Methods & Protocols

# Manual therapy and canal enlargement exercises versus conventional physiotherapy in lumbar stenosis – a study protocol

# Terapia manual e exercícios de ampliação de canais versus fisioterapia convencional em estenose lombar - um protocolo de estudo

**Priya Gaur**[1]
**Manu Goyal**[2]
**Gurjant Singh**[3]

[1-2]Maharishi Markandeshwar Institute of Physiotherapy and Rehabilitation, Maharishi Markandeshwar (Deemed to be University), Mullana-Ambala, Haryana, India. 133207. priyagaurdec18@gmail.com, manu.goyal@mmumullana.org
[3]Corresponding author. Maharishi Markandeshwar Institute of Physiotherapy and Rehabilitation, Maharishi Markandeshwar (Deemed to be University), Mullana-Ambala, Haryana, India. 133207. singh.gurjant@mmumullana.org

**ABSTRACT | INTRODUCTION:** Lumbar Canal Stenosis (LCS) is known as the well-established reason for pain and depleted walking capacity in patients with manifestations of paresthesia and pain in the lower back, gluteal region, posterior thigh, and legs which are termed as 'Neurogenic Claudication' (NC). Manual therapy combined with canal enlargement exercises and conventional physiotherapy may be considered in eradicating pain and NC symptoms, hence improving the quality of life. **METHODS AND MATERIALS:** Patients with LCS with canal diameter 8-12 mm at the level of L4 and below will be recruited for this study. Through the Block randomization method, they will be randomized into two interventional groups: Manual Therapy & Canal Enlargement (MTCE) (n=16) and Conventional Physiotherapy (Cp) (n=16) groups. MTCE group will receive manual therapy and canal enlargement exercises, while the Cp group will receive only conventional physiotherapy. Both interventional groups will receive 3 days of treatment per week for 4 weeks. Modified Oswestry Disability questionnaire (MODI), Antero-Posterior (AP) canal diameter, Numeric Pain Rating Scale (NPRS), and Claudication Distance (CD) will be used for the evaluation. In addition, modified Oswestry Disability Index, AP canal Diameter, NPRS, Claudication distance, an SLR will be measured at baseline and post-intervention. **DISCUSSION:** The results of this research will dictate the applicability of manual therapy with an exercise protocol of canal enlargement exercises on pain and functional disability in patients with LCS.

**KEYWORDS:** Constriction. Exercise therapy. Lumbosacral region. Musculoskeletal manipulation. Physical therapy modalities.

**RESUMO | INTRODUÇÃO:** A estenose do canal lombar (ECL) é conhecida como a razão bem estabelecida de dor e capacidade de marcha reduzida em pacientes com manifestações de parestesia e dor na parte inferior das costas, região glútea, coxa posterior e pernas, denominadas 'Claudicação Neurogênica' (NC). A terapia manual combinada com exercícios de alargamento do canal e fisioterapia convencional pode ser considerada na erradicação dos sintomas de dor e NC, melhorando assim a qualidade de vida. **MÉTODOS E MATERIAIS:** Pacientes com LCS com canal de diâmetro de 8-12 mm no nível de L 4 e abaixo serão recrutados para este estudo por meio do método de randomização em Bloco. Eles serão randomizados em dois grupos de intervenção: grupos Terapia Manual e Alargamento dos Canais (MTCE) (n = 16) e Fisioterapia Convencional (Cp) (n = 16). O grupo MTCE receberá terapia manual e exercícios de alargamento do canal, enquanto o grupo Cp receberá apenas fisioterapia convencional. Ambos os grupos de intervenção receberão 3 dias de tratamento por semana durante 4 semanas. O questionário de deficiência de Oswestry modificado (MODI), diâmetro do canal ântero-posterior (AP), escala numérica de dor (NPRS) e distância de claudicação (CD) serão usados para a avaliação. O índice de deficiência de Oswestry modificado, diâmetro do canal AP, NPRS, distância de claudicação e SLR serão medidos no início e após a intervenção. **DISCUSSÃO:** Os resultados desta pesquisa ditarão a aplicabilidade da terapia manual com um protocolo de exercícios de alargamento do canal na dor e incapacidade funcional em pacientes com SCL.

**PALAVRAS-CHAVE:** Constricção. Terapia do exercício. Região lombossacral. Manipulação músculo-esquelética. Modalidades de fisioterapia.

