Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Thoracolumbar myofascial release and Graston technique on pain, range of motion and disability among patients with chronic low back

Protocol summary

Study aim

To determine the effects of thoracolumbar myofascial release and Graston technique on pain, range of motion, and disability among chronic low back pain patients.

Design

Randomized, parallel group trial with blinded outcome assessment. Randomization was centralized and computerized with concealed randomization sequence carried out at an external site between sample size of 72 patients. All the screened and willing participants will be randomly allocated to two groups by lottery method. This study will be a single-blinded study in which the assessor will be kept blinded

Settings and conduct

Department of Physical Therapy, University of Lahore Teaching Hospital, Defense Road, Lahore.

Participants/Inclusion and exclusion criteria

Inclusion Criteria will be patients aged between 35 and 50 years both males and females with low back pain for more than 3 months in a year, having a 4 score on the Visual Analogue Scale and the prone position must be pain-free for the patients ; Exclusion Criteria will include patients with history of fracture, tumor, and infections, if had undergone any spine-related surgery between Th 12 and S1, had radiating pain in the legs, and had pacemakers or pregnancy.

Intervention groups

All the screened and willing participants will be randomly allocated to two groups by lottery method. This study will be a single-blinded study in which the assessor will be kept blinded. Group A participants will be received Myofascial release technique and Group B participants will be received Graston technique with routine physical therapy. Both groups will be received routine physical therapy which included 15 minutes of electrical muscle stimulation (application of Transcutaneous Electrical Nerve Stimulation (TENS) for 10 minutes (pulse width: 50-100 µs and frequency: 60-120 Hz) at bearable intensity along with heating pad at the same time covering the lumbosacral and gluteal region in a prone position.) with heat therapy. The intervention groups will be received three sessions per week for 8th week of follow-up.

Main outcome variables

Pain, ROM (range of motion), Disability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240724062532N1**
Registration date: **2024-10-19, 1403/07/28**
Registration timing: **retrospective**

Last update: **2024-10-19, 1403/07/28**
Update count: **0**

Registration date

2024-10-19, 1403/07/28

Registrant information

Name
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-10, 1402/10/20

Expected recruitment end date

2024-09-30, 1403/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Thoracolumbar myofascial release and Graston technique on pain, range of motion and disability among patients with chronic low back

Public title

Thoracolumbar myofascial release and Graston technique on pain, range of motion and disability among patients with chronic low back

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Aged between 35 and 50 years Both Male and females Low back pain for more than 3 months in a year Having a 4 score on the Visual Analogue Scale The prone position must be pain-free for the patients

Exclusion criteria:

History of fracture, tumor, and infections Had undergone any spine-related surgery between Th 12 and S 1 Had radiating pain in the legs, and had pacemakers Pregnancy

Age

From **35 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

A randomization clinical trail will be conducted using purposive sampling technique to collect data. Participants will be randomly allocated into two groups by lottery method.

Blinding (investigator's opinion)

Single blinded

Blinding description

A single blinded study is a clinical trial design in which accessor does not know which treatment is administered to the patients.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of University of Lahore

Street address

University of Lahore Teaching Hospital Lahore , Punjab , Pakistan

City

Lahore

Postal code

55150

Approval date

2024-01-10, 1402/10/20

Ethics committee reference number

REC-UOL-643-01-2024

Health conditions studied

1

Description of health condition studied

Low back pain is a highly prevalent condition that affects individuals worldwide and represents one of the most common complaints in primary care settings. LBP can originate from a variety of sources, including musculoskeletal, neural, and skeletal structures, and may be exacerbated by factors such as prolonged postures, physical strain, and age-related degenerative changes.

ICD-10 code

M54.50

ICD-10 code description

Low back pain

Primary outcomes

1

Description

The pain visual analog scale (VAS) is a one-dimensional way to quantify the intensity of pain; it's used for keeping track of how a patient's pain develops over time or for comparing the pain levels of people with similar medical conditions.

Timepoint

8th weeks

Method of measurement

The most basic VAS is a horizontal line with a fixed length, typically 100 mm. At each end of the line are the extremes of the parameter that is going to be measured, on the left side are the worst symptoms, and on the right side are the best health outcomes.

2

Description
When looking for a reduction in lumbar spine range of motion (flexion), as might happen with conditions like ankylosing spondylitis, the traditional gold standard is Schober's test.

Timepoint
8th weeks

Method of measurement
While the patient is upright, the examiner makes two marks on the PSIS and then, in the exact middle of those marks, draws a horizontal line. A second line is indicated fifteen centimeters above the first line. The examiner next has the patient bend forward as if reaching for their toes and takes new measurements from the top and bottom lines.

3

Description
One popular self-report tool for gauging the extent to which low back pain impairs a person's functional capacity and quality of life is the Modified Oswestry Disability Index.

Timepoint
8th weeks

Method of measurement
On a scale from 0 to 5 or 6, the respondent scores their level of disability for each of the ten parts that cover different everyday tasks. A higher percentage indicates a greater degree of disability, as the results are combined and expressed as a whole.

Secondary outcomes

empty

Intervention groups

1

Description
Experimental group A: Myofascial release technique The intervention to the MFR group will be placed in the prone position for subjects. The therapist will be stand at the subject's back level and will be placed the hands crossed over the spinous processes of the thoracic vertebrae (T12) and the iliac crest. Soft tissue mobilization will be applied for 10 min to the TL area, with the hands moving away from each other and compressing the fascial tissue.

Category
Treatment - Other

2

Description
Experimental group B: Soft tissue mobilization with Graston instruments will be applied to the TLF on the GT group. Individuals will be asked to kneel directly on the bed and lie forward. The largest Graston instrument (GT1) will be used for large surface areas and will be chosen for treatment. The Graston instrument will be applied superficially on the TLF between the sacrum and T12 (lumbosacral and lower thoracic region) at an angle of 45° for 10 min. The treatment will be applied to the entire fascial surface without being bound to any direction

Category
Treatment - Other

Recruitment centers

1

Recruitment center
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University of Lahore Teaching Hospital
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Dr. Asim Arif
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Sponsors / Funding sources

1

Sponsor
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Grant name
None

Grant code / Reference number
N/A

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

Title of funding source
University of Lahore

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
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Position
Consultant
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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
Undecided - It is not yet known if there will be 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 confidentially
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
Ainan Siddique
Under which criteria data/document could be used
For researcher purpose
From where data/document is obtainable
To the corresponding author of the study, Ainan Siddique and can contact on +92 323

2323334,ainansiddique980@gmail.com

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

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

Comments