Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 impairement.

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, comibination 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 asssigned 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 Randomalocation. 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, Kachoee 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
Tehran
Postal code
1985711151
Phone
+98 21 2243 2560
Email
taleghanihospital@sbmu.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 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