Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of emotional regulation training on the relationship between mothers and attention-deficit hyperactivity disorder

Protocol summary

Study aim
Determining the effect of emotional regulation training on the relationship between mothers and attention-deficit hyperactive disorder

Design
Clinical practice, pre-test and post-test plan, case and control group, 40 people in each group randomly

Settings and conduct
After obtaining informed consent from mothers who referred to welfare centers and explaining the research goals, mother_child relationship evaluation questionnaire will be completed in both the intervention and control groups, and then the intervention group will be trained emotion regulation based on the Grass model, in 8 sessions each session 90 minutes, once in a week. One month after the end of training sessions, questionnaires will be distributed simultaneously in intervention group and control group. During the training period of intervention group, control group will receive routine training like all centers. Participants in the intervention group would imagine that the other group will be trained after ending their sessions due to lack of space, so that "training sessions" cause no orientation in completing the second phase questionnaire

Participants/Inclusion and exclusion criteria
Inclusion criteria included mothers with at least one child with attention-deficit hyperactive disorder and no previous history of presence in emotional regulation sessions and not using psychiatric medications. Exclusion criteria included mothers had stress during last 6 months.

Intervention groups
Desired intervention in this study is training the emotional regulation to mothers with overactive children. Control group, if interested, will receive 8 training sessions after completing the second point questionnaire

Main outcome variables
Relationship between mothers with hyperactive children

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190210042675N1**
Registration date: **2019-03-11, 1397/12/20**
Registration timing: **registered_while_recruiting**

Last update: **2019-03-11, 1397/12/20**
Update count: **0**

Registration date
2019-03-11, 1397/12/20

Registrant information

Name
Zohre Arabi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 7713 9296

Email address
zohreharabi96@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-03-06, 1397/12/15

Expected recruitment end date
2019-03-18, 1397/12/27

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of emotional regulation training on the relationship between mothers and attention-deficit hyperactivity disorder

Public title
The effect of emotion regulation on the relationship mothers with attention-deficit hyperactivity disorder
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Having at least one child with attention deficit/ hyperactivity disorder Not having history of attending emotional regulation therapy sessions Not to participate in the same interventions simultaneously not to use psychosocial drugs in mothers Not having a new stressor in mothers during the last 6 months Not to use drugs by mother
Exclusion criteria:
Mental illness in the mother
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Samples were selected by simple random sampling method and based on the criteria for entering the study, and then, according of participants list, random numbers are assigned to each participant, then a sortition is drawn between the numbers and each number allocated to intervention or control groups
Blinding (investigator's opinion)
Single blinded
Blinding description
The participants will not know that they are member of intervention group or control group of study
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Islamic Azad University, Medical Sciences Unit
Street address
Azad University of Medical Sciences, Danesh Alley, Attari Moghaddam Street, Zarganeh street, Shariati Avenue
City
Tehran
Province
Tehran
Postal code
1916893813
Approval date
2018-10-31, 1397/08/09
Ethics committee reference number
IR.IAU.TMU.REC.1397.200

Health conditions studied

1

Description of health condition studied
relationship between mother and attention-deficit hyperactivity disorder
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The relationship between mothers and attention- deficit hyperactivity disorder in the mother-child relationship evaluation
Timepoint
At the beginning of the study and one month after the training
Method of measurement
Mother-Child Relationship Evaluation

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group, the samples will complete the mother-child relationship questionnaire first. Then they will be trained emotion regulation, in 8 sessions each session 90 minutes, once in a week. Then, one month after the last session, they will complete the mother-child relationship questionnaire again. At the end, each sample will receive a emotion regulation training booklet prepared by researcher
Category
Behavior

2

Description
Control group: At first, samples completed the mother-child relationship questionnaire, but they will not receive any training. One month after completing emotional regulation training in the intervention group, the samples in the control group concurrently with the intervention group will again complete the mother-child relationship questionnaire and will receive the emotional regulation training if they wish

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Sadi Girls' Elementary School

Full name of responsible person
Nasrin Asad Beyk

Street address
Sadi Girls' Elementary School, Ja'far Panah Street, End of Jashnvare Street

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1658654461

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+98 21 7732 1514

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zohreharabi96@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Dr Fatemeh Azizabadi Farahani

Street address
Azad University of Medical Sciences, Danesh Alley, Attari Moghaddam Street, Zarganeh street, Shariati Avenue

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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
Islamic Azad University

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
Islamic Azad University

Full name of responsible person
Zohreh Arabi

Position
student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
Unit 6, No.41, Talei Alley(Easterns Forth), South Takavaran Street, Delaavaran Blvd, Al-ghadir Square, Resalat Square

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Total data of participants in the study after un identifying individuals will be shared. Study protocol, statistical analysis map and clinical study report will be fully shared

When the data will become available and for how long

beginning of access period to data will be 6 months after the results are printed

To whom data/document is available

Data and other study documents can be sent to all who are interested in this field

Under which criteria data/document could be used

Data will be provided to anyone who needs information in this area or to conduct similar research in this area, without any special conditions

From where data/document is obtainable

Applicants can contact e-mail at zohreharabi96@yahoo.com for gaining information

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

Information will be sent to the applicant immediately after request by e-mai

Comments