Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigation of Virtual reality’s rehabilitative effects for mild cognitive impairment compared to control group

Protocol summary

Study aim

Investigation of "virtual reality" rehabilitation's effect on improving cognitive function in people with mild cognitive impairment (MCI)

Design

Clinical trial with two groups including intervention and control, with a study population of 72 people (36 in the intervention group and 36 in the control group), double blind, simple randomized using a random number table

Settings and conduct

Participants will be randomly assigned into 2 groups. Patients, secretary, evaluator, and interceptor are blinded. In addition to routine treatment, the first group will receive VR-based rehabilitation (with the use of Oculus Quest 2 256G virtual reality headset) in Roozbeh Hospital. The control group receives only routine treatment. All participants will be assessed with cognitive instruments before, immediately after and one month after the interventions to evaluate the effectiveness of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria include age over 55, diagnosis of mild cognitive impairment by a physician, and a score in range of 21-25 on The Montreal Cognitive Assessment (MoCA) test. Exclusion criteria include alcohol or drug dependence, chronic neurological disease, major psychiatric disorder, and a history of moderate to severe brain injury.

Intervention groups

The intervention group in addition to routine treatment, will receive VR cognitive rehabilitation 3 days a week (12 sessions in 1 month). Each intervention session includes 30 minutes of cognitive rehabilitation based on two games of aiming and maze. The control group receives routine treatment, including physician consultation and diagnostic and therapeutic measures.

Main outcome variables

Attention and executive function, verbal memory, visual-spatial function, verbal fluency, language function, gait speed, gait action and balance, processing speed and quality of life

General information

Reason for update

Acronym

EVRIMCI

IRCT registration information

IRCT registration number: **IRCT20220120053773N1**
Registration date: **2022-05-14, 1401/02/24**
Registration timing: **prospective**

Last update: **2022-05-14, 1401/02/24**
Update count: **0**

Registration date

2022-05-14, 1401/02/24

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of Virtual reality’s rehabilitative effects for mild cognitive impairment compared to control group

Public title

Effect of virtual reality intervention on mild cognitive impairment

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age more than 55 years Mild cognitive impairment should be diagnosed by neurologist or psychiatrist according to these items: cognitive complaints coming from the patients or their families, the reporting of a decline in cognitive functioning relative to previous abilities during the past year by the patient or informant, cognitive disorders as evidenced by clinical evaluation(impairment in memory or in another cognitive domain), absence of major repercussions on daily life, absence of dementia Initial Montreal Cognitive Assessment (MoCA) between 21 and 25

Exclusion criteria:

Addiction or alcohol abuse Another chronic neurologic condition such as drug-resistant epilepsy, Parkinson's disease, dementia (lewy body dementia, vascular dementia, Alzheimer's disease, frontotemporal dementia , etc.), stroke, etc. Psychologic conditions such as Psychosis, personality disorder, major depressive disorder, etc. History of moderate to severe brain injury

Age

From **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

the simple randomization method using random number tables will be used. for allocation concealment Sequentially numbered, sealed, opaque envelopes will be used for this process: The random numbers are placed in the opaque envelopes and the allocation of these opaque envelopes to groups is done randomly, this allocation is confidential and without informing the executor, patient, and investigators.

Blinding (investigator's opinion)

Double blinded

Blinding description

All patients will be informed that they will be participating in a research study, with the permission of them or their caregivers. The consent form will be completed. However, the patients, the project secretary, the evaluator, and the intervenor are blind to grouping.

