

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 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

**Age**

From **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

##### **Street address**

No 24 , Khaghani Street , Shariati Street

##### **City**

Tehran

##### **Province**

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##### **Postal code**

1913994543

##### **Phone**

+98 21 2260 4352

##### **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

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

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##### **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

**Street address**

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The University of Shahid Beheshti

**Full name of responsible person**

Saeed Karbasi Ravari

**Position**

Master Student

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**Position**

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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**