Submitted 06/03/2021, Accepted 07/09/2021, Published 08/12/2021
J. Physiother. Res., Salvador, 2021 August;11(3):549-560
http://dx.doi.org/10.17267/2238-2704rpf.v11i3.3864 | ISSN: 2238-2704
Designated editors: George Dias, Kátia Sá

*How to cite this article:* Gaur P, Goyal M, Singh G. Manual therapy and canal enlargement exercises versus conventional physiotherapy in lumbar stenosis – a study protocol. J Physiother Res. 2021;11(3):549-560. http://dx.doi.org/10.17267/2238-2704rpf.v11i3.3864

## Introduction

With the escalating longevity of humankind, it is prophesied that about 90% of the population at some point in their life will experience low backache.[1] Lumbar canal stenosis (LCS) is an increasingly prevailing condition designated as narrowing the spinal canal, a cavity that travels through each vertebra and encloses the spinal cord. LCS causes cauda equina or spinal nerve roots compression, thereby resulting in inevitable low back pain (LBP).[2]

LCS is recognized as the decrease in the Antero-posterior (AP) lumbar canal diameter[3], which usually ranges between 15-27 mm, causing heterogeneous clinical features.[4] Neurogenic claudication is one of the cornerstone features of LCS that induce discomfort and pain in the buttocks, legs, and thighs and is indubitably a reason for spinal surgeries like laminectomies among individuals with stenosis.[5] It can have a declining impact on the global front and is reported to intensify lumbar extension or walking and classically relieved on flexion maneuvers of the lumbar spine.[6]

Magnetic resonance imaging (MRI), because of its high sensitivity and specificity of the lumbar spine, is a widely used persistent examination to detect LCS.[7] Numerous researches in the past have unanimous agreement that physiotherapy interventions like manual therapy (lumbar mobilization, neural mobilization, massage, etc.), core stability exercises, moist heat pack, aquatic therapy, remedial exercises, cryotherapy, acupuncture, flexion exercises, and electrotherapy (ultrasound therapy, electrical stimulation)are effective in treating the patients of LCS.[8] However, to the best of the authors' knowledge, little evidence has been found depicting the effectiveness of manual therapy, lumbar canal enlargement exercises, and conventional therapy. Therefore, a study protocol has been designed to assess the significance of manual therapy and canal enlargement exercises compared to the conventional physiotherapy treatment.

### Research Hypothesis

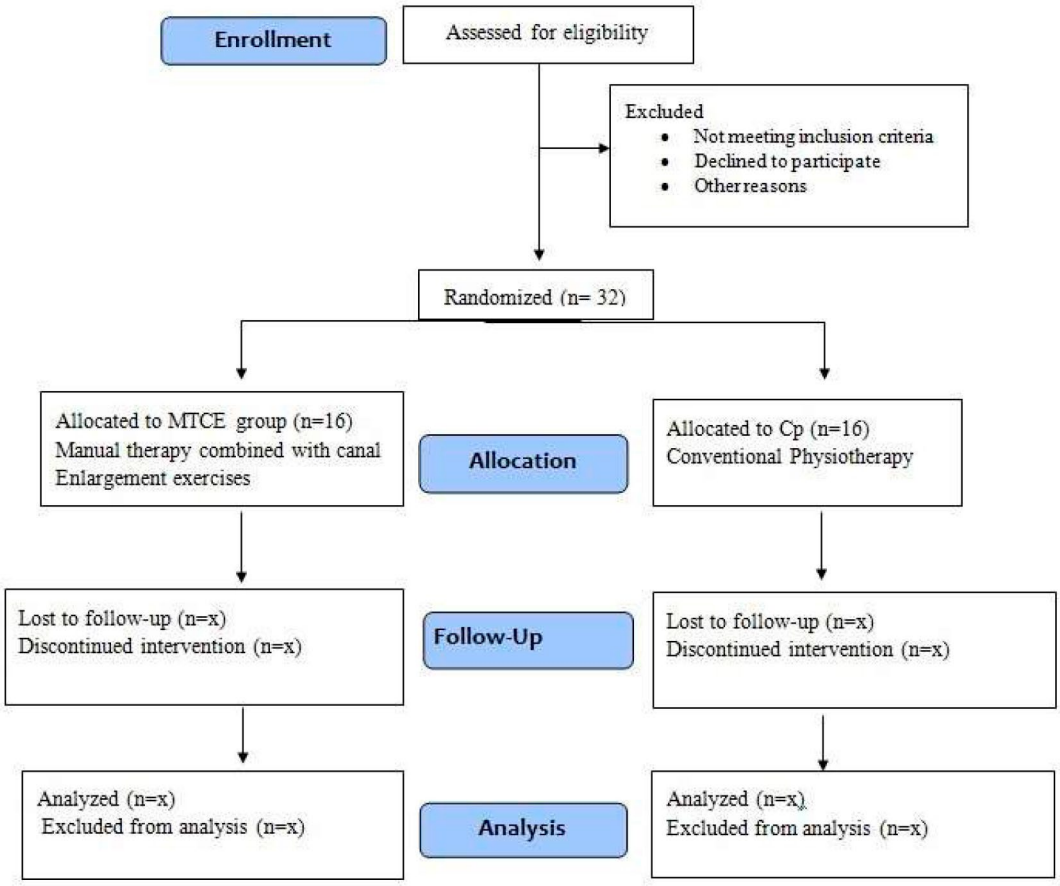
Null Hypothesis: Manual therapy and canal enlargement exercises may not have a significant effect on patients with LSS

Alternate Hypothesis: Manual therapy and canal enlargement exercises may prove to be significant in the improvement of the symptoms of patients with LSS.

