

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The potential effect of transcranial direct current stimulation(tDCS) as an add-on to main-stream cognitive treatment in subjective cognitive impairment referring to cognitive clinics in Shiraz (A sham-control study)

Protocol summary

Study aim

1.Evaluation of cognitive function in Subjective Cognitive Impairment(SCI) subjects after receiving tDCS in the dorsolateral part of Pre Frontal Cortex (dIPFC) and Parietal Cortex (PC) 2. Evaluation of fMRI components including Functional Connectivity after receiving tDCS in the(dIPFC) and(PC) 3. Determining the correlation of fMRI findings with the outcome of cognitive functions of patients after receiving tDCS 4.Comparing the effectiveness of real-tDCS and Sham-tDCS in improving cognitive functions in SCI .

Design

A randomized, double blinded, sham controlled clinical trial with a parallel group design of 20 patients, we will use block method for randomization

Settings and conduct

The primary interview and basic cognitive tests are conducted in the neuroscience laboratory ,participants randomly enroll in to the one of two groups of study, and receive ten treatment sessions(real or sham tDCS +cognitive rehabilitation exercises).At the end, the cognitive tests of the first session will be repeated. Ten of these people will do MRI at the beginning and end of the sessions.

Participants/Inclusion and exclusion criteria

incl. criteria: People (male/female) who have complaints about their cognitive functions, In performing cognitive tests, impairment can be seen in at least two cognitive areas; age between 30- 65 ex. criteria: Presence of clinical diagnosis of any neuropsychological disorder in medical history; drug abuse; VAS(visual analog scale) scale > 5 ; Presence of sever attention and concentration disorder; chronic sleep disorder ; using drugs with memory disturbances side effects; sever anxiety; history of head trauma; history of brain surgery; epilepsy

Intervention groups

intervention group: real-tDCS + cognitive rehabilitation

control group: Sham-tDCS + cognitive rehabilitation

Main outcome variables

Improving the cognitive status of SCI patients, especially in memory domain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181109041598N2**

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

Registration timing: **registered_while_recruiting**

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

Update count: **0**

Registration date

2022-11-15, 1401/08/24

Registrant information

Name

Seyedeh-saeedeh Yahyavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3230 5471

Email address

saeedehyahyavi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-22, 1401/07/30

Expected recruitment end date

2023-02-19, 1401/11/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The potential effect of transcranial direct current stimulation (tDCS) as an add-on to main-stream cognitive treatment in subjective cognitive impairment referring to cognitive clinics in Shiraz (A sham-control study)

Public title
effect of transcranial direct current stimulation (tDCS) on treatment of subjective cognitive impairment (SCI)

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
People who have complaints about their cognitive functions In performing cognitive tests, impairment can be seen in at least two cognitive areas
Exclusion criteria:
Presence of clinical diagnosis of any Neuropsychological and Neurological disorder in the patient's medical history
Drug abuse Caffeine consumption in the last 12 hours before the primary test. VAS scale > 5 before the primary test
Presence of severe attention and concentration disorder
Chronic sleep disorder
Using drugs with memory disturbances side effects
Severe Anxiety
History of head trauma
History of Head and Brain Surgery
Epilepsy

Age
From **30 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Data analyst

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the law of random allocation will be used, for this purpose, first, it is equal to the size of the total sample, we assign twenty papers with equal sizes to the groups of real and sham electrical stimulation with the codes A and B. Determining the group of people included in the study, a piece of paper is randomly removed from the container, they receive the real stimulation for code A and the B code receive sham stimulation. The removal of the papers will be without returning and replacing.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the people participating in the study do not know whether they are receiving a real tDCS or a sham tDCS, so that even in the sham group, the current is

applied for thirty seconds with a less than effective intensity so that the person feels that he is performing an electrical stimulation to give it has become real. Also, in the continuation of the analyzers, he does not know about the grouping.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Science

