Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of dynamic neuromuscular stabilization exercise combined with neurofeedback and cognitive functional training on plantar pressure variables, brain electrical activity patterns, and lumbar muscle strength in men with chronic non-specific low back pain

Protocol summary

Study aim

Effect of dynamic neuromuscular stabilization exercise combined with neurofeedback and cognitive functional training on plantar pressure variables, brain electrical activity patterns, and lumbar muscle strength in men with chronic non-specific low back pain

Design

Clinical trial having 3 groups including 2 exercise groups and 1 control group, with parallel groups, single-blind, randomized on 60 patients and the randomization method by lottery

Settings and conduct

This study will be conducted at Dar al-Shafa Physiotherapy Center in Qom. Participants in all three groups will complete kinesiophobia and disability questionnaires at pre- and post-test. Pain intensity will be assessed using a pain rating scale, plantar pressure using a Foot Pressure device, brain electrical activity using EEG, and back muscle strength using a handheld dynamometer. Assessors will be blinded to group allocation.

Participants/Inclusion and exclusion criteria

Inclusion criteria for the research include 1) At least three months of pain 2) Age between 40 and 60 years 3) Normal body mass index 4) Pain score above 4. Exclusion criteria for the research include 1) History of injury in the past year in the trunk and lower limbs 2) Surgery in the lower limbs or lower back 3) Inflammation of the spine 4) Fracture of the spine 5) Tumor in the lower back area 6) Low back pain of non-mechanical origin 7) Having neurological, cardiovascular, and psychological diseases (severe mental disorders and depression)

Intervention groups

Group (1) will receive dynamic neuromuscular stabilization exercises + neurofeedback, group (2) will receive dynamic neuromuscular stabilization exercises + cognitive functional therapy, and the control group will receive no intervention.

Main outcome variables

plantar pressure variables, brain electrical activity patterns, lumbar muscle strength, disability, Pain intensity and kinesiophobia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20261028071589N1**
Registration date: **2026-11-21, 1405/08/30**
Registration timing: **retrospective**

Last update: **2026-11-21, 1405/08/30**
Update count: **0**

Registration date

2026-11-21, 1405/08/30

Registrant information

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Name of organization / entity

The University of Bu-Ali Sina

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2026-11-03, 1405/08/12
Expected recruitment end date
2026-11-16, 1405/08/25
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of dynamic neuromuscular stabilization exercise combined with neurofeedback and cognitive functional training on plantar pressure variables, brain electrical activity patterns, and lumbar muscle strength in men with chronic non-specific low back pain

Public title
Effect of dynamic neuromuscular stabilization exercise combined with neurofeedback and cognitive functional training on plantar pressure variables, brain electrical activity patterns, and lumbar muscle strength in men with chronic non-specific low back pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
At least three months of pain. Age range: 40–60 years. Normal body mass index (BMI). Pain score greater than 4.
Exclusion criteria:
History of injury to the trunk and lower limbs within the past year Surgery on the lower limbs or back Spinal inflammation Spinal fracture Tumor in the lower back region Back pain of non-mechanical origin Having neurological, cardiovascular, or mental health conditions (severe mental disorders and depression)
Age
From **40 years** old to **60 years** old
Gender
Male

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization was by the lottery method. We write the control and experimental titles on papers and ask the subjects that each of them take one of them.
Blinding (investigator's opinion)
Single blinded
Blinding description
Data analysts will not be informed of the group division (group information in the form of group 1 and 2 and 3 for each participant with a code will be provided to the analysts).
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Bu Ali Sina University-Hamedan
Street address
Shahid Mostafa Ahmadi Roshan Street
City
Hamedan
Province
Hamadan
Postal code
38695-65178
Approval date
2026-09-13, 1405/06/22
Ethics committee reference number
IR.BASU.REC.1405.066

Health conditions studied

1

Description of health condition studied
Chronic Non-Specific Low Back Pain
ICD-10 code
M54.5
ICD-10 code description
Low back pain

Primary outcomes

1

Description
Pain intensity
Timepoint
Pre-test and post-test refer to the time before the start of the first training session and one day after the conclusion of the final training session
Method of measurement
Visual Analog Scale (VAS)

Secondary outcomes

1

Description
Psychological indicators (functional disability –

kinesiophobia), plantar pressure variables, brain electrical activity patterns, and lumbar muscle strength

Timepoint

Pre-test and post-test

Method of measurement

Assessment of psychological and physiological indicators: The Oswestry questionnaire will be used to measure functional disability, and the TEMPA questionnaire will be employed to assess kinesiophobia. Furthermore, a foot pressure measurement system will be used to evaluate plantar pressure variables, an electroencephalography (EEG) device will be utilized to assess patterns of electrical brain activity, and a handheld dynamometer will be used to evaluate the strength of the lower back muscles.