## Materials and methods

The schematic Consolidated Standards of Reporting Trials flow chart for the study protocol (MTCE-Cp) is projected in Figure 1.

**Figure 1.** Schematic Consolidated Standards of Reporting Trials flow chart for the study protocol (MTCE-Cp)




MT-Manual Therapy; CE-Canal Enlargement exercise; Cp-Conventional Physiotherapy

## Trial Design

The study's protocol has been reviewed and got its approval by the Institutional Ethics Committee of the recognized University. The trial has been registered in the Clinical Trials Registry– India. The study will be conducted according to the guidelines of the Indian Council of Medical Research (2017), National Ethical Guidelines for biomedical and health research involving human participants, and the ethical principles for biomedical research involving human subjects stated in the Declaration of Helsinki (revised 2013).

## Study Design

This study is a Pre-test, Post-test, single-centered, and single-blinded Randomized clinical trial comprising two groups, entailing patients of secondary LCS at the level of L4 and below.

**Participants recruitment**

Patients of LCS will be recruited from the Outpatient department (OPD) of Tertiary care Hospital from October 2020 to March 2021. All the patients recruited in this study will sign an informed consent before the commencement of the intervention, which will be provided to them in the local language in which they are comfortable to read and understand. The patient's information will be secured by following the principles of confidentiality. The codes will be assigned to all the patients to prevent any biasing, and only the primary researcher will be the key holder to the patient's codes in each group.

**Eligibility criteria**

Inclusion criteria- In this study, male and female patients with secondary LCS at the level of L4 and below exhibiting symptoms of neurogenic claudication will be included. The condition of LCS should be pre-diagnosed with an MRI scan depicting an Antero-posterior lumbar canal diameter of 8-12mm. A MODI questionnaire will be included to assess the functional disability and quality of life. Conditions like disc herniation which can cause narrowing of the spinal canal, will also be encompassed in this study.

Exclusion criteria- Patients with Primary LCS and Musculoskeletal conditions like spondylitis, sacroiliitis, hip or knee osteoarthritis, or any metabolic diseases along with any bone infections (e.g., osteomyelitis) will be excluded. Any previous history of lumbar surgeries like laminectomy or spinal fractures will again be excluded. Any cardiac or pulmonary disease that limits walking, thereby representing vascular claudication, will not be considered eligible for the study. Pregnant females will also be excluded.

**Randomization, allocation, and blinding**

A total of 32 eligible patients will be randomized to two interventional groups, Group 1(MTCE) of Manual therapy and Canal enlargement exercises and Group 2 (Cp) consisting of Conventional physiotherapy via allocation ratio of 1:1 random method the principle of concealed allocation. Concealment of the patients will be assured by allocating the patient's detail in a sealed, opaque, and sequentially numbered envelope. The study will be single-blinded, i.e., the patients will be kept blinded by their interventional group.

**Enrollment and baseline measurement**

After the enrollment of the patients, the baseline measurements of each patient will be carefully measured by the physiotherapist before commencing the interventions. Anthropometric measurements such as age, height, weight, and BMI (body mass index) will be quantified and noted. Other demographic data of the patient such as chief complaint history of present and past illness, history of pain with its type and duration, socioeconomic status, and comorbidities will also be accounted for in the assessment Performa of LCS. The pain will be measured by the Numeric pain rating scale (NPRS); Antero-posterior canal diameter will be documented precisely with the help of an MRI. A modified Oswestry disability index (MODI) questionnaire will be used to calculate the percentage of disability and quality of life. Claudication distance will be measured with the help of a measuring tape through an over-ground walking method by measuring the distance the patient can walk till the symptoms of absolute claudication arise. (Table 1)

**Table 1.** Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) schedule for patient participation

| | **STUDY PERIOD** | | | | | | |
|---|---|---|---|---|---|---|---|
| | **Enrolment** | **Allocation** | **Post-allocation** | | | | **Follow up (evaluation)** |
| **TIMEPOINT** | **0 week** | **0 week** | **1st week** | **2nd week** | **3rd week** | **4th week** | **$t_x$** |
| **Enrolment:** | | | | | | | |
| **Eligibility screen** | X | | | | | | |
| **Informed consent** | X | | | | | | |
| **Clinical evaluation, inclusion and exclusion criteria** | X | | | | | | |
| **Allocation** | | X | | | | | |
| **Interventions:** | | | | | | | |
| **Manual therapy and Canal enlargement exercise** | | | X | X | X | X | |
| **Conventional physiotherapy** | | | X | X | X | X | |
| **Assessments:** | | | | | | | |
| **Demographic data** | | X | | | | | |
| **Pain** | | X | | | | | X |
| **AP canal diameter** | | X | | | | | X |
| **Modified oswestry disability index (MODI)** | | X | | | | | X |
| **Claudication distance** | | X | | | | | X |

**Interventions**

The intervention will be given after completing the thorough assessment of the patient and obtaining the baseline measures. Each patient will have to undergo three treatment sessions per week on alternate days for a total of 4 weeks (Table 2). The intervention protocol is also copyrighted under Copyright Office, Government of India with Registration No. L-98210/2021.

