Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 strengthen 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 strengthen 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 Commitee

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 join 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 join 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
Faisalabad
Postal code
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, Faislabad
City
Faisalabad
Postal code
37251
Phone
+92 41 8869861
Email
info@mth.org.pk
Web page address
https://mth.org.pk

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
The university of Faisalabad
Full name of responsible person
Mahzaib Khalid
Street address
University Avenue, Faisal Town Canal Road Faisalabad
City
Faisalabad
Postal code
37000
Phone
+92 305 7666514
Email
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

Street address

No. 9, L Block, Wapda city, Faisalabad

City

Faisalabad

Province

Punjab

Postal code

37000

Phone

+92 305 7666514

Email

mahzaib01@gmail.com

Person responsible for scientific 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

Street address

University Avenue, Faisal Town Canal Road Faisalabad

City

Faisalabad

Province

Punjab

Postal code

37000

Phone

+92 305 7666514

Email

mahzaib01@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

The university of Faisalabad

Full name of responsible person

Asma

Position

lecturer

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

709-B people's colony no.1

City

Faisalabad

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