

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the Effectiveness of adding Transcranial Direct Current Stimulation (tDCS) to the Camperdown program on the Stuttering Severity index in Adults with Stuttering: A Randomized Double-Blind Clinical Trial

Protocol summary

Study aim

Objectives: The aim of this study is to investigate the effectiveness of tDCS stimulation along with conventional speech therapy in reducing the severity of stuttering in adults.

Design

The study is designed as a randomized clinical trial.

Settings and conduct

60 adults with stuttering from Golestan Hospital in Ahvaz will be randomly divided into two intervention and control groups. Both groups will be given conventional speech therapy, but the intervention group will also be given electrical stimulation with tDCS. In the control group, tDCS is provided in a sham and silent form. The duration of the intervention period is 8 sessions and a one-month follow-up period is considered for treatment follow-up.

Participants/Inclusion and exclusion criteria

Study inclusion and exclusion criteria: Adults with stuttering, age range 18 to 50 years, no metallic objects or abnormalities in the skull, Unwillingness to continue participating in the research.

Intervention groups

Intervention group: 30 adults with stuttering receiving speech therapy plus tDCS electrical stimulation
Control group: 30 adults with stuttering receiving speech therapy without tDCS electrical stimulation (sham tDCS)

Main outcome variables

Main outcomes: stuttering severity and stuttering-related quality of life.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110928007657N5**

Registration date: **2026-03-17, 1404/12/26**

Registration timing: **prospective**

Last update: **2026-03-17, 1404/12/26**

Update count: **0**

Registration date

2026-03-17, 1404/12/26

Registrant information

Name

Peyman Zamani

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 61 3322 1002

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-03-21, 1405/01/01

Expected recruitment end date

2026-09-21, 1405/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effectiveness of adding Transcranial

Direct Current Stimulation (tDCS) to the Camperdown program on the Stuttering Severity index in Adults with Stuttering: A Randomized Double-Blind Clinical Trial

Public title

Effectiveness of adding Transcranial Direct Current Stimulation (tDCS) to the Camperdown program on the Stuttering Severity index in Adults

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having developmental stuttering Having moderate to severe stuttering being Right-handed being Farsi-language Not receiving stuttering-related treatment in the past month prior to the start of the intervention

Exclusion criteria:

Having skin lesions or bone defects in the skull area Presence of other speech disorders with stuttering Taking brain-stimulating drugs Having metal implants in the skull

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple Randomized-block design Randomization will be performed by using Randomized-block design method through WINPEPI software as well as applying 4-block for each group. This software create a sequence of random numbers that is used to assign participants to one of the groups. The person who is responsible to make a random list will be blinded to participants.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding of participants is done using a sham method. Assessor blinding: The assessor is unfamiliar with the name, gender, and grouping of the study subjects. Blinding of the data analyst: The assessor is unfamiliar with the name, gender, and grouping of the study subjects.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan Ave., Golestan Hospital., School of Rehabilitation, Speech Therapy Department.

City

Ahvaz

Province

Khouzestan

Postal code

6135733133

Approval date

2025-12-06, 1404/09/15

Ethics committee reference number

IR.AJUMS.REC.1404.491

Health conditions studied

1

Description of health condition studied

Stuttering

ICD-10 code

ICD-10 code description

لکنت

Primary outcomes

1

Description

Stuttering Severity

Timepoint

Before of intervention, After intervention, one month for follow up

Method of measurement

Questionary of Stuttering Severity Scale

2

Description

Quality of Life

Timepoint

Before of intervention, After intervention, one month for follow up

Method of measurement

Overall Assessment of the Speakers Experiences of Stuttering

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:Electrical stimulation is provided using the Segal Stim AT-12 device from Pharmed Tajhiz Company, in tDCS mode. An electroencephalography cap will be used to identify the location of the stimulation, so the brain areas are designated on it with the international 10-20 system. Stimulation is performed by passing a current of 2 mA and a resolution of 0.1 mA between two 5 cm x 7 cm electrodes for 20 minutes.Simultaneously with the device's stimulation, a speech therapy program is presented at a slow and drawn-out pace.

Category

Treatment - Devices

2

Description

Control group: In the control group, the device's electrical current will increase to 2 mA for 15 seconds and then immediately turn off. Simultaneously with the device's stimulation, a speech therapy program is presented at a slow and drawn-out pace.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital, Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Peyman Zamani

Street address

Golestan Ave., Golestan Hos., Ahvaz Jundishapur University of Medical Sciences, School of Rehabilitation, Speech Therapy Department.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Abdollah Rafiei

Street address

Golestan Blvd., Ahvaz Jundishapur University of Medical Sciences, School of rehabilitation.

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Peyman Zamani

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Speech therapy

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Person responsible for scientific

inquiries

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Publishing an article, participating in a speech therapy scientific conference

When the data will become available and for how long

Access period starts 12 months after results are published.

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

-

From where data/document is obtainable

Peyman Zamani 09166176780

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

Email and phone

Comments