

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Investigating the effect of virtual- reality vestibular rehabilitation on Visio-spatial memory of elderly in Hamedan city

Protocol summary

Study aim

Investigating the effect of virtual- reality vestibular rehabilitation on Visio-spatial memory of elderly

Design

A clinical trial with an intervention group and a control group, with parallel groups, single-blind, randomized, on 40 patients. Random assignment software was used for randomization.

Settings and conduct

School of Rehabilitation, UMSHA Recruitment of patients based on inclusion criteria Intervention based on the group description Assessment of cognitive outcomes before and after interventions

Participants/Inclusion and exclusion criteria

elderly / - Age over 65 years - No cognitive impairment (MMSE $\geq$ 24) - No history of central and peripheral nervous system damage according to medical records (including Parkinson's, stroke, transient ischemic attacks, cerebellar problems, myelopathy and epilepsy) - No history of orthopedic problems in the last 6 months according to the individual's report (lower limb fractures, dislocations, sprains and pain in the lower limb or trunk) - No history of cardiovascular lesions according to the medical records (uncontrolled blood pressure, hypotension and myocardial infarction) and severe pulmonary - No history of rheumatic or metabolic diseases according to the medical records (diabetes) - No history of falling more than once in the last 6 months according to the individual's report - No severe hearing problems (use of hearing aids) according to the medical records - No alcohol and smoking according to the individual's report - Ability to read and write

Intervention groups

Intervention group 1 (VR): receiving virtual-vestibular rehabilitation (eight 45-minute sessions of Nintendo Wii fit plus exercises, twice a week, 4 weeks) control group : no intervention

Main outcome variables

1. Visual Search Test/ VS 2. Corsi Blocks Test

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241018063403N2**

Registration date: **2025-01-26, 1403/11/07**

Registration timing: **prospective**

Last update: **2025-01-26, 1403/11/07**

Update count: **0**

Registration date

2025-01-26, 1403/11/07

Registrant information

Name

Bahareh Khavarghazalani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 81 3838 1571

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b.khavarghazalani@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-22, 1404/03/01

Expected recruitment end date

2026-02-20, 1404/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of virtual- reality vestibular rehabilitation on Visio-spatial memory of elderly in Hamedan city	
Public title	vestibular rehabilitation on memory of elderly
Purpose	Supportive
Inclusion/Exclusion criteria	
Inclusion criteria:	Age over 65 years No cognitive impairment (MMSE $\geq$ 24) No central or peripheral nervous system damage in the medical record (including Parkinson's, stroke, transient ischemic attack, cerebellar problems, myelopathy and epilepsy) No orthopedic problem in the last 6 months in the self-report (lower limb fracture, dislocation, sprain and pain in the lower limb or trunk) No cardiac lesions- Medical record (uncontrolled blood pressure, hypotension and myocardial infarction) and severe pulmonary No history of rheumatic or metabolic diseases in the medical record (diabetes) No more than one fall in the 6 months in the self-report No severe hearing problems (use of Hearing aids) Medical records Absence of alcohol and smoking Self-report Reading and writing
Exclusion criteria:	Unwillingness to continue cooperation Inability to properly understand the test procedure Unusual mental and physical fatigue
Age	From 65 years old
Gender	Both
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 40
Randomization (investigator's opinion)	Randomized
Randomization description	Given that the subjects do not enter the study at the same time and the researchers cannot predict in advance which group each person entering the study will belong to, the random binary block method was used to assign the patients in the target group to one of the two study groups, using random allocation software to two groups that were the same in terms of age. In order to conceal the random assignment, the sealed opaque envelope method was used. In such a way that each of the random sequences created is recorded on a card and the cards are placed inside the envelopes in order. Finally, the envelopes are glued shut and placed in a box in order. At the time of participant registration, based on the order of the eligible participants entering the study, one of the envelopes is opened in order and the assigned group of that participant is revealed.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Research Ethics Committees of Hamadan University of Medical Sciences
Street address	School of Rehabilitation, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.
City	Hamadan
Province	Hamadan
Postal code	6517838695
Approval date	2025-01-18, 1403/10/29
Ethics committee reference number	IR.UMSHA.REC.1403.757
Health conditions studied	
<u>1</u>	
Description of health condition studied	Cognition in elderly
ICD-10 code	R41.81
ICD-10 code description	Age-related cognitive decline
Primary outcomes	
<u>1</u>	
Description	Visuospatial span length
Timepoint	Before and after intervention
Method of measurement	Corsi block test
<u>2</u>	
Description	Percentage of correct choices in visual search
Timepoint	Before and after intervention
Method of measurement	Visual search test

Secondary outcomes

empty

Intervention groups

1

Description

For virtual reality-based balance training, the Nintendo Wii Fit Plus device and its related games are used. This device has a balance board, handle, monitor, and receiver. The subject can interact with the games and instructions on the monitor through the balance board and control the game by performing physical activity. The elderly in the intervention group were required to attend 8 sessions (twice a week, 45 minutes each time) for a month to participate in vestibular rehabilitation sessions.

Category

Rehabilitation

2

Description

Control group: no intervention

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital in Hamadan city

Full name of responsible person

Dr. Bahareh Khavarghazalani

Street address

Besat Hospital, Shahed Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Alireza Soltanian

Street address

Hamadan University of Medical Sciences, Shahid

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Bahareh Khavarghazalani

Position

Assistant Professor of Audiology

Latest degree

Ph.D.

Other areas of specialty/work

Audiology

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

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Person responsible for updating data

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Position

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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

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