

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of efficacy of focused language treatment and working memory training on some of the components of grammar in children with cochlear implant

Protocol summary

Summary

The aim of this study is to compare the effectiveness of reinforcement of working memory and the language treatment on certain components of grammar of children are receiving cochlear implants. The study included: The intervention group1: grammar intervention done on it. Intervention group2: intervention is done on the working memory and control group who continue their routine sessions of speech therapy. The sample is consisted of 15 subjects (each group consisted of 5 patients who were randomly divided into groups by closed envelope). This study is a single-center, randomized and blinded. Participants between 5 and 8 years of age and have at least two years of experience using cochlear implants. Working memory intervention and grammar intervention, done in 5 weeks. During the five weeks of the child and family once a week to come therapist, this session includes evaluating aspects taught in the previous session, treatment and education family for workouts during the week. The family is responsible for 30 to 45 minutes a day 5 days a week, practice with the child at home. Primary and secondary outcome variables (grammar and memory) will be measured before and after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016071726083N1**
Registration date: **2016-07-17, 1395/04/27**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-07-17, 1395/04/27

Registrant information

Name

soodeh khoramian

Name of organization / entity

Tehran University of Medical Sciences

Country

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+98 21 7753 3939

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mkhoramian@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2016-10-21, 1395/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of focused language treatment and working memory training on some of the components of grammar in children with cochlear implant

Public title

efficacy of focused language treatment and working memory training on some of the components of grammar in children with cochlear implant

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: aged between 5 to 8 years; They are congenital hearing loss; Two years have passed since the implants; Their language is Persian language; Based on test of language 50 have said, at least; Hearing loss is not caused by the syndrome; They have not Neuromuscular disorder; They have normal non-verbal; Unilateral cochlear implant; implant on the right ear; the child is right-handed; 22-channel nucleus prosthesis
Exclusion criteria: Child has other deficit with hearing loss; child is bilingual.

Age

From **5 years** old to **8 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **15**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Parallel allocation; Randomized using sealed envelopes

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Enghelab Ave

City

Tehran

Postal code

Approval date

2016-02-15, 1394/11/26

Ethics committee reference number

IR.TUMS.REC.1394.1971

Health conditions studied

1

Description of health condition studied

hearing loss

ICD-10 code

H90.2

ICD-10 code description

Conductive hearing loss, unspecified

Primary outcomes

1

Description

Reception of Grammar

Timepoint

5 weeks

Method of measurement

Test of Language Development

Secondary outcomes

1

Description

working memory

Timepoint

5 weeks

Method of measurement

forward & backward digit span of WISC

Intervention groups

1

Description

Intervention group 1: language intervention for 5 weeks (25 days) - each session is 30 to 45 minutes- Will be implemented in partnership with parents. Method of treatment in this group include modelling and focused stimulation on comprehension and expression grammar. Mothers will be trained how to intervene by therapist.

Category

Rehabilitation

2

Description

working memory intervention for 5 weeks (25 days)- each session is 30 to 45 minutes- Will be implemented in partnership with parents. Method of memory enhancement is providing auditory stimuli such as the retrieval number, word, sentence. Mothers will be trained how to intervene by therapist.

Category

Rehabilitation

3

Description

Control group: routine speech therapy they receive

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir-Alam Hospital

Full name of responsible person

Masoud Motasaddi zarandy

Street address

E.N.T department, Amiralam Hospital, Saadi ave. ,
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City

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Other areas of specialty/work

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

tehran University of Medical sciences

Full name of responsible person

Masud Yunesian

Street address

Department of Environmental Health Engineering,
School of Public Health, Tehran University of Medical
Sciences

City

Tehran

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

tehran University of Medical sciences

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

Tehran University of Medical Sciences

Full name of responsible person

soodeh khoramian

Position

master of Science

Person responsible for scientific inquiries

Contact

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Assistant Professor

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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