

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of physical exercises with physical exercises and psychological exercises on pain, range of motion, lower extremity strength. Quality of life and Kinesiophobia in the elderly with chronic back pain

Protocol summary

Study aim

The main purpose of the research is to compare physical therapy exercises and the combination of physical exercises with psychological exercises on pain, range of motion, lower limb strength, quality of life and kinesiophobia in the elderly with chronic back pain.

Design

Clinical trial with two exercises groups, with parallel groups, double-blind, randomized, phase 2 on 30 patients. A random generator software will be used for randomization.

Settings and conduct

The present research will be conducted at Bu-Ali Sina University for eight weeks, three sessions per week. Due to the nature of exercise therapy and assessment, blinding of practitioners will not be possible, but participants and one of the researchers who will measure assessments before and immediately after eight weeks will be blinded to group allocation.

Participants/Inclusion and exclusion criteria

Inclusion criteria include elderly people 60-80 years old; history of low back pain for more than three months; back pain in the range of 2.5 out of 10 on the Numerical Pain Rating Scale (NPRS); independence in daily activities; no use of assistive devices; no history of illness. cardiovascular and respiratory problems, and exclusion criteria included having any respiratory disease; pregnancy or history of surgery in the lumbar region; inability to exercise; occurrence of pain during the exercise protocol; obvious abnormality; body mass index (BMI) more than 30; non-cooperation and withdrawing from the research; absence in two consecutive sessions and three alternating training sessions.

Intervention groups

1. Combined Feldenkrais exercises and dynamic

neuromuscular stability group. 2. Dynamic neuromuscular exercises group.

Main outcome variables

Intensity of pain; range of motion of the spine; lower limb strength; quality of life; kinesiophobia

General information

Reason for update

Acronym

DNS

IRCT registration information

IRCT registration number: **IRCT20211018052801N2**

Registration date: **2024-09-17, 1403/06/27**

Registration timing: **prospective**

Last update: **2024-09-17, 1403/06/27**

Update count: **0**

Registration date

2024-09-17, 1403/06/27

Registrant information

Name

Marziyeh Ziya

Name of organization / entity

Bu-Ali Sina University of Hamedan

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-09-20, 1403/06/30

Expected recruitment end date

2024-10-21, 1403/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of physical exercises with physical exercises and psychological exercises on pain, range of motion, lower extremity strength. Quality of life and Kinesiophobia in the elderly with chronic back pain

Public title

Effect of physical exercises and psychological exercises in chronic back pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Low back pain in the range of 2-5 out of 10 on the Numerical Pain Rating Scale (NPRS) History of back pain for more than three months Non-use of auxiliary equipment No history of cardiovascular diseases and respiratory problems No history of fractures and severe injuries in the lower limbs and spine Non-participation in therapeutic interventions during the last 4 weeks Voluntary participation in research Independence in daily activities

Exclusion criteria:

Having any respiratory disease, pregnancy or history of surgery in the lumbar region Inability to exercise Occurrence of pain during the training protocol Obvious abnormality that is problematic for the implementation of research Body mass index (BMI) greater than 30

Age

From **60 years** old to **80 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be divided into two groups, Feldenkrais and DNS combined exercises group and DNS exercise group by Random Number Generator. This method ensures that each participant has an equal chance of being assigned to either group, reducing selection bias.

Blinding (investigator's opinion)

Double blinded

Blinding description

Due to the nature of the therapeutic exercise and evaluation, athletes will not be able to do it, but the participants and one of the researchers who will evaluate will measure after eight weeks, they will be assigned to groups.

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 oh Hamedan

Street address

Bu-Ali Sina university oh Hamedan, Shahid Ahmadi Roshan Avenue, Hamedan

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6517838695

Approval date

2024-08-28, 1403/06/07

Ethics committee reference number

IR.BASU.REC.1403.011

Health conditions studied**1****Description of health condition studied**

Low back pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes**1****Description**

Pain

Timepoint

Pre-test at the beginning of the study (3 to 5 days before the start of the intervention) and post-test at the end of the intervention (three to five days after the last training session)

Method of measurement

Using Visual Analogue Scale of pain intensity

2

Description

Lumbar range of motion

Timepoint

Pre-test at the beginning of the study (3 to 5 days before the start of the intervention) and post-test at the end of the intervention (three to five days after the last training session)

Method of measurement

Modified -Modified Schober's Test

3

Description

Lower limb strength

Timepoint

Pre-test at the beginning of the study (3 to 5 days before the start of the intervention) and post-test at the end of the intervention (three to five days after the last training session)

Method of measurement

30 Seconds Sit To Stand Test

4

Description

Quality of life

Timepoint

Pre-test at the beginning of the study (3 to 5 days before the start of the intervention) and post-test at the end of the intervention (three to five days after the last training session)

Method of measurement

36-Item Short Form Survey Instrument

5

Description

Kinesiophobia

Timepoint

Pre-test at the beginning of the study (3 to 5 days before the start of the intervention) and post-test at the end of the intervention (three to five days after the last training session)

Method of measurement

Tempa scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Combined Feldenkrais and dynamic neuromuscular stabilization exercises.

Category

Rehabilitation

2

Description

Intervention group: Dynamic neuromuscular stabilization

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu-Ali Sina university of Hamedan

Full name of responsible person

Marziyeh Ziya

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice President of Research and Technology of Bu-Ali Sina university of Hamedan

Full name of responsible person

Arash Ghorbani Choghamarani

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Grant name

Grant code / Reference number

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

No

Title of funding source

Iran National Science Foundation

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 University

Full name of responsible person

Farzaneh Saki

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Exercise Rehabilitation

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Files related to the information measured in the pre-test and post-test

When the data will become available and for how long

Access is possible after the articles related to the research plan are published.

To whom data/document is available

Students and specialists in the field of sports rehabilitation and injury prevention are allowed access.

Under which criteria data/document could be used

There will be no analysis of the data for others.

From where data/document is obtainable

Refer to the authors of the research plan.

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

This is possible by receiving permission from the National

Science Foundation of Iran.
Comments