Manual Therapy (Figure 2)

• Maitland Grade III Central Posterior-Anterior (PA) spinal mobilization – It is a passive accessory and physiological intervertebral movement that will be performed at the involved lumbar intervertebral segments according to the methods described by Maitland et al.[9] The patient will be asked to lie prone on a manual therapy couch with his head rotated to one side and hands above the head or on either side. Mobilization will be provided to the involved vertebrae through the ulnar border of the therapist's hand, between the hook of the hamate and pisiform bone. Three sets of 40-second oscillations will be provided at the highest amplitude that the patient can tolerate at a rate of approximately 1 to 2 Hz. The duration of the PA mobilization will be approximately 8-10 minutes, with one-minute resting time being allotted between each mobilization.

• Canal Enlargement exercises- These are the specific exercises that will help to increase the lumbar canal dimensions.

a) Bilateral Knee-to-chest - It will be performed in supine lying. The patient will grasp the posterior thighs of both limbs together and bring them to the chest as close as possible by fully flexing the hip and knee. This maneuver will stretch the lumbar Para-spinal muscles.[10]

b) LIONS stretch- This will be initiated in a kneel sitting position. The patients will be asked to lean forward with both hands placed on the couch and bring their butts close to the heels for a proper stretch. This will stretch the lumbar extensors and thoracolumbar fascia. Pillows can be used under the knees to avoid any unnecessary pain.

c) Cat and Camel exercise- In this, the entire spine from cervical to lumbar undergoes flexion and extension cycles simultaneously. The patient will be instructed to get into a quadruped position with the knees under the hips and the hands under the shoulders with the spine in a neutral position. The patients will then take a deep breath and arch their thoracic spine upwards towards the ceiling and thereby flex the cervical spine along with the thoracic spine and will then breathe out, holding the position for at least 10 seconds. Then, they will return to the neutral by again taking a deep breath, thereby increasing the lordotic curvature and extending the thoracic spine by retracting both scapulae and lifting the neck towards the ceiling. Any hyperextension to the lumbar spine will be avoided. All three sections of the spine will be flexed and extended together.

**Figure 2.** Lumbar canal enlargement exercises & manual therapy


A- Bilateral knee-to-chest; B&C- Cat and Camel exercises; D- Lions stretch; E- Hand positioning during Maitland Grade Ⅲ Central Posterior-Anterior spinal mobilization ; F- application of force during Maitland Grade Ⅲ Central Posterior-Anterior spinal mobilization
*Arrows (black) indicates the direction of movement or pressure

Conventional Physiotherapy (Figure 3)

a) A Hydro-collator pack will be given over the lumbar region for 15-20 minutes.[11] The region will be first examined for any signs of inflammation.

b) TENS - Transcutaneous Electrical Nerve Stimulation will be applied over the lumbar Para-spinal region. Parameters will be two channels, biphasic pulse, frequency 90 Hz, pulse width 100 ms, duration 20 min, intensity according to the sensation of the patient.[12]

c) Hamstrings stretching- It will be performed in supine lying with the hip flexed to 90 degrees and then the knee will be extended till the stretch is felt. The contralateral extremity will be properly stabilized.[13]

d) Piriformis stretching - It will also be performed in supine lying. The therapist will flex the patient's hip to 90° and internally rotate the hip. The passive stretch will be applied in adduction towards the opposite hip joint.[14]

e) Pelvic Rotations- It will be performed in a crook lying position. The patient will join both his legs together and gradually drop it to one side, thereby holding it for 10 seconds. The same will be repeated to another side too.[15]

**Figure 3.** Conventional Physiotherapy


A- Pelvic Rotations; B- Hamstrings stretching; C- Piriformis stretching
*Arrows (black) indicates the direction of movement or pressure

