

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

The effectiveness of emotion regulation training on improving symptoms of anxiety, depression and coping strategies for mothers of children with attention deficit hyperactivity disorder

Protocol summary

Study aim

The effectiveness of group training in emotion regulation and coping strategies for anxiety and depression symptoms in mothers of children with ADHD

Design

Quasi-experimental design with a control group per-test, post-test and follow-up The method of randomization in this study was simple and the method of doing this simple randomization with Flip the coin method was performed in such a way that the experimental group was considered as the heads and the control group as a tails and The number of samples was as high as the coin number and the subjects were assigned to the two groups.

Settings and conduct

Emotion regulation training in 8 sessions, The time of each session lasting 90 minutes. Holds training sessions at the Atieh Clinical Neuroscience Center, in tehran city

Participants/Inclusion and exclusion criteria

Inclusion Criteria 1. Mothers whose children have been diagnosed with ADHD. 2. Mothers of children with ADHD from 4 to 12 years old 3. No use of psychiatric drugs 4. No participation in any individual psychological or group intervention simultaneously. 5. No drug addiction in mothers 5. Mothers 25 to 60 years old Exclusion criteria: Need and start psychiatric treatment after entering the plan; No regular attendance at meetings (absence more than two sessions) Unwillingness to continue attending at group therapy

Intervention groups

experimental group: 20 mothers of children with attention deficit hyperactivity disorder that receiving group training in emotion regulation. Control group: 20 mothers of children with attention deficit hyperactivity disorder, They do not receive any intervention.

Main outcome variables

Anxiety; Depression; Stress; Coping strategies

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180514039656N1**

Registration date: **2018-08-25, 1397/06/03**

Registration timing: **retrospective**

Last update: **2018-08-25, 1397/06/03**

Update count: **0**

Registration date

2018-08-25, 1397/06/03

Registrant information

Name

Hossein Dadashzadeh

Name of organization / entity

Atieh Clinical Neuroscience Center

Country

Iran (Islamic Republic of)

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+98 41 4225 6278

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-04, 1397/01/15

Expected recruitment end date

2018-04-25, 1397/02/05

Actual recruitment start date

2018-04-28, 1397/02/08

Actual recruitment end date

2018-05-03, 1397/02/13

Trial completion date

empty	
Scientific title	The effectiveness of emotion regulation training on improving symptoms of anxiety, depression and coping strategies for mothers of children with attention deficit hyperactivity disorder
Public title	The effectiveness of emotion regulation training on improving symptoms of anxiety, depression and coping strategies
Purpose	Education/Guidance
Inclusion/Exclusion criteria	Inclusion criteria: Mothers whose child has received ADHD diagnosis. Mothers of children with ADHD from 4 to 12 years old Not taking psychiatric drugs or participating in any individual psychological or group intervention simultaneously by these mothers. No drug addiction in mothers Mothers 25 to 60 years old Exclusion criteria: 1. Need and start psychiatric treatment after entering the plan 2. Lack of regular attendance at meetings (absence of more than two sessions) Unwillingness to continue attending group therapy
Age	From 25 years old to 60 years old
Gender	Female
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 40 Actual sample size reached: 40
Randomization (investigator's opinion)	Randomized
Randomization description	The method of randomization in this study was simple and the method of doing this simple randomization with Flip the coin method was performed in such a way that the experimental group was considered as the heads and the control group as a tails and The number of samples was as high as the coin number and the subjects were assigned to the two groups.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Other
Other design features	
Secondary Ids	empty

Ethics committees	
1	
Ethics committee	
Name of ethics committee	Ethics Committee of Shahid Beheshti University of Medical Sciences
Street address	7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.
City	Tehran
Province	Tehran
Postal code	19839-63113
Approval date	2017-12-19, 1396/09/28
Ethics committee reference number	IR.SBMU.REC.1396.691
Health conditions studied	
1	
Description of health condition studied	Symptoms of Anxiety, depression and stress
ICD-10 code	
ICD-10 code description	
Primary outcomes	
1	
Description	Depression Scales, Anxiety, Stress in the Anxiety, Stress, and Depression Inventory Questionnaire
Timepoint	Before the intervention, after intervention, 2 months after the end of the intervention
Method of measurement	Depression, anxiety and stress syndrome scale (DASS-21)
Secondary outcomes	
1	
Description	Coping inventory for stressful situations
Timepoint	Before the intervention, after intervention, 2 months after the end of the intervention
Method of measurement	The coping inventory for stressful situations includes 48 articles that respond to the Likert method from never (1) until always (5). The CISS questionnaire contains three main areas of coping behavior: 1) Problem-based coping or active collision with Problem to manage and solve it; 2. to deal with emotional concentration; or to focus on

emotional responses to the problem; 3. avoidance or avoidance of the problem..

Intervention groups

1

Description

Intervention group: Grass's Exercise Therapy training protocol is implemented in 8 sessions for the group. The sessions include: first session, familiarity and communication of the members with each other; second session; choice of position (providing emotional training); session Third: Assessing the Emotional Vulnerability and Emotional Skills of the Fourth Session: Creating Changes in Emerging Emotional Situation; Session Five: Attention Skills; Session Six: Cognitive Evaluation; Session Seventh: Modifying Exposure Behavioral and Physiological Consequences; Eighth Session: Evaluation Revising and planning for the use of training

Category

Other

2

Description

Control group: A group that did not receive any type of intervention during the study

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Atieh Clinical Neuroscience Center

Full name of responsible person

Reza Rostsmi

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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Atieh Clinical Neuroscience Center

Proportion provided by this source

20

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hossein Dadashzadeh

Position

MSc student of medical science

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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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

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

Only the total scores and some demographic characteristics of the participants can be published

When the data will become available and for how long

Start Access 9 months after the publication of results

To whom data/document is available

Shahid Beheshti University of Medical Sciences, Mental Health Specialist

Under which criteria data/document could be used

Only about research and research data descriptive overview, use the

From where data/document is obtainable

Email researcher hossein_dadashzadeh@sbmu.ir

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

Written request from the Research Center of Shahid Beheshti University of Medical Sciences to provide written permission to the research officer and to receive the data.

Comments