Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Combined Effects of Repetitive Transcranial Magnetic Stimulation (rTMS) of the Cerebellum and the Dorsolateral Prefrontal Cortex (DLPFC) on Cognitive Functions in Older Adults with Mild Cognitive Impairment (MCI)

Protocol summary

Study aim

To evaluate the effects of repetitive transcranial magnetic stimulation of the cerebellum, the dorsolateral prefrontal cortex, and their combined stimulation on cognitive functions in older adults with mild cognitive impairment.

Design

Single blind, randomized, sham controlled, parallel group clinical trial with four groups and 24 participants. Block randomization with concealed allocation will be used. This is a non drug clinical trial.

Settings and conduct

The study will be conducted in the research laboratories of the Cognitive Neuroscience Center at the University of Tabriz and neurotherapy clinics equipped with transcranial magnetic stimulation devices in Tabriz, Iran. Eligible participants will receive 10 intervention sessions according to their assigned group. Participants will be blinded to treatment allocation. Cognitive assessments will be performed before and after completion of the intervention.

Participants/Inclusion and exclusion criteria

Older adults aged 60 to 80 years with mild cognitive impairment and a Montreal Cognitive Assessment score of 19 to 25. Exclusion criteria include dementia, epilepsy or seizure history, contraindications to transcranial magnetic stimulation, major psychiatric disorders, severe neurological diseases, or medications that increase seizure risk.

Intervention groups

Four groups: sham stimulation; cerebellar repetitive transcranial magnetic stimulation; dorsolateral prefrontal cortex repetitive transcranial magnetic stimulation; combined cerebellar and dorsolateral prefrontal cortex repetitive transcranial magnetic stimulation.

Main outcome variables

Episodic memory; visuospatial working memory; executive function.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260722070303N1**
Registration date: **2026-07-24, 1405/05/02**
Registration timing: **registered_while_recruiting**

Last update: **2026-07-24, 1405/05/02**
Update count: **0**

Registration date

2026-07-24, 1405/05/02

Registrant information

Name

Masoud Ghaffarvand-Mokari

Name of organization / entity

University of Tabriz

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-04-21, 1405/02/01

Expected recruitment end date

2026-08-06, 1405/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Combined Effects of Repetitive Transcranial Magnetic Stimulation (rTMS) of the Cerebellum and the Dorsolateral Prefrontal Cortex (DLPFC) on Cognitive Functions in Older Adults with Mild Cognitive Impairment (MCI)

Public title

Combined rTMS for Mild Cognitive Impairment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adults aged 50 years and older Diagnosis of Mild Cognitive Impairment according to Petersen Criteria MoCA score 19-25 Ability to provide informed consent medication during the previous 4 weeks Right-handedStable

Exclusion criteria:

Diagnosis of dementia History of epilepsy or seizure Metallic implants contraindicated for TMS Major psychiatric disorders History of stroke or other severe neurological disease Current use of medications lowering seizure threshold

Age

From **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants who meet the eligibility criteria and provide written informed consent will be randomly allocated to one of four parallel groups, including Sham stimulation, Cerebellar rTMS, DLPFC rTMS, and Combined Cerebellar plus DLPFC rTMS, with an allocation ratio of 1:1:1:1. Block randomization will be performed using a computer-generated random sequence prepared by an independent researcher. Allocation concealment will be maintained using sequentially numbered, opaque, sealed envelopes. After completion of the baseline assessment, the intervention operator will open the corresponding envelope and administer the assigned intervention. The participants will remain blinded to group allocation, while the intervention operator will be aware of the assigned group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants who meet the eligibility criteria and provide written informed consent will be randomly allocated to one of four parallel groups, including Sham stimulation, Cerebellar rTMS, DLPFC rTMS, and Combined Cerebellar plus DLPFC rTMS, with an allocation ratio of 1:1:1:1. Block randomization will be performed using a computer-generated random sequence prepared by an independent researcher. Allocation concealment will be maintained using sequentially numbered, opaque, sealed envelopes. After completion of the baseline assessment, the intervention operator will open the corresponding envelope and administer the assigned intervention. The participants will remain blinded to group allocation, while the intervention operator will be aware of the assigned group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University

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29 Bahman Blvd.,Tabriz, Iran 5166616471

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Approval date

2026-02-18, 1404/11/29

Ethics committee reference number

IR.TABRIZU.REC.1404.228

Health conditions studied

1

Description of health condition studied

Mild Cognitive Impairment (MCI)

