

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The effectiveness of Unified Transdiagnostic Treatment on the symptoms of emotional disorders and emotion regulation of parents and improvement of behavioral problem in 3-6 years old hard of hearing children

Protocol summary

Study aim

Investigating the effectiveness of integrative transdiagnostic treatment on the symptoms of emotional disorders and emotional regulation of parents and behavioral problems of hearing-impaired children aged 3-6

Design

The clinical trial has a control group with parallel groups, randomized using a table of random numbers on 30 people.

Settings and conduct

In this study, parents of hearing impaired children aged 3 to 6 years who have symptoms of emotional disorders and at the same time their children have behavioral problems participate. This study is conducted in the form of twelve group therapy sessions, one hour each session in virtual space. The researcher implements the treatment course. This approach uses emotional exposure and emotional awareness and increasing the emotional tolerance capacity in the form of exercises. Blinding is not done.

Participants/Inclusion and exclusion criteria

Parent entry criteria - A parent with symptoms of emotional disorders - Hearing - Being a Persian speaker - Minimum diploma education Criteria for exiting people to research: - Acute behavioral and psychological problems that the researcher suspects during the sessions or after the questionnaires. - Failure to attend more than two sessions

Intervention groups

The intervention group of the metadiagnostic integrated protocol is held in twelve sessions, which work on the emotional exposure and excitement of awareness and increasing the capacity to tolerate emotions. The control group received usual services.

Main outcome variables

the symptoms of emotional disorders; parental emotion regulation; the behavioral problems of hearing-impaired children aged 3-6

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230124057202N1**

Registration date: **2023-03-27, 1402/01/07**

Registration timing: **prospective**

Last update: **2023-03-27, 1402/01/07**

Update count: **0**

Registration date

2023-03-27, 1402/01/07

Registrant information

Name

mahsa khakpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3722 9293

Email address

khakpormahsa76@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-04, 1402/01/15

Expected recruitment end date

2023-05-05, 1402/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of Unified Transdiagnostic Treatment on the symptoms of emotional disorders and emotion regulation of parents and improvement of behavioral problem in 3-6 years old hard of hearing children

Public title

The effectiveness of Unified Transdiagnostic Treatment on the symptoms of emotional disorders

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All parents with a deaf child over the age of three
Parent's willingness The parent has symptoms of emotional disorder Minimum education is diploma Being a Persian speaker

Exclusion criteria:

Acute behavioral and psychological problems that the researcher suspects during the sessions or after the questionnaires. Absent more than two sessions

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked*No information***Sample size**

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, people are randomly assigned to one of the two study groups using a table of random numbers. The randomization method is simple. The randomization unit is individual.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of University of social welfare and rehabilitation of tehran

Street address

University of Rehabilitation Sciences and Social Health, Tehran, Evin, Dargheh Blvd

City

tehran

Province

Tehran

Postal code

1985713834

Approval date

2023-01-18, 1401/10/28

Ethics committee reference number

IR.USWR.REC.1401.218

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

emotional disorders

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Anxiety score in Beck's questionnaire

Timepoint

Beck questionnaire anxiety score at the beginning of the study and 4 weeks, 8 weeks, 12 weeks and 3 months after the end of the intervention

Method of measurement

Beck's anxiety questionnaire

Secondary outcomes**1****Description**

Emotion regulation score in Gertz and Romer emotion regulation difficulty questionnaire

Timepoint

Emotion regulation score in the emotion regulation difficulty questionnaire at the beginning of the study and 4 weeks, 8 weeks, 12 weeks and 3 months after the end of the intervention.

Method of measurement

Gratz and Roemer Difficulties in Emotion Regulation Scale

2**Description**

Beck questionnaire depression score

Timepoint

Beck questionnaire depression score at the beginning of the study and 4 weeks, 8 weeks, 12 weeks and 3 months after the end of the intervention

Method of measurement

Beck depression questionnaire

3**Description**

Children's Behavioral Problems Score of Eyberg Questionnaire

Timepoint

The score of children's behavioral problems in the Ayberg questionnaire at the beginning of the study and 4 weeks, 8 weeks, 12 weeks and 3 months after the end of the intervention

Method of measurement

Eyberg Behavioral Problems Questionnaire

Intervention groups**1****Description**

Intervention group: The intervention with an integrative meta-diagnostic approach consists of twelve group therapy sessions in the form of a one-hour session per week. which takes place on the Internet. Currently, the protocol of the integrative metadiagnostic approach consists of eight parts. The first part is increasing motivation, the second part is the adaptive nature of emotions and the main components of emotional experience, the third part is emotional awareness training, the fourth part is cognitive reevaluation, the fifth part is behaviors caused by excitement and emotional avoidance, the sixth part is awareness and tolerance of physical feelings, the seventh part is exposure. internal and situational and the eighth section is to prevent recurrence. The researcher has completed the training course related to the approach and organizes the meetings.

Category

Treatment - Other

2**Description**

Control group: No intervention

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

parvanr ha group

Full name of responsible person

gita movaleli

Street address

University of Rehabilitation Sciences and Social Health, Evin, Tehran

City

Tehran

Province

Tehran

Postal code

1985713834

Phone

+98 915 987 7174

Email

khakpournmahsa76@gmail.com

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

University of social welfare and rehabilitation sciences

Full name of responsible person

kianosh abdi

Street address

University of Rehabilitation Sciences and Social Health, Evin, Tehran

City

Tehran

Province

Tehran

Postal code

1985713834

Phone

+98 21 7173 2000

Email

webmaster@uswr.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

University of social welfare and rehabilitation 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**

University of social welfare and rehabilitation sciences

Full name of responsible person

Mahsa Khakpour

Position

Student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
Street address
Esfarayen. taleghani3.negar5.12
City
Tehran
Province
Tehran
Postal code
9661873618
Phone
+98 58 3722 9293
Fax
Email
khakpournmahsa76@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Neda alibeigi
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
University of Welfare and Rehabilitation Sciences,
Student Blvd.
City
Tehran
Province
Tehran
Postal code
1985713834
Phone
+98 21 3340 1604
Email
nedapsych@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Mahsa Khakpour
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
Street address
Esfarayen. taleghani3.negar5.12
City
Tehran
Province
Tehran
Postal code
9661873618
Phone
+98 58 3722 9293
Fax
Email
khakpournmahsa76@gmail.com

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