

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of traditional therapy accompanied with music therapy on speech intelligibility of children with cochlear implant.

Protocol summary

Summary

The aim of this study is to evaluate the effect of music therapy on increasing speech intelligibility of children with cochlear implant. This study is designed randomly and single blind. Target population included 30 children with hearing loss over 3 years old who are used with cochlear implant at least 5 months and did not have any disabilities other than hearing loss. 15 children will participate in the control group. They will benefit from traditional treatment for 4 weeks (2 session in a week). 15 more children will be in the intervention group. In addition to traditional treatment, at the same time, they will also benefit from music therapy of 4 weeks (2 session in a week).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015101724561N1**

Registration date: **2015-10-30, 1394/08/08**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-10-30, 1394/08/08

Registrant information

Name

Masoume Hosseini Beydokhti

Name of organization / entity

Ahvaz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3447 2571

Email address

hosseini.mas@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahvaz University of Medical Sciences Jundishapur

Expected recruitment start date

2015-11-06, 1394/08/15

Expected recruitment end date

2015-12-06, 1394/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of traditional therapy accompanied with music therapy on speech intelligibility of children with cochlear implant.

Public title

The effect of music therapy to increase speech intelligibility

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: at least 3 years of chronological age. At least 5 months of cochlear implant. Training after planting in Persian. Lack of information of children with any disability, except for hearing loss. Lack of appropriate speech intelligibility for each of the target words. Exclusion criteria: create any problems in the child's cochlear implant. Lack of parental involvement.

Age

From **3 years** old to **10 years** old

Gender

Both

Phase

N/A

Groups that have been masked
No information

Sample size
Target sample size: 30

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
University of medical science jondishopur

Street address
daneshgah square

City
Ahwaz

Postal code
61357-15794

Approval date
2015-07-25, 1394/05/03

Ethics committee reference number
IR.AJUMS.REC.1394.282

2

Ethics committee

Name of ethics committee
University of medical science jondishopur

Street address
daneshgah square

City
Ahwaz

Postal code
61357-15794

Approval date
2015-07-25, 1394/05/03

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Health conditions studied

1

Description of health condition studied
Hearing Loss

ICD-10 code

H90.3

ICD-10 code description
Sensorineural hearing loss, bilateral

Primary outcomes

1

Description
Speech intelligibility of words

Timepoint
A week before intervention - A week after intervention

Method of measurement
Acoustic intelligibility of speech in percent

2

Description
Speech intelligibility of sentences

Timepoint
A week before intervention - A week after intervention

Method of measurement
SIR scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group : 4 weeks music therapy (2 session of 30 minutes in every week) and at the same time,4 weeks of traditional treatment about speech intelligibility increasing (2 session of 30 minutes in every week) .(Music therapy trainings include of simple musical lyrics which is applied and traditional treatment trainings include of modifying the placement and expression of letters.)

Category
Other

2

Description
Control group : 4 weeks of traditional treatment about speech intelligibility increasing (2 session of 30 minutes in every week).(traditional treatment trainings include of modifying the placement and expression of letters.)

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Hearing cochlear implant center

Full name of responsible person

Dr.Saki-Nader(Ear.Throat.Nose Specialist)

Street address

Alamolhoda Street - between Naderi and Kafi

City

Ahwaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of medical science jondishapur

Full name of responsible person

Saki Nader

Street address

Education Development Deputie of jondishapur
medical science university

City

Ahwaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

University of medical science jondishapur

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

Jondishapur Medical science University

Full name of responsible person

Hosseini Beydokhti.Masoume

Position

M.A student of speech therapy

Other areas of specialty/work

Street address

Daneshgah Square

City

Ahwaz

Postal code

61357-15794

Phone

+98 61 3336 2414

Fax

+98 61 3336 1544

Email

Hosseini.mas@ajums.ac.ir

Web page address

vchresearch.ajums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Jondishapur Medical Science University

Full name of responsible person

Moradi Negin

Position

PhD.Speech therapy

Other areas of specialty/work

Street address

Daneshgah Square

City

Ahwaz

Postal code

61357-15794

Phone

+98 61 3336 2414

Fax

+98 61 3336 1544

Email

neginmoradist@gmail.comitc@ajums.ac.ir

Web page address

vchresearch.ajums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Jondishapur Medical Science University

Full name of responsible person

Hosseini Beydokhti.Masoume

Position

M.A student of speech therapy

Other areas of specialty/work

Street address

Daneshgah Square

City

Ahwaz

Postal code

61357-15794

Phone

+98 61 3336 2414

Fax

+98 61 3336 1544

Email

Hosseini.mas@ajums.ac.irMasoume64hosseini@gmail.com

Web page address

vchresearch.ajums.ac.ir

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