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)

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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
Age
From **18 years** old to **54 years** old
Gender
Male

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target 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 yo 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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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 updating data

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Name of organization / entity
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Full name of responsible person
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Position
phd candidate

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Neuroscience

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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