Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the Impact of computer-based cognitive rehabilitation on cognitive function of older adults with diabetes and mild cognitive impairment

Protocol summary

Study aim
Determining the effect of computer-based cognitive rehabilitation on cognitive function in older adults with diabetes and mild cognitive impairment

Design
Randomized controlled trial, with parallel groups, single-blind. SPSS software was used for randomization.

Settings and conduct
Location of the study: Diabetes Center of Yazd city
Procedure: The intervention was conducted using a cognitive rehabilitation package

Participants/Inclusion and exclusion criteria
Inclusion criteria for the study include: elderly individuals aged 60 to 75 years, diagnosis of type 2 diabetes, having a medical record at the diabetes center, willingness to participate in the research, scoring below 26 on the MoCA test, possessing basic literacy skills, and having the ability to work with a computer. Exclusion criteria include: presence of diabetic foot ulcers, absence from at least two intervention sessions, use of medications affecting cognitive status, hospitalization, history of stroke, severe diabetes complications (such as requiring dialysis, complete blindness, or severe disability) that hinder proper implementation of the intervention and tests, and any medical or psychiatric condition that prevents the elderly from continuing participation in the study

Intervention groups
Cognitive rehabilitation tasks based on the 'Aram' and 'Parisa' packages will be provided to the intervention group twice a week over 10 sessions, each lasting 45 minutes. For the control group, a general educational session about diabetes and disease management, along with a pamphlet, will be provided

Main outcome variables
Improvement of cognitive function in the domains of selective attention, working memory, and inhibitory control in older adults with diabetes and mild cognitive impairment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240505061658N1**
Registration date: **2025-03-16, 1403/12/26**
Registration timing: **prospective**

Last update: **2025-03-16, 1403/12/26**
Update count: **0**

Registration date
2025-03-16, 1403/12/26

Registrant information

Name
Hassan Rezaeipandari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 35 3820 9148

Email address
hrezaeipandari@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-05-10, 1404/02/20

Expected recruitment end date
2025-06-10, 1404/03/20

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Impact of computer-based cognitive rehabilitation on cognitive function of older adults with diabetes and mild cognitive impairment

Public title

Investigating the Impact of Cognitive Rehabilitation on Improving Cognitive Function in Older Adults

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Elderly individuals aged 60 to 75 years Diagnosis of type 2 diabetes Willingness of the patient to participate in the study Scoring below 26 on the MoCA test Possessing basic literacy Ability to work with a computer Having a medical record at the diabetes center

Exclusion criteria:

Presence of diabetic foot ulcers Absence from at least two intervention sessions Use of medications affecting cognitive status Hospitalization Stroke Development of severe diabetic complications (such as the need for dialysis, complete blindness, or severe disability) that hinder proper implementation of the intervention and tests Presence of any medical or psychiatric condition that prevents the elderly individual from continuing participation in the study

Age

From **60 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Stratified randomization: To create equal entry conditions, an equal number of women and men will be assigned to each of the two intervention and control groups using a list created by SPSS software. Individuals eligible for study entry will be assigned to one of the two intervention and control groups based on this list, and the relevant interventions will be administered to that individual individually based on the intervention protocol. At the beginning of the study, the design partner will provide the principal investigator with envelopes containing the individuals' interventions in the order of entry into the study, based on the stratified random list created by the software, so that the assignment to the two groups remains hidden until the volunteer enters (allocation concealment).

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the nature of the intervention, it is not possible to blind the researcher and participants. Data Analyst: Data for analysis are provided to the analyst in coded form without identifying group affiliation. The analyst only examines the raw data and is not informed of the allocation of participants.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Faculty of Public Health - Shahid Sadoughi University of Medical Sciences, Yazd

Street address

Alam Square, Shohada-ye Gomnami Blvd, Shahid Sadoughi University of Medical Sciences and Health Services Campus, School of Public Health, Yazd

City

Yazd

Province

Yazd

Postal code

۸۹۱۵۱۷۳۱۶۰

Approval date

2025-03-01, 1403/12/11

Ethics committee reference number

IR.SSU.SPH.REC.1403.228

Health conditions studied

1

Description of health condition studied

Type 2 diabetes and Mild Cognitive Impairment

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Improvement in working memory performance, improved selective attention, and improved inhibitory control

Timepoint

Measurement of cognitive performance score at the beginning of the study and after the intervention

Method of measurement

Selective attention variable with Stroop test, Working Memory variable with N-back test, and Inhibitory Control

variable with Go-No-Go test.

