

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparative effects of self myofascial release and instrument-assisted soft tissue mobilization on non-specific low back pain patients

Protocol summary

Study aim

To evaluate and compare the effects of self-myofascial release and Instrument-assisted soft tissue mobilization on pain, hamstrings tightness and functional disability.

Design

A randomized clinical trial was conducted with two parallel groups, a single blinded study of third phase with 17 patients in each group that are 34 in total.

Settings and conduct

Allied Hospital Faisalabad and Madinah Teaching Hospital.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Individuals diagnosed with non-specific lower back pain Individuals with hamstring tightness Subjects who voluntarily participated in the study Who had greater than 20 degrees knee extension lag while performing Active Knee Extension Test 27-46 years of age, male and female subjects. Exclusion Criteria: Individuals who had any previous lumbar spine surgeries Subjects who had any radiating pain or neurological deficit Subjects who had spine tumors, Ankylosing Spondylitis, or Spondylolisthesis With any any systemic illnesses, such as TB or spine infection

Intervention groups

Group A Patients in this group performed self-myofascial release on hamstrings bilaterally using a tennis ball for 4 minutes, 2 minutes per leg. Hot pack was applied for 15 minutes as a baseline treatment in both groups. Group B Patients in this group had bilateral soft tissue mobilization of the hamstring muscles using the GT number 1 Graston device. each participant received 30 repetitions for 60 seconds of Graston instrument technique from the gluteal line to the popliteal fossa

Main outcome variables

- Numeric Pain Rating Scale (NPRS): For pain assessment
- Active Knee Extension Test (AKET): For hamstring tightness
- Oswestry Disability Index (ODI): For functional disability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240528061932N1**

Registration date: **2024-07-31, 1403/05/10**

Registration timing: **registered_while_recruiting**

Last update: **2024-07-31, 1403/05/10**

Update count: **0**

Registration date

2024-07-31, 1403/05/10

Registrant information

Name

Nadia Rani

Name of organization / entity

The University of Faisalabad

Country

Pakistan

Phone

+92 41 2647086

Email address

thenadiarani@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-15, 1403/01/27

Expected recruitment end date

2024-08-20, 1403/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative effects of self myofascial release and instrument-assisted soft tissue mobilization on non-specific low back pain patients

Public title

Comparison of self myofascial release and IASTM on non-specific low back pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Individuals diagnosed with non-specific lower back pain
Individuals with hamstring tightness
Subjects who voluntarily participated in the study
Who had greater than 20 degrees knee extension lag while performing Active Knee Extension Test
27-46 years of age, male and female subjects.

Exclusion criteria:

Individuals who had any previous lumbar spine surgeries
Subjects who had any radiating pain or neurological deficit
Subjects who had spine tumors, Ankylosing Spondylitis, or Spondylolisthesis
With any any systemic illnesses, such as TB or spine infection

Age

From **27 years** old to **46 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was done by lottery method and individuals were divided into two groups. Participants were blinded. They did not know to which group they were allocated.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants were blinded in this study. They did not know to which group they were allocated.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research and Ethics/ Technical committee for The University of Faisalabad

Street address

University Avenue, Faisal Town Canal Road

City

Faisalabad

Postal code

38000

Approval date

2024-02-17, 1402/11/28

Ethics committee reference number

TUF/DR/SA/MSPP/2024/420

Health conditions studied

1

Description of health condition studied

Non-specific low back pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain and Hamstring tightness

Timepoint

Before intervention and after 6 weeks of treatment

Method of measurement

NPRS and Active knee Extension Test

Secondary outcomes

1

Description

Functional Disability

Timepoint

Before intervention and at the end of 6 weeks of intervention

Method of measurement

Oswestry Disability Index

Intervention groups

1

Description

Intervention group: Group A received self myofscial release using a tennis ball on both legs.

Category

Treatment - Devices

2

Description

Intervention group: Group B received graston technique on hamstrings of both legs.

Category

Treatment - Devices

Recruitment centers**1****Recruitment center****Name of recruitment center**

Madinah Teaching Hospital

Full name of responsible person

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2**Recruitment center****Name of recruitment center**

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Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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Web page address**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

The University of Faisalabad

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**

The University of Faisalabad

Full name of responsible person

Nadia Rani

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

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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

No - There is not a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Comparative Effects of Self Myofascial Release and Instrument-assisted Soft Tissue Mobilization in Non-specific Low Back Pain Patients

When the data will become available and for how long

Starting 6 months after publication and it will remain available for everyone.

To whom data/document is available

This will be available for everyone.

Under which criteria data/document could be used

thenadiarani@gmail.com 0092 3016167796

From where data/document is obtainable

thenadiarani@gmail.com 0092 3016167796

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

Any applicant just need to contact for data, contact through email at thenadiarani@gmail.com

Comments