Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Teachning 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 repititions 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

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Pakistan

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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

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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
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Recruitment center
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Sponsors / Funding sources

1

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sidra.majeed@tuf.edu.pk
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
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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
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From where data/document is obtainable
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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