

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Implementing a family-based educational interventional program to empowerment mothers of children suffering from hearing impairments to promote children's speech and mother's health status

Protocol summary

2017-02-19, 1395/12/01

Summary

This study is a double-blind clinical trial, with interventional and control groups. The subjects will be allocated in the groups using the blocked randomization method. The aim of this study is to evaluate the effect of a family-based educational interventional program on empowerment of mothers who own children suffering from hearing impairments to develop children's speech and improve the general health status of the mother. The population of study contains mothers who own one to seven years old children with cochlear implantation. Inclusion criteria include Hearing ability of child's parents; Having a one to seven years old child with hearing impairment and speech problems; Mothers who have one child with hearing impairments; lack of other disabilities except hearing loss and speech disorder in children; Interested to participate in the study voluntarily. Exclusion criteria include Unwillingness to continue to participate during study; Lack of access to participants. The total sample size of the study will be 70 persons. The interventional training program will be based on empowerment of mothers and expected outcomes will be: Speech development in deaf children suffering from speech disorders and mothers' general health status development.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016111230857N1**
Registration date: **2017-02-19, 1395/12/01**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

Registrant information

Name

Firoozeh Mostafavi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3668 8628

Email address

mostafavi@hlth.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2015-11-22, 1394/09/01

Expected recruitment end date

2015-12-16, 1394/09/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Implementing a family-based educational interventional program to empowerment mothers of children suffering from hearing impairments to promote children's speech and mother's health status

Public title

Designing and implementing a family-based educational interventional program to empowerment mothers of children suffering from hearing impairments to promote

children's speech and mother's health status

Purpose
Supportive

Inclusion/Exclusion criteria
(Inclusion criteria: The Hearing ability of child's parents; Having a one to seven years old child with hearing impairment and speech problems; Mothers who have one child with hearing impairments; lack of other disabilities except hearing loss and speech disorder in children; Interested to participate in the study voluntarily).
(Exclusion criteria: Unwillingness to continue to participate during study; Lack of access to participants)

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Science Ethics Committee

Street address

Department of Health Education and Promotion,
Faculty of Health, Isfahan University of Medical
Science, Hezar Jarib Ave, Isfahan

City

Isfahan

Postal code

Approval date

2014-12-15, 1393/09/24

Ethics committee reference number

393789

Health conditions studied

1

Description of health condition studied

Speech Disorders

ICD-10 code

F80

ICD-10 code description

Specific developmental disorders of speech and language

Primary outcomes

1

Description

Speaking development

Timepoint

0-3-6 month

Method of measurement

Niosha questionnaire

Secondary outcomes

1

Description

The general health of mothers

Timepoint

0-1-3

Method of measurement

Questionnaire

Intervention groups

1

Description

"Intervention groups: Implementation of educational intervention program based on empowerment of mothers during training sessions at two speech therapy centers for deaf children"

Category

Behavior

2

Description

"Control group: Without action"

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Soroush Rehabilitation Center

Full name of responsible person

Zandi Zahra

Street address

Plague:5473, 9/6 Alley, Ninth Street, Western Golchin

Ave, South Motahari Boulevard, Shiraz

City

Shiraz

2

Recruitment center

Name of recruitment center

Gasedak Rehabilitation Center

Full name of responsible person

Khaksar Aida

Street address

Plague:91, 3 Alley, Fazilat Ave, Modarres Boulevard,
Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Isfahan University of
Medical Sciences

Full name of responsible person

Doctor Mahdi Nemat Bakhsh

Street address

Isfahan University of Medical Science, Hezar Jarib Ave,
Isfahan

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research Isfahan University of Medical
Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Firoozeh Mostafavi

Position

Associate Professor

Other areas of specialty/work

Street address

Department of Health Education and Promotion,
Faculty of Health, Isfahan University of Medical
Science, Hezar Jarib Ave, Isfahan

City

Isfahan

Postal code

Phone

+98 31 3668 8628

Fax

+98 31 3668 2509

Email

mostafavi@hlth.mui.ac.ir

Web page address

**Person responsible for scientific
inquiries**

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Firoozeh Mostafavi

Position

Associate Professor

Other areas of specialty/work

Street address

Department of Health Education and Promotion,
Faculty of Health, Isfahan University of Medical
Science, Hezar Jarib Ave, Isfahan

City

Isfahan

Postal code

Phone

+98 31 3668 8628

Fax

+98 31 3668 2509

Email

mostafavi@hlth.mui.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Leila Ravanyar

Position

PhD Candidate

Other areas of specialty/work

Street address

Department of Health Education and Promotion,
Faculty of Health, Isfahan University of Medical
Science, Hezar Jarib Ave, Isfahan

City

Isfahan

Postal code

Phone

+98 31 3668 8628

Fax

Email

ravanyar2007@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty