

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of pain neuroscience education and physical exercise for patients with lumbar radiculopathy

#### Protocol summary

##### Study aim

This study aimed to verify the effects of PNE pain neuroscience education compared with the physical exercises techniques in patients with lumbar radiculopathy.

##### Design

The goal of PNE to re-conceptualizing pain observation from a biological or structural model to a bio psychosocial pain perception.

##### Settings and conduct

conduct; Allied Hospital Faisalabad, Aziz Fatima Hospital Faisalabad , Madina Teaching Hospital Faisalabad

##### Participants/Inclusion and exclusion criteria

34 participants were enrolled, non probability convenience sampling technique was used. Patients divided into 2 groups interventional group and control group. Inclusion criteria: both genders male and female , Age group (40-60) , Lumbar pain which radiates down to leg or radiating below the knee, Diagnosed patients with lumbar radiculopathy , As a minimum Pain score 3/10 on VAS, The following radicular signs:1 Any dermatome between L4 and S1 that is numbness paresthesia, 2 Loss of muscle strength any of the L4-S1 myotomes  
Exclusion Criteria: Spine fracture, Pregnancy, Cauda equine syndrome , Oncological pain ,History of pelvis, hip or spine surgical intervention in the last year, Unimpaired cognition / intelligence (Mini Mental State Examination Score of >24)

##### Intervention groups

In experimental group patients was performed a PNE approach which consists in six sessions 2 time per week, for about 60 minutes with therapeutic physical exercise performed session; 3 sessions per week. Session was completed in 35-45 minutes then cool down phase including with relaxation exercises for 10-15 minutes.

##### Main outcome variables

Pain intensity and Functional disability

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230614058479N1**

Registration date: **2023-09-23, 1402/07/01**

Registration timing: **retrospective**

Last update: **2023-09-23, 1402/07/01**

Update count: **0**

##### Registration date

2023-09-23, 1402/07/01

##### Registrant information

##### Name

Mahzaib Khalid

##### Name of organization / entity

The University of Faisalabad

##### Country

Pakistan

##### Phone

+92 41 8750971

##### Email address

2021-ms-pt-050@tuf.edu.pk

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-04-24, 1402/02/04

##### Expected recruitment end date

2023-06-26, 1402/04/05

##### Actual recruitment start date

2023-04-24, 1402/02/04

##### Actual recruitment end date

2023-06-26, 1402/04/05

##### Trial completion date

2023-06-26, 1402/04/05

## Scientific title

Effect of pain neuroscience education and physical exercise for patients with lumbar radiculopathy

## Public title

Effect of pain neuroscience education PNE and physical exercise for patients with lumbar radiculopathy

## Purpose

Health service research

## Inclusion/Exclusion criteria

### Inclusion criteria:

• Patients of both genders male and female • Age group (40-60) • Lumbar pain which radiates down to leg or radiating below the knee • Diagnosed patients with lumbar radiculopathy • As a minimum Pain score 3/10 on VAS • The following radicular signs: 1. Any dermatome between L4 and S1 that is numbness paresthesia 2. Loss of muscle strength any of the L4-S1 myotomes

### Exclusion criteria:

• Spine fracture • Pregnancy • Cauda equine syndrome • Oncological pain • History of pelvis, hip or spine surgical intervention in the last year • Unimpaired cognition / intelligence (Mini Mental State Examination Score of >24)

## Age

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

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant

## Sample size

Target sample size: **34**

Actual sample size reached: **34**

## Randomization (investigator's opinion)

Randomized

## Randomization description

the non probability convenience sampling technique.(random allocation by computer generative Lottery method), Patients divided into two groups one is interventional group while other is control group.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

participants are blinded during the trial

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

## Name of ethics committee

Ethical Review Committee

## Street address

University Avenue, Faisal Town Canal Road

## City

Faisalabad

## Postal code

38000

## Approval date

2023-08-09, 1402/05/18

## Ethics committee reference number

TUF/DR/SA/MSPP/2023/246

## Health conditions studied

### 1

#### Description of health condition studied

Lumbar Radiculopathy

#### ICD-10 code

M54.16

#### ICD-10 code description

Radiculopathy, lumbar region

## Primary outcomes

### 1

#### Description

pain

#### Timepoint

1, 3, 6 week

#### Method of measurement

Pain intensity: Visual Analogue scale for screening of patients and outcomes measured by Roland Morris low back pain and disability questionnaire, The back pain functional scale , Fear-Avoidance belief questionnaire.

## Secondary outcomes

### 1

#### Description

Functional Disability

#### Timepoint

1, 3 ,6 week

#### Method of measurement

Pain intensity: Visual Analogue scale for screening of patients and outcomes measured by Roland Morris low back pain and disability questionnaire, The back pain functional scale , Fear-Avoidance belief questionnaire

## Intervention groups

### 1

#### Description

Intervention group: this group patients was performed a PNE approach which consists in six sessions 2 time per week, for about 60 minutes with therapeutic physical exercise (PE) performed session; 3 sessions per week

which are consisting on Warm-up, slow and deep breathing exercise for about 3 minutes to relax the patient, then activation and joint mobility exercises, balance and agility exercises, strength exercises and resistance training (in includes ankle pump, heel slide, Straight leg raise, Bridging and modified bridging with leg raise, 4 point kneeling, and kneeling with arm and leg lift) hold all positions for 5 to 10 seconds with 10 repetitions starts moderate exercises that was gradually increased. Each exercises session was completed in 35-45 minutes and then cool down phase including with relaxation exercises for 10-15 minutes.

**Category**

Rehabilitation

**2**

**Description**

Intervention group: this group patients was performed a PNE approach which consists in six sessions 2 time per week, for about 60 minutes with therapeutic physical exercise (PE) performed session; 3 sessions per week which are consisting on Warm-up, slow and deep breathing exercise for about 3 minutes to relax the patient, then activation and joint mobility exercises, balance and agility exercises, strength exercises and resistance training (in includes ankle pump, heel slide, Straight leg raise, Bridging and modified bridging with leg raise, 4 point kneeling, and kneeling with arm and leg lift) hold all positions for 5 to 10 seconds with 10 repetitions starts moderate exercises that was gradually increased. Each exercises session was completed in 35-45 minutes and then cool down phase including with relaxation exercises for 10-15 minutes.

**Category**

Rehabilitation

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Allied Hospital

**Full name of responsible person**

Dr. Sobia Nawaz

**Street address**

Jail Road, adjacent Faisalabad Medical University,  
Near Sargodha Road, Faisalabad

**City**

Faisalabad

**Postal code**

37000

**Phone**

+92 41 9210082

**Email**

info@pmc.edu.pk

**Web page address**

http://www.pmc.edu.pk

**2**

**Recruitment center**

**Name of recruitment center**

Aziz Fatima Hospital

**Full name of responsible person**

Dr. Basit Mehmood

**Street address**

Raja Road Gulistan Colony 1, Faisalabad

**City**

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38000

**Phone**

+92 41 8780910

**Email**

hr@afh.com.pk

**Web page address**

http://afh.com.pk

**3**

**Recruitment center**

**Name of recruitment center**

Madina Teaching Hospital

**Full name of responsible person**

Dr. Kishwar

**Street address**

Sargodha Road, University Town, Faisalabad

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Faisalabad

**Postal code**

37251

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

The university of Faisalabad

**Full name of responsible person**

Mahzaib Khalid

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University Avenue, Faisal Town Canal Road  
Faisalabad

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37000

**Phone**

+92 305 7666514

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mahzaib01@gmail.com

**Grant name**

No

**Grant code / Reference number**

No  
**Is the source of funding the same sponsor organization/entity?**  
No  
**Title of funding source**  
Self Funded  
**Proportion provided by this source**  
100  
**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**  
Other

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
The university of Faisalabad  
**Full name of responsible person**  
Mahzaib Khalid  
**Position**  
Student  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Physiotherapy  
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No. 9, L Block, Wapda city, Faisalabad  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
Asma  
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lecturer  
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**Province**  
Punjab  
**Postal code**  
38000  
**Phone**  
+92 321 7607141  
**Email**  
baigasma96@gmail.com

## 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

EFFECT OF PAIN NEUROSCIENC EDUCATION AND PHYSICAL EXERCISE FOR PATIENTS WITH LUMBAR RADICULOPATHY: A RONDAMISED CLINICAL TRAIL

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

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

### 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 Mahzaib Khalid gmail: mahzaib01@gmail.com

**From where data/document is obtainable**

Mahzaib Khalid gmail: mahzaib01@gmail.com

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

The data/ document could be used by communicating with the principle investigator Mahzaib Khalid gmail: mahzaib01@gmail.com

**Comments**