

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of virtual reality training in older people with chronic low back pain

#### Protocol summary

##### Study aim

The aim of this study was to reduce back pain through virtual reality training to help older people to improve motor function and quality of life and reduce their falls.

##### Design

Double-blind randomized clinical trial with control group (n=27).

##### Settings and conduct

The present quasi-experimental study is performed in the rehabilitation laboratory of Bu Ali Sina University. The experimental group performs virtual reality exercises for 8 weeks, 3 sessions per week for 30 minutes using a headset (Xbox Kinect). Pain intensity and quality of life index are measured using the Visual Pain Scale (VAS) and SF-36 questionnaire, respectively. The risk of falls is assessed using a Biodex balance system and the foot pressure variables are assessed by a plantar pressure. The muscular strength is measured using dynamometer. Participants and evaluators do not know how to allocate and group.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: experience of low back pain in the last six months, age range 60-80 years, no history of spine surgery and hip replacement. Exclusion criteria: history of cardio-respiratory disorders in the last two years, visual impairment, severe musculoskeletal disorders such as severe osteoarthritis.

##### Intervention groups

Intervention group: The participants in the intervention group perform virtual reality exercises with xbox kinect headset for eight weeks, three sessions per week, and 30 minutes per session. Control group: They will have the usual routine of their lives.

##### Main outcome variables

Pain; Quality of life index; Risk of falls; Foot pressure variables; Muscular strength

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200204046368N7**

Registration date: **2021-09-23, 1400/07/01**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-09-23, 1400/07/01**

Update count: **0**

##### Registration date

2021-09-23, 1400/07/01

##### Registrant information

##### Name

Zahra Raeisi

##### Name of organization / entity

Arak University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3417 3492

##### Email address

z\_raisi13@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-09-22, 1400/06/31

##### Expected recruitment end date

2021-09-27, 1400/07/05

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The effect of virtual reality training in older people with chronic low back pain

## Public title

Virtual reality exercises and aging

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age 60 to 80 years No neurological disorders such as Alzheimer's, MS, Parkinson's No musculoskeletal disorders such as rheumatoid arthritis and muscular dystrophy

### Exclusion criteria:

History of spine or hip surgery Use muscle relaxants 30 days before the study Visual impairment

## Age

From **60 years** old to **80 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Outcome assessor
- Data analyser

## Sample size

Target sample size: **27**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The randomization method is parallel. The randomization unit is individual. The Randlist software is used to randomly assign subjects to study groups. At , the number of subjects and groups is given to the software. Then, with this software, each subject is assigned a code. A group is then randomly assigned to each code by the software.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The researcher that do laboratory tests were not aware of the allocation of study groups. The data analyzer will not be aware of the groups classification. The information of the groups will be provided to the data analyzer in the form of numbers 1, 2, 3 and 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

Bu Ali Sina university ethics committee in research

#### Street address

Shahid Mostafa Ahmadi Roshan Street

#### City

Hamedan

#### Province

Hamadan

#### Postal code

6517838695

#### Approval date

2021-02-28, 1399/12/10

#### Ethics committee reference number

IR.BASU.REC.1399.035

## Health conditions studied

## 1

### Description of health condition studied

Low back pain

### ICD-10 code

M54.5

### ICD-10 code description

Low back pain

## Primary outcomes

## 1

### Description

Pain

### Timepoint

Before and after the intervention

### Method of measurement

Visual analogue scale

## 2

### Description

Quality of life index

### Timepoint

Before and after the intervention

### Method of measurement

SF-36 Questionnaire

## 3

### Description

Risk of falls

### Timepoint

Before and after intervention

### Method of measurement

Biodex balance system

## 4

### Description

Plantar pressure variables

### Timepoint

Before and after the intervention

**Method of measurement**

Zebris plantar pressure system

**5**

**Description**

Muscle Strength

**Timepoint**

Before and after fatigue

**Method of measurement**

Dynamometer

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group: The intervention group performs virtual reality exercises for 8 weeks, 3 sessions per week for 30 minutes using a headset (Xbox Kinect).

**Category**

Rehabilitation

**2**

**Description**

Control group: The control group performs their normal activities for 8 weeks.

**Category**

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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Bu-Ali Sina University, Shahid Mostafa Ahmadi Roshan Street

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Bu Ali-Sina University

**Full name of responsible person**

Gholamhossein Majzoubi

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Vice Chancellery For Research Affairs, Bu Ali Sina University, Chahar Bagh Martyr Mustafa Ahmadi Roshan

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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**

Arak University

**Full name of responsible person**

Zahra Raeisi

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Sport Medicine

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## Person responsible for scientific inquiries

### Contact

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Associate professor  
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## Person responsible for updating data

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Assistant professor  
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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**  
Not applicable  
**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**  
Not applicable  
**Data Dictionary**  
Not applicable