Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 (dlPFC) and Parietal Cortex (PC) 2. Evaluation of fMRI components including Functional Connectivity after receiving tDCS in the(dlPFC) 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 rehablitation

control group: Sham-tDCS + cognitive rehablitation

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

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Iran (Islamic Republic of)

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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 sever attention and concentration disorder Chronic sleep disorder Using drugs with memory disturbances side effects Sever 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 analyser

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
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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
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
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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