

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The investigation of efficacy of theory of mind practices on perception of mental verbs in Farsi-speaking children aged 5-7 -year- old with hearing aid and cochlear implant

Protocol summary

Study aim

Effectiveness of theory of mind exercises on perception of mental verbs in Persian children with hearing aid and cochlear implant

Design

We choose the children based on inclusion and exclusion criteria. After that we will doing Randomized, parallel group trial with blinded outcome assessment. Randomization will performed with sealed envelopes in each of the intervention and control groups.

Settings and conduct

The children will be grouped in a simple random manner. Children in groups A and B are cochlear implant users and in groups C and D are hearing aid users, A and C were as intervention groups and groups B and D were as control groups. First, the perception of mental verbs and the theory of mind of children in each group are examined and the scores are recorded. Theory of mind exercises are performed twice a week for both intervention groups for 8 weeks by speech therapist. Finally, the children's understanding of mental verbs is re-evaluated, and then the scores of each group before and after the study are compared with the control group. Mental verbs and theory of mind skills will be re-assessment after one month.

Participants/Inclusion and exclusion criteria

Normal IQ, sensorineural type congenital hearing loss, Unilateral cochlear implant, At least one year has passed since receiving the prosthesis ,Farsi language, Ability to speak simple sentences; Absence of cognitive, sensory, neurological, psychological and emotional problems

Intervention groups

Children with hearing impairment who use hearing aids and cochlear implant will be randomly assigned to four intervention and control groups

Main outcome variables

improvement in theory of mind and perception of mental

verb

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230827059274N1**

Registration date: **2023-09-05, 1402/06/14**

Registration timing: **prospective**

Last update: **2023-09-05, 1402/06/14**

Update count: **0**

Registration date

2023-09-05, 1402/06/14

Registrant information

Name

Fatemeh Hassanati

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2024-06-21, 1403/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The investigation of efficacy of theory of mind practices on perception of mental verbs in Farsi-speaking children aged 5-7 -year- old with hearing aid and cochlear implant

Public title

The efficacy of theory of mind practices on perception of mental verbs

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

IQ in the normal range congenital hearing loss before the language learning period of sensorineural type Unilateral cochlear implantation before 5 years of age At least one year has passed since receiving the prosthesis Passing speech therapy programs in the past year Predominance of Farsi language in the speech of the child and her family(feminine) Ability to speak simple sentences Age range between 5 and 7 years Natural cognitive skills based on children's history and medical records and the Wechsler intelligence test, which is administered by a psychologist Absence of sensory problems such as blindness diagnosed by a specialist doctor based on the history and medical records of children Absence of neurological problems such as movement disorders and paralysis in the limbs and face, epilepsy and convulsions diagnosed by a specialist doctor based on the history and medical file of children Absence of psychological and emotional problems such as mental retardation, hyperactivity, autism, and medical syndromes No receiving interventions in the field of theory of mind or understanding mental actions

Exclusion criteria:

Discontinuing the research process on behalf of the child or the child's parents Prosthesis or hearing aid failure or the need for major repairs that lead to the child being deprived of the prosthesis for several weeks The occurrence of diseases that lead to the process of research interventions being interrupted for several weeks (simple colds are excluded from this rule) History of receiving theory of mind exercises Using hearing aids and cochlear implants at the same time

Age

From **5 years** old to **7 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

First, based on the inclusion and inclusion criteria, the

names of eligible children are extracted and their names are placed in a simple random manner and individually in sealed envelopes in each of the intervention and control groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

The evaluators who rate, code and analyze the results will be unaware of the demographic information of the children, the time period of the evaluations and the grouping of the children. Therefore, the present randomized clinical trial is a blind.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of university of social welfare and rehabilitation sciences

Street address

University of Social Welfare and Rehabilitation Sciences, Kodakyar Ave., Daneshjo Blvd.,Evin, Tehran

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Province

Tehran

Postal code

1985713871

Approval date

2023-08-22, 1402/05/31

Ethics committee reference number

IR.USWR.REC.1402.094

Health conditions studied**1****Description of health condition studied**

hearing loss

ICD-10 code

H91.90

ICD-10 code description

Unspecified hearing loss, unspecified ear

Primary outcomes**1****Description**

Improvement in perception of mental verbs with changing in perception of mental verb test.

Timepoint

8 weeks

Method of measurement

Perception of mental verbs test

2**Description**

Improvement in theory of mind

Timepoint

8 weeks

Method of measurement

Perception of theory of mind test

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Children with hearing impairment who use hearing aids and cochlear implant (2 intervention groups) will be evaluated by mental verb perception test and theory of mind test. Then, the theory of mind intervention will be implemented for 16 sessions of thirty minutes in 8 weeks. One month after the end of the intervention period, evaluations will be done again and the amount of changes will be recorded.

Category

Rehabilitation

2**Description**

Control group: Children with hearing impairment who use hearing aids and cochlear implant (2 intervention groups) will be evaluated by mental verb perception and theory of mind test. Then, for 16 sessions of thirty minutes in 8 weeks, common speech therapy will be performed. One month after the end of the intervention period, evaluations will be done again and the amount of changes will be recorded.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Sokhan center

Full name of responsible person

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2**Recruitment center****Name of recruitment center**

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

University of social welfare and rehabilitation sciences

Full name of responsible person

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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

University of social welfare and rehabilitation sciences

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
University of social welfare and rehabilitation sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The information remains confidential with the researcher

Study Protocol

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

Statistical Analysis Plan

No - There is not 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

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The information will be sent to the welfare and exceptional education organization in the form of a protocol, which will be used if approved

When the data will become available and for how long

2025

To whom data/document is available

The final protocol will be available to researchers and therapists

Under which criteria data/document could be used

It can be used in research and clinical matters by regarding the principles of trustworthiness and following the correct principles of its methods

From where data/document is obtainable

Main researcher or published article
What processes are involved for a request to access data/document

Sending email and signing the contract to comply with the ethical principles of using the protocol
Comments