

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the Effect of Core Stability Exercise with and without the use of Virtual Reality System on Pain, Physical Function and Muscle activity in Athletes with non-Specific Chronic Low Back Pain : A Randomized Controlled Clinical Trial

Protocol summary

Study aim

Comparing the Effect of Core Stability Exercise with and without the use of Virtual Reality System on Pain, Physical Function and Muscle activity in Athletes with non-Specific Chronic Low Back Pain

Design

The clinical trial has one control group and two experimental groups with parallel groups, randomized, on 45 athletes with chronic non-specific low back pain, which randomization is done by lottery.

Settings and conduct

The research process includes pre-test, intervention for 6 weeks and post-test. The place of the process is building number 2 of Shahid Beheshti University Faculty of Sports Sciences.

Participants/Inclusion and exclusion criteria

Entry conditions: The presence of non-specific chronic low back pain diagnosed by an orthopedic specialist The individual has been suffering from non-specific chronic low back pain for at least 3 months Having a pain intensity between 3 and 7 based on the Visual Analog Scale A minimum of 2 years of regular athletic experience BMI between 18.5 and 26 body fat percentage of less than 20% for men and less than 28% for women Non-entry conditions: history of any surgery on the spine and lower limbs Having symptoms or a history of nerve root compression Having an acute disc herniation

Intervention groups

Intervention group 1: This group will do core stability exercises for 6 weeks. Intervention group 2: This group will perform core stability exercises for 6 weeks simultaneously using the virtual reality system. In the virtual reality system, truck driving and roller coaster simulator games are run and can be controlled by head movements. Control group: This group does their daily

activities during the research period.

Main outcome variables

pain using a visual analogue scale , core muscle endurance using McGill tests, functional disability using the Quebec questionnaire , muscle activity using EMG and balance with the Biodex device

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240810062711N1**

Registration date: **2025-01-02, 1403/10/13**

Registration timing: **registered_while_recruiting**

Last update: **2025-01-02, 1403/10/13**

Update count: **0**

Registration date

2025-01-02, 1403/10/13

Registrant information

Name

Saeed Karbasi Ravari

Name of organization / entity

The University of Shahid Beheshti

Country

Iran (Islamic Republic of)

Phone

+98 21 2260 4352

Email address

s.karbasiravari@mail.sbu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-12-05, 1403/09/15

Expected recruitment end date

2025-02-03, 1403/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Effect of Core Stability Exercise with and without the use of Virtual Reality System on Pain, Physical Function and Muscle activity in Athletes with non-Specific Chronic Low Back Pain : A Randomized Controlled Clinical Trial

Public title

Comparing the Effect of Core Stability Exercise with and without the use of Virtual Reality System on Pain, Physical Function and Muscle activity in Athletes with non-Specific Chronic Low Back Pain

Purpose

Basic science

Inclusion/Exclusion criteria**Inclusion criteria:**

The presence of non-specific chronic low back pain diagnosed by an orthopedic specialist The individual has been suffering from non-specific chronic low back pain for at least 3 months Having a pain intensity between 3 and 7 based on the Visual Analog Scale A minimum of 2 years of regular athletic experience BMI between 18.5 and 26 body fat percentage of less than 20% for men and less than 28% for women

Exclusion criteria:

history of any surgery on the spine and lower limbs Having symptoms or a history of nerve root compression Having an acute disc herniation

AgeFrom **18 years** old to **40 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **45****Randomization (investigator's opinion)**

Randomized

Randomization description

In this study, simple randomization will be performed using SPSS software. The steps are planned as follows: 1- First, a random variable will be created using the Transform > Compute Variable tool. This variable will be defined with the formula $TRUNC(RV.UNIFORM(0,1) * 3) + 1$, which randomly assigns individuals to one of three groups (1, 2, or 3). 2- The data will be sorted based on this variable using the Data > Sort Cases tool. 3- Finally, participants will be randomly divided into three groups: the control group (number 1) and two experimental

groups (numbers 2 and 3). This method represents a simple and transparent randomization process that will be applied in the future for the execution of the study.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Shahid Beheshti University

Street address

No 24 - Khaghani Street - Shariati Street - Tehran

City

Tehran

Province

Tehran

Postal code

1913994543

Approval date

2023-06-30, 1402/04/09

Ethics committee reference number

IR.SBU.REC.1402.173

Health conditions studied**1****Description of health condition studied**

non-Specific Chronic Low Back Pain

ICD-10 code

M54.5

ICD-10 code description

Low Back Pain

Primary outcomes**1****Description**

Pain

Timepoint

before the start of the intervention and after 6 weeks of the intervention

Method of measurement

Visual Analogue Scale

2

Description

Core Muscle Endurance

Timepoint

before the start of the intervention and after 6 weeks of the intervention

Method of measurement

McGill core muscle endurance tests

3

Description

Functional Disability

Timepoint

before the start of the intervention and after 6 weeks of the intervention

Method of measurement

Quebec questionnaire

4

Description

Balance

Timepoint

before the start of the intervention and after 6 weeks of the intervention

Method of measurement

Biodex Balance test device

5

Description

Muscle Activity

Timepoint

before the start of the intervention and after 6 weeks of the intervention

Method of measurement

Electromyography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: This group will do core stability exercises for 6 weeks.

Category

Treatment - Other

2

Description

Intervention group 2: This group will perform core stability exercises for 6 weeks simultaneously using the virtual reality system. In the virtual reality system, truck driving and roller coaster simulator games are run and can be controlled by head movements.

Category

Treatment - Other

3

Description

Control group: This group does their daily activities during the research period.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti University

Full name of responsible person

Saeed Karbasi Ravari

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No 24 , Khaghani Street , Shariati Street

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Email

s.karbasi Ravari@mail.sbu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Shahid Beheshti

Full name of responsible person

Seyedeh Mehri Hamidi Sangdehi

Street address

Shahid Shahriari sq - Evin - Tehran

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Province

Tehran

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1983969411

Phone

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Email

m_hamidi@sbu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

The University of Shahid Beheshti

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**

The University of Shahid Beheshti

Full name of responsible person

Saeed Karbasi Ravari

Position

Master Student

Latest degree

Bachelor

Other areas of specialty/work

sport injuries and corrective exercise

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

The University of Shahid Beheshti

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Person responsible for updating data**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)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The final results of the current research will be published in the form of statistical analysis in the form of articles or dissertations and not in the form of raw data of individual participants.

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

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

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

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

Title and more details about the data/document

The information and statistical analyzes carried out in the format of articles and dissertations will be shared from the results of this research. Thesis title: Comparing the Effect of Core Stability Exercise with and without the use of Virtual Reality System on Pain, Physical Function and Muscle activity in Athletes with non-Specific Chronic Low Back Pain : A Randomized Controlled Clinical Trial

When the data will become available and for how long

The access period starts after the registration of the final thesis in the period of January 2025 to January 2026.

To whom data/document is available

Researchers interested in the field of chronic low back pain, core stability exercises and virtual reality system

Under which criteria data/document could be used

It is possible to cite the results of this research by mentioning the source for other researchers.

From where data/document is obtainable

Researchers can contact the author through the following email address in order to obtain information about the article: s.karbasiravari@mail.sbu.ac.ir

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

Applicants to receive information after introducing their field of study and why they want to study the information of the present study in the text of the email can receive their desired data up to a maximum period of 2 weeks after receiving the said email and checking it by the author.

Comments