Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Oct 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 Nematallahi

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

City
Qom

Province
Ghoum

Postal code
3719686496

Phone
+98 25 3661 2384

Email
Sokhan1379@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Lorestan University

Full name of responsible person
Kourosh Amraei

Street address
Lorestan University, Lorestan, Khorramabad

City
Khorramabad

Province
Lorestan

Postal code
۶۸۱۵۱۴۴۳۱۶

Phone
+98 66 3312 0106

Email
LUChancellor@lu.ac.ir

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

Street address
No. 35, the first dead end on the right, Second alley., Besat St., Ghamar bani hashem Ave., Isar Town

City
Qom

Province
Ghoum

Postal code
3713198339

Phone
+98 25 3270 2979

Email
s.hajikhodadadi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Lorestan University

Full name of responsible person
Kourosh Amraei

Position

assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

Street address
Lorestan University, Khorramabad, Lorestan, Iran

City
Khorramabad

Province
Lorestan

Postal code
۴۴۳۱۶-۶۸۱۵۱

Phone
+98 66 3312 0097

Email
amraei.k@lu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Lorestan University

Full name of responsible person
Samaneh Haji khodadadi

Position
Master's Student

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3713198339

Phone
+98 25 3270 2979

Email
s.hajikhodadadi@gmail.com

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