

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Investigating the effect of play on self-esteem and coping of hearing impaired children

Protocol summary

Study aim

Determining the effect of play on self-esteem and adaptation of hearing impaired children

Design

Clinical trial with a control group, with parallel groups, a blinded, randomized, on 62 hearing impaired children, block randomization

Settings and conduct

The researcher has visited the educational centers of hearing impaired children in Hamedan city and provides a list of these children, then he contacts the families of the children who are in the study age and invites them. In this study, the children in the control group received routine training and the children in the intervention group will be trained in a group game in 10 sessions under the supervision of the researcher during 2.5 months. Each game session will last about 45 minutes. The data analyst will be unaware of the allocation of children to the control and intervention group

Participants/Inclusion and exclusion criteria

Inclusion criteria: Desire of children and their parents, Hearing impairment in the range of 35 to 90 decibels
Exclusion criteria: Failure to participate in more than one game session

Intervention groups

During 2.5 months, children in the intervention group, under the supervision of the researcher, will play group games in 10 sessions according to a certain schedule, in order to examine its effect on the children's self-esteem and adaptation. Each game session will last about 45 minutes, and the control group will receive routine care. will receive

Main outcome variables

Coppersmith's self-esteem score : Social adjustment of children

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190703044082N7**

Registration date: **2023-03-21, 1402/01/01**

Registration timing: **registered_while_recruiting**

Last update: **2023-03-21, 1402/01/01**

Update count: **0**

Registration date

2023-03-21, 1402/01/01

Registrant information

Name

Fateme Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 4567 8904

Email address

f-mohammadi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-11, 1401/12/20

Expected recruitment end date

2023-06-19, 1402/03/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of play on self-esteem and coping of hearing impaired children

Public title

play on self-esteem and coping of hearing impaired children

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Satisfaction of children and their parents Children aged 8 to 12 who have hearing impairment Having no other physical or mental disorders Children should not be under psychiatric or psychological treatment. Hearing loss in the frequency range of 35 to 90 (dB)

Exclusion criteria:

Reluctance of parents and children to continue studying Failure to attend more than one meeting

Age

From **8 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of random allocation of samples in two intervention and control groups was block random. For random allocation of samples in two control and intervention groups, 6 types of blocks of 4 will be used in the form of block random allocation with replacement method. In this way, the letter A for the intervention group and the letter B for the control group will be considered using a simple random method. We will write the following blocks on the pieces of paper and put them in the envelope and remove them randomly. Then, according to the possible order of sampling, it will start as AABB, BBAA, ABBA, BAAB, ABAB, BABA. Based on the order of the letters of the blocks, children will be assigned to the intervention or control group. Then the next blocks will be selected in the same way.

Blinding (investigator's opinion)

Single blinded

Blinding description

With the coordination of the center manager, the people who are in the test group will visit on even days and the people in the control group will visit on odd days .The statistical analyst also does not know the allocation of people in the intervention and control groups and their names

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research ethics committee of Hamadan University of Medical Sciences

Street address

Beginning of Khajeh Rashid Blvd, Hamedan University of Medical Sciences

City

Hamedan

Province

Hamadan

Postal code

6517838698

Approval date

2023-03-09, 1401/12/18

Ethics committee reference number

IR.UMSHA.REC.1401.1045

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

Hearing loss

ICD-10 code

H90

ICD-10 code description

Conductive and sensorineural hearing loss

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

Coppersmith's self-esteem score

Timepoint

The beginning, immediately after the intervention, one month after the intervention

Method of measurement

Coppersmith self-esteem scale

2**Description**

Social adjustment of children

Timepoint

The beginning, immediately after the intervention, one month after the intervention

Method of measurement

Sinha and Singh student compatibility questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: During ten 45-minute sessions, the intervention group will receive group games according to the pre-determined schedule under the supervision of the researcher. (including: crafts, bubble making, play dough...)

Category

Treatment - Other

2

Description

Control group: The control group will receive routine care.(including the use of limited play equipment available in the center and without grouping and group play)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Nyusha Deaf Center

Full name of responsible person

Nyusha Deaf Center

Street address

Turkman alley, Taleghani street, Hamadan

City

Hamedan

Province

Hamadan

Postal code

6517838698

Phone

+98 81 3334 5634

Email

F-mohammadi@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Fatemeh mohammadi

Street address

Khajeh Rashid Blvd, Hamedan University of Medical sciences, Hamadan Town

City

Hamedan

Province

Hamadan

Postal code

6517838698

Phone

+98 81 3334 5634

Email

F-mohammadi@umsha.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan University of Medical 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

Hamedan University of Medical Sciences

Full name of responsible person

Fatemeh mohammadi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Khajeh Rashid Blvd, Hamedan University of Medical sciences, Hamadan Town

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Phone

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Hamedan University of Medical Sciences

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Person responsible for updating data

Contact

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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