

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)

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+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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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Sport Medicine

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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