

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jul 2026

**Comparison of cognitive rehabilitation, Transcranial Alternating Current Stimulation (tACS), combination of cognitive rehabilitation and Transcranial Alternating Current Stimulation ,and the effect of vitamin D on cognitive and executive functions of patients with mild cognitive impairment (MCI).**

### Protocol summary

#### Study aim

Comparison of the effectiveness of cognitive rehabilitation, Transcranial Alternating Current Stimulation, combination of cognitive rehabilitation and Transcranial Alternating Current Stimulation, and the effect of vitamin D on cognition and executive functions of patients with mild cognitive impairment.

#### Design

Four parallel group will be randomised trail design of 32 patients with mild cognitive impairment.

#### Settings and conduct

The study will be conducted randomly and based on two-stage sampling on people who have mild cognitive impairment in Ayatollah Taleghani Hospital.

#### Participants/Inclusion and exclusion criteria

Entry criteria: Over 60 years old. Literacy for reading and writing. Having mild cognitive impairment according to MMSE and Moca test. No history of head injury. Absence of digestive disorders. Not having medical background. Exit criteria: No wanting to participate in the test and continue the treatment.

#### Intervention groups

Cognitive rehabilitation group (8 patients). Transcranial Alternating Current Stimulation group (8 patients). Combination cognitive rehabilitation and Transcranial Alternating Current Stimulation group (8patients). Vitamin D recipient (8 patients).

#### Main outcome variables

The effect of cognitive rehabilitation on the executive and cognitive functions of the brain. The effect of intermittent brain stimulation on the executive and cognitive functions of the brain. The effect of combination of cognitive rehabilitation and intermittent brain stimulation on the executive and cognitive

functions of the brain. The effect of vitamin D on the executive and cognitive functions of the brain.

### General information

#### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230125057214N1**

Registration date: **2023-03-11, 1401/12/20**

Registration timing: **retrospective**

Last update: **2023-03-11, 1401/12/20**

Update count: **0**

#### Registration date

2023-03-11, 1401/12/20

#### Registrant information

##### Name

Fariba Ebrahimbabaie

##### Name of organization / entity

Ayatollah Taleghani Hospital

##### Country

Iran (Islamic Republic of)

##### Phone

+98 912 819 9386

##### Email address

faribaebrahimbabaie@yahoo.com

#### Recruitment status

##### Recruitment complete

#### Funding source

#### Expected recruitment start date

2023-01-27, 1401/11/07

#### Expected recruitment end date

2023-01-27, 1401/11/07  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Comparison of cognitive rehabilitation, Transcranial Alternating Current Stimulation (tACS), combination of cognitive rehabilitation and Transcranial Alternating Current Stimulation ,and the effect of vitamin D on cognitive and executive functions of patients with mild cognitive impairment (MCI).

**Public title**  
Investigating the effect of cognitive rehabilitation, Transcranial Alternating Current Stimulation, combination of and cognitive rehabilitation and Transcranial Alternating Current Stimulation, and the effect of vitamin D on cognitive and executive functions.

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Over 60 years old Ability to reading and writing Having MCI according to MMSE and MOCA No history of head. injury Absence of digestive disorders Not having underlying diseases  
**Exclusion criteria:**  
Not wanting to participate in the test and continue the treatment.

**Age**  
From 60 years old

**Gender**  
Both

**Phase**  
2

**Groups that have been masked**  
No information

**Sample size**  
Target sample size: 16

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
In order to randomly assign subjects to test groups and create balance in the samples assigned to each group, the method of 8 random blocks will be used. The size of all the blocks will be equal and 8 subjects will be placed in each block. 8 people in the first intervention group, 8 people in the second, 8 people in the third and 8 people in the fourth intervention group. The randomization tool is the random generation software Randomallocation. In this way, the output of the software includes different modes of random order A-A, B-B, C-C and D-D. For each of the blocks, a different order will be applied to the gambling of the participants in the study groups. In this process, the order of participants based on blocks cannot be predicted.

**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

Ethic committee of Lorestan University of Medical Sciences.

##### Street address

No. 106, Kachoe Ave, Velenjak.

##### City

Tehran

##### Province

Tehran

##### Postal code

1983914514

#### Approval date

2022-09-11, 1401/06/20

#### Ethics committee reference number

IR.LUMS.REC.1401.136

## Health conditions studied

### 1

#### Description of health condition studied

Mild cognitive impairment

#### ICD-10 code

F06

#### ICD-10 code description

Other mental disorders due to brain damage and dysfunction and to physical disease

## Primary outcomes

### 1

#### Description

The percentage of people whose Montreal Cognitive Assessment scores will improve.

#### Timepoint

Before the start of the test, the second and fourth week and one month after the treatment.

#### Method of measurement

Montreal Cognitive Assessment.

### 2

#### Description

The percentage of people whose Mini-Mental State Examination scores will improve.

**Timepoint**

Before the start of the test, the second and fourth week and one month after the treatment.

**Method of measurement**

Mini-Mental State Examination.

**Secondary outcomes****1****Description**

The percentage of people whose Beck Depression Inventory will decrease.

**Timepoint**

Before the start of the test, the second and fourth week and one month after treatment

**Method of measurement**

Beck's Depression Inventory

**Intervention groups****1****Description**

Intervention group 1: The effect of ten 20- minute sessions of Transcranial Alternating Current Stimulation on executive functions of people with mild cognitive impairment

**Category**

Treatment - Other

**2****Description**

Intervention group 2: The effect of ten 20- minute sessions of cognitive rehabilitation on executive functions of people with mild cognitive impairment

**Category**

Treatment - Other

**3****Description**

Intervention group3 : Combination of ten 20- minute sessions of ranscranial Alternating Current Stimulation and cognitive rehabilitation on executive functions of people with mild cognitive impairment

**Category**

Treatment - Other

**4****Description**

Intervention group 4: The effect of one month of vitamin D consumption on executive functions of people with mild cognitive impairment

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Ayatollah Taleghani Hospital

**Full name of responsible person**

Parisa Taheri Tanjani

**Street address**

Ayatollah Taleghani Hospital, Shahid Arabi Ave, Yaman Ave.

**City**

Tehran

**Province**

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**Postal code**

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**Phone**

+98 21 2243 2560

**Email**

taleghanihospital@sbm.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Cognitive Sciences and Technologies Council

**Full name of responsible person**

Sayed Kamal Kharazi

**Street address**

No. 3, Daryabandari avenue, Nelson Mandella,Jordan, Valiasr.

**City**

Tehran

**Province**

Tehran

**Postal code**

1967875319

**Phone**

+98 21 2266 0770

**Email**

info@cogc.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Cognitive Sciences and Technologies Council

**Proportion provided by this source**

20

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

Other

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Khoram-Abad University of Medical Sciences

**Full name of responsible person**

Fariba Ebrahimbabaie

**Position**

Phd student

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

PHD, student

**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

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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**

Undecided - It is not yet known if there will be 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**

Thesis data and articles.

**When the data will become available and for how long**

Untill 20 February ۲۰۲۳

**To whom data/document is available**

Psychologists and Researchers.

**Under which criteria data/document could be used**

Email

**From where data/document is obtainable**

Contact Number 09128199386 Refer to Cognitive Science and Technologies Council and contact Number 02122660770

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

Collection of research data, statistical data analysis, writing an article, acceptance of articles n the journal

**Comments**