Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

Designing and producing an evaluation and rehabilitation program based on the fundumental frequency and the vocal tract length and investigating its effect on speech recognition in noise of children with cochlear implants

Protocol summary

Study aim
Determining the skill of cochlear implant user children in distinguishing the difference between F0 and VTL cues by making a test make a rehabilitation intervention program based on the difference between F0 and VTL cues to improve speech recognition in noise for cochlear implant user children

Design
The present study is an interventional clinical trial of a randomized blind strain using the block method on 24 patients, which will be used random allocation software for random allocation .

Settings and conduct
Cochlear implant users who refer to the audiology clinic of Iran University of Medical Sciences Faculty of Rehabilitation which have inclusion criteria participate in this study. they are randomly divided into control and intervention groups by blocking method. Blinding is such that the participants do not know which study group they are in. Initial evaluations and vocal cue discrimination evaluation will be done for both groups, then the intervention group will receive the rehabilitation program designed based on the vocal cues, and after the rehabilitation sessions, pre-rehabilitation evaluations for both control and intervention groups will be repeated and results will be compared

Participants/Inclusion and exclusion criteria
Children aged 10 to 12 years with unilateral cochlear implantation before 4 years of age with a history of using hearing aids before implantation are the inclusion criteria. Having neurological disorders is a criterion for non-entry

Intervention groups
Intervention group: cochlear implant users who received rehabilitation training Control group: cochlear implant users without rehabilitation training

Main outcome variables
discrimination the difference in the of the vocal tract length; discrimination difference in fundamental frequency; speech recognition in noise

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220206053952N3**
Registration date: **2023-04-30, 1402/02/10**
Registration timing: **registered_while_recruiting**

Last update: **2023-04-30, 1402/02/10**
Update count: **0**

Registration date
2023-04-30, 1402/02/10

Registrant information

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Farnoush Jarollahi

Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-03-06, 1401/12/15

Expected recruitment end date

2024-02-15, 1402/11/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Designing and producing an evaluation and rehabilitation program based on the fundumental frequency and the vocal tract length and investigating its effect on speech recognition in noise of children with cochlear implants

Public title

Investigating the efficacy of rehabilitation based on vocal cues on speech recognition in noise in children with cochlear implants

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

10 to 12 years old Unilateral cochlear implantation Performing cochlear implant surgery before 4 years old Having normal general health No history of neurological disorders No history of psychological disorders Absence of external ear l anomalies Normal middle ear function Onset of severe to profound hearing loss before 2 years old History of hearing aid use before implantation Participation in auditory training classes at least 6 months before implantation Monolingual Daily use of standard Persian language

Exclusion criteria:

Reluctance to continue participating in the study at any stage

Age

From **10 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the blocking method is used in the form of 6 quadruple blocks with individual units for random allocation between two control and intervention groups. Random allocation software will be used for random allocation. In order to hide the random allocation, non-transparent sealed envelopes will be used for this purpose, a number of envelopes will be prepared and each of the random sequences created will be recorded on a card and the cards will be placed in the envelope in order to preserve, random sequence is done on the outer surface of the envelopes, numbering is done in the same order, and finally the lid of the envelopes is glued and placed inside the box, then according to the number of each participant envelope will be given to her and her group will be determined

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Iran University of Medical Sciences

Street address

Hemat Highway next to Milad Tower of Iran University of Medical Sciences

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1449614535

Approval date

2022-08-22, 1401/05/31

Ethics committee reference number

IR.IUMS.REC.1401.750

Health conditions studied

1

Description of health condition studied

cochlear implant

ICD-10 code

Z96.21

ICD-10 code description

Cochlear implant status

Primary outcomes

1

Description

Improved discrimination of VTLΔ and F0Δ vocal cues

Timepoint

After ten sessions of rehabilitation based on vocal cues

Method of measurement

VTLΔ vocal cue discrimination test, F0Δ vocal cue discrimination test

2

Description

Improvement of speech in noise perception

Timepoint

After ten sessions of rehabilitation based on vocal cues

Method of measurement

PARVIN speech in noise perception test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention in this study is a new rehabilitation program based on vocal cue discrimination. This program is designed to investigate the effect of improvement speech recognition in noise by vocal cue discrimination exercises. Rehabilitation exercises are divided into 3 general categories of gender voice discrimination, ΔVTL discrimination and ΔF0 discrimination and will be performed in an free field at a comfortable listening level. The easiest exercise is gender voice discrimination. In this case, the training material will be recorded by a female speaker. Then the amount of VTL changes in the ratios of 0.84, 0.92, 0.96, 0.98, 0.21, 04.1, 08.1 and 1.16. The amount of F0 will be decreased in 3, 6, 9, and 12 semitones (producing a male voice) and in 3, 6, and 9 semitones will be increased (producing a thin female voice). the patient should show on monitor that heard the man or the woman. The next exercise in gender voice discrimination is that the items will be recorded once with a male speaker and changes will be applied to reduce the VTL in the ratios of 0.84, 0.92, 0.96, 0.98. Then the items (two consecutive monosyllabic words) with ΔVTL are presented to the individual and the individual is asked to determine whether the first voice or the second voice was spoken by the female speaker (because the changes were towards the female voice), the same exercise with increasing F0 will be presented, that is, items (two consecutive monosyllabic words) with ΔF0 of 3, 6, 9 and 12 semitones will be presented to the individual and the individual will be asked to identify the first voice or the second voice by the female speaker (because the changes were towards the female voice Is),The same exercise will be recorded once with a female speaker, and this time the changes will be in the direction of increasing VTL or decreasing F0 separately, and the person will be asked to specify whether the first or second voice was played by the male speaker. It will be marked on the monitor. The next step is ΔVTL and ΔF0 differentiation exercises, which will be divided into 3 groups of two-syllable, monosyllabic and consonant-vowel words. The exercises in this stage include two modes of distinguishing between two options, and distinguishing between three options. Fist practice of ΔVTL discrimination, is presented to the person in the form of two options that differ or are the same in VTL, and the person must specify whether he heard two options that are the same or different, and the examiner marks on the monitor. The second mode is the distinction between 3 options, where three identical two-syllable or monosyllabic or consonant-vowel words are presented consecutively, one of which has a different VTL from the other two, the person must determine which presentation was different, and the examiner marks on monitor . ΔF0 discrimination exercises will be designed and implemented like ΔVTL exercises. In each of the training stages, after the child's response, visual feedback will appear for him. The optimal situation for auditory perception learning includes active and repeated listening during consecutive training sessions that It is done in a short period of time and considering that long-term rehabilitation is not very suitable for clinical work. Therefore, 40-minute exercises (two 20-minute sessions with a 10-minute break in one day) will be performed twice a week for 10 sessions.

Category

Rehabilitation

2

Description

Control group: These people do not receive the rehabilitation program developed in this study

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Rehabilitation Sciences, Iran University of Medical Sciences

Full name of responsible person

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Sponsors / Funding sources

1

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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
Iran 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

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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

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

Undecided - It is not yet known if there will be 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