

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Role of Total Motion Release in Patients with Lumbar Radiculopathy

Protocol summary

Study aim

To determine the effects of Total motion release in patients with lumbar radiculopathy functional

Design

This two arm parallel randomized trial with a sample size of 68 participants, will feature blinded assessors to evaluate outcomes related to quality of life , pain and functional disability outcome will assess

Settings and conduct

Data will be collected from Physiotherapy department in University of Lahore teaching hospital. This will be single blinded study where assessor will remain unaware of participants belong to which groups but aware of measuring outcomes.

Participants/Inclusion and exclusion criteria

Inclusion Criteria • Aged between 18-50 years • Both Male and females • Patients referred from orthopedic • Patients with positive SLR test • Having at least 5 score of Numeric Pain Rating Scale Exclusion Criteria • Patients with neurological symptoms (such as cognitive) • Patients with inflammatory disorders (rheumatoid arthritis) • Patients with specific disorders of spine (ankylosing spondylitis, severe osteoporosis, sacroiliac joint pathology) • Patients with previous spinal surgery • Current pregnancy or early postpartum period (6 months)

Intervention groups

All the screened and willing participants will be randomly allocated to two groups where Group A will receive Total motion release. This technique will be given to unaffected side thus relieving symptoms of affected side with 5 reps & 10 times. It is very simple technique in which patient is made to perform five motion they are: 1) Arm raise 2) Trunk twist 3) Leg raise 4) Sit to stand and 5) Toe reach. And group B will receive conventional Therapy. The nerve sliding technique will be applied for 20-30 repetitions in 2-3 sets per day, and the nerve tensioning technique will be implemented in addition for 15-25 seconds in 5-7 repetitions.

Main outcome variables

Pain Quality of life Functional disability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240923063127N1**

Registration date: **2024-11-22, 1403/09/02**

Registration timing: **retrospective**

Last update: **2024-11-22, 1403/09/02**

Update count: **0**

Registration date

2024-11-22, 1403/09/02

Registrant information

Name

Ayesha Maroof

Name of organization / entity

University of Lahore

Country

Pakistan

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-05, 1402/12/15

Expected recruitment end date

2024-10-05, 1403/07/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Role of Total Motion Release in Patients with Lumbar Radiculopathy

Public title

Role of Total Motion Release in Patients with Lumbar Radiculopathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Aged between 18-50 years Both Male and females
Patients referred from orthopedic Patients with positive SLR test Having at least 5 score of Numeric Pain Rating Scale

Exclusion criteria:

Patients with neurological symptoms (such as cognitive)
Patients with inflammatory disorders (rheumatoid arthritis) Patients with specific disorders of spine (ankylosing spondylitis, paget’s disease, vertebral collapse, spondylolisthesis, severe osteoporosis, Tb spine, diabetic neuropathy, stenosis, sacroiliac joint pathology) Patients with previous spinal surgery Current pregnancy or early postpartum period (6 months)

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Individual simple randomization will be performed by one research team member who is blinded to the study and not involved in patient recruitment. The randomization process will utilize sealed, opaque envelopes to ensure allocation concealment. The random sequence will be generated using a random number table or computer software to avoid bias. This approach ensures proper probability-based allocation and maintains the integrity of the randomization process.

Blinding (investigator's opinion)

Single blinded

Blinding description

This is a single blinded study in which outcome assessor will be blinded to group allocation

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

University of Lahore

Street address

University of Lahore Teaching Hospital Lahore , Punjab , Pakistan

City

Lahore

Postal code

55150

Approval date

2024-05-09, 1403/02/20

Ethics committee reference number

REC-UOL-/163/08/24

Health conditions studied

1

Description of health condition studied

A disorder known as lumbar radiculopathy, which is characterized by irritation or compression of the nerve roots in the lumbar spine, frequently causes severe pain, functional restrictions, and a decline in quality of life.

ICD-10 code

M54.16

ICD-10 code description

Radiculopathy, lumbar region

Primary outcomes

1

Description

The pain VAS is a unidimensional measure of pain intensity, used to record patients’ pain progression, or compare pain severity between patients with similar conditions.

Timepoint

Before intervention and 2nd , 4th weeks after intervention.