Secondary outcomes

1

Description
Overall cognitive performance score
Timepoint
At the beginning of the study and immediately after the end of the intervention
Method of measurement
Cognitive performance score on the MOCA test

Intervention groups

1

Description
Intervention group: The Attention and Memory Rehabilitation Program is an applied software that is part of the educational neuroscience intervention called Cognitive Rehabilitation Intervention. The principles of this program are for hierarchical organization of easier to more difficult tasks. Immediate receipt for initial correct responses and lengthening of the final points; Design of working memory functions including change, transfer and ability; Entertainment and presentation with emotional stimuli have been found to increase motivation and the tasks can be repeated to the desired extent. The decision to perform higher stages has been tested and in the image that he cannot respond to a stage up to 80%, that stage will be repeated and the presence of the therapist is required to upgrade the task level. In the “Calm” program, three main entertaining computer tasks are given to the participants: the unilateral face task to shift attention, the similar windows task and the house finding task to maintain stability. These tasks are graded and the level of their responses is increased. The grading is based on the number of stimuli, the speed of stimuli presented, the number of targets, and the change of role of the roles. Several studies have examined the effectiveness of this training package. Also, in the computer program for the rehabilitation of the ability and attention of "PRISA", the packaging task will be used to promote inhibition. This program was developed in 2019 at the Center for Cognitive Behavioral Neuroscience, Shahid Beheshti University. Its validity and reliability in Iran have been evaluated by Nejati and research has shown the effectiveness of this program.
Category
Rehabilitation

2

Description
Control group: General educational session about diabetes and disease management with pamphlet
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
مرکز تحقیقاتی، درمانی دیابت یزد
Full name of responsible person
دکتر محمد افخمی اردکانی
Street address
End of Talaar Honar Alley, Shahid Sadoughi Blvd, Diabetes Research and Treatment Center
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Web page address
https://ydrc.ssu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Amir Houshang Mehrparvar
Street address
Banar Square, Central Building of Shahid Sadoughi University of Medical Sciences, Yazd
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Web page address
https://ssu.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Mohammadhossien Ahadi
Position
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Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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Phone
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m.hossien.ahadi@gmail.com

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
Not applicable
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The data will be made available in anonymized form (without identifying information such as name, contact number or address). All data will be shareable after individuals are rendered non-identifiable. The protocol will be made available to other researchers in its entirety and without restriction. The clinical study report will be made available to other researchers after the study is completed and approved by the ethics committee. The statistical analysis plan will be made available to other researchers in its entirety. The data dictionary contains definitions and codes for the variables collected in the study. This file will be made available to other researchers in its entirety.
When the data will become available and for how

long

Anonymized participant data will be available 6 months after the final study results are published in a reputable journal.

To whom data/document is available

Academic and scientific researchers, industrial researchers, governmental and non-governmental organizations, and students and independent researchers are permitted for research purposes and academic theses only.

Under which criteria data/document could be used

Permitted purposes of using data and documents: Scientific research, theses and dissertations, policy and planning, technology development. Requirements for submitting an access request: Submitting a written request: Applicants must send their written request along with details of the research project to the official study email. Purposes of use: Applicants must clearly state the exact purposes of using the data and documents. Commitment to complying with research ethics: Applicants must provide a written commitment to comply with the principles of research ethics and confidentiality of information.

From where data/document is obtainable

Send your application via email: Dr. Hassan Rezaei Pandari (Supervisor); Email: hrezaeipandari@yahoo.com

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

Applicants must complete the following steps to receive study data and documentation. This process typically takes 7 to 14 business days. The details of each step are as follows: Step 1: Submit a written request Applicant Action: The applicant must submit a written request to hrezaeipandari@yahoo.com with the following information: First and last name Organizational affiliation (university, institute, organization, etc.) Project title or purpose of data use Ethics committee approval (if applicable) Duration: This step begins immediately after the email is sent. Step 2: Initial review of the request Research team action: The research team reviews the request for completeness of the information and compliance with the permitted purposes of use. Duration: This step typically takes 1 to 2 business days. Review result: If the request is initially approved, the request is forwarded to the next step. If additional information is required, the applicant will be asked to submit additional information. Step 4: Prepare and submit data/documents Research team action: Data and documents are anonymized and prepared in Excel/CSV (for data) and PDF (for documents) files. Duration: This step usually takes 1-2 business days. Delivery method: Data and documents are provided to the applicant via email or secure download link. Was. Overall process duration: Minimum time: 7 business days (if the application is complete and no additional information is needed) Maximum time: 14 business days

Comments