Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

The effect of word in noise training on speech perception in the noise of children with unilateral hearing loss 8 to 12 years old

Protocol summary

Study aim
The effect of the word in noise training on children with UHL 8 to 12 years old

Design
A consent form is completed, and a personal information form and SSQ questionnaire are completed for each person. The evaluation process, Immittance, otoscopy, and audiometry will be performed. The PQ-SIN test runs. Each list has six sentences of five keywords each, and if they are correctly repeated, are assigned a point. Finally, the number of correct words for each sentence is recorded and, SNR LOSS is obtained for each list. Then CAEPs of individuals are recorded. Components A1, N1, P2, and, N2 are identified based on the respective times. After the pre-tests, the children enter the intervention group.

Settings and conduct
Pre- and post-test and rehabilitation interventions have been performed in the Faculty of Rehabilitation of Tehran University of Medical Sciences.

Participants/Inclusion and exclusion criteria
8 to 12-year-old, UHL, the PTA threshold in one ear is ≥ 55 dB and < 15 dB in the other ear, no use of hearing aids, no dysfunction in the middle ear, do not have any auditory and music rehabilitation before this study

Intervention groups
The sample includes children 8-12 years old with UHL, which is evaluated before and after receiving rehabilitation treatment. Recruiting this group has been considered according to the relative maturity of the cortex, the ease of performing the test, and the possibility of plasticity. The exercises are repeated every day for 45 minutes twice a week. In practice, the speech intensity is fixed at 62dBHL and the initial noise level is 50dBHL. If the child makes less than four to six errors out of ten words in the eight lists, the SNR is reduced to 2 dB. Completion of the exercise is the stage when the child can reach an SNR 0 dB.

Main outcome variables
CAEPT wave amplitude, CAEP response latency, SNR Loss in Q-SIN test, SSQ questionnaire score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20161206031257N2**
Registration date: **2022-05-04, 1401/02/14**
Registration timing: **registered_while_recruiting**

Last update: **2022-05-04, 1401/02/14**
Update count: **0**

Registration date
2022-05-04, 1401/02/14

Registrant information

Name
Nematollah Rouhbakhsh

Name of organization / entity
Dept of Audiology, School of Rehabilitation, Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-04, 1401/02/14

Expected recruitment end date
2022-07-04, 1401/04/13

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of word in noise training on speech perception in the noise of children with unilateral hearing loss 8 to 12 years old

Public title
The effect of word in noise training on speech perception in the noise
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
8 to 12-year-old- Unilateral hearing loss, the pure tone average threshold in one ear is greater than or equal to 55 dB (moderate hearing loss) and less than 15 dB in the other ear Do not use hearing aids No dysfunction in the middle ear Do not have any auditory and music rehabilitation before this study
Exclusion criteria:
Experience using hearing aids Receive any rehabilitation services History of receiving ototoxic drugs History of exposure to noise harmful to the auditory system (for example, exposure to noise greater than 85 dBA) The existence of any neurological disorder that is proven in the initial case history using a questionnaire.
Age
From **8 years** old to **12 years** old
Gender
Both

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **13**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of School of Nursing and Midwifery, and School of Rehabilitation, Tehran
Street address
Enghelab
City
Tehran
Province
Tehran
Postal code
1148965111
Approval date
2021-10-27, 1400/08/05
Ethics committee reference number
IR.TUMS.FNM.REC.1400.137

Health conditions studied

1

Description of health condition studied
Unilateral hearing loss
ICD-10 code
H90.4
ICD-10 code description
Sensorineural hearing loss, unilateral with unrestricted hearing on the contralateral side

Primary outcomes

1

Description
Amplitude of Cortical Auditory Evoked Potentials
Timepoint
Before and after auditory rehabilitation
Method of measurement
WIN and CAEPs

2

Description
Latency of Cortical Auditory Evoked Potentials
Timepoint
Before and after auditory rehabilitation
Method of measurement
WIN and CAEPs

3

Description
50% SNR in WIN test
Timepoint
Before and after the intervention
Method of measurement
Calculate it through formulas

4

Description
Moderate hearing loss
Timepoint
Before and after the intervention

Method of measurement
Audiometric data

5

Description
Severe hearing loss
Timepoint
Before and after the intervention
Method of measurement
Audiometric data

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: After baseline assessments, the child enters the rehabilitation treatment phase. To perform rehabilitation exercises in the presence of noise, one of the ten lists without noise is first presented to the children so that they become familiar with the style of words and how to respond. Then the main exercise begins. The simplest mode of practice is when the signal-to-noise ratio is the ratio of speech to noise consisting of eight speakers. In practice, the speech intensity is fixed at 62dBHL and the initial noise level is 50dBHL, ie SNR = + 12. It should be noted that the best way to do the noise exercise is to align the ear, but if the first step is difficult for the child, the noise can be sent to the other ear and after the child progresses, the noise will be presented in the same ear. At each stage, the child's mistakes must be recorded. Errors include mispronouncing a word, omitting one of the letters, or not saying the whole word. If the child makes less than four to six errors out of ten words in the eight lists, the signal-to-noise ratio is reduced to 2 dB. Exercises are repeated every day for 45 minutes (average about 8 lists) twice a week. Completion of the exercise is the stage when the child can reach the final stage, which is the SNR 0 dB. Or it is better to say that if the child has a total of four to six errors in this ratio and ratios close to zero (such as 2 and 4 decibels), it indicates the child's proper performance in these exercises. If an error occurs and there are more than four errors in each list, it is necessary to repeat other lists at the same SNR level or improve this ratio. So below is the answer to the question, "What should we do if they mispronounce the correct word?" Hold the exercise and tell the child to be careful, listen again, what word do you hear? And we say one of the letters to the child. For example, if the first letter was "n" and not "m", we keep practicing and improve the signal-to-noise ratio.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
School of Rehabilitation of TUMS
Full name of responsible person
Nematollah Rouhbakhsh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Khatoonabadi
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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
Private
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
Nematollah Rouhbakhsh

Position
Academic Member

Latest degree
Ph.D.

Other areas of specialty/work
Audiology

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Assitant Professor

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Person responsible for updating data

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Dr. Nematollah Rouhbakhsh

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Assistant Professor

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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
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
The data and documents of this study will be published via thesis and a journal paper

When the data will become available and for how long
Access date: form 2022

To whom data/document is available
Researchers

Under which criteria data/document could be used
Meta-analysis

From where data/document is obtainable
Contact the project manager

What processes are involved for a request to access data/document
Corresponding via email

Comments