

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effects of non-surgical decompression in addition to routine physical therapy in patients with lumbar radiculopathy; A Randomized Controlled Trial

#### Protocol summary

##### Study aim

To compare the effects of non-surgical spinal decompression therapy in addition to routine physical therapy in patients with lumbar radiculopathy.

##### Design

A single blinded randomised controlled trial, conducted on 60 patients, equally divided into two groups, single centered study

##### Settings and conduct

Pain Center, single blinded study (patient will be blinded to the recruited group)

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria Both male and female patients, Age between 25-55 years, Clinically and radiologically diagnosed patients (by neuro-surgeon) of lumbar radiculopathy, Unilateral radiating low back pain (LBP) for at least 3 months, Willing to participate in the study  
Exclusion Criteria Recent fracture or dislocation of lumbar vertebra, History of surgery on lumbar spine, hip or pelvis, Spinal tumors or infections in the intervertebral disc, Inflammatory diseases such as rheumatism, Spinal deformity such as scoliosis, Spondylololsthesis, Osteoporosis below first lumbar vertebra (L1), Patients taking medications e.g Non-Steroidal Anti-Inflammatory Drugs (NSAIDS) for pain, Severe disc degeneration, Pregnant females, Having three or more herniation

##### Intervention groups

60 patients will be randomly divided into control and experimental groups. The control group will receive routine physical therapy while the experimental group will receive spinal decompression therapy alongwith the routine physical therapy.

##### Main outcome variables

1. Pain intensity 2. Level of disability 3. Quality of life 4. lumbar Range of motion 5. Endurance

#### General information

##### Reason for update

data collection has been completed

##### Acronym

RCT

##### IRCT registration information

IRCT registration number: **IRCT20190717044238N1**

Registration date: **2019-12-23, 1398/10/02**

Registration timing: **prospective**

Last update: **2021-07-06, 1400/04/15**

Update count: **2**

##### Registration date

2019-12-23, 1398/10/02

##### Registrant information

###### Name

Fareeha Amjad

###### Name of organization / entity

The University of Lahore

###### Country

Pakistan

###### Phone

+92 42 99200600

###### Email address

fari\_fairy22@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-10-20, 1397/07/28

##### Expected recruitment end date

2020-03-20, 1399/01/01

##### Actual recruitment start date

2020-01-01, 1398/10/11

##### Actual recruitment end date

2021-04-01, 1400/01/12  
**Trial completion date**  
2021-06-01, 1400/03/11

### Scientific title

The effects of non-surgical decompression in addition to routine physical therapy in patients with lumbar radiculopathy; A Randomized Controlled Trial

### Public title

The effects of non-surgical decompression in addition to routine physical therapy in patients with lumbar radiculopathy; A Randomized Controlled Trial

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Both male and female patients Age between 25-55 years Clinically and radiologically diagnosed patients (by neuro-surgeon) of lumbar radiculopathy Radiating Low Back Pain for at least 3 months Willing to participate in the study

#### Exclusion criteria:

Recent fracture or dislocation of lumbar vertebra History of surgery on lumbar spine, hip or pelvis Spinal tumors or infections in the intervertebral disc Inflammatory diseases such as rheumatism Spinal deformity such as scoliosis Spondylolysthesis Osteoporosis below L1 Patients taking medications e.g NSAIDS for pain Severe disc degeneration Pregnant females Having three or more herniation

### Age

From **25 years** old to **55 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Outcome assessor

### Sample size

Target sample size: **60**

Actual sample size reached: **60**

### Randomization (investigator's opinion)

Randomized

### Randomization description

By using computer generated random number table, patients will be randomly assigned into two groups. All those random numbers will be enclosed in sealed envelopes. A third person (who will further not be the part of research) will open envelopes and the patients will be allocated to the mentioned group accordingly.

