

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Effects of Progressive Stabilization Exercises Program and breathing exercises on pain, balance, performance and foot pressure variables in Patients with Lumbar Instability

Protocol summary

Study aim

Considering the high prevalence of low back instability and low back pain and its effect on disability and poor performance and due to the huge economic costs of this problem on society, the aim of this study was to investigate the effect of progressive stability exercises along with respiratory exercises in patients with low back instability.

Design

A clinical trial with the control group, with parallel groups, single-blinded, randomized

Settings and conduct

The tests will be carried out by the specialists at the Sport Rehabilitation Laboratory of Bu-Ali Sina University in Hamadan, and then interventions and exercises will take place in the gym. During the testing, the participant will be unaware of the main purpose of the research.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- People with low back pain in the last six weeks 2- People who are able to stand on one leg for 30 seconds 3- Positive three or more cases of low back instability test 4- Age range between 18 to 55 years.

Intervention groups

The progressive stability training group, progressive stability training group with breathing exercises

Main outcome variables

Foot pressure variables; Balance; Pain; Performance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190224042827N3**

Registration date: **2021-10-22, 1400/07/30**

Registration timing: **prospective**

Last update: **2021-10-22, 1400/07/30**

Update count: **0**

Registration date

2021-10-22, 1400/07/30

Registrant information

Name

Farzane Ramezani

Name of organization / entity

Bu Ali Sina University

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 1423

Email address

f.ramezani@phe.basu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2021-11-06, 1400/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Progressive Stabilization Exercises Program and breathing exercises on pain, balance, performance and foot pressure variables in Patients with Lumbar Instability

Public title

Effects of Exercise on Patients with Lumbar Instability

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People with low back pain in the last six weeks People who are able to stand on one foot for 30 seconds Positive three or more cases of lumbar instability test

Exclusion criteria:

Having respiratory disease, heart disease, or depression Have a history of the trunk or lower limb surgery Having a history of exercising

Age

From **18 years** old to **55 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization of subjects was done in two stages. First, each of the subjects selected a number between 1 - 28 using a lottery, then using Random number generator software between numbers 1 - 28, fourteen random numbers were selected and according to the numbers produced and The selected numbers of subjects were divided into two groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants participate in the study assuming they receive an exercise.

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

Street address

Bu Ali Sina University, Abu Taleb St, Modares Quarter, Hamedan

City

Hamedan

Province

Hamadan

Postal code

3869565178

Approval date

2021-07-10, 1400/04/19

Ethics committee reference number

IR.BASU.REC.1400.029

Health conditions studied

1

Description of health condition studied

Lumbar Instability

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

Foot pressure variables

Timepoint

Before the intervention begins, One day after the end of the intervention

Method of measurement

RS-Scan device

Secondary outcomes

1

Description

Balance

Timepoint

Before and after intervention

Method of measurement

Y Balance Test

2

Description

Pain

Timepoint

Before and after intervention

Method of measurement

Visual Analogue Scale

3

Description

Performance

Timepoint

Before and after intervention

Method of measurement

Roland-Morris Disability Questionnaire

Intervention groups

1

Description

Intervention group: Progressive Stabilization Exercises Program and breathing exercises, Exercises will be 3 sessions of 40 minutes per week for 8 weeks.

Category

Rehabilitation

2

Description

Control group: Progressive stability exercises

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamedan Municipality Office

Full name of responsible person

Behzad Nasiri

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bu Ali Sina University

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

Bu Ali Sina University

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

Behzad Nasiri

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Sport Rehabilitation

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available