

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The combined effect of the behavioral rehabilitation of auditory attention and transcranial direct current stimulation on improving speech perception in noise in children with hearing loss aged 8-11 years old

Protocol summary

Study aim

The combined effect of the behavioral rehabilitation of auditory attention and transcranial direct current stimulation on improving speech perception in noise in hearing loss children

Design

one-blind clinical trial with three groups, which is assigned to rehabilitation groups by the method of 6 random blocks.

Settings and conduct

children who scored lower than the norm in auditory attention and speech in noise tests will be included in the study. will include in the study. CV In Noise, Word in Noise tests and EEG recording will perform, too. Children will divide into three groups. Each group receives rehabilitation training. The post-test phase will be conducted for behavioral tests and EEG recording. This study is done in one-blind way and the participants do not know about the intervention group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: moderate to severe sensorineural hearing loss Children; binaural hearing aids user for at least three years: Equal or better than 30 dBHL aided hearing thresholds, Abnormal score in the BKB-SIN and at least one of the TEA-ch or mSAAT tests; Working memory capacity of at least 3 units in digit span test; normal IQ score Non-Inclusion criteria: Unwillingness to cooperate

Intervention groups

Group A-auditory attention training together with sham transcranial direct current stimulation (tDCS) Group B-tDCS with behavioral sham Group C- Combined Method (Auditory Attention Training + tDCS)

Main outcome variables

BKB Test Score; CV In Noise Test Score; Sustained attention score in the TEA- ch test; MSSAT Test Score; Word In Noise Test Score; Components of

Electroencephalography (EEG)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220918055979N1**

Registration date: **2022-11-12, 1401/08/21**

Registration timing: **prospective**

Last update: **2022-11-12, 1401/08/21**

Update count: **0**

Registration date

2022-11-12, 1401/08/21

Registrant information

Name

Nayiere Mansouri

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-01, 1401/09/10

Expected recruitment end date

2023-04-21, 1402/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The combined effect of the behavioral rehabilitation of auditory attention and transcranial direct current stimulation on improving speech perception in noise in children with hearing loss aged 8-11 years old

Public title

The combined effect of the behavioral rehabilitation of auditory attention and transcranial current stimulation in children with hearing loss

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Children with moderate to severe sensorineural hearing loss aged 8-11 years old Permanent user of binaural hearing aids for at least three years Equal or better than 30 dB HL aided hearing thresholds An abnormal score in the BKB-SIN and at least one of the TEA-ch and/or mSAAT tests right-handed In the age range of 8-11years Normal or corrected vision Complete the consent form to participate in the training program Normal findings in otoscopy and tympanometry Working memory capacity of at least 3 units in direct didit span test The standard IQ score or better than 85 score in Persian version of the revised Wechsler Intelligence Test for Children (R-WISC) The ability to cooperate in carrying out the tests foreseen in the research

Exclusion criteria:

Unwillingness to cooperate in each stage of the research Obvious developmental and behavioral problems based on the evaluation results recorded in the children's medical record A history of obvious neurological and cognitive diseases and head trauma Auditory neuropathy based on OAE and ABR indicators (according to children's hearing records)

Age

From **8 years** old to **11 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **45**

More than 1 sample in each individual

Number of samples in each individual: **2**
binaural

Randomization (investigator's opinion)

Randomized

Randomization description

for random allocation, 8 blocks of 6 AABBBCC, AABCBBC, AACBCB, ABCABC, BABCAC, ACBBCA will be prepared and placed in envelopes. In order of entry of the parents, one of the envelopes was selected at random and based on the obtained block, 6 patients will be assigned to

three groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

In each clinical trial design, three groups can influence the results of the study. Experiments, researcher, evaluator or analyst. In this study, by randomly selecting participants in two experimental and control groups and applying independent variables to both groups, which are in one sham and play the role of placebo. Also, the analyst is not aware of the sham of the intervention in the group and they become practically blind

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of University of Social Welfare and Rehabilitation Sciences (USWR)

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Postal code

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Approval date

2022-10-19, 1401/07/27

Ethics committee reference number

IR.USWR.REC.1401.128

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

Hearing Loss

ICD-10 code

H90.3

ICD-10 code description

Sensorineural hearing loss, bilateral

2**Description of health condition studied**

Auditory processing disorder

ICD-10 code

H93.25

ICD-10 code description

Central auditory processing disorder

Primary outcomes

1

Description

Bamford-Kowal-Bench Sentence Test Score

Timepoint

Before the intervention - after the intervention - one month after the end of the intervention

Method of measurement

The percentage of correctly expressed target words - the amount of SNR Loss based on the calculation formula

2

Description

Consonant-Vowel In Noise Test Score

Timepoint

Before the intervention - after the intervention - one month after the end of the intervention

Method of measurement

according to percentage of correct answers

3

Description

Sustained attention score in the test of everyday attention for children (TEA- ch) score

Timepoint

Before the intervention - after the intervention - one month after the end of the intervention

Method of measurement

according to the number of correct answers

4

Description

Monastral Selective Auditory Attention Test Score

Timepoint

Before the intervention - after the intervention - one month after the end of the intervention

Method of measurement

Calculation of the percentage of correct repetition of the target words

5

Description

Word In Noise Test Score

Timepoint

Before the intervention - after the intervention - one month after the end of the intervention

Method of measurement

Calculation of 50% of words in different signal-to-noise ratios

6

Description

Components of Electroencephalography (EEG)

Timepoint

Before the intervention - after the intervention - one month after the end of the intervention

Method of measurement

With EEGLab software

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Group A- Conventional behavioral auditory attention training will be provided together with transcranial direct current stimulation (tDCS), for 30 seconds, the current intensity of 1 mA will be applied (sham) during 10 sessions (3 sessions per week)

Category

Rehabilitation

2

Description

Intervention group: Group B-Transcranial direct current stimulation (tDCS) will be provided during 10 sessions (3 sessions per week). In each session for 20minutes, the current intensity of 1/5 mA will be applied to the participants.

Category

Treatment - Other

3

Description

Intervention group: Group C- Combined Method (Conventional behavioral auditory attention training online with transcranial direct electrical stimulation)- Conventional behavioral auditory attention training will be provided together with transcranial direct current stimulation (tDCS), for 20minutes, the current intensity of 1/5 mA will be applied during 10 sessions (3 sessions per week).

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz University of Medical Sciences

Full name of responsible person

Dr Bahman Naghipour

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

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

University of social welfare and rehabilitation 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

University of social welfare and rehabilitation sciences

Full name of responsible person

Nayiere Mansouri

Position

PhD candidate

Latest degree

Master

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