Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

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

Protocol summary

Study aim
Determining the effect of group play on self-esteem and quality of life in hearing impaired children
Design
A clinical trial with a control group, with parallel groups, one-blind, randomized, on 62 hearing-impaired children, block randomization was performed.
Settings and conduct
This study is conducted in a one-sided blind way at Nyusha Center for the Hearing Impaired in Hamedan. The data analyst will be blinded
Participants/Inclusion and exclusion criteria
Entry conditions: willingness of participants and their parents, hearing impairment to hear sounds with a frequency of 30 dB Exclusion criteria: children undergoing psychiatric or psychological treatment, having physical, mental, developmental, behavioral disorders
Intervention groups
In the study, children in the control group received routine training, and children in the intervention group will be trained in a group game under the supervision of the researcher in 10 sessions, one session a week, for 2.5 months. Each game session will last about 45 minutes.
Main outcome variables
Quality of Life; Self-esteem

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230429058023N1**
Registration date: **2023-05-01, 1402/02/11**
Registration timing: **prospective**

Last update: **2023-05-01, 1402/02/11**
Update count: **0**
Registration date
2023-05-01, 1402/02/11

Registrant information
Name
Sima Alihosseini
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 81 3228 6253
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-05-22, 1402/03/01
Expected recruitment end date
2023-11-22, 1402/09/01
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 quality of life of hearing impaired children

Public title
Play on self-esteem and quality of life of hearing impaired children
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Children and their parents should be satisfied with their

participation in the study Children aged 8 to 12 who have hearing loss Not having other physical, mental, developmental, behavioral disorders Children should not be under psychiatric or psychological treatment Inability to hear sounds with a frequency of 30 dB in one or both ears

Exclusion criteria:

The reluctance of parents and children to participate in the studying Children undergoing psychiatric or psychological treatment Having physical, mental, developmental, behavioral disorders

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

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Hamadan

Postal code

6517838698

Approval date

2023-01-28, 1401/11/08

Ethics committee reference number

IR.UMSHA.REC.1401.934

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

Children's quality of life

Timepoint

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

Method of measurement

Children's quality of life scale

Secondary outcomes

empty

Intervention groups

1

Description

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

Sima Alihosseini

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Turkman alley, Taleghani street, Hamadan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical 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?

No

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

Sima Alihosseini

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data

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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