Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effects of transcranial direct current stimulation (tDCS) combined with computer-based cognitive rehabilitation on brain mapping and cognitive functions in individuals with amnestic mild cognitive impairment (a-MCI)

Protocol summary

Study aim

Investigating the combined effect of transcranial direct current stimulation (tDCS) of the left temporal pole along with computer-based cognitive rehabilitation on brain maps and cognitive functions in individuals with mild cognitive impairment of the amnesic type (a-MCI): A study based on brain maps and neuropsychological assessment

Design

A randomized, double-blind, parallel-group controlled clinical trial on 30 individuals with a-MCI.

Settings and conduct

Thirty individuals diagnosed with mild cognitive impairment of the amnesic type in the city of Isfahan will be divided into two groups after meeting the entry criteria and will undergo paper-and-pencil and computer assessments, as well as electroencephalography (EEG). The intervention will consist of real and sham stimulation accompanied by cognitive rehabilitation for both groups. Finally, post-intervention assessments will be conducted, and the results will be compared and analyzed.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Diagnosis of mild cognitive impairment between the ages of 55 to 75 years. Exclusion Criteria: Presence of metal in the head and neck, and major psychiatric and neurological disorders.

Intervention groups

Intervention group: Received 12 sessions of direct stimulation along with cognitive rehabilitation using Rehacom software. Control group: Received the same intervention as the intervention group with a difference in the type of stimulation. This group received sham stimulation.

Main outcome variables

Computerized cognitive functions in MCI-related domains General cognitive performance Picture naming accuracy EEG indices

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250410065281N1**
Registration date: **2025-04-19, 1404/01/30**
Registration timing: **prospective**

Last update: **2025-04-19, 1404/01/30**
Update count: **0**

Registration date

2025-04-19, 1404/01/30

Registrant information

Name

Maedeh Shariat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-21, 1404/02/01

Expected recruitment end date

2026-04-21, 1405/02/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effects of transcranial direct current stimulation (tDCS) combined with computer-based cognitive rehabilitation on brain mapping and cognitive functions in individuals with amnestic mild cognitive impairment (a-MCI)

Public title
Investigating the effects of tDCS combined with computer-based cognitive rehabilitation on cognitive functions in individuals with a-MCI
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Individuals with a diagnosis of mild cognitive impairment between the ages of 55 and 75. Being a native Persian speaker Being right-handed Having at least a 5th-grade education Ability to collaborate in all stages of assessment, treatment, and follow-up (EEG acquisition, computerized and paper-pencil cognitive tests, rehabilitation sessions, and brain stimulation with tDCS)
Exclusion criteria:
Any uncorrectable defects in visual and auditory senses Presence of any metal implants in the head and chest History of untreated neurological disorders and history of epilepsy History of major psychiatric disorders in the past year function History of cardiovascular, respiratory, and skin diseases History of substance abuse and alcohol consumption Current use of medications affecting brain function Simultaneous participation in another study related to the nervous system and cognitive
Age
From **55 years** old to **75 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
A simple randomization method is used for randomization. The tool utilized is an online randomization software. In this way, the principal investigator assigns codes from one to thirty, which are distributed into the intervention and control groups using random distribution software, to the participants in the order of their entry into the study. Thus, individuals are randomly assigned to the two groups. There is no concealment of any part of the study conducted by the principal investigator.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, regarding the type of transcranial electrical stimulation, the participant remains uninformed, such that all procedures are conducted similarly to the intervention group, and the sham stimulation produces similar skin effects as the real stimulation. The individual performing the data analysis conducts the analysis using group codes (A and B) instead of the names of the interventions, remaining unaware of the type of intervention for each group
Placebo
Used
Assignment
Parallel
Other design features
The stimulation area with tDCS in this study is the temporal pole, and EEG data will be analyzed before and after the intervention.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shiraz University of Medical Sciences Ethics Committee
Street address
Central Building of Shiraz University of Medical Sciences Zand Street, Opposite Palestine Street Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
71348-14336
Approval date
2025-04-09, 1404/01/20
Ethics committee reference number
IR.SUMS.REC.1404.013

Health conditions studied

1

Description of health condition studied
Mild Cognitive Impairment
ICD-10 code
F06.7
ICD-10 code description
Mild cognitive disorder: A disorder characterized by impairment of memory, learning difficulties, and reduced ability to concentrate on a task for more than brief periods. There is often a marked feeling of mental fatigue when mental tasks are attempted,

Primary outcomes

1

Description
EEG indicators
Timepoint
Pre and post the intervention
Method of measurement
Complete tools and software for recording and analyzing electroencephalography signals

Secondary outcomes

1

Description
Cognitive performance in domains related to MCI in CANTAB
Timepoint
Pre and post the intervention
Method of measurement
Scores obtained from performing the MCI-related domains in the CANTAB Computerized Assessment Battery

2

Description
Overall cognitive performance in MoCA and Adenbrook tests
Timepoint
Pre and post the intervention
Method of measurement
Score obtained from the performance on the MoCA and Adenbrook pencil-paper tests

3

Description
Percentage of accuracy in picture naming
Timepoint
Pre and post the intervention
Method of measurement
Percentage of correctly named items in the picture naming test

Intervention groups

1

Description
Intervention Group: Each individual in this group will undergo intervention over 12 sessions during a period of 4 weeks. The intervention consists of receiving 45 minutes of cognitive rehabilitation using the RehaCom software, focusing on memory and language-related indices, along with 20 minutes of anodal-transcranial direct current stimulation (anodal-tDCS) at an intensity of 2 milliamperes applied to the left temporal pole, which begins simultaneously with the start of the rehabilitation. At the beginning of each session, the setup and connections for the electrical stimulation are made on the individual's head while they are positioned in front of a touchscreen computer. Then, after explaining what is about to happen, the stimulation begins, and simultaneously, the individual receives the various stages of cognitive rehabilitation according to the necessary instructions provided by the therapist. The difficulty level of the exercises gradually increases, based on an 80% correct response rate. After 20 minutes, the stimulation is completed, and the rehabilitation continues in the same manner.
Category
Treatment - Devices

2

Description
Control Group: Each individual in this group will undergo intervention over 12 sessions during a period of 4 weeks. The intervention includes 45 minutes of cognitive rehabilitation using the RehaCom software, focusing on memory and language-related indices, along with 20 minutes of sham transcranial direct current stimulation (sham-tDCS) that creates sensations similar to real stimulation on the left temporal pole, which is provided simultaneously with the start of the rehabilitation.At the beginning of each session, the settings and connections for the electrical stimulation are made on the individual's head, similar to real stimulation, while they are positioned in front of a touchscreen computer. Following an explanation of what is about to happen, the stimulation begins, and simultaneously, the individual receives various stages of cognitive rehabilitation based on the necessary instructions provided by the therapist. The difficulty level of the exercises gradually increases, based on an 80% correct response rate. After 20 minutes, the sham stimulation concludes, and the rehabilitation continues in the same manner.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan Cognitive Lab
Full name of responsible person
Dr. Maahgol Tavakolli
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Cognitive Laboratory, Second Floor, Faculty of Educational Sciences, University of Isfahan, University Street
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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
Shiraz 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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Person responsible for updating data

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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