Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Feb 2026

The Effect of Pain Neuroscience Education on the Effectiveness of Neuromuscular Exercise in Women with Both Knee Osteoarthritis and Chronic Low Back Pain

Protocol summary

Study aim

The Effect of Pain Neuroscience Education on the Effectiveness of Neuromuscular Exercise in Women with Both Knee Osteoarthritis and Chronic Low Back Pain.

Design

Clinical Trial, With a control group, Parallel group design, Double blind, Randomized, With a sample size of 60 participants, Randomization will be performed using a (Random Number Generator) software.

Settings and conduct

The required tests will be conducted in the Rehabilitation and Sports Sciences Laboratory at Bu,Ali Sina University, Hamedan, by specialists in the field. Subsequently, the intervention and exercises will take place in the university's sports hall. During the testing phase, outcome assessors and data analysts will be blinded to the main objective of the study.

Participants/Inclusion and exclusion criteria

Entry criteria: Joint stiffness and rigidity in the morning, Onset of menopause, Unilateral or bilateral knee osteoarthritis (as diagnosed by a physician), No steroid injection into the joint in the past 6 months, Mild to moderate pain in the lower back and knees, Osteophytes and crypts. Exit criteria: Body Mass Index (BMI) greater than 30 kilogram/square meter, A history of surgery or fracture in the lower limb joints within the past 6 months, Having a prosthesis in the lumbar region, A history of cardiovascular diseases and cancer, Severe cognitive impairments.

Intervention groups

Neuromuscular Exercise and Pain Neuroscience Education Group, Control Group

Main outcome variables

Knee and low back pain, proprioception of the knee and low back, strength of knee flexor and extensor muscles, strength of hip abductor muscles, strength of multifidus and transverse abdominis muscles, assessment of motor skills, physical performance index, range of motion of the knee and low back, static and dynamic balance, psychological factors including kinesiophobia, pain catastrophizing, self-efficacy, and balance confidence.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250527065931N1**
Registration date: **2025-11-07, 1404/08/16**
Registration timing: **prospective**

Last update: **2025-11-07, 1404/08/16**
Update count: **0**

Registration date

2025-11-07, 1404/08/16

Registrant information

Name
Sepideh Eizadi
Name of organization / entity
Bu Ali Sina University
Country
Iran (Islamic Republic of)
Phone
+98 81 3830 3243
Email address
s.eizadi@phe.basu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-11-22, 1404/09/01

Expected recruitment end date

2025-12-01, 1404/09/10

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Pain Neuroscience Education on the Effectiveness of Neuromuscular Exercise in Women with Both Knee Osteoarthritis and Chronic Low Back Pain

Public title
The Effect of Pain Neuroscience Education on Neuromuscular Exercise in Women with Knee Osteoarthritis and Chronic Low Back Pain
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Joint stiffness and rigidity in the morning Onset of menopause Unilateral or bilateral knee osteoarthritis (as diagnosed by a physician) No steroid injection into the joint in the past 6 months Mild to moderate pain in the lower back and knees Osteophytes and crypts
Exclusion criteria:
Body Mass Index (BMI) greater than 30 kg/m² A history of surgery or fracture in the lower limb joints within the past 6 months Having a prosthesis in the lumbar region A history of cardiovascular diseases and cancer Severe cognitive impairments
Age
From **60 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be performed using a random number generator software. Allocation will be concealed using the SNOSE method, and participants will be assigned to two groups. The randomization process will occur in two stages. First, each participant will be randomly assigned a number between 1 and 60 through a lottery system, with 30 numbers selected randomly. Based on the generated numbers and the selected participants, they will be divided into two groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, outcome assessors (laboratory technicians) are asked to perform the specified tests on the participants, while the data analyst is responsible for processing and interpreting the collected data. These individuals will be blinded to the study objectives, group allocation, and the reasons for the participants' presence in the laboratory. Their role is limited to assessing variables, processing data, and recording their observations.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Bu-Ali Sina University Hamadan
Street address
Bu Ali Sina University, Abu Taleb St, Modarres Quarter
City
Hamadan
Province
Hamadan
Postal code
6517838695
Approval date
2024-12-02, 1403/09/12
Ethics committee reference number
IR.BASU.REC.1403.039

Health conditions studied

1

Description of health condition studied
Knee Osteoarthritis
ICD-10 code
M17.9
ICD-10 code description
Osteoarthritis of knee, unspecified

2

Description of health condition studied
Chronic low back pain
ICD-10 code
M54.5
ICD-10 code description
Low back pain

Primary outcomes

1

Description
Knee pain
Timepoint

The variables will be measured one to four days before the start of the training sessions and again one to four days after the completion of the intervention

Method of measurement

Visual Analog Scale

2

Description

Low back pain

Timepoint

The variables will be measured one to four days before the start of the training sessions and again one to four days after the completion of the intervention

