

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

The effectiveness of language based executive function program on improving cognitive and language abilities and reducing behavioral problems in cochlear implanted children

Protocol summary

Study aim

Examining the effectiveness of language-based executive function training on improving language and cognitive skills and reducing behavior problems

Design

24 participants were randomly assigned to experimental and control groups. The experimental group will receive language-based executive function training. The control group will not receive this training.

Settings and conduct

Before the intervention, children are assessed by Test of Language Development, Binet Working Memory Test, Structured Observation of Self-regulation and Dimensional Change Card Sort. Strength and Difficulties Questionnaire is filled by mothers as well. Then, participants will be assigned to two groups. experimental group will receive Executive function training (inhibition, working memory and cognitive flexibility) in 18 sessions. After finishing the training sessions post-test will be performed.

Participants/Inclusion and exclusion criteria

Target population: preschool cochlear implanted children of Sokhan rehabilitation center in Qom. inclusion criteria: Age range (4-7 years old), At least, one year interval between cochlear implant operation and the study exclusion criteria: Psychiatric drug usage, signs of any other physical illness and psychological problems, lack of motivation of the child or parents' desire on continuing cognitive training

Intervention groups

Intervention group: cochlear implanted children who receive language-based executive function training
Control group: cochlear implanted children without language-based executive function training

Main outcome variables

language skills, cognitive skills (inhibition, working memory, cognitive flexibility) and behavior problems

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230515058200N1**

Registration date: **2023-05-28, 1402/03/07**

Registration timing: **registered_while_recruiting**

Last update: **2023-05-28, 1402/03/07**

Update count: **0**

Registration date

2023-05-28, 1402/03/07

Registrant information

Name

Samaneh Haji khodadadi

Name of organization / entity

Lorestan University

Country

Iran (Islamic Republic of)

Phone

+98 25 3270 2979

Email address

hajikhodadadi.sm@fh.lu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-20, 1402/02/30

Expected recruitment end date

2023-07-20, 1402/04/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of language based executive function program on improving cognitive and language abilities and reducing behavioral problems in cochlear implanted children

Public title

The effectiveness of executive function training on cochlear implanted children

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age range 4-7 At least, one year interval between cochlear implant operation and the study Normal range intelligence quotient

Exclusion criteria:

Psychiatric drug usage signs of any other physical illness and psychological problems

Age

From **4 years** old to **7 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomizing, single, with the table of random numbers: First, a number, from 1 to 24, is assigned to each participant. Then we start from a random number in the table as the start point and move in that line to the right. Numbers less or equal 24 are chosen. The first 12 numbers would be in the intervention group and the remaining numbers would be in the control group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Lorestan University of Medical Sciences

Street address

Lorestan University of Medical Sciences., Anooshirvan Rezaei Square., Moalem St., Khorramabad,

City

Khorramabad

Province

Lorestan

Postal code

6813833946

Approval date

2023-04-26, 1402/02/06

Ethics committee reference number

IR.LUMS.REC.1402.047

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

Subscale scores of Test of Language Development

Timepoint

Before the intervention - after the intervention

Method of measurement

Test of Language Development

2

Description

cognitive skills that will be assessed by inhibition, working memory and cognitive flexibility tests.

Timepoint

Before the intervention - after the intervention

Method of measurement

Binet working memory test, Structured Observation Self-regulation, Dimensional Change Card Sort

3

Description

Behavior problems

Timepoint

Before the intervention - after the intervention

Method of measurement

Subscale scores of Strength and Difficulties Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Language-based executive function training. This study is performed in Sokhan rehabilitation center in 18 sessions in 1 month and a half. First, exercises will be designed according to learning content. Then, essential tools such as toys and pictures will be prepared. the exercises will be set in a way that require the child's verbal response for instance: digit or word span in working memory training or day/night stroop in inhibition training.

Category

Rehabilitation

2

Description

Control group: This group does not receive the training program developed in this study.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Sokhan rehabilitation center

Full name of responsible person

Narges Nematollahi

Street address

Shokhan rehabilitation center., 50th alley., Emam Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Lorestan University

Full name of responsible person

Kouros Amraei

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Lorestan University

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

Lorestan University

Full name of responsible person

Samaneh Haji khodadadi

Position

Master's Student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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Full name of responsible person

Kouros Amraei

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assistant professor

Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available