**Table 2.** Advanced Physiotherapy protocol of Manual therapy, Canal enlargement exercise and Conventional physiotherapy for patients with LCS (LCS) (to be continued)

| ***Week1*** | **Conventional Physiotherapy (Cp)** | **Manual Therapy + Canal Enlargement exercise (MTCE)** |
|---|---|---|
| **Day 1** | • Hydro-collator pack (15 mins )<br>• T.E.N.S<br>• Pelvic Rotations (10 reps, 10 secs hold) | • Hydro-collator pack (15 mins )<br>• T.E.N.S<br>• Maitland Grade Ⅲ Central Posterior-Anterior spinal mobilization<br>• Bilateral knee-to-chest (5 reps, 10 secs hold) |
| **Day 2** | • Hydro-collator pack (15 mins)<br>• T.E.N.S<br>• Pelvic Rotation (10 reps, 10 secs hold)<br>• Stretching of Hamstrings and Piriformis muscles (3-5 reps,30 sec hold) | • Hydro-collator pack (15 mins )<br>• T.E.N.S<br>• Maitland Grade Ⅲ Central Posterior-Anterior spinal mobilization<br>• Bilateral knee-to-chest (5 reps, 10 secs hold) |
| **Day 3** | • Hydro-collator pack (15 mins)<br>• T.E.N.S<br>• Pelvic Rotation (10 reps, 10 secs hold)<br>• Stretching of Hamstrings and Piriformis muscles ( 3-5 reps,30 sec hold) | • Hydro-collator pack (15 mins )<br>• T.E.N.S<br>• Maitland Grade Ⅲ Central Posterior-Anterior spinal mobilization<br>• Bilateral knee-to-chest (5 reps, 10 secs hold) |
| ***Week2*** | | |
| **Day 1** | • Hydro-collator pack (15 mins)<br>• T.E.N.S<br>• Stretching of Hamstrings and Piriformis muscles ( 5-10 reps ,30 sec hold) | • Hydro-collator pack (15 mins )<br>• T.E.N.S<br>• Maitland Grade Ⅲ Central Posterior-Anterior spinal mobilization<br>• Bilateral knee-to-chest (5-10 reps, 10 secs Hold )<br>• LIONS stretch (3-5 reps, 10secs hold) |
| **Day 2** | • Hydro-collator pack (15 mins)<br>• T.E.N.S<br>• Stretching of Hamstrings and Piriformis muscles ( 5-10 reps ,30 sec hold) | • Hydro-collator pack (15 mins )<br>• T.E.N.S<br>• Maitland Grade Ⅲ Central Posterior-Anterior spinal mobilization<br>• Bilateral knee-to-chest (5-10 reps, 10 secs Hold )<br>• LIONS stretch (3-5 reps, 10secs hold) |
| **Day 3** | • Hydro-collator pack (15 mins)<br>• T.E.N.S<br>• Stretching of Hamstrings and Piriformis muscles ( 5-10 reps ,30 sec hold) | • Hydro-collator pack (15 mins )<br>• T.E.N.S<br>• Maitland Grade Ⅲ Central Posterior-Anterior spinal mobilization<br>• Bilateral knee-to-chest (5-10 reps, 10 secs Hold)<br>• LIONS stretch (3-5 reps, 10secs hold) |
| ***Week3*** | | |
| **Day 1** | • Hydro-collator pack (15 mins)<br>• T.E.N.S<br>• Stretching of Hamstrings and Piriformis muscles (10 reps ,30 sec hold) | • Hydro-collator pack (15 mins )<br>• T.E.N.S<br>• Maitland Grade Ⅲ Central Posterior-Anterior spinal mobilization<br>• Bilateral knee-to-chest (5-10 Reps ,20 secs Hold<br>• LIONS stretch (3-5 reps, 15secs hold)<br>• Cat and Camel exercise (5-7 reps, 10secs hold) |

**Table 2.** Advanced Physiotherapy protocol of Manual therapy, Canal enlargement exercise and Conventional physiotherapy for patients with LCS (LCS) (conclusion)