Placebo

Used

Assignment

Factorial

Other design features

Due to the significant effects of dementia on the life quality of the elderly, it is essential to prevent it. People with mild cognitive impairment or MCI (with a prevalence of 15% to 20% in people over 60) are at a much higher risk of developing dementia (Annual rate of dementia in MCI people is between 10% to 15% versus 1% to 2% of this rate in the whole community), and these patients are the target group for the prevention of this disease. [3-1]. It is very important to perform effective interventions to prevent dementia, but unfortunately, no suitable treatment has been discovered for them and drug interventions have not had a significant effect [4]. However, many recent studies have shown that virtual reality-based cognitive rehabilitation can have a significant impact on improving cognitive and motor function in these patients [5]. This rehabilitation, by using sight, touch and movement, provides a suitable space for people to perform daily activities in a "virtual reality" environment [6]. This technology can be adjusted based on the needs and characteristics of patients and has a variety of effects depending on the type, duration, etc. [7]. As a result, there is a discussion about the type, frequency of intervention sessions, duration of each session and the number of sessions required, etc. to achieve optimal results and this is what makes our study unique [9,8]. Also, compared to many previous studies (with a small population limit), the population of this study is much larger and one month follow-up is going to performed after the intervention [9,8]. The extent of its impact on elderly Iranian patients with their level of literacy, culture and understanding and ability to use technology is also questionable. As a result, this study with these distinctive features has not been performed before and conducting it (for the first time in Iran) is very important to help improve the quality of life in the elderly. Refrences: 1. Petersen, R.C., Mid Cognitive Impairment. Continuum (Minneap Minn), 2016 22 (2 Dementia): p. 404-18 2. Eshkor, SA, et al., Mild cognitive impairment and its management in the elderly. Clin Interv Aging, 2015. 10: p. 687-93. 3. Petersen, R.C., et al., Mild Cognitive Disorder: Ten Years Later. Arch Neurol, 2009. 66 (12): p. 1447-55 4. Huckans, M., et al., The effectiveness of cognitive rehabilitation therapies for mild cognitive impairment (MCI) in older adults: Work toward a theoretical model and evidence-based interventions. Neuropsychol Rev, 2013. 23 (1): p. 63-80. 5. Roosink, M., et al. Improve interactive virtual feedback of motion pictures of walking after spinal cord injury: An exploratory study. Restor Neurol Neurosci, 201 6. 34 (2): p. 227-35 6.Rizzo, A.A., et al., Virtual Classroom: A Virtual Reality Environment for Assessing and Rehabilitating Attention Deficit Disorders. 2000. 3 (3): p. 483-499 7.Wu, J., Y. Ma and Z. Ren, Rehabilitation effects of virtual

reality technology for mild cognitive impairment: A systematic review by meta-analysis. Front Psychol, 2020. 11: p. 1811 8. Gao Y, Ma L, Lin C, Zhu S, Yao L, Fan H, Gong J, Yan X, Wang T. Effects of virtual reality-based intervention on cognition, motor function, mood, and activities of daily living In patients with chronic stroke: A systematic review and meta-analysis of randomized and controlled trials. Anterior Nerve Aging December 13, 2021; 13: 766525. doi: 10.3389 / fnagi.2021.766525. PMID: 34966267; PMCID: PMC8710683. 9. Wu J, Ma Y, Ren Z. Rehabilitation effects of virtual reality technology for mild cognitive disorders: A systematic review by meta-analysis. Psychological forward. 2020, September 25 11: 1811. doi: 10.3389 / fpsyg.2020.01811. PMID: 33101098; PMCID: PMC7545425.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee in Research of Imam Khomeini Hospital Complex - Tehran University of Medical Scienc

Street address
Imam Khomeini Hospital Complex, Dr. Gharib St, at the end of Keshavarz Blvd., Tehran.,

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Tehran

Province
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Postal code
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Approval date
2022-03-15, 1400/12/24

Ethics committee reference number
IR.TUMS.IKHC.REC.1400.502

Health conditions studied

1

Description of health condition studied
Mild cognitive impairment (MCI) is a common condition in the elderly characterized by impaired memory, attention, and cognitive function with regard to person's age and education. More specifically, MCI is characterized by cognitive complaint by the patient or his family, report of cognitive decline (compared to last year), the presence of obvious cognitive impairment with evident clinical evaluation, the absence of major problems in daily life and the absence of dementia.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Information processing speed: The amount of speed at which the brain can process and perceive information received from the environment.

Timepoint
before intervention, after (1-month) intervention and 1 month after the end of intervention period

Method of measurement
Integrated Cognitive Assessment(ICA)

2

Description
Visual-spatial function: includes the cognitive processes necessary to "identify, integrate and analyze space and visual form, details, structure and spatial relationships" in more than one dimension. Spatial visual skills are required for movement, depth and distance perception, and spatial navigation.

Timepoint
before intervention, after (1-month) intervention and 1 month after the end of intervention period

Method of measurement
Addenbrooke's Cognitive Examination III, Integrated Cognitive Assessment(ICA)

3

Description
Verbal memory: refers to the ability of memory to store information verbally. Vocabulary definitions, key details in a story, or the name of a species of living thing are all examples of verbal memory.

Timepoint
before intervention, after (1-month) intervention and 1 month after the end of intervention period

Method of measurement
Integrated Cognitive Assessment(ICA)

4

Description
Attention: It is the behavioral and cognitive process of selective focus on one aspect of information, whether subjective or objective, while ignoring other comprehensible information.

Timepoint
before intervention, after (1-month) intervention and 1 month after the end of intervention period

Method of measurement
Addenbrooke's Cognitive Examination III

5

Description
Executive Performance: A set of mental skills that include working memory, flexible thinking, and self-control.

