

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The comparative effects of Butler's neural tissue mobilization and Mulligan's bent leg raise in patients with chronic lumbar radiculopathy.

#### Protocol summary

##### Study aim

To determine the comparative effects of Butler neural tissue mobilization and Mulligan Bent leg raise in patients with chronic lumbar radiculopathy.

##### Design

Parallel groups, single-blind, randomized controlled trial, 62 participants were enrolled

##### Settings and conduct

OPD physiotherapy department Sheikh Zayed Hospital

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients diagnosed with lumbar radiculopathy with unilateral radiating pain by an orthopedist; Aged 25-50 years; Both Male and Female; Positive neurodynamic test i.e. SLR test and Slump test. Exclusion Criteria: Patients having somatic referred pain; specific diseases of the spine like ankylosing spondylitis, Paget's disease, vertebral collapse, rheumatoid arthritis, and spondylolisthesis; spine Tb, intermittent claudication, diabetic neuropathy; Recent infection; Mental retardation; hemiparesis.

##### Intervention groups

Group A: The conventional treatment (hot pack and exercise) includes 10 minutes of hot pack and exercise in addition to Butler neural tissue mobilization. Group B: The conventional treatment (hot pack and exercise) contains 10 minutes of hot pack and exercise in addition to Mulligan bent leg raise, applied for pain, functional activity, and SLR.

##### Main outcome variables

Pain; ROM (lumber flexion, extension, SLR); Functional Disability

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200611047734N4**

Registration date: **2021-10-13, 1400/07/21**

Registration timing: **retrospective**

Last update: **2021-10-13, 1400/07/21**

Update count: **0**

##### Registration date

2021-10-13, 1400/07/21

##### Registrant information

###### Name

AYESHA RAZZAQ

###### Name of organization / entity

King Edward Medical University, Lahore

###### Country

Pakistan

###### Phone

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-06-28, 1399/04/08

##### Expected recruitment end date

2020-06-29, 1399/04/09

##### Actual recruitment start date

2020-06-29, 1399/04/09

##### Actual recruitment end date

2021-03-29, 1400/01/09

##### Trial completion date

2021-03-29, 1400/01/09

##### Scientific title

The comparative effects of Butler's neural tissue mobilization and Mulligan's bent leg raise in patients with chronic lumbar radiculopathy.

##### Public title

The comparative effects of Butler's neural tissue

mobilization and Mulligan's bent leg raise in patients with chronic lumbar radiculopathy.

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

Patients diagnosed with lumbar radiculopathy with unilateral radiating pain by an orthopedics Age 25-50 years Both Male and Female Positive neurodynamic test i.e. SLR test and Slump test

##### **Exclusion criteria:**

Patients having Somatic referred pain Specific diseases of spine like ankylosing spondylitis, paget's disease, vertebral collapse, rheumatoid arthritis, and spondylolisthesis Tb spine, intermittent claudication, diabetic neuropathy Recent infection Mental retardation hemiparesis previous spinal Surgery Pelvis Fracture Pregnancy Red Flags such as trauma, cancer, constitutional symptoms (fever, malaise, weight loss)

#### **Age**

From **25 years** old to **50 years** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

- Participant

#### **Sample size**

Target sample size: **62**

More than 1 sample in each individual

Number of samples in each individual: **2**

31 Patients in each group was estimated by using 5% level of significance, 90% power of test

Actual sample size reached: **62**

More than 1 sample in each individual

Actual sample size in each individual: **2**

31 patients in each group was estimated by using 5% level of significance, 90% power of test

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

The lottery method was used for allocating the patient in groups A or B by even and odd numbers. Participants with an even number were placed in group A and with an odd number were placed in group B.

#### **Blinding (investigator's opinion)**

Single blinded

#### **Blinding description**

It was a single-blinded study in which participant/ patients were kept blind for treatment technique. 2 different technique were provided to patients. and they were blind about that which technique was given to which patients. patients were blind regarding the technique. baseline treatment was the same, but they were not aware of the technique. which techniques they were receiving.

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

Parallel groups, single blinded, single setting

#### **Secondary Ids**

empty

#### **Ethics committees**

##### 1

##### **Ethics committee**

###### **Name of ethics committee**

Institutional Review Board

###### **Street address**

Raiwind road

###### **City**

Lahore

###### **Postal code**

55150

##### **Approval date**

2020-06-28, 1399/04/08

##### **Ethics committee reference number**

IRB-UOL-FASH/725-VIII/2020

#### **Health conditions studied**

##### 1

##### **Description of health condition studied**

Lumber Radiculopathy

##### **ICD-10 code**

M47.26

##### **ICD-10 code description**

Other spondylosis with radiculopathy, lumbar region

#### **Primary outcomes**

##### 1

##### **Description**

Pain

##### **Timepoint**

pre and post treatment

##### **Method of measurement**

Numeric pain rating scale

##### 2

##### **Description**

ROM (lumber flexion, extension, SLR)

##### **Timepoint**

Pre and post treatment

##### **Method of measurement**

Goniometer , Modified Modified Schober's Test

##### 3

##### **Description**

Functional Disability

##### **Timepoint**

pre and post treatment

**Method of measurement**  
Oswestry Disability Index

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Application of conventional therapy and Butler neural tissue mobilization. Butler neural tissue mobilization procedure: Patient was in supine position. Therapist's position was standing and facing towards the patient position and positioned one hand beneath the ankle to prevent pressure on peripheral nerves and the second hand above the patella. The knee was in extended position, and hip was flexed position in one plane and the leg was take to the point where symptoms was reproduced. Dosage: Slow oscillations or sustained stretch was given by the therapist for 10 s depending on the grade of mobilization after which the leg was returned to a non-painful position. This procedure was repeated three times.

#### Category

Treatment - Devices

### 2

#### Description

Intervention group: Application of conventional therapy and Mulligan bent leg raise. Mulligan bent leg raise Technique. The therapist was stand at limited SLR side of the patient. Patients was flex knee was kept over therapist's shoulder. Therapist instructed patient to push her away with patient's leg and then relax. At this point therapist extended the patient's bent knee up as far as possible in the direction of patient's ipsilateral shoulder provided there was no pain. If it was painful the direction was altered by taking the leg more medially or laterally. Dosage: Sustained stretch for several seconds was given and leg lowered down to the bed. This technique was repeated 3 times.

#### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**  
university of Lahore  
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Sonia Yasmeen  
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## Sponsors / Funding sources

### 1

#### Sponsor

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#### Grant name

Sonia Yasmeen

#### Grant code / Reference number

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

Yes

#### Title of funding source

university of Lahore, Lahore

#### Proportion provided by this source

20

#### 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**  
university of Lahore, Lahore  
**Full name of responsible person**  
Sonia Yasmeen  
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physiotherapist  
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## Person responsible for scientific inquiries

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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

Undecided - It is not yet known if there will be 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

Yes - There is a plan to make this available

### Data Dictionary

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

### Title and more details about the data/document

The comparative effects of Butler's neural tissue mobilization and Mulligan's bent leg raise in patients with chronic lumbar radiculopathy.

### When the data will become available and for how long

The study is completed and become available after its publication

### To whom data/document is available

Person in academic institute. Patient data will not be shown

### Under which criteria data/document could be used

Under the usage with terms in which journal is accessed /processed for publication, it could be used in the request.

### From where data/document is obtainable

+923367595206 from the University office and Responsible supervisor and from a journal we will process in future

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

Can be on call or mail It will be only used in a confidential way for improving research and benefit of humanity

### Comments

Data can be provided on request