Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 included elderly people aged 60 to 75 years, type 2 diabetes and having a file at the diabetes center, the patient's willingness to participate in the study, mild cognitive impairment according to Peterson's criteria, and computer skills. The presence of diabetic foot ulcers, use of medications that affect cognitive status, stroke, severe complications of diabetes (such as the need for dialysis, complete blindness, or severe disability) that prevent the appropriate implementation of the intervention and tests, and the presence of any medical or psychiatric disorder that prevents the elderly from continuing to participate in the study are considered as exclusion criteria.

Intervention groups

Rehabilitation tasks based on the Sina package will be provided to the intervention group once a week for 8 45-minute sessions. The control group will also be provided with a general education session about diabetes and disease management.

Main outcome variables

Improving performance in the areas of selective attention, working memory, inhibitory control, and overall cognitive function in elderly people with diabetes and mild cognitive impairment

General information

Reason for update

Following the final review and revision of the research protocol, some methodological details of the study require updating in the IRCT record to increase transparency, accuracy, and greater compliance with the actual research implementation process. Specifically, the amendments made to the fields related to inclusion and exclusion criteria, and intervention description are as follows: Inclusion criteria: The inclusion criteria have been revised and refined based on a more detailed review of the characteristics of the target population, the methodological requirements of the study, and the conditions necessary for the proper implementation of cognitive tests and intervention. Exclusion/exclusion criteria: The exclusion and exclusion criteria have also been revised and supplemented with regard to clinical conditions and factors that could affect the ability to perform cognitive assessments, receive the intervention, or continue participation of participants. These amendments are made with the aim of increasing participant safety, reducing confounding factors, and ensuring the proper implementation of the protocol. Intervention Description: The intervention description has been revised and supplemented to provide more detailed and clearer details about how the computer-based cognitive rehabilitation was implemented, the number and duration of sessions, the frequency of intervention, the delivery of sessions, and the conditions under which the intervention was implemented. The purpose of this revision is to more accurately reflect the actual implementation of the intervention and to provide greater reproducibility for the research. Overall, this update aims to refine and supplement the information recorded and to increase methodological transparency.

Acronym

IRCT registration information

IRCT registration number: **IRCT20240505061658N1**

Registration date: **2025-03-16, 1403/12/26**
Registration timing: **prospective**

Last update: **2026-09-17, 1405/06/26**
Update count: **1**

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

Registrant information

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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 Ability to work with a computer Having a medical record at the diabetes center Meeting Petersen criteria for mild cognitive impairment: (1) subjective cognitive decline (self or informant report), (2) objective cognitive impairment on MoCA (score < 26), (3) preserved independence in functional activities (no significant functional impairment based on clinical interview), and (4) not meeting criteria for dementia (memory impairment plus impairment in at least one other cognitive function, including aphasia, apraxia, agnosia, or disturbance in executive functioning)

Exclusion criteria:
Presence of diabetic foot ulcers Use of medications affecting cognitive status 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
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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
A) Computer program for training and improving attention and working memory: In this study, the computer program for training attention and working memory of the Sina Institute of Behavioral and Cognitive Sciences will be used for the intervention. This program was developed in 2010 by Khodadi et al., based on existing theories and modeled after the RoboMemo software. The program uses a simulation-based approach to elucidate the components of working memory and presents exercises in the form of an interactive computer game. The program includes a wide range of tasks designed to strengthen working memory through forward, reverse, and consolidation exercises, targeting auditory and visual components. The tasks are structured to start with simpler items and progress to more complex items over multiple sessions as the user progresses. Users are supported by memory improvement strategies embedded in the program, and feedback is provided by therapists and reinforced through audio-visual rewards to maintain engagement and motivation. The computer program organizes its exercises into three main categories: forward memory, reverse memory, and consolidation memory. Tasks are presented in two modes—verbal and visual—using stimuli such as shapes, letters of the alphabet, and numbers. Each category is divided into nine levels of increasing difficulty. In the numerical component, the numbers 1 through 9 are displayed in a 3 × 3 grid; in the letter-based tasks, 9 letters with similar pronunciations are used; and in the visual component, various shapes are presented. Users are required to respond to the stimuli using a software interface, usually by marking the location of each stimulus with a mouse. In forward tasks, users repeat the order of stimuli presented, while in reverse tasks, they respond in the opposite order. A scoring system provides real-time feedback, which is displayed in a score bar on the left side of the screen. Twenty points are awarded for each correct answer, while 10 points are deducted for each incorrect answer. Achieving five consecutive correct answers advances the user to a higher stage with greater stimulus complexity. Conversely, not earning enough points results in a return to the previous stage, ensuring adaptive difficulty commensurate with the user’s performance. Adapted to align with the Iranian cultural context, the software mirrors the structure of its English counterpart provided by CogMed, while incorporating culture-specific modifications to increase accessibility and engagement for Persian-speaking users. This localization ensures that the stimuli and user interface are tailored to the target population, maintaining the relevance and effectiveness of the program. B) Behavioral Inhibition Skill Computer Program: This computer program was developed at the Sinai Cognitive Behavioral Neuroscience Research Center by Khoddadi and colleagues in 2023 and has four different tasks, including green and red light tasks, auditory discrimination and inhibition, spinning wheel, and bird discrimination, to help improve inhibition skills. The difficulty level and timing of the tasks are adjustable. In the initial exercises, a lower difficulty level (longer stimulus presentation interval) and shorter execution time are used, and after acquiring skills and progress, the practice time is longer and the stimulus presentation interval is shorter to provide good mental challenge conditions. The results of all tasks and the subject's performance are recorded and can be accessed and reviewed. The score is calculated based on the following

formula: Score = number of correct answers - (number of incorrect answers * 3). The intervention group will participate in 8 45-minute cognitive rehabilitation sessions, once a week. The intervention will be delivered via the researcher's laptop and participants will receive guidance on how to complete the assignments. The sessions will be held in a distraction-free room at the Diabetes Research Center, with researcher supervision to ensure proper implementation.

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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

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Full name of responsible person

Mohammadhossien Ahadi

Position

Student

Latest degree

Master

Other areas of specialty/work

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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