Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Investigation of the effect of the combined treatment method of fluency shaping and transcranial Direct Current Stimulation(tDCS) for improvement of speech fluency in adults who stutter

Protocol summary

Study aim

Determining the effect of a combined treatment of speech fluency shaping and transcranial direct current stimulation on improving speech fluency in adults with stuttering

Design

The Phase 3 clinical experiment is a randomized, double-blind, two-arm controlled trial with 62 adult stuttering participants.Participants will be assigned to one of two groups: anodal tDCS or sham tDCS. The website www.randomization.com will be used to develop a computer-generated randomization method. Each participant will be assigned to one of the experimental groups and given a unique ID.

Settings and conduct

Speech fluency shaping and transcranial direct current stimulation (tDCS) are used in the intervention, which is carried out in two stages over a three-week period at Tehran University of Medical Sciences' School of Rehabilitation Sciences.This study is double-blind . Neither the participants nor the investigators know which group (anodal or sham) each participant is assigned to.

Participants/Inclusion and exclusion criteria

Inclusion criteria:1)Range of ages between 15 and 50 2)Right-handed 3)History of developmental stuttering with mild to very severe stuttering Exclusion criteria:1)Other speech and language impairements/cognitive or psychological diseases,attention deficit hyperactivity disorder(ADHD),brain surgery or tumors may coexist with stuttering 2)History of seizures 3)Intake of any medication that effects central nervous system function such as antiseizures and antidepression

Intervention groups

Participants will be randomized to one of two groups at random: intervention or control. Speech therapy will be combined with anodal transcranial direct current stimulation in the intervention group, whereas sham transcranial direct current stimulation will be used in the control group.

Main outcome variables

Percentage of stuttered syllables

General information

Reason for update

The implementation of this project began in December 2022, but due to the lengthy therapy sessions of the project's participants and the long follow-up process of these participants up to 3 months, as well as a sample size of 62 patients, more time is needed to complete the sampling process. Therefore, the completion date of the sampling process has been revised

Acronym

IRCT registration information

IRCT registration number: **IRCT20230907059369N1**
Registration date: **2023-12-05, 1402/09/14**
Registration timing: **prospective**

Last update: **2025-07-15, 1404/04/24**
Update count: **2**

Registration date

2023-12-05, 1402/09/14

Registrant information

Name

Kowsar Esfandeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

ksfande@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date
2023-12-10, 1402/09/19

Expected recruitment end date
2026-10-21, 1405/07/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigation of the effect of the combined treatment method of fluency shaping and transcranial Direct Current Stimulation(tDCS) for improvement of speech fluency in adults who stutter

Public title
Investigation of the effect of the transcranial Direct Current Stimulation(tDCS) for improvement of speech fluency in adults who stutter

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Range of ages between 18 and 50 Right-handedness History of developmental stuttering, with mild to very severe stuttering Not having stuttering treatment speech therapy within the month before the intervention Monolingual and Persian-speaker Normal visual and auditory abilities

Exclusion criteria:
Other speech and language impairments, cognitive or psychological diseases, attention deficit hyperactivity disorder (ADHD), brain surgery, or tumors may coexist with stuttering History of seizures Intake of any medication that affects central nervous system functions, such as antiseizures and antidepression Cranial/brain metal implants Skin lesions and sensitivity of the scalp skin to stimulation

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **62**

Randomization (investigator's opinion)
Randomized

Randomization description
The random allocation will take place on the website www.randomization.com. The randomization list will be created by a collaborator who is not involved in the study process. The following is the procedure: the number of groups and total sample size are entered into the appropriate section of the website. Each participant will be issued a unique code, which will be randomly assigned to either Group A or Group B. The control group is Group A, and the intervention group is Group B. In the following phase, we will use the sealed envelope method to conceal the website's constructed list. As a result, a sample size of sealed envelopes will be made, with the participant's code inscribed on each envelope. The letter A or B will be inserted inside each envelope based on the list. Thick envelopes will be used to ensure that the letter within the envelope is not visible. The list on the internet will then be deleted.

Blinding (investigator's opinion)
Double blinded

Blinding description
One collaborator is in charge of regulating the stimulation delivery length of the tDCS device. When the participant turns over the sealed envelope to the collaborator, they decide how long the stimulation will last based on the letter inside. If the letter is A, the stimulation lasts 15 seconds, while the letter B lasts 20 minutes. Following that, the lead researcher continues on to the treatment's subsequent steps. As a result, the primary researcher, who leads the therapy sessions, is fully uninformed of the group designations. As can be seen, neither the participants nor the treatment provider know whether the individual is in the intervention or control group. Furthermore, the assessors who measure the primary and Secondary outcomes are not involved in any other aspect of the study.As a result, this study is a double-blind randomized controlled trial.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee in Tehran University of Medical Sciences

Street address
Intersection of Keshavarz Boulevard and Qods Street, Central Headquarters Building of Tehran University of Medical Sciences, 6th floor, Room 604, Ethics Committee Secretariat in the University's Research Ethics Office.

