Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Sep 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 minuets 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
Street address
Bu Ali Sina University, Abu Taleb St, Modares Quarter, Hamedan
City
Hamedan
Province
Hamadan
Postal code
3869565178
Phone
+98 81 3838 1423
Email
f.ramezani@phe.basu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bu Ali Sina University
Full name of responsible person
Farzane Saki
Street address
Bu Ali Sina University, Abu Taleb St, Modares Quarter, Hamedan
City
Hamedan
Province
Hamadan
Postal code
3869565178
Phone
+98 81 3838 1423
Email
f.ramezani@phe.basu.ac.ir
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
Street address
Bu Ali Sina University, Abu Taleb St, Modares Quarter, Hamedan
City
Hamedan
Province
Hamadan
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Fax
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Person responsible for scientific inquiries

Contact
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Bu Ali Sina University
Full name of responsible person
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Student
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Postal code

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Phone

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Fax

Email

f.ramezani@phe.basu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Bu Ali Sina University

Full name of responsible person

Behzad Nasiri

Position

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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