| | | |
|---|---|---|
| **Day 2** | • Hydro-collator pack (15 mins)<br>• T.E.N.S<br>• Stretching of Hamstrings and Piriformis muscles (10 reps ,30 sec hold) | • Hydro-collator pack (15 mins )<br>• T.E.N.S<br>• Maitland Grade Ⅲ Central Posterior-Anterior spinal mobilization<br>• Bilateral knee-to-chest (5-10 Reps ,20 secs Hold)<br>• LIONS stretch (3-5 reps, 15 secs hold)<br>• Cat and Camel exercise (5-7 reps, 10secs hold) |
| **Day 3** | • Hydro-collator pack (15 mins)<br>• T.E.N.S<br>• Stretching of Hamstrings and Piriformis muscles (10 reps ,30 sec hold) | • Hydro-collator pack (15 mins )<br>• T.E.N.S<br>• Maitland Grade Ⅲ Central Posterior-Anterior spinal mobilization<br>• Bilateral knee-to-chest (5-10 Reps ,20 secs Hold)<br>• LIONS stretch (3-5 reps, 15secs hold)<br>• Cat and Camel exercise (5-7 reps, 10 secs hold) |
| ***Week4*** | | |
| **Day 1** | • Hydro-collator pack (15 mins)<br>• T.E.N.S<br>• Stretching of Hamstrings and Piriformis muscles (10-15 reps ,30 sec hold) | • Hydro-collator pack (15 mins )<br>• T.E.N.S<br>• Maitland Grade Ⅲ Central Posterior-Anterior spinal mobilization<br>• Bilateral knee-to-chest (5-10 Reps ,30 secs Hold<br>• LIONS stretch (3-5 reps, 20 secs hold)<br>• Cat and Camel exercise (5-7 reps, 15 secs hold) |
| **Day 2** | • Hydro-collator pack (15 mins)<br>• T.E.N.S<br>• Stretching of Hamstrings and Piriformis muscles (10-15 reps ,30 sec hold) | • Hydro-collator pack (15 mins )<br>• T.E.N.S<br>• Maitland Grade Ⅲ Central Posterior-Anterior spinal mobilization<br>• Bilateral knee-to-chest (5-10 Reps ,30 secs Hold<br>• LIONS stretch (3-5 reps, 20secs hold)<br>• Cat and Camel exercise (5-7 reps, 15 secs hold) |
| **Day 3** | • Hydro-collator pack (15 mins)<br>• T.E.N.S<br>• Stretching of Hamstrings and Piriformis muscles (10-15 reps ,30 sec hold) | • Hydro-collator pack (15 mins )<br>• T.E.N.S<br>• Maitland Grade Ⅲ Central Posterior-Anterior spinal mobilization<br>• Bilateral knee-to-chest (5-10 Reps ,30 secs Hold<br>• LIONS stretch (3-5 reps, 20 secs hold)<br>• Cat and Camel exercise (5-7 reps, 15 secs hold) |

**Kindly Note:**

- TENS- Transcutaneous Electrical Nerve Stimulation
- These exercises will be performed under the guidance/supervision of the physiotherapist.
- The above-mentioned Reps (Repetitions) and Holding time are tentative. Thus, can change according to the patient's status of performance.
- 1-2 minutes of rest interval will be given after every exercise.
- Stretching will only be given to patients with muscle tightness.
- Hydro-collator packs can be avoided in case of any signs of inflammation; instead, Cryotherapy can be used until the inflammation subsides.

**Outcome Measures**

All the outcomes of the study will be evaluated at the baseline and post-intervention. Therefore, all instruments or tools that are going to be used for the study should have good validity and reliability.

• Antero-posterior canal diameter:

Sagittal T1 and T2 weighted MRI are considered the most appropriate, non-invasive, and reliable method to determine central stenosis.16 MRI will be performed by the experienced radiologist of the University who will be kept blinded to the patient's details. The sequences of the MRI performed will be through a 1.5 T Philips Multiva Magnetic Resonance Imaging System with imaging sequences, Sagittal T1, Sagittal T2, Coronal STIR, Axial T1, and Axial T2.

• Functional disability :

For measuring the functional disability and quality of life, the Modified Oswestry disability index (MODI) is a self-administered questionnaire that has been used vastly in patients with lumbar spine disorders treated with both surgical and non-surgical interventions. This questionnaire acquaints the therapist about the disability level of the patient and its impact on the activities of daily living. There are a total of 10 sections with each section comprising a total possible score of 5 and the total score ranges from 0-50.[17] Subcategories have been devised according to the disability percentage wherein patients can be allocated accordingly: 0%–20% (minimal disability), 20%–41% (moderate disability), 41%–60% (severe disability), 61%–80% (crippled), and 81%–100% (bedridden).[18] In the modified version the 'sexual life' section has been superseded with the employment and homemaking' domain as it is reported to have been ignored by many reluctant patients.[19] This measure has been proven to have good validity and reliability with the minimal clinically important difference (MCID) of 6.[20]

• Pain intensity:

Pain intensity associated with LCS will be best measured by the Numeric Pain Rating Scale (NPRS) which is one of the well-founded and approachable measures to assess self-reported levels of pain and is widely used to measure pain intensity in various musculoskeletal conditions. The scale consists of 11 points in which the patient has to rate the level of pain (best, average, and worst) in the last 48 hours. It consists of two anchors '0 and 10'. On the left 0 represents "no pain" whereas 10 on right represents "maximal pain". NPRS is considered to have good validity with MCID values as 1.50 for thighs and legs and 1.25 for back and buttock in patients of LCS.[21]

• Claudication distance (CD):

It will measure the prodrome of neurogenic claudication which may be defined as an exhibition of pain, heaviness, or cramping linked with lower limb paresthesia, which is experienced while walking or standing erect and is relieved on bending forward or stooping.[22] CD will be measured with the help of a measuring tape by measuring the floor distance that the patient can cover till the symptoms of absolute claudication arises.

