

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Comparing the Effects of Cognitive Training and Repetitive Transcranial Magnetic Stimulation On Improvement of Cognitive Functions and Activities of Daily Living Among Mild Cognitive impairment Individuals with High and Low Levels of Cognitive Reserve: An Embedded Study

Protocol summary

Study aim

Determining the effectiveness of cognitive training and recurrent transcranial magnetic stimulation (rTMS) on improving cognitive functions (attention, visual-spatial function, memory, executive function, language) in the elderly with mild cognitive impairment

Design

To compare the effectiveness of therapies in the groups, the required sample size in each group was calculated to be 3 subjects in each group (12 people in total), which will be selected after a diagnostic interview and from among qualified individuals.

Settings and conduct

The statistical population of the study includes all elderly people over 60 years old living in Isfahan and Kerman. Executive steps of research 1- Refer to centers for the elderly such as retirement centers, accommodation centers for the elderly (day and night accommodation centers), hospitals, and cognitive research centers 2- Clinical interview of those interested in participating in the research in accordance with DSM-5 diagnostic criteria 3- Separation of subjects with MCI in terms of cognitive reserve level 4- Implementing research tools for all participants (baseline assessment) 5 - Random assignment of subjects with MCI in four intervention groups 6- Performing all intervention sessions

Participants/Inclusion and exclusion criteria

Inclusion criteria: The subject in the NUCOG test should get a score between 75 and 85 and be over 60 years old.

Intervention groups

Four groups will participate in this study: cognitive intervention group with high cognitive reserve; Cognitive intervention group with low cognitive reserve; RTMS intervention group with high cognitive reserve; RTMS intervention group with low cognitive reserve

Main outcome variables

Analysis and comparison of two methods of cognitive training and repetitive transcranial magnetic stimulation (rTMS) taking into account the amount of cognitive reserve of individuals

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221031056347N1**

Registration date: **2022-11-15, 1401/08/24**

Registration timing: **prospective**

Last update: **2022-11-15, 1401/08/24**

Update count: **0**

Registration date

2022-11-15, 1401/08/24

Registrant information

Name

Mohammad Ghaderi Rammazi

Name of organization / entity

Isfahan University

Country

Iran (Islamic Republic of)

Phone

+98 34 3252 5756

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-30, 1401/10/09

Expected recruitment end date

2023-01-29, 1401/11/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Effects of Cognitive Training and Repetitive Transcranial Magnetic Stimulation On Improvement of Cognitive Functions and Activities of Daily Living Among Mild Cognitive impairment Individuals with High and Low Levels of Cognitive Reserve: An Embedded Study

Public title

Comparing the Effects of Cognitive Training and Repetitive Transcranial Magnetic Stimulation On Improvement of Cognitive Functions and Activities of Daily Living Among Mild Cognitive impairment Individuals

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

At least 60 years old NUCOG score between 75 and 85

Exclusion criteria:

Severe physical or mental disability that prevents the person from actively participating in the study Not having the minimum level of education (reading and writing literacy)

AgeFrom **60 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **12****Randomization (investigator's opinion)**

Not randomized

Randomization description**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**

Research Ethics Committees of University of Isfahan

Street address

No 325, 3rd Floor, Central Building, University of Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673441

Approval date

2021-09-18, 1400/06/27

Ethics committee reference number

IR.UI.REC.1400.049

2**Ethics committee****Name of ethics committee**

Research Ethics Committees of Kerman University of Medical Sciences

Street address

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

City

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7616913555

Approval date

2022-03-07, 1400/12/16

Ethics committee reference number

IR.KMU.REC.1400.698

Health conditions studied**1****Description of health condition studied**

Mild cognitive impairment

ICD-10 code

F06.7

ICD-10 code description

Mild cognitive disorder

Primary outcomes**1****Description**

The participant's score on the Neuropsychiatry Unit Cognitive Assessment Tool (NUCOG)

Timepoint

Before intervention, Session 3, Session 7, and Session 10

Method of measurement

The Neuropsychiatry Unit Cognitive Assessment Tool (NUCOG)

2

Description

The participant's score on the Instrumental Activities of Daily Living Scale (IADL)

Timepoint

Before intervention, Session 3, Session 7, and Session 10

Method of measurement

Instrumental Activities of Daily Living Scale (IADL)

Secondary outcomes

1

Description

Cognitive functions

Timepoint

Before starting the intervention and in sessions 3, 7, and 10

Method of measurement

NUCOG TEST

2

Description

Activities of daily living

Timepoint

Before starting the intervention and in sessions 3, 7, and 10

Method of measurement

Instrumental activities of daily living scale

Intervention groups

1

Description

The first intervention group: the group of "participants with high cognitive reserve" who receive "cognitive training intervention" for 10 sessions. Cognitive intervention is carried out twice a week and lasts a total of 5 weeks. The content of various training sessions is in the following six areas:1. Memory (Episodic memory)2. Attention3. Executive Function (cognitive flexibility)4. Executive Function (inhibitory control)5. Executive Function (working memory)6. Language (word finding)

Category

Rehabilitation

2

Description

The second intervention group: the group of "participants with low cognitive reserve" who receive "cognitive training intervention" for 10 sessions. Cognitive intervention is carried out twice a week and lasts a total of 5 weeks. The content of various training sessions is in the following six areas:1. Memory (Episodic memory)2. Attention3. Executive Function (cognitive flexibility)4. Executive Function (inhibitory control)5. Executive Function (working memory)6. Language (word finding)

Category

Rehabilitation

3

Description

The third intervention group: the group of "participants with high cognitive reserve" who receive "rTMS intervention" for 10 sessions. The rTMS intervention consists of two repeated sessions of transcranial magnetic stimulation during the week, each session will last for about 20 minutes, which will last for a total of 5 weeks.

Category

Treatment - Devices

4

Description

The fourth intervention group: the group of "participants with low cognitive reserve" who receive "rTMS intervention" for 10 sessions. The rTMS intervention consists of two repeated sessions of transcranial magnetic stimulation during the week, each session will last for about 20 minutes, which will last for a total of 5 weeks.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Nouri Psychiatric Hospital

Full name of responsible person

Dr. Hojjatullah Moradi

Street address

Nouri Psychiatric Hospital, Modiriyat Three Ways, Kerman

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Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Isfahan

Full name of responsible person

Dr. Hadi Amiri (Deputy Research and Technology

University of Isfahan)

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Isfahan, Azadi square, University of Isfahan

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Web page address

<https://research.ui.ac.ir/page-MainResearch/fa/17/form/pld15432>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Cognitive Science and Technologies Council (CSTC)

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

2

Sponsor

Name of organization / entity

Cognitive Science and Technologies Council (CSTC)

Full name of responsible person

Seyyed Kamal Kharazi

Street address

No 35, CSTC Building, Alvand St, Argentina Sq, Tehran, Iran.

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Email

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Web page address

<https://cogc.ir/?lang=2>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Cognitive Science and Technologies Council (CSTC)

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

Isfahan University

Full name of responsible person

Mohammad Ghaderi Rammazi

Position

PhD candidate

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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Name of organization / entity

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Person responsible for updating data

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Position

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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

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

Yes - There is 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

Title and more details about the data/document

Only part of the data such as information about the main outcome or the like can be shared.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

Request by email only

From where data/document is obtainable

The request should be sent by email and in person to:
mohammade.ghaderi@gmail.com

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

After receiving the email, the researcher will be answered as soon as possible

Comments