

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison of the Effectiveness of Instrument Assisted Soft Tissue Mobilization Techniques with and without Routine Physical Therapy in Chronic Low Back Pain Patients

Protocol summary

Study aim

The aim of this study is to compare the effects of instrument-assisted soft tissue mobilization with routine physical therapy and isolated treatment of routine physical therapy on the function of the lumbar spine and pain during the achievement of daily life in patients with chronic low back pain.

Design

Parallel group, single-blind, randomized control trial

Settings and conduct

38 subjects will be studied at TABA Medical Complex, Lahore. Participants and assessors will be blinded. During the first visit, the researcher will complete thorough case history and lumbar regional assessment. Patients will be assessed using the Rolland Morris Questionnaire and Modified Oswestry Disability Index score for function and Numeric Pain Rating Scale for pain. Treatment will be then continued according to the allotted group intervention. All participants will receive a total of 12 treatment sessions over a 4-week period, which will consist of 3 treatment sessions per week. The researcher will take a follow-up value after 12 sessions. A follow-up assessment will be done at the end of 12 sessions as the post-treatment reading.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 40 and 60 years, Not make use of continuous drugs for low back pain, Previous spine surgeries, Do not present medical restriction to practice physical exercise or if they presented any limitations in lower limbs that physical exercises
Exclusion Criteria: neurological signs, specific spinal pathology (e.g. malignancy, or inflammatory joint or bone disease), Patients who will be reported osteoarthritis or disc lesions (prolapse, protrusion, or herniation without neurological compromise) with or without leg pain, Pregnant women

Intervention groups

Group A: Instrument assisted soft tissue mobilization with routine physical therapy
Group B: Routine physical therapy.

Main outcome variables

Pain and function

General information

Reason for update

Acronym

EIASTM&CPT

IRCT registration information

IRCT registration number: **IRCT20210205050256N1**

Registration date: **2021-02-10, 1399/11/22**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-10, 1399/11/22**

Update count: **0**

Registration date

2021-02-10, 1399/11/22

Registrant information

Name

Tooba Asif

Name of organization / entity

TIMES Institute

Country

Pakistan

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+92 21 36410331

Email address

tooba573@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-05, 1399/10/16

Expected recruitment end date

2021-06-07, 1400/03/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Instrument Assisted Soft Tissue Mobilization Techniques with and without Routine Physical Therapy in Chronic Low Back Pain Patients

Public title

Effects of Instrument Assisted Soft Tissue Mobilization Techniques in Patients with Chronic Low Back Pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 40 and 60 years Not make use of continuous drugs for low back pain Previous spine surgeries Do not present medical restriction to practice physical exercise or if they presented any limitations in lower limbs that physical exercises

Exclusion criteria:

Participants will be excluded if they had neurological signs, specific spinal pathology (e.g. malignancy, or inflammatory joint or bone disease) Patients who will be reported osteoarthritis or disc lesions (prolapse, protrusion or herniation without neurological compromise) with or without leg pain Pregnant women

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **38**

Randomization (investigator's opinion)

Randomized

Randomization description

Non probability convenient sampling will be used. Subjects will be randomly distributed to two groups with the use of the lottery method of randomization. Slips will be prepared from 1 to 38. They will be homogeneous in shape, color, and size etc. Furthermore, they will be shuffled and will be placed in a box. The selected 19 slips will be allocated to Group 1, who will receive instrument assisted soft tissue mobilization with routine physical therapy and the other 19 will be allocated to Group 2, who will receive routine physical therapy.

Blinding (investigator's opinion)

Single blinded

Blinding description

Outcome assessor blinding: Every patient will be

assessed by independent assessor at the start and end of total treatment sessions to keep the assessment unbiased.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Riphah Ethical Committee

Street address

Quaid e Azam Campus, 28-M, Quaid-e-Azam, Industrial Estate, Kot Lakhpath, Lahore.

City

Lahore

Postal code

54000

Approval date

2020-03-27, 1399/01/08

Ethics committee reference number

REC/RCRS/20/1056

Health conditions studied**1****Description of health condition studied**

Low Back Pain

ICD-10 code

M54.5

ICD-10 code description

Chronic Low Back Pain

Primary outcomes**1****Description**

Pain

Timepoint

before intervention and 4 weeks after intervention

Method of measurement

Numeric Pain Rating Scale (NPRS)

2**Description**

Function

Timepoint

before intervention and 4 weeks after intervention

Method of measurement

Modified Oswestry Disability Index (MODI) and Rolland

Morris Questionnaire (RMQ)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Instrument assisted soft tissue mobilization with routine physical therapy. In this group, patients will receive instrument assisted soft tissue mobilization during 4 weeks: sacrum, hip lateral rotators, and hamstring bilaterally and general exercise. In the first, subjects will be asked to kneel directly on the bed. The hip lateral rotators instrument assisted soft tissue mobilization will be applied to kneeling prone position with knee and hip flexion side lying position at gluteus maximus and gluteus medius. The hamstring bilaterally instrument assisted soft tissue mobilization will be applied to prone position at biceps femoris, semitendinosus, and semimembranosus. This treatment will be applied for approximately 20-seconds in a direction parallel to the muscle fibers being treated with the instrument at a 45° angle. Following immediately by treating the muscles in a direction perpendicular to the muscle fibers with the instrument at a 45° angle for additional 20-seconds, resulting in a total treatment time of approximately 40 seconds. However, this group will also be given conventional treatment which will be hot pack and lumbar isometrics to maintain the blood circulation and muscle strength.

Category

Treatment - Devices

2

Description

Intervention group 2: Routine Physical Therapy. In this group, the patients will receive general exercise. It will include stretching exercises and stationary bicycling for 10-15 minutes. Three sets of fifteen repetitions will be performed, with rest times of 1 minute between sets during 4 weeks. These patients will also receive conventional treatment which will be hot pack and lumbar isometrics to maintain the blood circulation and muscle strength.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

TABA Medical Complex

Full name of responsible person

Dr. Abdullah Chaudhery

Street address

AR Complex, Service Road, Ring road, Lahore Cantonment, Lahore.

City

Lahore

Postal code

54000

Phone

+92 42 35701090

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abdullah.khalid1210@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Riphah International University

Full name of responsible person

Dr. Naveed Anwar

Street address

Quaid e Azam Campus, 28-M, Quaid-e-Azam, Industrial Estate, Kot Lakhpath, Lahore.

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Riphah International University

Proportion provided by this source

20

Public or private sector

Private

Domestic or foreign origin

Foreign

Category of foreign source of funding

Sponsor: country of origin

Country of origin

PK

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Riphah International University

Full name of responsible person

Dr. Naveed Anwar

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Quaid e Azam Campus, 28-M, Quaid-e-Azam,
Industrial Estate, Kot Lakhpath, Lahore.

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Riphah International University

Full name of responsible person

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Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Tooba Asif

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

Undecided - It is not yet known if there will be 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