**Sample Size Estimation**

G*Power tool 3.1.9.4 version was used to calculate the sample size of the study.[23] MODI Questionnaire is considered the primary outcome measure for the study, and from a previous study done, the effect size was taken as 1.1220. To obtain a power of 95% (β=5%), a sample size of n=26 was calculated using G*Power ver. 3.1.9.4 software (Heinrich-Heine-Universität Düsseldorf) where level of Significance was set at 0.05. Moreover, a 20% dropout rate was considered, and then the total sample size estimated was n=32 (n=16 in each group).

**Data Analysis**

After collecting and assembling all data, statistical analysis will be done by the primary researcher using SPSS software (ver. 22.0, IBM Corp., Armonk, NY, USA). First, the separate baseline characteristics of all outcomes will be presented. The Shapiro Wilk test will be used to check the normality of the data. A paired t-test or Wilcoxon signed-rank test will be used as a statistical test for within-group analysis, whereas an Independent t-test or the Mann-Whitney U-test will be used for analysis between the groups.

## Results

According to the previous research on physiotherapy interventions provided to the patients of LCS, we can expect that the treatment given to the MTCE group for 4 weeks may significantly improve the patient's quality of life by ameliorating pain and increasing claudication distance.[24,25] However, since this will be the first preliminary study that will compare the AP canal diameter at baseline and post-intervention, the results cannot be anticipated whether there will be a considerable increase in the canal diameter or not.

## Discussion

This article has proposed a protocol for a clinical trial to appraise the conglomerated interventions of manual therapy, canal enlargement exercises, and conventional physiotherapy in patients of LCS. To the best of our knowledge, no published RCTs have enlightened the effects of combined physiotherapy interventions and compared the AP canal diameter at baseline and post-intervention through MRI. The rationale of this protocol constructed is entirely based on the pathophysiology of the LCS; therefore, with a better understanding of the pathomechanics, this protocol has been framed by keeping pragmatic therapeutic interventions to deal with the symptoms of LCS.

Neurogenic Claudication being one of the miserable symptoms of LCS, is revealed to deteriorate the patient's quality of life by hampering the ability to walk, which eventually affects the patient psychologically.[26] Furthermore, keeping the detrimental effects of LCS in mind, we have not planned any placebo or sham treatment for any group as it would be insensitive and unethical to do so as many studies state that hopelessness and depression can have a confounding effect on the patient's prognosis and walking capacity.[27]

### Author contributions

Goyal M, Singh G conceived and designed the study. Gaur P wrote the manuscript. All the authors approved the final draft of the article.

### Competing interests

No financial, legal, or political competing interests with third parties (government, commercial, private foundation, etc.) were disclosed for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.).

## References


1. Munakomi S, Foris LA, Varacallo M. Spinal Stenosis And Neurogenic Claudication. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2021. Cited: PMID: 28613622

2. Singh V, Sethi R, Chauhan BS, Thukral B. Lumbar spinal stenosis and morphometry of lumbar vertebral canal. J Anat Soc India. 2016;65(1):33–7. https://doi.org/10.1016/j.jasi.2016.07.008

3. Yadav U, Singh V, Bhargava N, Srivastav AK, Neyaz Z, Phadke RV, et al. Lumbar Canal Diameter Evaluation by CT Morphometry—Study of Indian Population. Int J Spine Surg. 2020;14(2):175–81. https://doi.org/10.14444/7028

4. Anasuya DG, Jayashree A, Moorthy NLN, Madan S. Anatomical Study of Lumbar Spinal Canal Diameter on Mri To Assess Spinal Canal Stenosis. Int J Anat Res. 2015;3(3):1441–4. http://dx.doi.org/10.16965/ijar.2015.261

5. Kim K, Hunt CL, Bauer BA, Lee J, Youn Y, Lee SH, et al. Nonsurgical integrative inpatient treatments for symptomatic lumbar spinal stenosis : A multi-arm randomized controlled pilot trial. J Pain Res. 2019;12:1103-13. https://doi.org/10.2147/jpr.s173178

6. Lurie J, Tomkins-Lane C. Management of lumbar spinal stenosis. BMJ. 2016;352:h6234. https://doi.org/10.1136/bmj.h6234

7. Kalff R, Ewald C, Waschke A, Gobisch L, Hopf C. Degenerative Lumbar Spinal Stenosis in Older People. Dtsch Arztebl Int. 2013;110(37):613–24. https://dx.doi.org/10.3238%2Farztebl.2013.0613

8. Schneider MJ, Ammendolia C, Murphy DR, Glick RM, Hile E, Tudorascu DL, et al. Comparative Clinical Effectiveness of Nonsurgical Treatment Methods in Patients With Lumbar Spinal Stenosis: A Randomized Clinical Trial. JAMA Netw open. 2019;2(1):e186828. https://doi.org/10.1001/jamanetworkopen.2018.6828

9. Maitland GD. Management of lumbar spine disorder. In: Banks K, Hengeveld E, editors. Maitland's vertebral manipulation. 8th ed. United Kingdom: Churchill Livingstone; 2013; p. 230-6.