### Blinding (investigator's opinion)

Single blinded

### Blinding description

An independent assessor, who will be a senior and experienced physiotherapist and further will not be the part of study will perform the assessment of patients

### Placebo

Not used

### Assignment

Parallel

### Other design features

no

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Institutional Review Board

###### Street address

The University of Lahore,Pakistan

###### City

Lahore

###### Postal code

54000

##### Approval date

2018-09-20, 1397/06/29

##### Ethics committee reference number

IRB-UOL-FAHS/373-X/2018

### Health conditions studied

#### 1

##### Description of health condition studied

Lumber Radiculopathy

##### ICD-10 code

M54.16

##### ICD-10 code description

Radiculopathy, lumbar region

### Primary outcomes

#### 1

##### Description

Pain Intensity

##### Timepoint

before intervention and after 4 weeks of intervention

##### Method of measurement

Visual Analogue Scale

#### 2

##### Description

Lumber range of motion

##### Timepoint

before intervention and after 4 weeks of intervention

##### Method of measurement

Clinical Test (Modified-Modified Schober's Test)

### Secondary outcomes

#### 1

##### Description

Quality of Life

### **Timepoint**

before intervention and after 4 weeks of intervention

### **Method of measurement**

SF 36 scoring calculator will be used

### **2**

#### **Description**

Level of disability

#### **Timepoint**

before intervention and after 4 weeks of intervention

#### **Method of measurement**

ODI scoring calculator

### **3**

#### **Description**

Endurance

#### **Timepoint**

before intervention and after 4 weeks of intervention

#### **Method of measurement**

Stop Watch will be used to calculate the endurance time

## **Intervention groups**

### **1**

#### **Description**

Control group: The control group will receive conventional physiotherapy including electrotherapy and trunk stability exercises. The treatment will be performed as follows:1) Electrotherapy components will consist of 5 minutes of therapeutic ultrasound and 15 minutes of continuous transcutaneous electrical nerve stimulation with concurrent hot pack 2) Trunk stability Exercises

#### **Category**

Treatment - Other

### **2**

#### **Description**

Intervention group: In addition to the interventions given in control group, participants in the experimental group will also receive spinal decompression therapy. The treatment session of 20 minutes will be given three days a week, for a total of 4 weeks. For non-surgical spinal decompression therapy of lumbar spine, the patient will be in supine lying position on a motorized table, which has movable lower half. A harness is placed around the hips and is attached to the lower table near the feet. The upper part of the table remains in a fixed position while the lower part, to which the patient is harnessed, slides back and forth to provide the traction and relaxation. Decompression isolates the distraction forces to a specific motor unit of the spine and affects a specific disc level.

#### **Category**

Treatment - Devices

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Pain Center

##### **Full name of responsible person**

Fareeha Amjad

##### **Street address**

The University of Lahore,Pakistan

##### **City**

Lahore

##### **Postal code**

54000

##### **Phone**

+92 42 99200600

##### **Email**

fari\_fairy22@yahoo.com

##### **Web page address**

<https://pk.enrollbusiness.com>

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

The University of Lahore

##### **Full name of responsible person**

Fareeha Amjad

##### **Street address**

The University of Lahore,Pakistan

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##### **Email**

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##### **Web page address**

<https://www.uol.edu.pk>

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

The University of Lahore

#### **Proportion provided by this source**

100

#### **Public or private sector**

Public

#### **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**

The University of Lahore

**Full name of responsible person**

Fareeha Amjad

**Position**

Assistant Professor

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

The University of Lahore

**Full name of responsible person**

Fareeha Amjad

**Position**

Assistant Professor

**Latest degree**

Master

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

The University of Lahore

**Full name of responsible person**

Fareeha Amjad

**Position**

Assistant Professor

**Latest degree**

Master

**Other areas of specialty/work**

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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**

Yes - There is 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**

All collected identified IPD

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

Data will be available after the completion of study and will remain available till 6 months

**To whom data/document is available**

Data will be available for other people almost 6 months after the completion of study

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

The data/document could be used by communicating with the principle investigator "Fareeha Amjad" on email address: fari\_fairy22@yahoo.com

**From where data/document is obtainable**

Fareeha Amjad, fari\_fairy22@yahoo.com

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

Data/document can be accessed through communicating with principle investigator "Fareeha Amjad" on institutional email address: fari\_fairy22@yahoo.com

**Comments**

N/A