

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of novel stimulation waveform of the cranial stimulation on the biochemical and electrophysiological markers of acute psychosocial stress.

Protocol summary

Study aim

The effect of new stimulus waveforms on transcranial brain stimulation on biochemical and electrophysiological responses induced by acute social stress.

Design

single blind randomized clinical trial, placebo-controlled

Settings and conduct

Eligible individuals are selected for the study. After obtaining written consent and accepting the study conditions, they enter the study. During rest and sitting, hormonal and electrophysiological variables are taken. The individual goes into acute stress conditions based on the TSST (triad social stress test) protocol. After the session, those variables are taken again. Subsequently, the individuals are randomly divided into three groups. (Using www.graphpad.com) to: Group 1) TDCS (transcranial direct current stimulation) device used for 10 minutes, but no current is applied. subjects are not aware of the current flow and thus the study will be blinded. Group 2) actively used the 10 minutes TDCS current based on the conventional protocol Group 3) new bioelectric stimulation is used in consist of TDCS. After the stimulation session, hormonal and electrophysiological variables are taken again. Then all participants enter the recovery phase and rest. At this point, for twenty minutes, people do not do anything special and only rest in the room. the variables are then taken. At the end, the questionnaires on personal characteristics and anxiety questionnaires are filled out.

Participants/Inclusion and exclusion criteria

Volunteer healthy young men who are physically and mentally healthy, are not athletes, and do not smoke

Intervention groups

Intervention group 1: TDCS stimulation Intervention group 2: bioelectrical brain stimulation Control group: sham-TDCS

Main outcome variables

Salivary cortisol R-R interval of heart rate fluctuation
Relative Strength of Frequency Bands of Brain Activity
Based on Electroencephalography

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171128037666N3**

Registration date: **2020-04-06, 1399/01/18**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-06, 1399/01/18**

Update count: **0**

Registration date

2020-04-06, 1399/01/18

Registrant information

Name

Boshra Hatef

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3225 3495

Email address

boshrahatef@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-04, 1399/01/16

Expected recruitment end date

2020-07-06, 1399/04/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of novel stimulation waveform of the cranial stimulation on the biochemical and electrophysiological markers of acute psychosocial stress.

Public title

the comparison of novel electrical cranial stimulation by TDCS in the management of stress.

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

general health, absence of systemic diseases such as diabetes, autoimmune and cardiovascular disease

Exclusion criteria:

psychiatric disorders (such as epilepsy, chronic headaches, migraine, attention deficit disorder, bipolar disorder, acute anxiety, etc.) regular use of any mental medication smoking and other same drugs regular exercise until one month before the test

Age

From **18 years** old to **45 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Subjects are randomly assigned into three groups for post-stress intervention. How to group people into groups is randomized by using the website www.graphpad.com.

Blinding (investigator's opinion)

Single blinded

Blinding description

The brain stimulator is put on everyone's head and they are not notified if the device is on or off.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee for Research at Baqiyatallah University of Medical Sciences

Street address

Mulla Sadra Street, South Sheikh Bahai Street, Nusrat Street

City

Tehran

Province

Tehran

Postal code

881435916471

Approval date

2019-05-21, 1398/02/31

Ethics committee reference number

IR.BMSU.REC.1398.053

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

Acute social stress

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

Salivary cortisol

Timepoint

Before stress, immediately after stress, after brain stimulation intervention, after recovery

Method of measurement

ELISA Test

2**Description**

R-R interval heart rate fluctuations

Timepoint

Before stress, immediately after stress, after brain stimulation intervention, after recovery

Method of measurement

The ECG machine records the heartbeat and extracts the index above

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

Relative Strength of Frequency Bands of Brain Activity Based on Electroencephalography

Timepoint

Before stress, immediately after stress, after brain stimulation intervention, after recovery

Method of measurement

The brain waves are recorded by the EEG device and extracted from the index above

Intervention groups

1

Description

Intervention group: brain stimulation TDCS: subjects are exposed to 10 minutes of TDCS current with the electrode size : 7 * 5 cm, 2 intensity of 1 mA, DC constant current and anode placed on the right side of the medial frontal cortex between the channel (FPZ-F2) and the cathode electrode placed on the head Center (O2-P4)

Category

Treatment - Devices

2

Description

Control group: placebo brain stimulation TDCS: size and place the electrodes like above intervention but the electric current is not established.

Category

Treatment - Devices

3

Description

Intervention group: bioelectrical brain stimulation: size and place the electrodes like above intervention but the induced current is the recorded EEG that saved before with amplitude and duration of TDCS

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Hajar Hospital

Full name of responsible person

Marzieh Barzegar

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Valiasr Ave, Shahid Beheshti Street intersection

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Dr Boshra Hatef

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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

Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Boshra hatef

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for updating data

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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

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

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Title and more details about the data/document

As an article published in internationally accredited scientific journals

When the data will become available and for how long

Since 1400

To whom data/document is available

Everyone

Under which criteria data/document could be used

no specific condition

From where data/document is obtainable

Boshra Hatef Baqiyatallah university of medical science
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What processes are involved for a request to access data/document

with email and agreement with Boshra Hatef

Comments