

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Investigation of the effect of a Phonological awareness training program on the phonological awareness skills in the Persian-speaking first grade primary-school aged students with cochlear implant .

Protocol summary

Summary

The aim of this study is to determine the effectiveness of a phonological awareness training program on phonological awareness skills in the first grade Persian students with cochlear implant. 40 children with cochlear implant aged 72 to 84 months who received their cochlear implant operation up to the age 3 years, with no psychiatric disorders history and a normal IQ and mean lengths of utterances more than 3 words will be recruited from cochlear implant centers and elementary schools for this study. They will then be randomly assigned into either intervention or control groups. After completing a phonological awareness test in both groups, the intervention group will be received the phonological awareness training program which will be in group format and includes discrimination of rhyme, syllable segmentation, blending of phonemes, and identifying the opening and closing phonemes of the words. The experimental group will receive 24 45-minutes sessions totally, two sessions per week. After completing the intervention sessions, both groups will re-sit for the same phonological awareness test as pre-intervention. The cochlear implanted children will be expected to have better performance in phonological awareness test which will improve their reading skills at school.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017071235041N1**

Registration date: **2017-09-02, 1396/06/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-02, 1396/06/11

Registrant information

Name

Nahid Baharloe

Name of organization / entity

Isfahan University of Medical Sciences Faculty of Rehabilitation Sciences

Country

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+98 31 3669 3089

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2017-08-06, 1396/05/15

Expected recruitment end date

2017-09-06, 1396/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of a Phonological awareness training program on the phonological awareness skills in the Persian-speaking first grade primary-school aged students with cochlear implant .

Public title

The effect of phonological awareness training on

phonological awareness in children with cochlear implant.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: sign the informed consent form to participate in therapy sessions; use one of the three types of the following cochlear implant models: Dentures, Cochlear, or Advanced Bionics ; speak the Persian language (by asking preschool teacher, parents, or by checking the child file at school); have mean lengths of utterance more than three words (by taking spontaneous connected speech samples); aged between 72 to 84 months; had cochlear implant surgery up to the age 3 years; does not use a hearing aid in the other ear; have a similar linguistic profile to a 60 months normal children using the Persian version TOLD - P: 3; has normal IQ based on the child file at school;no history of psychiatric disorders such as seizures, epilepsy or Pervasive Developmental Disorders, etc. (based on the child's medical records). Exclusion criteria: receiving a psychological or medical treatment during the study; absence in more than two treatment sessions during the study.

Age

From **6 years** old to **7 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Hezarjarib street,Isfahan University of Medical Sciences

City

Isfahan

Postal code

81745164

Approval date

2016-07-20, 1395/04/30

Ethics committee reference number

IR.MUI.REC.1395.3.356

Health conditions studied

1

Description of health condition studied

hearing loss

ICD-10 code

H90,H95

ICD-10 code description

other disorders of ear

Primary outcomes

1

Description

phonological awareness

Timepoint

before intervention

Method of measurement

phonological awareness test

Secondary outcomes

empty

Intervention groups

1

Description

For the intervention group, a phonological awareness training program is used that includes discrimination of rhyme, syllable segmentation, blending phonemes, identification onset and final phonemes of words and the therapist silently says that the child should be able to identification the word in the direction of the lips, and show the image and educate intra-syllabic awareness training introduce this rhyme from understanding and expressing the rhyme. Phonemic awareness training includes three parts of the program for teaching phonemic blending and phoneme segmentation, and identification onset and final phonemes.

Category

Treatment - Other

2

Description

intervention is not performed For the control group

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

CochlearImplant Center

Full name of responsible person

Majid Karimi

Street address

24Metri street, Sharifzade street

City

Ahvaz

2

Recruitment center

Name of recruitment center

EducationCenter

Full name of responsible person

Abbas Rostami

Street address

Mordadesharghi street, Kiyanpars

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences,Vice chancellor for research

Full name of responsible person

Dr.Nematbakhsh

Street address

Isfahan University of Medical Sciences, Hezarjarib street,

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan University of Medical Sciences,Vice chancellor for research

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Nahid Baharloe

Position

Instructor/Member of Speech and Language Department

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Master of speech therapy student

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Person responsible for updating data

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty