Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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; kinesiophibia

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

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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
City
Hamedan
Province
Hamadan
Postal code
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 limp 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 neuromascular 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
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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
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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