Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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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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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No23,alinezhad vn..,anak Squ,Vali-e-Asr St,Tehran

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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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Medical ficulty.,shahid beheshti university of medical sciences.,Velenjak St., Shahid Chamran Highwa,Tehran.,Iran

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Person responsible for scientific inquiries

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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