10. Bodack MP, Monteiro M. Therapeutic Exercise in the Treatment of Patients With Lumbar Spinal Stenosis. 2001;(384):144–52. https://doi.org/10.1097/00003086-200103000-00017

11. Sahin F, Yilmaz F, Kotevoglu N, Kuran B. The efficacy of physical therapy and physical therapy plus calcitonin in the treatment of lumbar spinal stenosis. Yonsei Med J. 2009;50(5):683–8. https://doi.org/10.3349/ymj.2009.50.5.683

12. Krekoukias G, Gelalis ID, Xenakis T, Gioftsos G, Dimitriadis Z, Sakellari V. Spinal mobilization vs conventional physiotherapy in the management of chronic low back pain due to spinal disk degeneration: a randomized controlled trial. J Man Manip Ther. 2017;25(2):66–73. https://doi.org/10.1080/10669817.2016.1184435

13. Murphy DR, Hurwitz EL, Gregory AA, Clary R. A non-surgical approach to the management of lumbar spinal stenosis: A prospective observational cohort study. BMC Musculoskelet Disord. 2006;7:16. https://dx.doi.org/10.1186%2F1471-2474-7-16

14. Gulledge BM, Marcellin-Little DJ, Levine D, Tillman L, Harrysson OLA, Osborne JA, et al. Comparison of two stretching methods and optimization of stretching protocol for the piriformis muscle. Med Eng Phys. 2014;36(2):212–8. https://doi.org/10.1016/j.medengphy.2013.10.016

15. Kisner C, Colby LA. Therapeutic Exercise: Foundations and techniques. 6th ed. Philadelphia: F.A. Davis Company; 2012.

16. Cowley P. Neuroimaging of Spinal Canal Stenosis. Magn Reson Imaging Clin N Am. 2016;24(3):523–39. https://doi.org/10.1016/j.mric.2016.04.009

17. Fairbanks JC, Couper J, Davies JB, O'Brien JP. The Oswestry Low Back Pain Disability Questionnaire. Physiotherapy. 1980;66(8):271-273. Cited: PMID: 6450426

18. Alcántara-Bumbiedro S, Flórez-García MT, Echávarri-Pérez C, García-Pérez F. Oswestry low back pain disability questionnaire. Rehabilitacion. 2006;40(3):150–8.

19. Nishant, Chhabra HS, Kapoor KS. New modified english and hindi oswestry disability index in low back pain patients treated conservatively in Indian population. Asian Spine J. 2014;8(5):632–8. https://doi.org/10.4184/asj.2014.8.5.632

20. Fritz JM, Irrgang JJ. A comparison of a modified Oswestry Low Back Pain Disability Questionnaire and the Quebec Back Pain Disability Scale. Phys Ther. 2001;81(2):776–88. https://doi.org/10.1093/ptj/81.2.776

21. Cleland JA, Whitman JM, Houser JL, Wainner RS, Childs JD. Psychometric properties of selected tests in patients with lumbar spinal stenosis. Spine J. 2012;12(10):921–31. https://doi.org/10.1016/j.spinee.2012.05.004

22. Snow GJ. Chiropractic management of a patient with lumbar spinal stenosis. J Manipulative Physiol Ther. 2001;24(4):300–4. https://doi.org/10.1067/mmt.2001.114359

23. Erdfelder E, Faul F, Buchner A, Lang AG. Statistical power analyses using G*Power 3.1: Tests for correlation and regression analyses. Behav Res Methods. 2009;41(4):1149–60. https://doi.org/10.3758/brm.41.4.1149

24. Kumar S, Narkeesh A. Effect of Integrated Exercise Protocol in Lumbar Spinal Stenosis as Compare with Conventional Physiotherapy- A Randomized Control Trial. Int J Neurorehabilitation. 2017;4:6. http://dx.doi.org/10.4172/2376-0281.1000301

25. Shum GL, Tsung BY, Lee RY. The Immediate Effect of Posteroanterior Mobilization on Reducing Back Pain and the Stiffness of the Lumbar Spine. Arch Phys Med Rehabil. 2013;94(4):673–9. https://doi.org/10.1016/j.apmr.2012.11.020

26. Ammendolia C, Schneider M, Williams K, Zickmund S, Hamm M, Stuber K, et al. The physical and psychological impact of neurogenic claudication: The patients' perspectives. J Can Chiropr Assoc. 2017;61(1):18–31. Cited: PMID: 28413220

27. Mckillop AB, Carroll LJ, Battié MC. Depression as a prognostic factor of lumbar spinal stenosis: A systematic review. Spine J. 2014;14(5):837–46. https://doi.org/10.1016/j.spinee.2013.09.052