Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effectiveness and comparison of transcranial direct current stimulation (tDCS) and transcranial alternating current stimulation (tACS) on emotion regulation, mood symptoms, and cognitive performance in women with premenstrual syndrome

Protocol summary

Study aim
Studying the effectiveness and comparison of two methods: direct transcranial electrical stimulation (tDCS) and alternative transcranial electrical stimulation (tACS) on three variables: emotion regulation, mood symptoms, and cognitive function in women with premenstrual syndrome

Design
Controlled clinical trial, with parallel groups, double-blind, randomized; Simple randomization method with sealed envelope device is used for randomization

Settings and conduct
This research will be informed through cyberspace and posters in Tehran and will be conducted at Shahed University, Mostafa Khomeini Hospital, and Varsh Counseling Center In this study, Participants, experimenters, and statisticians were blinded..

Participants/Inclusion and exclusion criteria
Women living in Tehran between the ages of 18 and 45 Have premenstrual syndrome Having regular menstruation Not currently taking medication for premenstrual syndrome No prosthesis in the skull area No history of brain tumor No battery in the heart No history of seizures Absence of clinical disorders such as Major Depression Disorder, Bipolar Disorder, Generalized Anxiety Disorder, Acute Stress Disorder, and Post-Traumatic Stress Disorder Not having a Personality Disorder

Intervention groups
One group received tDCS with an electric current of 2 mA for 20 minutes in the dorsolateral prefrontal cortex (DLPFC) for 10 sessions (10 consecutive days) with the left side (F3) being the anode and the right side (F4) being the cathode One group will receive tACS with an electric current of 2 mA at an alpha frequency of 10 Hz in the DLPFC by placing the active electrode in the F3 area and the reference electrode in the F4 area for 10 sessions (10 consecutive days) A sham group

Main outcome variables
Are tDCS and tACS effective and different in improving emotion regulation; mood symptoms; and cognitive function in women with premenstrual syndrome?

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260512069367N1**
Registration date: **2026-05-17, 1405/02/27**
Registration timing: **prospective**

Last update: **2026-05-17, 1405/02/27**
Update count: **0**

Registration date
2026-05-17, 1405/02/27

Registrant information

Name
Zahra Tavana

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 6642 6288

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Recruitment status
recruiting

Funding source

Expected recruitment start date

2026-05-22, 1405/03/01

Expected recruitment end date

2026-11-22, 1405/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness and comparison of transcranial direct current stimulation (tDCS) and transcranial alternating current stimulation (tACS) on emotion regulation, mood symptoms, and cognitive performance in women with premenstrual syndrome

Public title

Effectiveness and comparison of transcranial direct current stimulation (tDCS) and transcranial alternating current stimulation (tACS) on emotion regulation, mood symptoms, and cognitive performance in women with premenstrual syndrome

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Women between the ages of 18 and 45 who have had more than two periods with symptoms of premenstrual syndrome Having regular menstruation

Exclusion criteria:

at the moment , taking medication for premenstrual syndrome Prosthesis in the skull area History of brain tumor History of seizures Battery in the heart Clinical disorders such as Major Depression Disorder, Bipolar Disorder, Generalized Anxiety Disorder, Acute Stress Disorder, and Post-Traumatic Stress Disorder Personality Disorder

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, after examining the entry and non-entry conditions, 45 eligible participants are selected by simple randomization using a lottery. Each participant is randomly assigned to one of the groups. This is done again using a lottery. Finally, 3 groups (2 intervention groups and a placebo group) are named using the same lottery method again.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants do not know which group (there are 2 intervention groups and a placebo group) they are in, and the 2 collaborators who are responsible for evaluating the outcome and analyzing the data are also unaware of which group the individuals are in.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the Faculty of Medicine, Shahed University

Street address

opposite the Holy Shrine, Persian Gulf Highway,

City

Tehran

Province

Tehran

Postal code

3319118651

Approval date

2026-05-03, 1405/02/13

Ethics committee reference number

IR.SHAHED.MED.REC.1405.008

Health conditions studied

1

Description of health condition studied

Premenstrual syndrome

ICD-10 code

N94.3

ICD-10 code description

Premenstrual tension syndrome

Primary outcomes

1

Description

Emotion regulation score, based on the Difficulties in Emotion Regulation Scale – 16 items(DERS-16)

Timepoint

Before starting interventions once in the follicular phase In the luteal phase, once in the first session before the start of the intervention; at the end of the fifth session of the intervention; at the end of the tenth session of the intervention; After the intervention is completed, once in

the follicular phase and once in the luteal phase.

Method of measurement

Difficulties in Emotion Regulation Scale – 16 items(DERS-16) Bjureberg

2

Description

Mood symptom score based on the Depression Anxiety Stress Scales - 21(DASS-21)

Timepoint

Before starting interventions once in the follicular phase In the luteal phase, once in the first session before the start of the intervention; at the end of the fifth session of the intervention; at the end of the tenth session of the intervention; After the intervention is completed, once in the follicular phase and once in the luteal phase.

Method of measurement

Depression Anxiety Stress Scales - 21(DASS-21) Lovibond

3

Description

Cognitive performance score in attention and response inhibition by the Integrated Visual and Auditory Continuous Performance Test(IVA-2)

Timepoint

Before starting interventions once in the follicular phase In the luteal phase, once in the first session before the start of the intervention; at the end of the fifth session of the intervention; at the end of the tenth session of the intervention; After the intervention is completed, once in the follicular phase and once in the luteal phase.

Method of measurement

Integrated Visual and Auditory Continuous Performance Test(IVA-2)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: This group receives tDCS with an electric current of 2 mA for 20 minutes in the dorsolateral prefrontal cortex (DLPFC) for 10 sessions (10 consecutive days) during the luteal phase of the menstrual cycle, with the left side (F3) being the anode and the right side (F4) being the cathode.

Category

Treatment - Devices

2

Description

Intervention group 2: During the luteal phase of the menstrual cycle, this group receives tACS with an electric current of 2 mA at an alpha frequency of 10 Hz in the DLPFC by placing the active electrode in the F3 area and the reference electrode in the F4 area for 10 sessions (10 consecutive days).

Category

Treatment - Devices

3

Description

Control group: This group receives sham stimulation for 20 minutes in the DLPFC for 10 sessions (10 consecutive days) during the luteal phase of the menstrual cycle.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahed University

Full name of responsible person

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Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person
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Central building, Shahed University, opposite of shrine of Imam Khomeini, Persian Gulf Highway Shrine of Imam Khomeini, khali the shrim ine of Imam Khomeini
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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
Shahed 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
Undecided - It is not yet known if there will be a plan to

make this available

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

Not applicable

Data Dictionary

Not applicable