Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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≥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

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Iran (Islamic Republic of)

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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 ≥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

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Hamadan University of Medical Scieneces
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

1

Description of health condition studied
Cognition in elderly
ICD-10 code
R41.81
ICD-10 code description
Age-related cognitive decline

Primary outcomes

1

Description
Visuospatial span length
Timepoint
Before and after intervention
Method of measurement
Corsi block test

2

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 intervantion
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital in Hamadan city
Full name of responsible person
Dr. Bahareh Khavarghazalani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
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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
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Other areas of specialty/work
Audiology
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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