

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### A study of the effectiveness of a tDCS session in controlling craving for cigarette smoking

#### Protocol summary

##### Study aim

A study of the effectiveness of a tDCS session in controlling craving for cigarette smoking

##### Design

Control group, with parallel groups, single blind, randomized

##### Settings and conduct

This study is a clinical trial conducted in people with craving who are referred to Firoozgar Hospital. Patients are randomly divided into control and tDCS treatment groups. The excitation current is generated by a direct current generating device with a maximum voltage of 4 mA. In the intervention group, the subjects receive 2 mA for 20 minutes. Like the active excitation band, after the electrodes are inserted into the device It turns on and off after a few seconds and the ramp up is completed by the hospital and the patient receives no electrical stimulation.

##### Participants/Inclusion and exclusion criteria

Inclusion: Healthy people between the ages of 18 and 55, active smokers (at least 10 cigarettes daily) at least one year  
Epilepsy, history of Cerebral Stroke, Exclusion: Stroke, Cerebral Surgery, Psychiatric Disorders, Antipsychotic Drug Use, Pregnancy, use (Alcohol; Cocaine; Amphetamine), History of cigarette withdrawal receiving treatment for withdrawal, A history of decreased consciousness for more than 15 minutes, metal objects in the body such as a cochlear implant heart rate monitor, a history of seizures.

##### Intervention groups

. All patients are electrodes placed on the left DLPFC region and on the right DLPFC catheter. The excitation current is produced by a direct current generating device with a maximum voltage of 4 mA. In the intervention group, subjects receive 2 mA for 20 minutes. In the control group, as in the active stimulation group, the electrodes are turned on after the electrodes are inserted in the device, and after a few seconds, the ramp up is euthanized by the hospital, and the patient receives

no electrical stimulation.

##### Main outcome variables

Reduce craving for cigarettes

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170910036107N5**

Registration date: **2020-05-02, 1399/02/13**

Registration timing: **prospective**

Last update: **2020-05-02, 1399/02/13**

Update count: **0**

##### Registration date

2020-05-02, 1399/02/13

##### Registrant information

##### Name

Naseh Yousefi

##### Name of organization / entity

Iran university of medical science and health services

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8896 6574

##### Email address

nasehusefi@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-06-21, 1399/04/01

##### Expected recruitment end date

2020-08-22, 1399/06/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

A study of the effectiveness of a tDCS session in controlling craving for cigarette smoking

**Public title**

Effect of tDCS on smoking craving control

**Purpose**

Supportive

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

Healthy people between the ages of 18 and 55 active smokers (at least 10 cigarettes daily) for at least one year

**Exclusion criteria:**

Epilepsy history of Cerebral Stroke Stroke Cerebral Surgery Psychiatric Disorders Antipsychotic Drug Use Pregnancy useing (Alcohol; Cocaine; Amphetamine) History of cigarette withdrawal or received treatment for withdrawal history of decreased consciousness over 15 minutes metal objects such as heart rate monitor, cochlear implant history of seizures

**Age**

From **18 years** old to **55 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **34**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Method of randomization: block Unit of randomization: individual Tools used in randomization such as table of random numbers.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

In order to blind the patient , it is said that tDCS is effective in controlling cravings for smoking, but the control and intervention group is not mentioned.

**Placebo**

Not 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**

valiasr Square, Alley to Afrin, Firoozgar Hospital

**City**

Tehran

**Province**

Tehran

**Postal code**

1593747811

**Approval date**

2019-07-23, 1398/05/01

**Ethics committee reference number**

IR.IUMS.FMD.REC.1398.153

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

Effectiveness of a tDCS session in controlling smoking craving

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

FTND questionnaire on smoking craving

**Timepoint**

The temptation to smoke before and immediately after the intervention

**Method of measurement**

FTND questionnaire

**Secondary outcomes**

empty

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

Intervention group: the intervention group, subjects receive 2 mA for 20 minutes

**Category**

Rehabilitation

**2****Description**

Control group: The Control group Like the active stimulation group, the electrodes are turned on after the electrodes are inserted and after 30 seconds they are switched off and receive no stimulation

**Category**

Rehabilitation

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

Firoozgar Hospital

**Full name of responsible person**

Marjan Fallah

**Street address**

Valiasr Square - Afrin Alley - Firoozgar hospital

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**Phone**

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marjan.fallah9594@gmail.com

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

Iran University of Medical Sciences

**Full name of responsible person**

Dr Abbas Motevaliyan

**Street address**Department of Physical Medicine and Rehabilitation,  
Firoozgar Hospital, Valiasr Square**City**

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**Grant name**

Research center of Physical Medicine and Rehabilitation

**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**

Marjan Fallah

**Position**

Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

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

Iran University of Medical Sciences

**Full name of responsible person**

Naseh Usefi

**Position**Associate Professor of Physical Medicine and  
Rehabilitation**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Marjan Fallah

**Position**

Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

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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**

All the patient's data can be shared with privacy in regard to patients name

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

Start accessing 6 months after publishing the results.

**To whom data/document is available**

For scholars working in academic centers.

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

It can be analyzed and printed by other people by mentioning the source.

**From where data/document is obtainable**

Marjan

fallah,98113229421,marjan.fallah9594@gmail.com

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

Upon authentication,data is provided to the individual.

**Comments**

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