

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 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)

###### Phone

+98 61 3322 1002

###### Email address

zamanip@ajums.ac.ir

##### 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.

#### City

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zamanipdrst@gmail.com

## 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**

### **Contact**

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Ahvaz University of Medical Sciences

**Full name of responsible person**

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**Position**

Associate professor

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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**