Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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

Hamedan

Province

Hamadan

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

Arak University

Full name of responsible person

Zahra Raeisi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

Street address

Arak University, Basij Square

City

Arak

Province

Markazi

Postal code

3848177584

Phone

+98 86 3417 3492

Fax

Email

Z_raisi13@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Bu Ali-Sina University

Full name of responsible person

Ali Yalfani

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Rehabilitation management

Street address

Bu Ali Sina University, Chahar Bagh of martyr Mustafa Ahmadi Roshan

City

Hamedan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 1422

Email

ali_yalfani@yahoo.com

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

Street address

Arak University, Basij Square

City

Arak

Province

Markazi

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

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