Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 includ 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)

Phone

+98 45 3323 8728

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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 AABBCC, AABCBC, 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 Rehbilitation Sciences (USWR)

Street address
kodakyar Ave., daneshjo Blvd.,Evin

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Tehran

Province
Tehran

Postal code
1985713871

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
Monaural 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
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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