Method of measurement

Visual Analog Scale

Secondary outcomes

1

Description

Lumbar flexion range of motion

Timepoint

The variables will be measured one to four days before the start of the training sessions and again one to four days after the completion of the intervention

Method of measurement

Schober test

2

Description

Lumbar extension range of motion

Timepoint

The variables will be measured one to four days before the start of the training sessions and again one to four days after the completion of the intervention

Method of measurement

Schober test

3

Description

Knee flexion range of motion

Timepoint

The variables will be measured one to four days before the start of the training sessions and again one to four days after the completion of the intervention

Method of measurement

Universal goniometer

4

Description

Knee flexor muscles strength

Timepoint

The variables will be measured one to four days before the start of the training sessions and again one to four days after the completion of the intervention

Method of measurement

Hand-held dynamometer

5

Description

Knee extensor muscles strength

Timepoint

The variables will be measured one to four days before the start of the training sessions and again one to four days after the completion of the intervention

Method of measurement

Hand-held dynamometer

6

Description

Thigh abductor muscles strength

Timepoint

The variables will be measured one to four days before the start of the training sessions and again one to four days after the completion of the intervention

Method of measurement

Hand-held dynamometer

7

Description

Knee proprioception

Timepoint

The variables will be measured one to four days before the start of the training sessions and again one to four days after the completion of the intervention

Method of measurement

Universal goniometer

8

Description

Lumbar proprioception

Timepoint

The variables will be measured one to four days before the start of the training sessions and again one to four days after the completion of the intervention

Method of measurement

Inclinometer

9

Description

Self-efficacy

Timepoint

The variables will be measured one to four days before the start of the training sessions and again one to four days after the completion of the intervention

Method of measurement

The Pain Self-Efficacy Questionnaire

10

Description

The Activities-specific Balance Confidence

Timepoint

The variables will be measured one to four days before the start of the training sessions and again one to four days after the completion of the intervention

Method of measurement

The Activities-specific Balance Confidence Scale

11

Description
Perceived fear of fall
Timepoint
The variables will be measured one to four days before the start of the training sessions and again one to four days after the completion of the intervention
Method of measurement
Falls Efficacy Scale

12

Description
Functional state
Timepoint
The variables will be measured one to four days before the start of the training sessions and again one to four days after the completion of the intervention
Method of measurement
Timed up and go test

13

Description
Static balance
Timepoint
The variables will be measured one to four days before the start of the training sessions and again one to four days after the completion of the intervention
Method of measurement
Berg Balance Scale

14

Description
Dynamic balance
Timepoint
The variables will be measured one to four days before the start of the training sessions and again one to four days after the completion of the intervention
Method of measurement
Berg Balance Scale

15

Description
McMaster Universities Arthritis Index
Timepoint
The variables will be measured one to four days before the start of the training sessions and again one to four days after the completion of the intervention
Method of measurement
WOMAC questionnaire

16

Description
Stability of the transverse abdominal muscles
Timepoint
The variables will be measured one to four days before the start of the training sessions and again one to four days after the completion of the intervention
Method of measurement
Pressure Bio-Feedback Unitn

17

Description
Stability of the multifidus muscles
Timepoint
The variables will be measured one to four days before the start of the training sessions and again one to four days after the completion of the intervention
Method of measurement
Pressure Bio-Feedback Unit

18

Description
Walking speed
Timepoint
The variables will be measured one to four days before the start of the training sessions and again one to four days after the completion of the intervention
Method of measurement
The walk 40 meter fast-paced test

Intervention groups

1

Description
Intervention group: In this group, participants will undergo a neuromuscular exercise program combined with Pain Neuroscience Education (PNE).The neuromuscular exercise sessions will be conducted over eight consecutive weeks, consisting of three sessions per week, each lasting approximately 50 minutes. Additionally, the pain neuroscience education will be delivered over the same eight-week period, in one group session per week lasting about 20 minutes. The program will be structured so that two sessions per week include only neuromuscular exercises, while one session per week integrates both neuromuscular exercises and pain neuroscience education.
Category
Rehabilitation

2

Description
Control group: Participants in the control group will receive only the neuromuscular exercise program. This intervention will be conducted over eight consecutive weeks, with three training sessions per week.
Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Omid Clinic

Full name of responsible person
Sepideh Eizadi

Street address
Omid Specialized and Subspecialized Clinic, beside Payam Hall, Sabad Bafan Street, Hamadan, Iran

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Province
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6517838736

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s.eizadi@phe.basu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bu Ali Sina University

Full name of responsible person
Farzaneh Saki

Street address
Bu Ali Sina University, Abu Taleb St, Modarres Quarter

City
Hamadan

Province
Hamadan

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3869565178

Phone
+98 81 3838 1423

Email
f.sport2008@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Bu Ali Sina University

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
Bu Ali Sina Universityلد

Full name of responsible person
Sepideh Eizadi

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Sport Rehabilitation

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Person responsible for scientific inquiries

Contact

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Position
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Sport rehabilitation

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available