

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Comparing the effectiveness of parenting training with life skills training on the mental health of mothers of children with hearing loss

Protocol summary

Study aim

The aim of this study is to find a more effective method between the two educational interventions of parenting and life skills so that by expanding and teaching this method, an effective action can be taken for mothers with children with hearing loss.

Design

Clinical trial with parallel control group, single blind, randomized with Excel software

Settings and conduct

Due to the limitations of COVID-19 disease epidemic, this study will be through the provision of virtual content (audio-video) with question and answer sessions for each training session. Therefore, participants will participate in this training in the form of WhatsApp or Skype groups. Each week, one and sometimes two training sessions are held and during the week, the trainings will be followed by two-way questions and answers between the instructor and the participants.

Participants/Inclusion and exclusion criteria

Inclusion criteria: having a child with hearing loss; absence of any psychiatric disorders requiring treatment with psychiatric drugs in the child; the age of the child should be 3-7 years old. Criterion for not entering the research: not one of the mothers referring to Soroush Rehabilitation Center

Intervention groups

After random assignment of people in two groups, participants will be assessed with a mental health questionnaire before and after the test to evaluate the main variable. Also, to evaluate the effectiveness of educational interventions, questionnaires appropriate to the educational intervention will be completed by the relevant group before and after the test. Also, in order to prevent the effect of overlapping educational interventions, the skills group of the other group will be answered by both groups before and after Amon.

Main outcome variables

Mothers' level of mental health

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201014049023N1**

Registration date: **2020-10-23, 1399/08/02**

Registration timing: **retrospective**

Last update: **2020-10-23, 1399/08/02**

Update count: **0**

Registration date

2020-10-23, 1399/08/02

Registrant information

Name

moamad abdan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 4372 4051

Email address

abdian.m74@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2020-10-15, 1399/07/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of parenting training with life skills training on the mental health of mothers of children with hearing loss		School	
Public title		Street address	
Comparing the effectiveness of parenting training with life skills training on the mental health of mothers of children with hearing loss		Shiraz Medical School, Izand St.	
Purpose		City	
Education/Guidance		Shiraz	
Inclusion/Exclusion criteria		Province	
Inclusion criteria:		Fars	
Having a child with hearing loss		Postal code	
Absence of any psychiatric disorders requiring treatment with psychiatric drugs in the child		۱۴۳۳۶ - ۷۱۳۴۸	
The age of the child is 3-7 years old		Approval date	
Exclusion criteria:		2020-09-26, 1399/07/05	
Do not refer to Soroush Rehabilitation Center		Ethics committee reference number	
Age		IR.SUMS.MED.REC.1399.369	
No age limit		Health conditions studied	
Gender		<u>1</u>	
Female		Description of health condition studied	
Phase		Mothers of children with hearing loss	
N/A		ICD-10 code	
Groups that have been masked		H90.3	
Participant		ICD-10 code description	
Sample size		Sensorineural hearing loss, bilateral	
Target sample size: 25		Primary outcomes	
Randomization (investigator's opinion)		<u>1</u>	
Randomized		Description	
Randomization description		General Health Questionnaire Score	
First, the participants were coded individually. Then, based on simple randomization and with the help of a table of random numbers, even numbers were considered for one intervention and odd numbers for the other intervention. Then, the type of intervention was assigned to each group by lottery method		Timepoint	
Blinding (investigator's opinion)		One week before and after starting educational interventions	
Single blinded		Method of measurement	
Blinding description		General Health Questionnaire	
Blindness were conducted for participants in a one-way manner. In this way, the participants are not aware of the title of the training method they receive and its difference from the training method provided to the other group.		Secondary outcomes	
Placebo		<u>1</u>	
Not used		Description	
Assignment		Quality of life score	
Parallel		Timepoint	
Other design features		One week before and after educational interventions	
Secondary Ids		Method of measurement	
empty		General Health Questionnaire	
Ethics committees		<u>2</u>	
<u>1</u>		Description	
Ethics committee		Depression score	
Name of ethics committee		Timepoint	
Ethics Committee in Research of Shiraz Medical		One week before and after educational interventions	
		Method of measurement	
		General Health Questionnaire	
		<u>3</u>	
		Description	
		Anxiety score	
		Timepoint	

One week before and after educational interventions

Method of measurement

General Health Questionnaire

4

Description

Physical symptoms score

Timepoint

One week before and after educational interventions

Method of measurement

General Health Questionnaire

Intervention groups

1

Description

First intervention group: a group that receives parenting skills training; During a ten-session workshop on parenting education, this group sees positive parenting in a positive way

Category

Lifestyle

2

Description

Second intervention group: a group that receives life skills training; The well-known life skills program will be held as a ten-session detective, in which one of the ten skills will be taught to mothers.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Soroush Rehabilitation Center Shiraz

Full name of responsible person

Maryam Wahab

Street address

6th Alley-9th Street-west gholchin street-south
motahari boulevard

City

shiraz

Province

Fars

Postal code

7194684695

Phone

+98 71 3842 4123

Email

abdan.m74@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Abbas Rezaeianzadeh

Street address

Zand Street - Opposite Palestine Street

City

Shiraz

Province

Fars

Postal code

1433671348

Phone

+98 71 3230 5410

Email

info@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Sara Dehbozrgi

Position

associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Psychiatrics

Street address

Shiraz, Chamran St., Abivardi beginning, Hafez
Educational and Medical Center, Office of Psychiatry

City

Shiraz

Province

Fars

Postal code

3478671946

Phone

+98 71 3647 9319

Email

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Position

associate professor

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Postal code

3478671946

Phone

+98 71 3647 9319

Email

dr.dehbozorgi@yahoo.com

Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All participants' data can be shared after not identifying individuals

When the data will become available and for how long

After publishing the final article

To whom data/document is available

All

Under which criteria data/document could be used

There will be no restrictions on the commitment to confidentiality

From where data/document is obtainable

Library of Shiraz Medical School

What processes are involved for a request to access data/document

Medical school library approval

Comments