Street address

Diamond Building, 29 Alley, Qasr al-Dasht Street

City

Shiraz

Province

Fars

Postal code

7133654361

Approval date

2021-12-05, 1400/09/14

Ethics committee reference number

IR.SUMS.REC.1400.655

Health conditions studied

1

Description of health condition studied

Subjective cognitive impairment (SCI) or a complaint about the cognitive inefficiency is defined as: the subjective dissatisfaction about cognitive function that have recently occurred, and this is despite the fact that there may be a problem from an objective point of view. and the quality of the person's life has not been affected

ICD-10 code

G32.8*

ICD-10 code description

subjective cognitive impairment, SCI, subjective memory impairment, SMI, subjective memory decline, SMD, transcranial direct current stimulation, tDCS

Primary outcomes

1

Description

The score obtained in RehaCom cognitive tests

Timepoint

The RehaCom cognitive test will be performed before the

intervention and at the end of the ten treatment sessions.

Method of measurement

RehaCom, HASOMED, 1992-2021

2**Description**

The score obtained in CANTAB cognitive tests

Timepoint

The CANTAB cognitive test will be performed before the intervention and at the end of the ten treatment sessions.

Method of measurement

CANTAB Research Suit software

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

sleep quality score

Timepoint

The sleep quality score of the participants will be measured by the Pittsburgh Sleep Quality Questionnaire before and after the treatment.

Method of measurement

The Pittsburgh Sleep Quality Index (PSQI)

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

Intervention group: transcranial direct current stimulation

Category

Treatment - Devices

2**Description**

Control group: SHAM trans Cranial Direct Current Stimulation

Category

Treatment - Devices

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

dana brain health institute

Full name of responsible person

Mohammad Nami

Street address

unit 13, Maryam building, Besat Blvd., Shiraz,

City

shiraz

Province

Fars

Postal code

7133654361

Phone

+98 71 3230 7129

Fax

+98 71 3234 0072

Email

info@danabrain.ir

Web page address

<https://danabrain.ir/>

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

Shiraz University of Medical Sciences

Full name of responsible person

Mohammadreza Namavar

Street address

Headquarters of Shiraz, University of Medical Sciences, Zand Street, opposite Palestine Street, Shiraz

City

Shiraz

Province

Fars

Postal code

14336 - 71348

Phone

+98 71 3230 5410

Email

info@sums.ac.ir

Web page address

<https://sums.ac.ir/Page-backupmain991001/en/448>

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**

Shiraz University of Medical Sciences

Full name of responsible person

Mohammadreza Namavar

Position

Associated professor

Latest degree

Ph.D.

Other areas of specialty/work

Neuroscience

Street address

Headquarters of Shiraz University of Medical Sciences, Zand Street, opposite Palestine Street, Shiraz

City

Shiraz

Province

Fars

Postal code

1433671348

Phone

+98 71 3230 5410

Email

namavarm@sums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Nami

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Neuroscience

Street address

Diamond Building, Alley 29, between Palestine and Mulla Sadra, Qasr al-Dasht St.

City

Shiraz

Province

Fars

Postal code

7133654361

Phone

+98 71 2300 7129

Email

Mtneurosci2@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Seyedeh Saeedeh Yahyavi

Position

PhD student in neuroscience

Latest degree

Master

Other areas of specialty/work

Neuroscience

Street address

Alley 2, Tondgoyan Blvd

City

Shiraz

Province

Fars

Postal code

7168866138

Phone

+98 71 3834 1004

Email

saeedehyahyavi@gmail.com

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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Part of the data, such as information related to the main outcome or similar, can be shared.

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

data would be available only for people working in academic institutions

Under which criteria data/document could be used

The data will be available for researchers working in academic and scientific institutions for use in review and systematic articles.

From where data/document is obtainable

Applicants can contact the following email address and phone number to receive the desired documents or data. saeedehyahyavi@gmail.com 09174171293

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

After sending an email and explaining how to use the data, if it is in accordance with the items mentioned here, the applicant can access the desired data after a maximum of two months.

Comments