Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 (triat social stress test) protocol. After the session, thoes variables are taken again Subsequently, the individuals are randomly divided into three groups. (Using www.graphpad.com) to: Group 1) TDCS (trascranial direct current stimulation) device used for 10 minutes, but no current is applied. subjects are not awared of the current flow and thus the study will be blinded. Group 2) activily 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: shame-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
Street address
Valiasr Ave, Shahid Beheshti Street intersection
City
تهران
Province
Tehran
Postal code
1411718546
Phone
+98 21 8871 0294
Fax
+98 21 8871 9515
Email
marziehbarzegar141@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Dr Boshra Hatef
Street address
Mulla Sadra Street, South Sheikh Bahai Street, Nusrat Street
City
Tehran
Province
Tehran
Postal code
881435916471
Phone
+98 21 8804 0060
Fax
+98 21 8804 0060
Email
boshrahatef@yahoo.com
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
Street address
Mulla Sadra Street, South Sheikh Bahai Street, Nusrat Street
City
Tehran
Province

Tehran

Postal code
881435916471

Phone
+98 21 8804 0060

Email
boshrahatef@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Bagheiat-allah University of Medical Sciences

Full name of responsible person
Boshra hatef

Position
Assistant Professor

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Province
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Postal code
881435916471

Phone
+98 21 8804 0060

Email
Boshrahatef@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Bagheiat-allah University of Medical Sciences

Full name of responsible person
Boshra Hatef

Position
Assistant Professor

Latest degree
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Other areas of specialty/work
Physiotherapy

Street address
Mulla Sadra Street, South Sheikh Bahai Street, Nusrat Street

City
Tehran

Province
Tehran

Postal code
881435916471

Phone
+98 21 8804 0061

Email
boshrahatef@yahoo.com

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 Tehran, Mollasadra, south Sheikh bahayi boshrahatef@yahoo.com

What processes are involved for a request to access data/document
with email and agreement with Boshra Hatef

Comments