

# 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

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

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

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

61537-15794

##### Phone

+98 61 3373 8383

##### 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

##### Street address

Naderi

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

6195655659

##### Phone

+98 61 3374 3506

##### Email

Sshomeil@gmail.com

## Person responsible for scientific 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

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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 plan 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**

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**Latest degree**

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