

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Adding Mindfulness Feldenkrais Exercises to Dynamic Neuromuscular Stability (DNS) Exercises on Pain, Activity of Selected Muscles, Postural Control and Dual Tasks Performance in Elderly with Chronic Low Back Pain

Protocol summary

Study aim

The aim of the current research is to combine Feldenkrais exercises with dynamic neuromuscular stability exercises on pain, range of motion of the spine, electrical activity of selected muscles and postural control in a dual task in the elderly with chronic back pain.

Design

This study will be a clinical trial with two intervention exercise groups, parallel groups, double-blinded, and randomized on 24 subjects. Based on the estimated sample size, at least 24 subjects were calculated for the two research groups. Randomization will be done using the Random Number Generator software.

Settings and conduct

The present study will be conducted using a pretest-posttest design. The research variables will be measured before the start and end of the exercise intervention. Then, the subjects for eight weeks, participants will attend three sessions of 60-90 minutes each week at the exercise sessions. The measurements will include the Numeric Pain Rating Scale, the Berg Balance Scale, surface electromyography (EMG) to record the electrical activity of selected muscles, and the Time Up and Go (TUG) test for both motor and cognitive assessment.

Participants/Inclusion and exclusion criteria

The participants will include elderly people aged 60-80 years with a history of low back pain for more than three months in the range of 2-5 out of 10 on the numerical rating scale of pain and independence in daily activities and not using assistive devices. Also, in case of having a history of cardio-respiratory diseases and musculoskeletal problems, obvious abnormalities that are problematic for the study, and BMI greater than 30, they will be excluded from the study.

Intervention groups

1. Combined group of Feldenkrais and Dynamic Neuromuscular Stabilization exercises
2. Dynamic Neuromuscular Stabilization training group

Main outcome variables

Pain, Balance, Electrical activity of muscles, Motor and cognitive assessments

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211018052801N1**

Registration date: **2023-11-14, 1402/08/23**

Registration timing: **prospective**

Last update: **2023-11-14, 1402/08/23**

Update count: **0**

Registration date

2023-11-14, 1402/08/23

Registrant information

Name

Marziyeh Ziya

Name of organization / entity

Bu-Ali Sina University of Hamedan

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-06, 1402/09/15

Expected recruitment end date

2024-01-05, 1402/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Adding Mindfulness Feldenkrais Exercises to Dynamic Neuromuscular Stability (DNS) Exercises on Pain, Activity of Selected Muscles, Postural Control and Dual Tasks Performance in Elderly with Chronic Low Back Pain

Public title

Adding Mindfulness Feldenkrais Exercises to Dynamic Neuromuscular Stability (DNS) Exercises on Pain, Activity of Selected Muscles, Postural Control and Dual Tasks Performance in Elderly with Chronic Low Back Pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Elderly individuals aged 60-80 years. A history of chronic back pain lasting more than three months. ack pain intensity rated on a Numeric Pain Rating Scale (NPRS) between 5 and 2 out of 10. Independence in daily activities. No use of assistive devices. No history of cardiovascular or respiratory diseases. No history of severe fractures or injuries in the lower limbs and spine. No participation in any therapeutic interventions in the past four weeks. Willingness to participate in the research voluntarily.

Exclusion criteria:

Presence of any respiratory diseases, pregnancy, or a history of surgery in the lumbar region. Inability to perform the prescribed exercises. Noticeable abnormalities that hinder the execution of the research. Body mass index over 30.

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be divided into two groups, using a purposive sampling method and a Random Number Generator software. The two groups will be allocated as follows: one group will receive a combination of Feldenkrais and Dynamic Neuromuscular Stabilization

exercises, while the other group will receive Dynamic Neuromuscular Stabilization exercises only.

Blinding (investigator's opinion)

Double blinded

Blinding description

One of the researchers will be blinded to the group allocation and will take the assessments before and after the training period. Also, the members of the groups will be blinded to the placement in the research groups due to the lack of accurate recognition of the differences in the exercise protocols used in the research and the exact purpose of each protocol.

Placebo

Not used

Assignment

Parallel

Other design features

Attention to the psychological aspect of patients in combination with the physical aspect

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Hamedan University of Medical Sciences

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Hamadan University of Medical Sciences
Headquarters, Shahid Fahmideh St.

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Hamadan

Postal code

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Approval date

2023-02-20, 1401/12/01

Ethics committee reference number

IR.BASU.REC.1402.020

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

The variable will be measured 1-4 days before the start of the exercise sessions and three days after the exercise sessions.

Method of measurement

Measurements by the Numeric Pain Rating Scale (NPRS)

Secondary outcomes

1

Description

Control posture

Timepoint

The variable will be measured 1-4 days before the start of the exercise sessions and three days after the exercise sessions.

Method of measurement

Measurements by Berg Balance Scale

2

Description

Electrical activity of the muscles

Timepoint

The variable will be measured 1-4 days before the start of the exercise sessions and three days after the exercise sessions.

Method of measurement

Measurements by surface electromyography (EMG)

3

Description

Functional tests

Timepoint

The variable will be measured 1-4 days before the start of the exercise sessions and three days after the exercise sessions.

Method of measurement

Measurements by Time Up and Go (TUG) test for both motor and cognitive assessment.

Intervention groups

1

Description

Intervention group: The duration of these exercises will be eight weeks, with three sessions per week, each session lasting 90-60 minutes. At the beginning of the exercises, participants will engage in warm-up activities, and at the end of the sessions, they will focus on cooldown exercises. The exercise levels will be adjusted based on the individual abilities of the participants. The DNS exercise protocol will be implemented, considering the muscle chain reflexes, and progressively applied from a basic to advanced level. Participants will not be allowed to progress to the next level until they have sufficient mastery at lower levels.

Category

Rehabilitation

2

Description

In this group, the first sessions of DNS exercises and then Feldenkrais exercises will be done: Feldenkrais exercises: 1st week (leg switching duration: 15-30 minutes - rest period: 3 minutes between each set of the training program) 2nd week (posterior pelvic tilt duration: 15-30 minutes - rest period: 2 minutes between each set). Third week (spine like a chain, duration: 30 minutes - rest period: 2 minutes between each set). 4th week (kneeling in pronation position duration: 30 minutes - rest period: 2 minutes between each set). Week 5 lying down (in the pronation position duration: 30 minutes - rest period: 2 minutes between each set). Weeks 6 to 8 all the above mastered techniques will be performed together for 30 minutes with retention periods in between the training program. The exercises will be done under the supervision of the therapists and also the subjects will be taught to do the exercises slowly and softly at home for three days.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Omid Hamadan Clinic

Full name of responsible person

Marziyeh Ziya

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Omid Hamedan Specialized and Subspecialized Clinic, next to Payam Hall, Sabd Bafan St, Hamedan.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Dr Farzaneh saki

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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 of Hamedan
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
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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

Data can potentially be shared after de-identifying individuals

When the data will become available and for how long

The access period starts one year after the results are published

To whom data/document is available

Researchers working in academic and scientific

institutions

Under which criteria data/document could be used

They can only use them to compare with their own data.
The use of data for analysis or printing is not allowed.

From where data/document is obtainable

Contact by email: Marziyeziyaaa@yahoo.com.

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

State the purpose of the data request Not to be used for printing purposes

Comments