City
Tehran

Province
Tehran

Postal code
65111-11489
Approval date
2023-09-05, 1402/06/14
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1402.318

Health conditions studied

1

Description of health condition studied
Developmental stuttering
ICD-10 code
F80
ICD-10 code description
Specific developmental disorders of speech and language

Primary outcomes

1

Description
Percentage of stuttered syllables
Timepoint
One week prior to the intervention, Immediately after the intervention, 6 weeks after the intervention, and 12 weeks after the intervention
Method of measurement
The percentage of stuttered syllables in unplanned telephone call is calculated in this study. The percentage is calculated as follows: The number of stuttered syllables in the speech sample is divided by the total number of syllables spoken in that speech sample, and then multiplied by 100. Each evaluation session consists of a 10-minute telephone call with an evaluator.

2

Description
Speech Naturalness
Timepoint
One week prior to the intervention, immediately after the intervention, 6 weeks after the intervention, and 12 weeks after the intervention
Method of measurement
The assessment of speech naturalness in this study will be done on a 9-point scale. A score of zero indicates that no speech treatment techniques were utilized, while a score of eight suggests that speech therapy techniques were used excessively

3

Description
Severity rating
Timepoint
One week prior to the intervention, immediately after the intervention, 6 weeks after the intervention, and 12 weeks after the intervention
Method of measurement
The severity of stuttering will be graded on a 9-point scale in this study. A score of zero indicates no stuttering, a score of 1 and 2 indicates very very mild stuttering, a score of 3 indicates mild stuttering, a score of 4 and 5 indicates moderate stuttering, a score of 6 and 7 suggests severe stuttering, and a score of 8 indicates very severe stuttering.

Secondary outcomes

1

Description
The severity of stuttering based on Severity Stuttering Instrument version-4
Timepoint
One week prior to the intervention and 12 weeks after the intervention
Method of measurement
This questionnaire assesses observable stuttering characteristics like frequency, duration, and associated bodily activities. In the current study, the Stuttering Severity Instrument-4 (SSI-4) is used to quantify the severity of stuttering in evaluations done one week before and 12 weeks after the intervention. Subtest scores and overall test scores will be recorded as dependent variables. The final score for this exam is calculated by adding the results of three subtests, including frequency, duration, and associated physical actions, and runs from 8 to 56.The duration subtest is based on the average of the three longest stuttering events, whereas the frequency subtest is based on the percentage of stuttering syllables in the speech sample and reading aloud (in literate people). In the associated physical behaviors subtest, a 6-point Likert scale (range from 0 to 5, indicating no associated physical behaviors) is used to assess the existence of physical behaviors accompanying stuttering in articulatory and body gestures.

2

Description
The severity of stuttering based on Overall Assessment of the Speaker's Experience of Stuttering
Timepoint
One week prior to the intervention and 12 weeks after the intervention
Method of measurement
A thorough questionnaire that examines the individual's stuttering experience is used to determine the severity of stuttering. This questionnaire is divided into four components that encompass the individual's experience: basic stuttering knowledge, stuttering reactions, communication in everyday situations, and quality of life. The questions are answered on a 5-point scale by the participant. The results of the tests are displayed in two dimensions: impact severity and impact level. The questionnaire results are organized into two categories: impact level and impact severity. The impact level is always between 20 and 100, and the severity of the impact is defined by this, ranging from mild to severe.

Intervention groups

1

Description
Intervention group:speech fluency shaping treatment and transcranial direct current stimulation treatment.The individual will undertake 6 rigorous sessions lasting 1 to 2 hours each for the therapy of speech fluency shaping. They will work with the therapist in the clinic to practice simple speech reconstruction procedures (phonemes, syllables, words, and small sentences or phrases). The purpose of this stage is for the participant to be able to use rudimentary speech reconstruction techniques (sentence level) during reading and monologue speech with the therapist before moving on to the combined intervention stage (speech therapy and brain stimulation). The researcher will give transcranial direct current stimulation (tDCS) to the left inferior frontal gyrus area (based on the worldwide 20-10 system) using the FC5 region during the transcranial direct current stimulation (tDCS) intervention using the Starstim model.

Category
Rehabilitation

2

Description
Control group:speech fluency shaping treatment.The individual will undertake 6 rigorous sessions lasting 1 to 2 hours each for the therapy of speech fluency shaping. They will work with the therapist in the clinic to practice simple speech reconstruction procedures (phonemes, syllables, words, and small sentences or phrases). The purpose of this stage is for the participant to be able to use rudimentary speech reconstruction techniques (sentence level) during reading and monologue speech with the therapist

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
School of Rehabilitation Sciences,Tehran University of Medical Sciences

Full name of responsible person
Dr Seyyed Ahmad Reza Khatoonabadi

Street address
At the intersection of Safi Ali Shah Street, Shemiran Corner, Enghelab street

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Email
rehabilitation@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
School of rehabilitation

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School of Rehabilitation,At the intersection of Safi Ali Shah Street,Shemiran Corner,Enghelab Street

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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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Kowsar Esfandeh

Position
PhD Candidate in Speech Therapy, Tehran University of Medical Sciences,Faculty member,Hamadan univer

Latest degree
Master

Other areas of specialty/work
Speech therapy

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Person responsible for updating data

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Other areas of specialty/work
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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
Not applicable
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