ICD-10 code

G31.84

ICD-10 code description

Mild cognitive impairment, so stated

Primary outcomes

1

Description

Episodic memory score

Timepoint

Before the intervention and after completion of 10

intervention sessions

Method of measurement

Rey Auditory Verbal Learning Test

Secondary outcomes

1

Description

Visuospatial working memory score

Timepoint

Before the intervention and after completion of 10 intervention sessions

Method of measurement

Corsi Block Tapping Test

2

Description

Executive function score

Timepoint

Before the intervention and after completion of 10 intervention sessions

Method of measurement

Tower of London Test

3

Description

Global cognitive function score

Timepoint

Before the intervention and after completion of 10 intervention sessions

Method of measurement

Montreal Cognitive Assessment

Intervention groups

1

Description

Control group: transcranial magnetic stimulation over both the cerebellum and the left dorsolateral prefrontal cortex for 10 sessions, one session per day. During each session, the coil will first be positioned over the cerebellar target and then over the left dorsolateral prefrontal cortex. The coil will be held at a 90-degree angle relative to the scalp to prevent effective brain stimulation. The duration and sequence of sham stimulation will be similar to those used in the active intervention groups, using the same device and figure-of-eight coil.

Category

Placebo

2

Description

Intervention group:followed by active repetitive transcranial magnetic stimulation over the left dorsolateral prefrontal cortex for 10 sessions, one session per day. First, the coil will be positioned over the cerebellar target at a 90-degree angle relative to the scalp, and sham stimulation corresponding to 1,000 pulses will be administered. Active stimulation will then be applied over the left dorsolateral prefrontal cortex at 10 Hertz, 100 percent of the resting motor threshold, and 2,000 pulses per session using a figure-of-eight coil.

Category

Treatment - Devices

3

Description

Intervention group:Participants in this group will receive active cerebellar repetitive transcranial magnetic stimulation followed by sham stimulation over the left dorsolateral prefrontal cortex for 10 sessions, one session per day. Active cerebellar stimulation will be delivered at 5 Hertz, 90 percent of the resting motor threshold, and 1,000 pulses per session using a figure-of-eight coil. The coil will then be positioned over the left dorsolateral prefrontal cortex at a 90-degree angle relative to the scalp, and sham stimulation corresponding to 2,000 pulses will be administered.

Category

Treatment - Devices

4

Description

Intervention group:magnetic stimulation over both the cerebellum and the left dorsolateral prefrontal cortex for 10 sessions, one session per day. Cerebellar stimulation will first be delivered at 5 Hertz, 90 percent of the resting motor threshold, and 1,000 pulses per session. Active stimulation will then be applied over the left dorsolateral prefrontal cortex at 10 Hertz, 100 percent of the resting motor threshold, and 2,000 pulses per session. Both stimulations will be delivered using the same device and figure-of-eight coil.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Farhoudi Neurology Clinic

Full name of responsible person

Dr Mehdi Farhoudi

Street address

8th Floor, Sib Medical Building, Opposite Pardis Building, New Pasteur 2 Street, between Haj Jabbar Nayeb Intersection and Taleghani Intersection, Tabriz, Iran.

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Sponsors / Funding sources

1

Sponsor
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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
University of Tabriz
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

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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
Not applicable

Analytic Code
No - There is not a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Deidentified individual participant data, the data dictionary, study protocol, statistical analysis plan, and a blank copy of the informed consent form will be available for sharing. The shared dataset may include demographic variables, group allocation, intervention parameters, and cognitive outcome scores measured before and after the intervention. All information that could identify participants will be removed before data sharing.

When the data will become available and for how long
Data and supporting documents will be available from 12 months after publication of the main study results and will remain available for 5 years.

To whom data/document is available
Researchers affiliated with recognized universities, research institutions, or scientific centers may request access after submitting a specific research proposal that is scientifically and ethically acceptable.

Under which criteria data/document could be used
The data may be used for scientific analyses related to mild cognitive impairment, transcranial magnetic stimulation, reanalysis of study findings, systematic reviews, and meta-analyses. Access will require approval of the research proposal, a commitment to confidentiality, agreement not to attempt participant identification, and completion of a data use agreement. Commercial use or transfer of the data to third parties without written permission will not be allowed.

From where data/document is obtainable
Requests should be submitted by email to the responsible researcher, Masoud Ghaffarvand Mokari, University of Tabriz, Tabriz, Iran. Applicants should provide their personal and institutional details, the purpose of the request, the proposed analysis plan, and relevant ethics approval documents.

What processes are involved for a request to access data/document
Requests must be submitted in writing and include the research objective, analysis plan, institutional affiliation of the researchers, and relevant ethics approval. The request will be reviewed by the responsible researcher and the study supervisor. A decision will be communicated within 30 days. Following approval and completion of a data use agreement, the files will be transferred through a secure electronic method.

Comments