Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 an 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 musclоskletal 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

Country

Iran (Islamic Republic of)

Phone

+98 71 3825 5617

Email address

m.zia@phe.basu.com

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 bbefore 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
Street address
Hamadan University of Medical Sciences Headquarters, Shahid Fahmideh St.
City
Hamedan
Province
Hamadan
Postal code
۶۵۱۷۸۳۸۶۷۸
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

Street address

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

City

Hamedan

Province

Hamadan

Postal code

6517838736

Phone

+98 81 3424 4731

Email

marziyeziyaaa@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bu-Ali Sina University of Hamedan

Full name of responsible person

Dr Farzaneh saki

Street address

Bu-Ali Sina University, Shahid Mostafa Ahmadi Roshan Street, Hamedan.

City

Hamedan
Province
Hamadan
Postal code
6516738695
Phone
+98 81 3838 1601
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 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
Bu-Ali Sina University of Hamedan
Full name of responsible person
Marziyeh Ziya
Position
Ph.D. candidate
Latest degree
Master
Other areas of specialty/work
Sport injuries and corrective exercises
Street address
Bu-Ali Sina University, Shahid Mostafa Ahmadi Roshan Street, Hamedan.
City
Hamedan
Province
Hamadan
Postal code
6516738695
Phone
+98 81 3838 1601
Email
Marziyeziyaaa@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Bu-Ali Sina University of Hamedan
Full name of responsible person
Farzaneh Saki
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Sport injures and corrective exercises
Street address
Bu-Ali Sina University, Shahid Mostafa Ahmadi Roshan Street, Hamedan Postcode: 6516738695 Tel: 081 - 38381601
City
Hamedan
Province
Hamadan
Postal code
۳۸۶۹۵۶۵۱۷۸
Phone
0098 813400000
Email
f.sport2008@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Bu-Ali Sina University Hamedan
Full name of responsible person
Marziyeh Ziya
Position
Ph.D. candidate
Latest degree
Master
Other areas of specialty/work
Sport injuries and corrective execises
Street address
Bu-Ali Sina University, Shahid Mostafa Ahmadi Roshan Street, Hamedan.
City
Hamedan
Province
Hamadan
Postal code
6516738695
Phone
+98 81 3838 1601
Email
marziyeziyaaa@yahoo.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

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