

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jul 2026

**The evaluation of moral decision making and its coherence with risky decision making and Sociocognitive profile in the patients with brain injuries (traumatic and stroke), before and after Transcranial direct current stimulation (tDCS), in comparison to Sham group.**

### Protocol summary

#### Study aim

assessment of Transcranial direct current stimulation (tDCS) on moral decision making in aim to better understand Neuro-anatomic network of moral decision making in brain

#### Design

In this clinical trial, randomized controlled trial are conducted on total 20 individuals dividing into two groups of 10 for stimulation and 10 without any. Randomization is individualized and simple. Analyzers and participants are not informed about whether a person is in the control group or in the trial group.

#### Settings and conduct

patients would be first assessed in Rasoul and firoozgar hospitals then referred to brain clinic for intervention. participants and analyzers are blinded in this study.

#### Participants/Inclusion and exclusion criteria

inclusion criteria: finishing middle school. no sever behavioral problem interfering with the project. no physical restriction interfering with the project. good drug compliance. no substance use disorder in the last month. no change in psychiatric medication in last month. no psychiatric hospitalization in the last moth. exclusion criteria : delirium or decrease in level of consciousness in time of the project. prominent aphasia. acute mood or psychotic phase. schizophrenia. acute intoxication. severe cluster B personality disorder. sever cognitive impairment interfering with the project. uncontrolled seizure. neurosurgery of brain with prominent skull deficit. acute intracranial hemorrhage.

#### Intervention groups

we will use high definition transcranial direct current stimulation for the intervention group fulfilling inclusion criteria. Used protocol will be based on similar studies for

behavioral interventions. the placement of electrodes will be on dorsolateral prefrontal cortex. In control group in spite of electrode placement no stimulation is used.

#### Main outcome variables

moral decision making, empathy

### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20191016045135N1**

Registration date: **2020-11-23, 1399/09/03**

Registration timing: **retrospective**

Last update: **2020-11-23, 1399/09/03**

Update count: **0**

#### Registration date

2020-11-23, 1399/09/03

#### Registrant information

##### Name

Fatemeh Sadat Mirfazeli

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6435 2331

##### Email address

f\_m\_tums@yahoo.com

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2019-09-22, 1398/06/31

**Expected recruitment end date**

2020-09-21, 1399/06/31

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The evaluation of moral decision making and its coherence with risky decision making and Sociocognitive profile in the patients with brain injuries (traumatic and stroke), before and after Transcranial direct current stimulation (tDCS), in comparison to Sham group.

**Public title**

impact of Transcranial direct current stimulation (TDCS) on moral decision making in stroke patients

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

finished middle school medication compliance no change in medication in last month no psychiatric hospitalization over the last month

**Exclusion criteria:**

decrease in level of consciousness prominent aphasia acute phase of mood or psychotic episode substance use disorder in the last month antisocial or borderline or narcissistic personality disorder severe cognitive impairment interfering cooperation in the intervention uncontrolled seizure active intracranial hemorrhage brain neurosurgery with prominent skull deficit schizophrenia diagnosis

**Age**

From **17 years** old to **70 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **20**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

A number of 20 participants with moral decision making impairment in divided into two groups of 10 people based on simple randomization by table of random numbers. one group of 10 will receive sham while the other will receive TDCS.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

In the current study, participants are blind to the situation whether they are receiving electrical stimulation through tDCS or not. Before undergoing

tDCS, the process will be properly explained to the patients. For some patients the electrodes of tDCS will be placed on the scalp without any electrical stimulation. Data analyzer and outcome assessors are also unaware of which participant has received electrical stimulation.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Iran University of Medical Sciences

**Street address**

Hemmat Highway

**City**

Tehran

**Province**

Tehran

**Postal code**

14665-354

**Approval date**

2019-09-17, 1398/06/26

**Ethics committee reference number**

IR.IUMS.REC.1398.633

**Health conditions studied****1****Description of health condition studied**

Traumatic brain injury

**ICD-10 code**

S06.2

**ICD-10 code description**

Diffuse traumatic brain injury

**2****Description of health condition studied**

Brain stroke

**ICD-10 code**

I63.9

**ICD-10 code description**

Cerebral infarction, unspecified

**Primary outcomes****1****Description**

Moral decision making score

**Timepoint**

Before intervention and within 1 hour of intervention

**Method of measurement**

Moral vignettes prepared by Knutson et al

**Secondary outcomes**

empty

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

Intervention group: will receive Transcranial direct current stimulation (tDCS).

**Category**

Treatment - Devices

**2****Description**

Control group: Sham: the electrodes of tDCS device will be placed on the skull of this group without any electrical stimulation.

**Category**

N/A

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

Rasoul-Akram Hospital

**Full name of responsible person**

Fatemeh Sadat Mirfazeli

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School of Behavioral Sciences and Mental Health  
,mental health research center Shahid Mansouri  
Street, Niyayesh Street, Satarkhan Avenue, Tehran,  
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**2****Recruitment center****Name of recruitment center**

Firoozgar Hospital

**Full name of responsible person**

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

Iran University of Medical Sciences

**Full name of responsible person**

Dr. Abbas motevalian

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Iran University of Medical Sciences, Shahid Hemmat  
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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**

Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Fatemeh Sadat Mirfazeli

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Neuroscience

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

there is no further information

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

No - There is not 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**

No - There is not 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**

only a part of data like main outcome measures

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

6 months after publication providing the journal editors agree on that.

**To whom data/document is available**

only for academic researchers

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

it is allowed for analysis in meta -analysis articles

**From where data/document is obtainable**

Through email address mentioning phone complete Id and numbers , email address is necessary.

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

it will be sent within 1 month. but sending the identification and affiliation of the person is necessary.

**Comments**