Intervention groups

1

Description

First Intervention group: The combined intervention (dynamic neuromuscular stabilization exercises integrated with neurofeedback) will be conducted over eight consecutive weeks, consisting of three sessions per week. Each session will last 75 to 80 minutes (comprising 45–50 minutes of dynamic neuromuscular stabilization exercises and 30 minutes of neurofeedback). The dynamic neuromuscular stabilization exercises include diaphragmatic breathing, the 90/90 supine position, prone positioning, rolling, side-sitting, oblique sitting, tripod positioning, kneeling, squatting, and rising to a standing position. Neurofeedback training will be conducted following dynamic neuromuscular stabilization exercises, utilizing an 8-channel ProComp Infiniti system paired with BioGraph software. Drawing upon established protocols for chronic pain, the neurofeedback protocol will focus on increasing the power of alpha waves (8–13 Hz) while suppressing beta (15–20 Hz) and theta (4–7 Hz) wave activity at the Cz site (the central region of the brain). The Cz site was selected due to its proximity to the sensorimotor cortex—an area that plays a vital role in postural control and pain processing.

Category

Treatment - Other

2

Description

Second Intervention group: The combined training program—consisting of dynamic neuromuscular stabilization exercises integrated with cognitive-functional exercises—will be conducted over eight consecutive weeks. This will involve three sessions per week, with each session comprising approximately 45 to 50 minutes of dynamic neuromuscular stabilization exercises, alongside a total of eighteen sessions (over the same eight-week period) of cognitive-functional exercises, each lasting 60 minutes. The dynamic neuromuscular stabilization exercises include diaphragmatic breathing, the 90/90 supine position, prone positioning, rolling initiation, side-sitting, oblique sitting, the tripod position, kneeling, squatting, and rising to a standing position. Cognitive-functional exercise sessions will be conducted on an individual basis in a quiet room. This protocol consists of three main components. The cognitive component focuses on identifying the primary factors contributing to pain—as determined during assessments—including the multidimensional nature of chronic pain, as well as the individual's beliefs, emotions, and behaviors (e.g., movement patterns and lifestyle) that may exacerbate a "domino effect" of pain and disability. Patients will be educated on the biopsychosocial model of pain, and unhelpful beliefs will be addressed through cognitive restructuring. Functional Component: This component includes specific functional exercises designed to normalize movements and postures that are maladaptive or provocative. Patients are gradually exposed to activities they fear or avoid (controlled exposure), ensuring they feel secure while engaging in painful activities or resting their bodies. Lifestyle Component: This component integrates functional activities into daily living tasks, such as bending, sitting, standing, and lying down. Gradual exposure to everyday activities, combined with fear-reduction strategies, is implemented to foster long-term behavioral change.

Category

Treatment - Other

3

Description

Control group: At the beginning of the study, all assessments will be administered to the individuals in the control group. These participants will not take part in any rehabilitation interventions; instead, they will continue with their normal, routine lives and daily activities throughout the 8-week period. Following these 8 weeks, a post-test will be conducted.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Nikuee hospital

Full name of responsible person

Ali Asghar Borzou

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Sponsors / Funding sources

1

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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?
Yes
Title of funding source
Research Deputy of Bu-Ali Sina University, 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
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Ali Yalfani
Position
Professor
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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
Not applicable
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
Not applicable

Title and more details about the data/document
Data files containing measurements taken by the testers will be shared after the study concludes, if necessary.
When the data will become available and for how long
The course begins one year after the publication of the results and articles.
To whom data/document is available
Researchers and scholars whose field of work aligns with the present study and who are employed at universities.
Under which criteria data/document could be used
The data from the present study will be made available to other researchers solely for the purpose of comparison with future studies; any use or analysis of these data is unauthorized.
From where data/document is obtainable
Email address: abolfazlborzouab1377@gmail.com
What processes are involved for a request to access data/document
If the applicant provides documentation demonstrating relevance to their field of work in relation to the thesis topic, and upon a reasonable request and commitment not to misuse the research data, the data will be sent to them within one working week.
Comments