

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

effect of pitch discrimination training on speech in noise of hearing impaired 6-10 years old children

Protocol summary

Study aim

The aim of this study is to investigate the effect of auditory rehabilitation based on pitch differentiation on speech perception in noise in hearing impaired children 6 to 10 years

Design

clinical trial without control group with convenience sampling on 18 hearing impaired children

Settings and conduct

The site of evaluation and rehabilitation is in the educational and rehabilitation center for children with hearing disorders. In this method, children with moderate to severe hearing loss evaluate before intervention with vowel consonant in noise test, sentence in noise test, pitch pattern sequence, harmonic evaluation and object-related negative wave. At the end of the intervention, the assessments were repeated and compared with before intervention. Hearing impaired children were examined as an convenience

Participants/Inclusion and exclusion criteria

age range 6 to 10 years with moderate to severe hearing loss, no auditory neuropathy, normal middle ear, lack of developmental, cognitive and behavioral problems, normal IQ, Persian language with single language Persian language parents, right hand superiority, no history of head trauma, epilepsy and seizures and use of nervous system drug

Intervention groups

. The intervention in this study is pitch training. In this type of rehabilitation, a 100 Hz complex stimulus included, frequency of 100 Hz and 10 harmonics present. Then, in different presents , each time one of the harmonics mistune and the person hears two separate sounds that compare and differentiate with the first stimulus. In the second stage, the 200Hz stimulus and in the third stage, the 300Hz stimulus present similar to 100 Hz frequency.

Main outcome variables

Consonant Vowel in noise, Sentence in noise, Pitch

pattern test, Harmonic discrimination, Object Related Negativity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201109049324N1**

Registration date: **2020-11-17, 1399/08/27**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-17, 1399/08/27**

Update count: **0**

Registration date

2020-11-17, 1399/08/27

Registrant information

Name

Nasrin Gohari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3627 1956

Email address

n.gohari@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-29, 1399/05/08

Expected recruitment end date

2020-12-14, 1399/09/24

Actual recruitment start date

2020-07-29, 1399/05/08

Actual recruitment end date

2020-12-14, 1399/09/24

Trial completion date

2020-12-14, 1399/09/24

Scientific title

effect of pitch discrimination training on speech in noise of hearing impaired 6-10 years old children

Public title

effect of pitch training on speech in noise

Purpose

Basic science

Inclusion/Exclusion criteria**Inclusion criteria:**

consent of parents and children to participate in the study age range 6 to 10 years and six month moderate to severe sensory neural hearing loss

Exclusion criteria:

Auditory neuropathy Developmental, cognitive and behavioral disorder Abnormal IQ History of head trauma, epilepsy and seizures and use of nervous system drug Not speaking Persian language and not having Persian language parents with single language Lack of right hand superiority Inability to perform tests

Age

From **6 years** old to **10 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **18**

Actual sample size reached: **18**

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**

Ethics Committee in Research, University of Social Welfare and Rehabilitation Sciences

Street address

No.7, Shahid Mansouri Alley., Ghodousi Bolvd., Varamin

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Province

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Postal code

33716-15738

Approval date

2019-11-24, 1398/09/03

Ethics committee reference number

IR.USWR.REC.1398.137

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

Hearing impaired

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

speech in noise

Timepoint

before intervention and 2 month and 3 month after intervention

Method of measurement

speech in noise tests-CV in noise-BKB

2**Description**

mistuned harmonic stimulation discrimination

Timepoint

before intervention and 2 month and 3 month after intervention

Method of measurement

harmonic assessment

Secondary outcomes**1****Description**

late latency response and object related negativity

Timepoint

before intervention and 2 month after intervention

Method of measurement

late latency response and object related negativity

Intervention groups**1****Description**

Intervention group: 14 sessions of harmonic(pitch) discrimination rehabilitation. intervention will be performed for hearing impaired children. Harmonic changes in each session are reduced according to the

individual's ability. Also, the harmonic evaluation, pitch pattern sequence, vowel consonant in noise, sentence in noise and late cortical responses and object related negative wave before and after rehabilitation are evaluated and compared. Necessary equipment is speech assessment and rehabilitation software in noise and electroencephalography device.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

rasa children hearing disorder center

Full name of responsible person

Nasrin Gohari

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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

Hamidreza Khankeh

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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

Nasrin Gohari

Position

PhD student

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

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