

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 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

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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

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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

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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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