

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### Effect of Brain Stimulation with Transcranial Direct Current Stimulation (tDCS) on Two Brain Regions of DLPFC and OFC in Promoting Hot and Cold Performance

#### Protocol summary

##### Study aim

The aim of this study is to investigate tDCS on DLPFC and OFC in hot and cold executive performance

##### Design

The study is performed on 45 healthy adults in three groups of experimental and sham. All subjects were selected based on convenience sampling and randomly assigned to either group.

##### Settings and conduct

The study was a single-blind that only the subjects are unaware. The experimental study is a single-blind with two types of stimulation condition that the subjects only are unaware of. All subjects are selected based on convenience sampling and randomly assigned to either group. Initially, the goals of the plan are explained to individuals, then, after obtaining demographic information and written informed consent, Each individual completed four types of n-back, London Tower, Bart and Iowa executive performance software as a pre-test. Then, each subject was stimulated by tDCS in a quiet room and in a comfortable chair. Intervention was performed continuously for ten days, and at the end of the 10 days after the intervention, subjects completed four types of n-back, London Tower, Bart and Iowa executive performance software as a post-test.

##### Participants/Inclusion and exclusion criteria

Entry criteria: 1) Right hand 2) No previous history of brain surgery, epilepsy, seizure or brain injury 3) History of drug use or any disturbances in the axis of one or two, 4) No metal, prosthesis, shunt on the skull

##### Intervention groups

1) Experimental group: By stimulating tDCS at about 2 mA on areas: anodal l-DLPFC/cathodal r-OFC 2) 1) Experimental group: By stimulating tDCS at about 2 mA on areas: cathodal l-DLPFC/anodal r-OFC 3) Sham group: Electrode placement is the same as the first experimental group without any intervention.

#### Main outcome variables

Change in hot and cold executive functions

#### General information

##### Reason for update

##### Acronym

tDCS

##### IRCT registration information

IRCT registration number: **IRCT20170429033690N2**

Registration date: **2019-11-23, 1398/09/02**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-11-23, 1398/09/02**

Update count: **0**

##### Registration date

2019-11-23, 1398/09/02

##### Registrant information

##### Name

Farzaneh Pouladi

##### Name of organization / entity

Shahid Bahonar university of Kerman

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3325 7255

##### Email address

farzaneh@ens.uk.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-10-21, 1398/07/29

##### Expected recruitment end date

2020-01-21, 1398/11/01

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Effect of Brain Stimulation with Transcranial Direct Current Stimulation (tDCS) on Two Brain Regions of DLPFC and OFC in Promoting Hot and Cold Performance

**Public title**  
The effect of tDCS on executive performance

**Purpose**  
Health service research  
**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
Right handed No previous history of brain surgery, epilepsy, seizure, or brain damage No history of drug use or any disturbance in the axis of one or two Absence of metal, prosthesis, shunt on the skull

**Exclusion criteria:**

**Age**  
From **20 years** old to **32 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  

- Participant

**Sample size**  
Target sample size: **45**

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

**Randomization description**  
Available samples that meet the criteria for entry are randomly treated in either of the two treatment groups or as semi-therapies.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
This study is a blind blind study in which subjects were not aware of the type of intervention.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

1

**Ethics committee**  
**Name of ethics committee**  
Veterinary Faculty of Shahid Bahonar University of Kerman

**Street address**  
Research Square, Shahid Bahonar University  
**City**  
Kerman  
**Province**  
Kerman  
**Postal code**  
7616914111

**Approval date**  
2019-10-20, 1398/07/28

**Ethics committee reference number**  
IR.UK.VETMED.REC.1398.024

**Health conditions studied**

1

**Description of health condition studied**  
Assessment of executive functions in healthy individuals  
**ICD-10 code**  
**ICD-10 code description**

**Primary outcomes**

1

**Description**  
Performance scores on nback, London Tower, Iowa and Bart tests

**Timepoint**  
Before intervention and 10 days after intervention

**Method of measurement**  
Investigation of cold executive functions using nback and tower of London and hot executive functions using Iowa and Bart

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**  
The first intervention involves anodal stimulation over the left DLPFC (F3) and cathodal stimulation over the right OFC (Fp2) at 2 mA to enhance cold executive performance. The intervention is performed continuously for 10 sessions that each session lasts 20 minutes

**Category**  
Behavior

2

**Description**  
The second intervention involves anodal stimulation over the right OFC (Fp2) and cathodal stimulation over the left DLPFC (F3) at 2 mA to enhance hot executive performance. The intervention is performed continuously for 10 sessions that each session lasts 20 minutes

**Category**

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

Shahid bahonar university

**Full name of responsible person**

Masood Bagher

**Street address**

Research Square, Shahid Bahonar University

**City**

Kerman

**Province**

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**Postal code**

7616914111

**Phone**

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**Email**

f.pouladi80@gmail.com

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

Shahid Bahonar University

**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**

Shahid Bahonar University

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

Shahid Bahonar University

**Full name of responsible person**

Farzaneh Pouladi

**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**

Shahid Bahonar University

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

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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**

Yes - There is 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**

Some of the data is shared

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

Access time will be from 1401

**To whom data/document is available**

only researcher

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

In order to investigate by email

**From where data/document is obtainable**

By email with the corresponding author

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

By email within a week the data will be available

**Comments**