Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Comparison of the effectiveness of Transcranial Direct Current Stimulation (tDCS), Acceptance and Commitment Therapy (ACT) and their combined effect on negative emotion, impulsiveness, perceived stress, cortisol، and estrogen levels in patients with migraine headache

Protocol summary

Study aim
Comparison of the effectiveness of tDCS, ACT, and their combined effect on reducing negative emotion, impulsiveness, perceived stress, blood cortisol levels, and increasing estrogen levels in patients with migraine headaches.

Design
Clinical trial with a control group, with parallel groups, one-sided blind, randomized, zero phase on 96 patients. Lottery was used for randomization.

Settings and conduct
Questionnaires and blood test results were taken from the subjects and randomly assigned in the experimental and control groups. The intervention of the tDCS group was conducted in the neurology clinic, by a professional tDCS performer, in 10 sessions (20 minutes), and the intervention of the ACT group was conducted in a group and online in 8 sessions of 60 minutes on the Skype application. The combined intervention was held both in person and online as mentioned. The control group did not receive any intervention. After the end of the interventions, the post-test (blood test and scales) was taken. For follow-up, blood tests and the scales were also done three months after the end of the interventions. During the whole period of the intervention, the subjects were blinded to the way of distribution in the groups, assumptions and possible results of the interventions.

Participants/Inclusion and exclusion criteria
Taking confirmed diagnosis of migraine, signing the written consent, Proficiency in Persian language, having access to the Internet and the Skype software (for groups taking the ACT course), being between the ages of 20 and 40, having no other effective physical or psychological conditions, and not undergoing drug and other treatments

Intervention groups
The tDCS group, the ACT group, the combination group of tDCS and ACT, and the control group

Main outcome variables
negative emotion, impulsiveness, perceived stress, blood cortisol, and estrogen levels

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220511054824N1**
Registration date: **2023-09-11, 1402/06/20**
Registration timing: **retrospective**

Last update: **2023-09-11, 1402/06/20**
Update count: **0**

Registration date
2023-09-11, 1402/06/20

Registrant information

Name
Yasaman Damirchi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-21, 1401/02/01

Expected recruitment end date
2022-05-21, 1401/02/31
Actual recruitment start date
2022-09-11, 1401/06/20
Actual recruitment end date
2022-11-01, 1401/08/10
Trial completion date
2023-02-04, 1401/11/15

Scientific title
Comparison of the effectiveness of Transcranial Direct Current Stimulation (tDCS), Acceptance and Commitment Therapy (ACT) and their combined effect on negative emotion, impulsiveness, perceived stress, cortisol، and estrogen levels in patients with migraine headache

Public title
Comparison of the effectiveness of tDCS, ACT and their combined effect on negative emotion, impulsiveness, perceived stress, cortisol، and estrogen levels in patients with migraine
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Taking confirmed diagnosis of migraine, signing the written consent, Proficiency in Persian language, having access to the Internet and the Skype software (for groups taking the ACT course), being between the ages of 20 and 40, having no other effective physical or psychological conditions, and not undergoing drug and other treatments
Exclusion criteria:
Receiving another treatment during the intervention, having a history of a serious medical or neurological disorder (for participants who received tDCS), such as multiple sclerosis, brain injury or tumors, Parkinson’s disease, seizures, dementia, brain stroke or any kind of heart disease, Huntington’s chorea, having cardiac pacemaker, having any metal objects in or near the head, and implanted medication pumps which would increase the risk of tDCS
Age
From **20 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **120**
Actual sample size reached: **96**
Randomization (investigator's opinion)
Randomized
Randomization description
Random assignment of patients to intervention and control groups was done by lottery. For this purpose, we write the names of all the people on small pieces of paper and put them in a container. We also prepare 4 different sheets with the names of 4 intervention and control groups. First, we open the sheet of the first intervention group and write the names of the first 30 subjects that come out of the container. For other groups, we continue until the end (30 people in the second intervention group, 30 people in the third intervention group, and 30 people in the control group).
Blinding (investigator's opinion)
Single blinded
Blinding description
All participants were blinded to the way of distribution in groups, possible and expected results, and research assumptions, and no information about this was provided to them.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Islamic Azad University-Karaj Branch
Street address
Amiral Mominin University Complex, Moazen Blvd., Rajaee Shahr.
City
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Province
Alborz
Postal code
3149968111
Approval date
2022-08-31, 1401/06/09
Ethics committee reference number
IR.IAU.K.REC.1401.086

Health conditions studied

1

Description of health condition studied
Migraine headaches
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Negative emotion, impulsiveness, perceived stress, blood cortisol and estrogen levels
Timepoint
Before the start of the intervention, after the end of the

intervention and three months after the end of the intervention

Method of measurement

Positive and negative affect scale (PANAS), Barratt impulsiveness scale (BIS), Perceived stress scale (PSS), Blood test to measure cortisol and estrogen levels.

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group, Transcranial Direct Current Stimulation (tDCS): The brain regions were localized using the EEG 10/20 system, and the anode and the cathode were located over the left and the right dorsolateral prefrontal cortex or DLPFC (F3 and F4), respectively. A current intensity of 2 mA for 20 min (30 s ramping up and 30 s ramping down at the start and end of stimulation) was used for 10 consecutive sessions (5 days per week). Direct current was transferred through a saline-soaked (0.9% NaCl) pair of surface sponge electrodes (size 5 cm x 5 cm=25 cm2 each) and powered by a battery-driven stimulator authorized for human use (NeuroStim 2, Medina Teb, Iran).

Category

Treatment - Devices

2

Description

The second intervention group, Acceptance and Commitment Therapy (ACT): Vowles, Wetherell, and Sorrell ACT protocol was used, in which the subjects participated in 8 online sessions of ACT (on Skype), one-hour session per week. In this protocol, after introducing people and getting to know the generalities of the course, we worked on recognizing and accepting unpleasant personal events and painful experiences and being aware of hidden consequences, discovering and contacting them, changing language concepts, teaching relaxation, explaining the concept of role and context, observing self without judgment, explaining the concept of values, goals, and needs, creating motivation for change, training to practice and reviewing the tasks.

Category

Treatment - Devices

3

Description

The third intervention group, the combination of Transcranial Direct Current Stimulation (tDCS) and Acceptance and Commitment Therapy (ACT): This intervention was performed as described in the intervention of the first and second groups.

Category

Treatment - Devices

4

Description

Control group: This group did not receive any intervention during the research. However, to comply with the principle of fairness, all control group participants were allowed to take one of the interventions after the end of the research (tDCS or ACT).

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Specialist neurology clinic of Dr. Behnam Safarpour Lima

Full name of responsible person

Dr. Behnam Safarpour Lima

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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
Islamic Azad 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
Academic

Person responsible for general inquiries

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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
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
Some information about the main outcome is shared.
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
All researchers are able to access the study results.

Under which criteria data/document could be used

The information is not provided to the organization or to another person.

From where data/document is obtainable

Yasaman Damirchi yasaman.damirchi@gmail.com

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

The study data are published in the article and other data are not available to the applicants.

Comments