

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 Conditions of non-entry: 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: **IRCT20190703044082N9**

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

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

2023-05-22, 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:**

Reluctance of parents and children to continue studying  
Failure to participate in more than one game session

**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**

2023-01-28, 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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S\_alihosseini@umsha.ac.ir

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

Hamedan University of Medical Sciences

**Full name of responsible person**

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

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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