

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Evaluation of the efficacy and efficiency of phonemic training programs in auditory processing status of prelingually deaf children with Cochlear implant: a single subject study

Protocol summary

Study aim

Reviewing the hearing difficulties due to susceptible auditory processing deficits in cochlear implant users and evaluating the efficacy of Phonemic training program and Phonemic Synthesis Program on these users based on single-subject study design

Design

A single arm pre- post test

Settings and conduct

A single-arm trial on 7-year-old patients referred to the Tabassom Clinic, Ahvaz, Iran for cochlear implant

Participants/Inclusion and exclusion criteria

Inclusion criteria - Healthy peripheral auditory system - Healthy hearing system - Normal IQ based on Wechsler Intelligence Test - No history of chronic otitis media - Right hand based on the Edinburgh Handwriting Questionnaire - Farsi-language monolingual Exclusion criteria - Non-participation in evaluation sessions - Individual or parent's unwillingness to participate in research - Middle ear infection between test and retest - Fatigue, reduction or lack of attention

Intervention groups

The intervention phase includes two training programs: The phonemic Synthesis Program and the Phonemic Training Program. Considering the nature of the study, no control group is needed.

Main outcome variables

The status of Word recognition score; The status of Phoneme recognition score in PRT; The status of Quantitative score in PST; The status of Qualitative score in PST; The status of Buffalo model subcategories including decoding, tolerance fading memory, and organization; The status of the pattern of phoneme errors including omission, substitution, added, and total phoneme errors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200120046209N1**

Registration date: **2020-04-14, 1399/01/26**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-14, 1399/01/26**

Update count: **0**

Registration date

2020-04-14, 1399/01/26

Registrant information

Name

Sahar Shomeil Shushtari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3750 5694

Email address

sshomeil@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-10, 1398/10/20

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy and efficiency of phonemic training programs in auditory processing status of prelingually deaf children with Cochlear implant: a single subject study

Public title

Evaluating the efficacy of phonemic training in cochlear implant users

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Healthy peripheral auditory system Healthy hearing system Normal IQ based on Wechsler Intelligence Test No history of chronic otitis media Right hand based on the Edinburgh Handwriting Questionnaire Persian-language monolingual

Exclusion criteria:

Non-participation in evaluation sessions Individual or parent's unwillingness to participate in research Middle ear infection between test and retest Fatigue, reduction or lack of attention

Age

From **8 years** old to **11 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **15**

Randomization (investigator's opinion)

Not randomized

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**

Joint Organizational Ethics Committee of Faculty of Nursing and Midwifery with Faculty of Rehabilitation

Street address

Keshavarz Blv

City

Tehran

Province

Tehran

Postal code

61537

Approval date

2019-10-15, 1398/07/23

Ethics committee reference number

IR.TUMS.FNM.REC.1398.140

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

Children with hearing loss

ICD-10 code

H91.90

ICD-10 code description

Unspecified hearing loss, unspecified ear

Primary outcomes**1****Description**

Phoneme recognition test: It is a test specifically designed to evaluate phonological level auditory processing ability in cochlear implant users.

Timepoint

The score is a percentage obtained through testing and observation. The test will be conducted eight weeks before the intervention phase, during the intervention phase once time every week, once a week after the intervention phase for eight-week.

Method of measurement

Phoneme recognition score based on PRT, Quantitative score based on PST, Qualitative score based on PST, Qualifiers representing buffalo model subcategories based on PST, Speech discrimination score based on WRS, Patterns, and frequency of phoneme errors including omission, substitution, added and total based on PEA

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

Phoneme synthesis Test: Presenting a phoneme to a phoneme is a meaningful (or nonsensical) word in which the listener is obliged to stick these phonemes together and to express the word forming it.

Timepoint

The raw data points are obtained through testing and observation. This test will be performed before the intervention once a week for eight weeks, during the intervention once a week for eight weeks and after the intervention once a week for eight weeks.

Method of measurement

The 54 words in the one-to-four syllable that are referred to as full-color images form the test items. The general requirements for word assignment are frequency testing,

high imaging capability and specific item allocation conditions are consistent with the test objectives. Among the vocabulary assigned to this test are 31 single syllables, 18 binary syllables, three syllables, and one quadratic syllable, and 29 end-of-sentence words.

Intervention groups

1

Description

Intervention group: Persian-speaking children 8-11 years old with cochlear implant

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabasam Comprehensive Hearing and Speech Rehabilitation Center

Full name of responsible person

Professor Nader Saki

Street address

24 metery street, Sharifzadeh street, Nezamvafa system, Tabasm complex

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Ahvaz

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Khouzestan

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61537

Phone

+98 61 3292 6851

Email

ahvaz.ent@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr Mohammad Badavi

Street address

Golestan Ave

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Phone

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Email

Research@ajumsa.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz 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

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Sahar Shomeil Shushtari

Position

PhD candidate

Latest degree

Master

Other areas of specialty/work

Audiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Sahar Shomeil Shushtari

Position

PhD candidate

Latest degree

Master

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

We didn't planed for data availability so far

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

empty

When the data will become available and for how long

empty

To whom data/document is available

empty

Under which criteria data/document could be used

empty

From where data/document is obtainable

empty

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

empty

Comments

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Sahar Shomeil Shushtari

Position

PhD candidate

Latest degree

Master

Other areas of specialty/work

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