Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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

Phone
+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

Email
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.

City
Lahore

Postal code
54000

Phone
+92 42 35126110

Email
naveed.anwer@riphah.edu.pk

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.
City
Lahore
Province
Punjab
Postal code
54000
Phone
+92 42 35126110
Email
naveed.anwer@riphah.edu.pk

Person responsible for scientific 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.
City
Lahore
Province
Punjab
Postal code
54000
Phone
+92 42 35126110
Email
naveed.anwer@riphah.edu.pk

Person responsible for updating data

Contact
Name of organization / entity
Riphah International University
Full name of responsible person
Tooba Asif
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
Street address
Quaid e Azam Campus, 28-M, Quaid-e-Azam, Industrial Estate, Kot Lakhpath, Lahore.
City
Lahore
Province
Punjab
Postal code
54000
Phone
+92 42 35126110
Email
tooba573@gmail.com

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