

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Design, Implementation, and Validation of a Virtual Reality Package based on 360-Degree Videos with Dual-Task Training for Enhancing Motor-Cognitive Functions in the Elderly

Protocol summary

Study aim

Design, implementation, and validation of a virtual reality package based on dual tasks including navigation and shopping scenarios from a virtual store based on 360-degree images to improve the cognitive and motor components of the elderly

Design

Single-Blinded Study with Block-Randomized Technique

Settings and conduct

Kahrizak Charitable Hospital

Participants/Inclusion and exclusion criteria

Having the Age of 60 Years and above and Physical Ability to Stand and Walk and Regular Physical Activity

Intervention groups

A Control Group with 15 Members, an Intervention Group treadmill with 15 Members (Motor), an Intervention Group Virtual Reality with 15 Members (Cognitive), and an Intervention Group Treadmill and Virtual Reality with 15 Members (Motor and Cognitive)

Main outcome variables

Balance, Attention, Memory, and Visual-Spatial Perception

General information

Reason for update

Acronym

VRS360

IRCT registration information

IRCT registration number: **IRCT20231229060567N1**

Registration date: **2024-02-07, 1402/11/18**

Registration timing: **registered_while_recruiting**

Last update: **2024-02-07, 1402/11/18**

Update count: **0**

Registration date

2024-02-07, 1402/11/18

Registrant information

Name

Mohsen Mohammadvaliee

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-30, 1402/11/10

Expected recruitment end date

2024-05-04, 1403/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Design, Implementation, and Validation of a Virtual Reality Package based on 360-Degree Videos with Dual-Task Training for Enhancing Motor-Cognitive Functions in the Elderly

Public title

Motor and Cognitive Empowerment of the Elderly Using Dual-Task Training

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Having an old age of 60 Years Or Older According to the Definition of the World Health Organization Normal Eyesight and Hearing None Serious Psychiatric, Cognitive and Psychological Disorders None Simultaneous Cognitive Interventions Being able to Stand, Walk, and Do Usual Physical Activity None Medical Prohibition for Physical Activities Weight Less Than 110 Kg Due to Prevent Damage to the Treadmill Platform Signing the Consent Form to Participate in the Research None Bone Lesion (Decentralized Fractures, Unstable Spine or Severe Osteoporosis)

Exclusion criteria:
 Need Help During Intervention Having Uncontrolled Blood Pressure Greater than 100/160 mmHg Lack of Ability to Follow Orders Several Falls During Intervention Not Being Able to Carry out Interventions Independently Physical Problems Occurrence During the Implementation of Interventions Simultaneous Concurrent Cognitive or Psychiatric Interventions Absence in more than One-Third of Intervention Sessions Cardio-Pulmonary Disorders Affecting Movement or Having Bone Lesions

Age
 From **60 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked

- Participant

Sample size
 Target sample size: **60**

Randomization (investigator's opinion)
 Randomized

Randomization description
 In this study, the block method is used for random allocation in such a way that a statistician designs blocks of four into four equal groups, using "sealedenvelope.com". A person not involved in the research, block and allocate sequence for concealment. The allocation ratio of the samples is 1:1. Finally, based on the obtained blocks and according to the sequence of allocation, dual-task rehabilitation training is presented to the participants.

Blinding (investigator's opinion)
 Single blinded

Blinding description
 Participants are randomly divided into four groups. These groups are the control group, the treadmill rehabilitation, the virtual reality rehabilitation, and the dual rehabilitation of treadmill and virtual reality. They are unaware of the allocation of study groups and the type of rehabilitation.

Placebo
 Not used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics committees of University of Isfahan

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Dept. 2, No.2, Sabzi Alley, Karimshahian St., Pirouzi Ave.

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Approval date

2023-12-23, 1402/10/02

Ethics committee reference number

IR.UI.REC.1402.129

Health conditions studied

1

Description of health condition studied

Empowering Healthy Elderly

ICD-10 code

Z76.3

ICD-10 code description

Healthy person accompanying sick person

Primary outcomes

1

Description

Balance

Timepoint

One Day before the Start of the Intervention Sessions and One Day after the End of the Intervention Sessions

Method of measurement

Berg Balance Scale (BBS), Timed Up and Go Test (TUG), and Functional Reach Test (FRT)

2

Description

Attention

Timepoint

One Day before the Start of the Intervention Sessions and One Day after the End of the Intervention Sessions

Method of measurement

Mini-Mental State Examination (MMSE) and Continuous Performance Test (CPT)

3 Description Memory Timepoint One Day before the Start of the Intervention Sessions and One Day after the End of the Intervention Sessions Method of measurement Mini-Mental State Examination (MMSE) and N-Back Working Memory Test 4 Description Visual-Spatial Perception Timepoint One Day before the Start of the Intervention Sessions and One Day after the End of the Intervention Sessions Method of measurement Mini-Mental State Examination (MMSE), Hooper Visual Organization Test (HVOT), and Judgment of Line Orientation (JLO) Secondary outcomes empty Intervention groups 1 Description Control group: 15 Healthy Elderly People Category N/A 2 Description Intervention group: 15 Healthy Elderly People only Treadmill (Motor) Category Rehabilitation 3 Description Intervention group: 15 Healthy Elderly People only Virtual Reality (Cognitive) Category Rehabilitation 4 Description Intervention group: 15 Healthy Elderly People Treadmill and Virtual Reality (Motor and Cognitive) Category Rehabilitation Recruitment centers	1 Recruitment center Name of recruitment center Kahrizak Charitable Hospital Full name of responsible person Dr. Hossein Nahvi Nejad Street address Dr. Hakimzadeh Blvd., Old Qom Road, City Tehran Province Tehran Postal code 1819117536 Phone +98 21 5652 5804 Fax +98 21 5652 3122 Email kcf@kahrizak.com Web page address https://kahrizakcharity.com/ Sponsors / Funding sources 1 Sponsor Name of organization / entity University of Esfahan Full name of responsible person Dr. Javad Rasti Street address Daneshgah Ave., Azadi Sq. City Tehran Province Tehran Postal code 8174673441 Phone +98 31 3793 2128 Email research.deputy@dean.ui.ac.ir Web page address https://www.ui.ac.ir/ Grant name Grant code / Reference number Is the source of funding the same sponsor organization/entity? Yes Title of funding source University of Esfahan 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
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Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

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

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

Title and more details about the data/document

Total Results of Scores of Intervention Sessions, Pre-Intervention and Post-Intervention Tests

When the data will become available and for how long

One Year after the Publishing of Results

To whom data/document is available

Researchers Working in Academic and Scientific Institutions

Under which criteria data/document could be used

Data Analysis and Comparison

From where data/document is obtainable

Email Address

What processes are involved for a request to access data/document

Sending Email and Authentication

Comments

