

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of virtual reality training in elderly women 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. 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 75-60 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.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200204046368N5**  
Registration date: **2021-05-23, 1400/03/02**  
Registration timing: **prospective**

Last update: **2021-05-23, 1400/03/02**

Update count: **0**

##### Registration date

2021-05-23, 1400/03/02

##### 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

2021-06-10, 1400/03/20

##### Expected recruitment end date

2021-06-21, 1400/03/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of virtual reality training in elderly women with chronic low back pain

**Public title**

Effect's of virtual reality training in elderly people

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age 60 to 75 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 **75 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Participant
- Data analyser

**Sample size**

Target sample size: **27**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The Randlist software is used to randomly assign subjects to intervention groups. At first, a code is assigned to each subject by this software. Then, they are randomly placed into three groups.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Participants will not be aware of the existence of other 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 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**

2021-03-08, 1399/12/18

**Ethics committee reference number**

IR.BASU.REC.1399.034

**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

**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

##### Street address

Bu-Ali Sina University, Shahid Mostafa Ahmadi Roshan Street

##### City

Hamedan

##### Province

Hamadan

##### Postal code

6517833131

##### Phone

+98 81 3838 1422

##### Email

Ali\_yalfani@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Bu Ali-Sina University

##### Full name of responsible person

Gholamhossein Majzoubi

##### Street address

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

##### City

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##### Province

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##### Postal code

6517833131

##### Phone

+98 81 3838 1601

##### Email

sakhai@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

Ali Yalfani

##### Position

Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Rehabilitation management

##### Street address

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Bu Ali-Sina University

##### Full name of responsible person

Ali Yalfani

##### Position

Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Rehabilitation management

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**Person responsible for updating data**

**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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**Province**

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**Postal code**

3848177584

**Phone**

+98 86 3417 3492

**Fax**

**Email**

Z\_raisi13@yahoo.com

**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**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Information on the main outcomes of the study will be shared.

**When the data will become available and for how long**

One year after the publication of the study results

**To whom data/document is available**

Researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

Using information to help treat patients

**From where data/document is obtainable**

Ali Yalfani E-mail : Ali\_yalfani@yahoo.com Tel :  
+988138381422

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

The data will be shared after the request is submitted via email and the required time has elapsed since the publication of the study results.

**Comments**