quick, and widely used performance-based measure of functional mobility in clinical populations. Each participant will sit on a standard chair with armrests and, on the command "go," will stand up, walk three meters at a comfortable and safe pace, turn, return to the chair, and sit down again. The total time taken to complete the task will be recorded in seconds using a stopwatch. Standardised instructions and the same testing environment will be maintained for all participants to ensure consistency. Lower TUG times indicate better functional mobility, whereas higher times reflect greater functional limitation. For interpretation, a time of less than 10 seconds indicates normal mobility, 10-20 seconds indicates good mobility with mild limitations, and more than 20 seconds suggests significant functional impairment. The TUG test demonstrates excellent reliability, with an intra-class correlation coefficient of 0.97 and inter-rater reliability of 0.99 [13].
3. ODI is a disease-specific, self-administered questionnaire widely used in patients with LBP. Each participant will be asked to complete the ODI independently under supervision to ensure all sections are answered appropriately. The questionnaire consists of 10 sections, including pain intensity, personal care, lifting, walking, sitting, standing, sleeping, social life, travelling, and employment, with each section scored from 0 to 5 based on the level of difficulty experienced. The total score will be calculated by summing all section scores, with a maximum possible score of 50. This score will then be converted into a percentage using the formula: (total score/50) × 100. Higher percentage scores indicate greater disability. For interpretation in this study, 0-20% will be considered minimal disability, 21-40% moderate disability, 41-60% severe disability, 61-80% crippled, and 81–100% bed-bound. The ODI has demonstrated good validity and responsiveness, with an area under the curve of 0.78 and significant correlation with other disability measures ($p<0.001$) [14].

The evaluation will take place before the initial treatment session and after the completion of six treatment sessions. Researchers will

gather data from participants who drop out of the study, but they will exclude this data from their final research findings. An independent assessor who remains unaware of the given treatment will perform the data evaluation process.

STATISTICAL ANALYSIS

Data analysis will be conducted using IBM SPSS software version 26.0. The researchers will assess changes in outcome variables following the six-session intervention, which occur every other day. The Shapiro-Wilk test will be used to assess the normality of the data. The researchers will apply a parametric test when the data shows a normal distribution. Within-group comparisons will be analysed using paired t-tests. If the data do not satisfy normality assumptions, non-parametric alternatives such as the Wilcoxon signed-rank test will be employed. Clinical significance will be evaluated using 95% confidence intervals alongside p-values <0.05, with consideration of moderate effect sizes. [Table/Fig-4] presents the study timeline and assessment schedule.

Study period / Items	Enrollment	Post-enrollment		Close-out
Time point*	T0	T1	T2	
Enrollment:				
Eligibility Screen	×			
Informed consent	×			
Medical history	×			
Allocation				
Intervention:				
Experimental group				
Assessment:				
Demographic characteristics	×			
VAS		×	×	
TUG Test		×	×	
ODI Scale		×	×	

[Table/Fig-4]: Study timeline and assessment schedule.
SPIRIT Checklist: T1: Pre-intervention, T2: Post-intervention
VAS: Visual analog scale;
TUG Test: Timed
up and go test;
ODI: Oswestry disability index.

Acknowledgement

The authors acknowledge and thank all participants for their participation in this study.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Mar 15, 2026
- Manual Googling: Apr 18, 2026
- iThenticate Software: Apr 20, 2026 (1%)

ETYMOLOGY: Author Origin

EMENDATIONS: 6

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. Yes

Date of Submission: **Feb 28, 2026**
Date of Peer Review: **Mar 19, 2026**
Date of Acceptance: **Apr 22, 2026**
Date of Publishing: **Jul 01, 2026**