

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

The effect of stress management program utilizing cognitive behavior approach on mental health of mothers of children with attention deficit hyperactivity disorder

Protocol summary

Summary

This study aimed to evaluate the effect of stress management program on mental health of mothers of children with attention deficit hyperactivity disorder. The study included 78 mothers that their stress is higher than moderate (25-19) and randomly divided into three groups, experiment, placebo and control groups. Inclusion criteria is mothers with children aged 6-12 years with ADHD, minimum score 17 of the strengths and difficulties questionnaire and the stress score is higher than average. If mothers previously or concurrently had participated in a program of stress management or stress score is lower than average will be excluded. The experimental group participated in 8 sessions of stress management. Placebo group participated in dialogue sessions for express their feelings with no approaches. The control group did not receive any intervention. At the end of the intervention to ethics the control group received an educational pamphlet and this group participated in two sessions. Before, immediately and one month after intervention, public health and stress of three groups was measured by the General Health Questionnaire and DASS.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201302242812N13**
Registration date: **2013-06-09, 1392/03/19**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-06-09, 1392/03/19

Registrant information

Name

Farkhondeh Sharif

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Shiraz University Of Medical Sciences

Expected recruitment start date

2012-12-08, 1391/09/18

Expected recruitment end date

2013-02-18, 1391/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of stress management program utilizing cognitive behavior approach on mental health of mothers of children with attention deficit hyperactivity disorder

Public title

The effects of stress management program on mental health of mothers of children with hyperactivity

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: achieve a minimum score of shear

strengths and difficulties questionnaire scale behavioral problems emotional problems hyperactivity, problems with peers; moderate to very severe score in stress, anxiety and depression; hyperactive children ages 6 to 12 years; no mental illness (according to self-report form); interest to participate in the study Exclusion criteria: the lack of willingness to continue participation in the study; receive similar training interventions before the study; mental or physical illness in a family member who will keep track of workouts at home

Age

From **22 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences and Health Services

Street address

Shiraz, Zand Ave, Shiraz University of Medical Science Building

City

shiraz

Postal code

Approval date

2013-03-13, 1391/12/23

Ethics committee reference number

CT-91-6458

Health conditions studied

1

Description of health condition studied

attention deficit hyperactivity disorder

ICD-10 code

F90.0

ICD-10 code description

Disturbance of activity and attention

Primary outcomes

1

Description

mental health

Timepoint

Before, immediately and one month after intervention

Method of measurement

general health questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

experimental group: cognitive behavioral stress management training in 8 sessions at 1/5hour

Category

Behavior

2

Description

control group:without any intervention

Category

N/A

3

Description

Placebo group attended in dialogue sessions for express their feelings with no approaches

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Imam Reza

Full name of responsible person

Dr Farkhonde Sharif

Street address

City

Shiraz

2

Recruitment center

Name of recruitment center

Hafez Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University Of Medical Science
Full name of responsible person
Dr Gholamreza Hatam
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Shiraz University of Medical Sciences, University
Central Building, Beside Red Cross, Zand Street
City
Shiraz
Grant name
Grant code / Reference number
CT91-6458
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University Of Medical Science
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
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Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty