

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Feb 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

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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

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37000

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info@pmc.edu.pk

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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

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Faisalabad

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+92 41 8780910

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The university of Faisalabad

Full name of responsible person

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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
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Mahzaib Khalid
Position
Student
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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

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