Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Iran (Islamic Republic of)

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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
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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
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
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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