

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of comprehensive core stability and lumbopelvic stabilization exercises on Plantar pressure variables, pain, and quality of life patients with chronic non-specific low back pain

Protocol summary

Study aim

The effect of comprehensive core stability and lumbopelvic stabilization exercises on Plantar pressure variables, pain, and quality of life patients with chronic non-specific low back pain

Design

Clinical trial with two control and exercise groups, with parallel groups, single-blind, randomized on 40 patients and randomization method by lottery

Settings and conduct

This study will be conducted in the Sports Rehabilitation Laboratory of Bu-Ali Sina University. Subjects will be assessed in two groups at two time points: pre-test and post-test, completing pain and disability questionnaires, quality of life, and performing a standing test on a plantar pressure distribution measuring device. The data analyst will be blinded to the grouping.

Participants/Inclusion and exclusion criteria

A history of more than three months of back pain, physician confirmation of chronic non-specific back pain, no spinal deformities, and no acute deformities in the lower limbs and soles of the feet

Intervention groups

comprehensive core stability and lumbopelvic stabilization

Main outcome variables

Pain, functional disability, quality of life, plantar pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251017067658N1**

Registration date: **2026-01-07, 1404/10/17**

Registration timing: **prospective**

Last update: **2026-01-07, 1404/10/17**

Update count: **0**

Registration date

2026-01-07, 1404/10/17

Registrant information

Name

Mehrane Azizpour

Name of organization / entity

The University of Bu Ali Sina

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-01-10, 1404/10/20

Expected recruitment end date

2026-01-15, 1404/10/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of comprehensive core stability and lumbopelvic stabilization exercises on Plantar pressure variables, pain, and quality of life patients with chronic non-specific low back pain

Public title

The effect of comprehensive core stability and

lumbopelvic stabilization exercises on Plantar pressure variables, pain, and quality of life patients with chronic non-specific low back pain

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 A history of more than three months of back pain, physician confirmation of chronic non-specific back pain spinal deformities no acute deformities in the lower extremities or soles of the feet People with chronic back pain in the age range between 30 and 50 years
Exclusion criteria:
 Having scoliosis advanced osteoporosis advanced cardiovascular disease uncontrolled blood pressure severe deformity in the lower limbs and soles of the feet, fractures in the spine unwillingness to participate in exercises

Age
From **30 years** old to **50 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization was done by drawing lots. We wrote the titles of control and experimental on pieces of paper and asked the subjects to each pick one of them.

Blinding (investigator's opinion)
Single blinded

Blinding description
The data analyst will not be aware of the group division (group information will be provided to the data analyst in the form of groups 1 and 2 for each participant with a code).

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

Hamedan, Shahid Mustafa Ahmadi Roshan Street

City
Hamrdan

Province
Hamadan

Postal code
۳۸۶۹۵-۶۵۱۷۸

Approval date
2025-10-05, 1404/07/13

Ethics committee reference number
IR.BASU.REC.1404.033

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

Timepoint
Pre-test and post-test, meaning before the start of the first practice session and one day after the end of the last practice session.

Method of measurement
VAS questionnaire

Secondary outcomes

1

Description
Quality of life

Timepoint
pre test & post test

Method of measurement
The Short Form Health Survey (SF-36) questionnaire

Intervention groups

1

Description
Intervention group: Intervention group: Comprehensive core stability exercise protocol with lumbopelvic stabilization in the present study was performed for eight weeks, three sessions per week, and each session lasted 60 minutes. These exercises included abdominal pull-in maneuver, leg bent-over abdominal, reverse crunch, clamshell, bridge, single-leg bridge, side bridge, modified sit-up, bird dog, leg extension, kick bag, and hip abduction to the side.

Category

Treatment - Other

2**Description**

Control Group: Control Group: Initially, all tests were taken from them and the people in this group did not participate in any rehabilitation intervention and simply lived their normal lives with daily activities during these 8 weeks, and then after 8 weeks, the post-test was taken from them.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Bu Ali Sina University

Full name of responsible person

Ali Yalfani

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Hamedan, Shahid Mustafa Ahmadi Roshan Street

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Web page address<https://www.basu.ac.ir>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice President for Research, Bu-Ali Sina University, Hamadan

Full name of responsible person

Gholamhossein Majzoobi

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Shahid Mustafa Ahmadi Roshan Chaharbagh, Bu Ali Sina University, Vice President for Research Affairs

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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

Vice President for Research, Bu-Ali Sina University, Hamadan

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

Ali Yalfani

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Rehabilitation management

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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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

The measured data files will be shared by the testers after the study is completed, if needed.

When the data will become available and for how long

The period begins one year after the publication of results and articles.

To whom data/document is available

Researchers and researchers whose field of work is similar to the present research and who are employed in universities.

Under which criteria data/document could be used

The data from this study will only be made available to other researchers for comparison with future studies, and the use and analysis of the data is prohibited.

From where data/document is obtainable

Email address m.azizpour@phe.basu.ac.ir

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

A complete explanation of the research should be provided and the details of the use of the data should also be fully explained.

Comments