Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the effectiveness of virtual reality and therapeutic exercise on improving balance and fear of falling in Military retirees and elderly

Protocol summary

Study aim
Investigating the effect of virtual reality on balance performance and fear of falling among the elderly
Design
A clinical trial with a control group, with parallel groups, assessor blind, randomized, on 30 elderly. A sealed envelope was used for randomization.
Settings and conduct
This study will be performed at the Setaregan-e-Derakhshan Elderly Center. Individuals are randomly divided into two groups of intervention and control, and evaluations are performed by a person who is unaware of randomization.
Participants/Inclusion and exclusion criteria
Inclusion criteria: age over 60 years; ability to walk independently with or without an assistive device for at least 10 meters; having an acceptable level of cognitive function means a score equal to or higher than 24 in the Mini-Mental State Examination. Non-inclusion criteria: Suffering from an acute neurological or orthopedic disorder or addiction according to the report of the individual, family, or doctor.
Intervention groups
Control group that receives physical balance exercises. Intervention group that receives balance exercises through the virtual reality system.
Main outcome variables
Balance - Fear of falling

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20211224053509N1**
Registration date: **2022-08-16, 1401/05/25**
Registration timing: **registered_while_recruiting**
Last update: **2022-08-16, 1401/05/25**
Update count: **0**
Registration date
2022-08-16, 1401/05/25

Registrant information
Name
Moslem Cheraghifard
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 6556 7278
Email address
chraghifard.m@iums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-07-06, 1401/04/15
Expected recruitment end date
2022-12-06, 1401/09/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effectiveness of virtual reality and therapeutic exercise on improving balance and fear of falling in Military retirees and elderly

Public title
Effect of virtual reality on balance of elderly
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:

Having an acceptable level of cognitive function, i.e. score equal to or greater than 21 on the Persian version of Mini Mental State Examination Ability to walk at least 10 meters with or without assistive device No severe orthopedic or psychological disorders, acute pain, or addictive disorder based on the report fromy the elderly, patient's family, physician, or medical record.

Exclusion criteria:

Having a history of neurological disorders such as stroke, traumatic brain injury, Parkinson, seizures.

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the sealed envelope method is used for randomization. Participants are allocated based on a selection of randomly arranged sealed envelopes labeled "virtual reality group" or "exercise therapy group." This process is done by someone who has no role in the data analysis or intervention process.

Blinding (investigator's opinion)

Single blinded

Blinding description

Evaluation of the outcomes is performed by experienced individuals who are blind to the patient's allocation to the groups .

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Research of Baqiyatallah Al-Azam Medical Center

Street address

Baqiatallah University of Medical Sciences, Mullasadra Street, Vanak Square,Tehran

City

Tehran

Province

Tehran

Postal code

1435916471

Approval date

2021-12-06, 1400/09/15

Ethics committee reference number

IR.BMSU.BAQ.REC.1400.045

Health conditions studied

1

Description of health condition studied

Older adult- fear of falling

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Fear of falling

Timepoint

Before intervention, after intervention and 4 weeks after intervention

Method of measurement

Activities-specific Balance Confidence questionnaire - Fall Efficiency Scale

2

Description

Balance ability

Timepoint

Before intervention, after intervention and 4 weeks after intervention

Method of measurement

Berg Balance scale - time up and go Test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group (Virtual Reality): The intervention in this group is based on the virtual reality system. The virtual reality system is designed based on force sensors and a motion detector system (Kinect). In performing interventions based on the force sensor, the person stands on the surface in dimensions of 50 x 30 in front of the monitor and performs the activities and games shown on the monitor by changing the center of mass of the body. The activities that a person performs can be leveled and its intensity increases as the person's performance changes. In performing interventions using the Kinect device, the person stands in front of the sensor and performs different motor activities in accordance with the designed activities and games that

are displayed on the screen. These motor activities include a variety of activities, such as standing on one leg, jumping, and maintaining balance in a variety of body postures.

Category

Rehabilitation

2

Description

Control group: In the control group, conventional interventions to improve balance are performed according to the Otago Exercise Program (OEP). OEP exercises consist of two parts: strengthening exercises and balance exercises. Strengthening exercises are aimed at increasing the strength of the pelvic floor, knee, and ankle muscles, which will move from an assetive to a resistance one. Balance exercises also include bending the knee, walking backward, walking sideways, standing in a tandem position, random walking, standing on one foot, walking on the toe and heel, sitting and standing up going up and down the stairs

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Setaregan Derakhshan nursing home

Full name of responsible person

Alireza Shamsoddini

Street address

Fadak Educational Complex, After Shahid Sani Khani Clinic, Dr. Abidi St, 8th km of Karaj road, Lashgari highway, Tehran

City

tehran

Province

Tehran

Postal code

13898

Phone

+98 21 4457 0356

Email

setareganderakhshannursinghome@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Alireza Shamsoddini

Street address

Baqiyatallah University of Medical Sciences, Mullasadra Street, Vanak Square, Tehran

City

tehran

Province

Tehran

Postal code

1435915371

Phone

+98 21 8805 0436

Email

info@bmsu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Bagheiat-allah University of Medical Sciences

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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Aliraza Shamsoddini

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

Street address

BaqiatallahUniversity of Medical Sciences, Mullasadra Street, Vanak Square, Tehran

City

tehran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8804 0060

Email

alirezaot@bmsu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Aliraza Shamsoddini
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiology
Street address
BaqiatallahUniversity of Medical Sciences, Mullasadra Street, Vanak Square, Tehran
City
tehran
Province
Tehran
Postal code
1435916471
Phone
+98 21 8804 0060
Email
alirezaot@bmsu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Aliraza Shamsoddini
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiology
Street address
BaqiatallahUniversity of Medical Sciences, Mullasadra Street, Vanak Square, Tehran
City
tehran
Province
Tehran
Postal code
1435916471
Phone
+98 21 8804 0060
Email
alirezaot@bmsu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
plagiarism
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available