Timepoint
before intervention, after (1-month) intervention and 1

month after the end of intervention period

Method of measurement

Addenbrooke's Cognitive Examination III

6

Description

Verbal psychology: A cognitive function that refers to retrieving information from memory.

Timepoint

before intervention, after (1-month) intervention and 1 month after the end of intervention period

Method of measurement

Addenbrooke's Cognitive Examination III

7

Description

Linguistic function: refers to a person's ability to use sign language. So that one can understand the meaning and also convey it.

Timepoint

before intervention, after (1-month) intervention and 1 month after the end of intervention period

Method of measurement

Addenbrooke's Cognitive Examination III

Secondary outcomes

1

Description

Walking speed: The basic criterion for walking is the initial ability of a person to walk. Walking speed shows us the time required to traverse a certain distance.

Timepoint

before intervention, after (1-month) intervention and 1 month after the end of intervention period

Method of measurement

10m dynamic walking speed test

2

Description

Gait ability: It is a measured to assess the patient's health in terms of walking which criterion such as the length and height of the step, the appearance of walking, symmetry of steps, continuity of steps, deviation from the path, walking speed, etc. are taken considered.

Timepoint

before intervention, after (1-month) intervention and 1 month after the end of intervention period

Method of measurement

Tinetti test

3

Description

Balance : It is an ability to maintain the line of gravity (vertical line from center of mass) of a body within the base of support and it is essential for success in performing daily life tasks.

Timepoint

before intervention, after (1-month) intervention and 1 month after the end of intervention period

Method of measurement

تست تینتی

4

Description

Life quality: It is the degree to which a healthy person is comfortable and can participate in or enjoy life events.

Timepoint

before intervention, after (1-month) intervention and 1 month after the end of intervention period

Method of measurement

SF-36 questionnaire

Intervention groups

1

Description

Intervention group: In addition to receiving routine services (physician consultation and diagnostic and therapeutic measures), this group receives virtual reality (VR) rehabilitation 3 days a week (for 1 month and a total of 12 sessions). VR rehabilitation is done in 30-minute sessions, under the supervision of trained experts, with the use of Oculus Quest 2 256G virtual reality headset (manufactured by Oculus from Facebook). This rehabilitation includes two games, "targeting" and "maze", the additional information of which is as follows: In the "oculus VR targeting game", the subject must use a virtual weapon to shot a moving target that appears in the environment. Over time, the difficulty of the task increases. For example, with increasing number of shots, the amount of movement, speed and size of the target changes, and it is expected that the accuracy and speed of action in targeting be affected. The aim of this game is to involve several cognitive processes by activating sensory-motor systems, information processing, speed of action and attention. In the "oculus VR maze game", a movement map is prepared from the VR environment in which the person is located and the person is asked to follow the path of the map to the end. Then the person has to re-enter the maze and reconstruct the movement plan based on what he remembers and move towards the destination. Also, the person faces challenges in his path that he has to overcome. The purpose of this game is to specifically engage cognitive processes related to visual-spatial attention and spatial memory. All members of this group are cognitively assessed before, immediately after and one month after the interventions to evaluate the effectiveness of the intervention in the process of cognitive development and improvement.

Category

Rehabilitation

2

Description

Control group: This group receives only the routine

services including physician consultation and diagnostic and therapeutic measures. These individuals are cognitively assessed before, immediately after, and one month after receiving the routine services.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh Hospital

Full name of responsible person

Zahra Vahabi

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Roozbeh Hospital, below Lashgar Crossroads, South Kargar Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Psychosomatic Research Center of Imam Khomeini Hospital

Full name of responsible person

Mrs. Babayi

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psychosomatcenter@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Psychosomatic Research Center of Imam Khomeini Hospital

Proportion provided by this source

30

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

Tehran University of Medical Sciences

Full name of responsible person

Zahra Vahabi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

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Person responsible for scientific inquiries

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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
Yes - There is 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
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
The results section of the study includes information of the main outcome (cognitive function) and related variables (executive function and attention, verbal memory, visual-spatial function, verbal psychology, linguistic function, information processing speed, gait and balance function, speed Walking and quality of life) can be shared after identifying people.
When the data will become available and for how long
Access starts 6 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Any kind of analysis is permissible except analyses which can result in personal information’s disclosures. The data must not be shared in any kind of social media or with other organizations.
From where data/document is obtainable
Via email address of the persons responsible for general inquiries and scientific inquiries.
What processes are involved for a request to access data/document
The reason for the information inquiry, the type of analysis to be performed, the type of study and the information of relevant organization should be explained the persons responsible for general inquiries and scientific inquires.
Comments