Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of cognitive rehabilitation on cognitive function in the elderly with mild cognitive impairment.

Protocol summary

Study aim
Investigating the effect of cognitive rehabilitation on cognitive function in the elderly with mild cognitive impairment.

Design
This is a randomized clinical trial with a parallel design and control group. This randomized, non-blinded study will be conducted on 78 eligible elderly people. A simple randomization method will be used for randomization, and participants will be assigned to three intervention groups (two intervention groups and one control group).

Settings and conduct
This study, which will be conducted at Farabi Hospital in Kermanshah, is non-blinded. At the beginning of the study, a cognitive function questionnaire will be provided to the elderly.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Informed consent; Age over 60 years; Obtaining a score between 18 and 25 on the Cognitive Performance Questionnaire; Having at least reading and writing skills Exclusion criteria: History of drug or alcohol addiction; History of neurological disorders or other psychiatric disorders (such as Parkinson's, multiple sclerosis, dementia, schizophrenia, bipolar, major depression) as diagnosed by a physician

Intervention groups
In the first intervention group, the elderly will undergo cognitive intervention in person for 12 two-hour sessions twice a week. In the second intervention group, they will undergo cognitive intervention digitally via computer (Rehacom software) for 12 two-hour sessions twice a week. In the control group, no intervention will be performed.

Main outcome variables
Cognitive function

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130812014333N271**
Registration date: **2025-12-27, 1404/10/06**
Registration timing: **prospective**

Last update: **2025-12-27, 1404/10/06**
Update count: **0**

Registration date
2025-12-27, 1404/10/06

Registrant information

Name
Feizollah Foroughi

Name of organization / entity
kermanshah University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-01-10, 1404/10/20

Expected recruitment end date
2026-03-16, 1404/12/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of cognitive rehabilitation on cognitive function in the elderly with mild cognitive

impairment.

Public title
Investigating the effect of cognitive rehabilitation on cognitive function in the elderly
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Informed consent Age over 60 years Obtaining a score between 18 and 25 on the Cognitive Performance Questionnaire Having at least reading and writing skills
Exclusion criteria:
History of drug or alcohol addiction History of neurological disorders or other psychiatric disorders (such as Parkinson's, multiple sclerosis, dementia, schizophrenia, bipolar, major depression) as diagnosed by a physician
Age
From **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **78**
Randomization (investigator's opinion)
Randomized
Randomization description
Using the simple random method. The names of the participants are written on the card. The cards are put into a box that cannot be seen from outside. One of the colleagues of the plan is asked to remove one card from the container at a time. The names of the 26 cards that are selected first are placed in the first intervention group, the second 26 selected cards are placed in the first control group, and the remaining 26 in the second control group
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
Ethics committee of Kermanshah University of Medical Sciences
Street address
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard
City
Keranshah
Province
Kermanshah
Postal code
6715847141
Approval date
2025-12-16, 1404/09/25
Ethics committee reference number
IR.KUMS.REC.1404.545

Health conditions studied

1

Description of health condition studied
Mild cognitive imparment
ICD-10 code
G31.84
ICD-10 code description
Mild cognitive impairment, so stated

Primary outcomes

1

Description
Cognitive function
Timepoint
Beginning of the study and end of the study (after 12 intervention sessions)
Method of measurement
Using the Montreal Cognitive Assessment Scale

Secondary outcomes

empty

Intervention groups

1

Description
In the first intervention group, the elderly will undergo in-person cognitive intervention for 12 two-hour sessions twice a week. Cognitive domain intervention will include visual-spatial, attention, language, executive functions, and abstract thinking and judgment.
Category
Treatment - Other

2

Description
In the second intervention group, they will undergo cognitive intervention digitally via computer (RehaCom software) for 12 ,two-hour sessions twice a week. Cognitive domain intervention will include visual-spatial, attention, language, executive functions, and abstract

thinking and judgment.

Category

Treatment - Other

3

Description

No intervention will be performed in the control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Farabi Hospital

Full name of responsible person

Yasaman Ghiasi

Street address

Farabi Hospital, Dolatabad Blvd, Isar Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Zohreh Rahimi

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Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

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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

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Yasaman Ghiasi

Position

Master's degree student in Geriatric Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Name of organization / entity

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Position

University faculty member

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Other areas of specialty/work

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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

There is no further information available.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available