

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

Country

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

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Person responsible for updating data

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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