Method of measurement

The simplest VAS is a straight horizontal line of fixed length, usually 100 mm. The ends are defined as the extreme limits of the parameter to be measured (symptom, pain, health) orientated from the left (worst) to the right (best).

2

Description

The Oswestry disability Index is most sensitive for patients with mild to moderate disability due to acute, sub-acute, or chronic low back pain.

Timepoint

Before intervention and 2nd , 4th weeks after intervention.

Method of measurement

The end score is the sum of the ticked boxes. The score ranges from 0 (no disability) to 24 (max. disability) depending on the questionnaire used. Roland and Morris omitted describing the various levels of disability (for example, 40%–60% of disability is severe).

3

Description

The SF-12 is a self-reported outcome measure assessing the impact of health on an individual's everyday life. It is often used as a quality of life measure.

Timepoint

Before intervention and 2nd , 4th weeks after intervention.

Method of measurement

The SF-12 uses the exact two domains mental and physical health score as the SF-36. Patients fill out a 12-question survey which is then scored by a clinician or researcher. The score ranges from 0 (worst health) to 100 (best health) depending on the questionnaire used.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The participants randomly will be allocated in Group A received the Total motion release. After 15 minutes of heat therapy along with TENS, neural mobilization exercises, consisting of both sliders and tensioners, will be provided. The patient will be positioned in high sitting, with the hands clasped behind and in slouched posture as base position. They will be performed neck extension and knee extension for the sliding technique, and neck flexion with knee extension for the tensioning technique . The movement range will be determined by the severity of symptoms and patient tolerance. The nerve sliding technique will be applied for 20-30 repetitions in 2-3 sets per day, and the nerve tensioning technique will be implemented in addition for 15-25 seconds in 5-7 repetitions. In total motion release treatment is given to unaffected side thus relieving symptoms of affected side with 5 reps & 10 times. It is very simple technique in which patient is made to perform five motion they are (Naik et al., 2019): 1) Arm raise 2) Trunk twist 3) Leg raise 4) Sit to stand and 5) Toe reach.

Category

Treatment - Other

2

Description

Intervention group: In Group B all allocated participants will be received conventional therapy. Conventional therapy includes 15 minutes of heat therapy along with TENS. Hot packs will be used to deliver superficial heating. Each treatment session will be lasted 30-45

minutes. TENS (Transcutaneous Electrical Nerve Stimulation) sessions will be lasted 15 min. The TENS will be applied in a conventional mode for 15 min at a high frequency of 70 Hz and wavelength of 100 microseconds by placing two 40 × 40 mm electrode sets cross arranged on each side of the lumbosacral spine. The intensity of the current will be increased to the point of observation of no contractions, but with a light tingling sensation, while ensuring the patient will be comfortable. Then mild stretches of hamstrings and piriformis muscle, core stabilization exercises and sciatic nerve mobilization will be done.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

University of Lahore Teaching Hospital

Full name of responsible person

Ayesha Maroof

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1-km Defence Road near Bhuptian Chowk Lahore

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Sponsors / Funding sources

1

Sponsor

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Grant name

None

Grant code / Reference number

None

Is the source of funding the same sponsor organization/entity?

No

Title of funding source
none
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
University of Lahore
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Ayesha Maroof
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Demographic data and data related to final outcome will be shared by maintaining the confidentiality

When the data will become available and for how long

Data will be available after the publication of findings till six months

To whom data/document is available

De-identified individual participant data (IPD) and supporting documents will be shared for research

purposes only and will be available up to six months after the publication of findings. Access is primarily for individuals working in academic institutions; however, those from other organizations, such as businesses, may also apply with a valid research proposal. Requests can be directed to the corresponding author, Ayesha Maroof, at ayeshaa.khan1512@gmail.com or +92 305 8803766. Additionally, data will be shared through public releases in accordance with established traditions for open access.

Under which criteria data/document could be used

For research purpose

From where data/document is obtainable

To the corresponding author of the study, Ayesha Maroof and can contact on +92 305 8803766 ,

Ayeshaa.khan1512@gmail.com

What processes are involved for a request to access data/document

Open access and there is the traditional public data releases where anyone can get access to the data

Comments