

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Electroencephalogram-Informed transcranial electrical stimulation together with speech therapy to remediate stuttering

Protocol summary

Study aim

Increasing the effectiveness and maintenance of speech therapy(ST) outcomes in adults who stutter through the use of ST together with transcranial electrical stimulation(TES) based on the processing of electrophysiological signals

Design

Clinical trial with control group, community based and pragmatic,with parallel groups,double bind,simple random allocation,intervention group=15,control group=15

Settings and conduct

The study will be executed in Shiraz University of Medical Sciences,School of Advanced Medical Sciences and Technologies in neurorehabilitation field.The procedure:Assessment of stuttering severity,recording and analyzing of EEG signals in fluent and nonfluent statements,detection of band frequency & phase coherence discriminating fluency,induction the patterns affecting fluency based on EEG by TES together with ST in intervention group,induction of conventional protocol with TES together with ST in control group,assessment of stuttering immediately and 3 months afterward ,comparison of stuttering severity in 2 groups,speech therapist is blind (putting a non-transparent hat on the head by TES operator),subjects are blind to allocation

Participants/Inclusion and exclusion criteria

Inclusion criteria:Affected by developmental stuttering Right-handed 18-42 years old Exclusion criteria:Acquired and developmental neurological disorders

Intervention groups

Intervention group:Induction the frequency bands and phase coherence affecting the fluency on determined areas(specified by EEG) through TES together with ST in two weeks,5 days a week & 30 minutes a day Control group:Applying anodal transcranial direct current stimulation over FC5(10-20 system) and reference electrode on supra orbital ridge(common protocol) in stuttering,together with ST in two weeks,5 days a week

& 30 minutes a day

Main outcome variables

Changes over course duration and durability of speech therapy outcomes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181215041975N1**

Registration date: **2019-01-02, 1397/10/12**

Registration timing: **prospective**

Last update: **2019-01-02, 1397/10/12**

Update count: **0**

Registration date

2019-01-02, 1397/10/12

Registrant information

Name

masoumeh bayat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3234 0034

Email address

m_bayat@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Electroencephalogram-Informed transcranial electrical stimulation together with speech therapy to remediate stuttering

Public title

Investigation of the effect of electrical stimulation of the brain on the basis of EEG in stuttering

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Affected by developmental stuttering with moderate to very severe Persian speaking Right-handed Without sensory, linguistic, and cognitive problems Holding a diploma, at least male

Exclusion criteria:

History of speech, language, cognitive, or hearing disorder(except for stuttering) according to self report
Acquired and developmental neurological disorders
Having a history of speech therapy from 3 months ago

AgeFrom **18 years** old to **54 years** old**Gender**

Male

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **30****Randomization (investigator's opinion)**

Randomized

Randomization description

Subjects were selected by random sampling from the community of stuttering adults. After meeting the inclusion and exclusion criteria of the study, they were assigned ,with a random number table, in one of two groups of study and control by simple random allocation method

Blinding (investigator's opinion)

Double blinded

Blinding description

The assessment of stuttering in the preceding, subsequent and follow-up intervention stages will be carried out by speech therapists who are blind to the assignment Participants will be blinded to the assignment Speech therapist is blind to the allocation so that after the assembly of the device and the installation of a non-transparent special hat by the operator, she enters the treatment room The brain signal recorders are blind to the allocation The brain signal analyzers are blind to the allocation The main researcher will be stayed

blind up to the end of the follow-up phase to the allocation. When the results of the stuttering assessment and brain signal analysis by the relevant agents at the end of the implementation of the plan were provided, the allocation information from the operator of the device, which is independent of the plan for analysis, will be received for statistical analyses

Placebo

Used

Assignment

Parallel

Other design features

In this study, the use of stimulation based on electrophysiologic data analysis of individuals (personalized treatment) is going to compare to a common predetermined protocol in previous studies.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd., Shiraz, Iran

City

shiraz

Province

Fars

Postal code

713451978

Approval date

2018-10-27, 1397/08/05

Ethics committee reference number

IR.SUMS.REC.1397.712

Health conditions studied**1****Description of health condition studied**

STUTTERING

ICD-10 code

F98.5

ICD-10 code description

Speech that is characterized by frequent repetition or prolongation of sounds or syllables or words, or by frequent hesitations or pauses that disrupt the rhythmic flow of speech. It should be classified as a disorder only if its severity is such as to ma

Primary outcomes

1

Description

stuttering severity based on ssi-4 and oases

Timepoint

Measuring the stuttering severity at the beginning of the study, immediately after the intervention and three months after the intervention

Method of measurement

Stuttering severity instrument-4 edition and Overall assessment the speaker`s experience of stuttering--adults

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Features in the electroencephalogram(EEG) signals related to fluent and non-fluent statements that determine the frequency and areas of electric stimulation will be determined in each subject. The montage and type of electrical stimulation will be selected based on the significant differences between the two modes of fluent and non-fluent statements in terms of power or phase coherence. Frequency bands and phase coherence affecting the speech fluency will be administered on areas marked with the 10 -20 system by direct (tDCS) or alternative (tACS) electrical stimulation. This stimulation together with speech therapy will be provided in two weeks, 5 days a week and 30 minutes a day.

Category

Treatment - Devices

2

Description

Control group: Features in the EEG signals related to fluent and non-fluent statements that determine the frequency and areas of electric stimulation will be determined in each subject. The montage and type of electrical stimulation, based on the common protocol in stuttering, will be anodal tDCS stimulation over FC5(10-20 system) and reference electrode on supra orbital ridge. This stimulation together with speech therapy will be provided in two weeks, 5 days a week and 30 minutes a day.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Behavioral Sciences and Mental Health, Iran University of Medical Sciences

Full name of responsible person

Masoumeh Bayat

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Shahid Mansouri Street, Niyayesh Street, Satarkhan Avenue, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Masoumeh Batat

Position

phd candidate

Latest degree

Master

Other areas of specialty/work

Neuroscience

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Person responsible for scientific inquiries

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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)

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

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

Data Dictionary

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

Title and more details about the data/document

The total individual participants' data is unobtrusive after being unidentified The report is a collaborative clinical study

When the data will become available and for how long

Access to individual data 6 months after publishing the results for one year Access to the clinical report after publishing the results for one year

To whom data/document is available

Researchers at universities

Under which criteria data/document could be used

Commitment to mention the source name and principal researcher for any use Commitment to non-application for clinical purposes

From where data/document is obtainable

Corresponding with the agent of project executor, Masoumeh Bayat, with the postal address: masumeh_bayat@yahoo.com

What processes are involved for a request to access

data/document

Investigate the application by the agent of project executor (1 month), and sharing the application with the

project executor (1 month), and final statement by the agent of project executor

Comments