

# 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

##### 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.

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**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

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**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

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**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