

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Effectiveness of group mindfulness based stress reduction on parents of children with Attention Deficit Hyperactivity Disorder on mental health, quality of life and child behavioral problems, a randomized controlled clinical trial

Protocol summary

Summary

Objectives: The purpose of the present study is to evaluate the effectiveness of group mindfulness based stress reduction on parents of children with Attention Deficit Hyperactivity Disorder on mental health, quality of life and child behavioral problems. Design: The present study is a randomized clinical trial with control group, a cross sectional study. Setting and conduct: 64 parents of children with ADHD age between 8-16 were selected from the ones who referred to Shiraz University of Medical Sciences polyclinic and divided into experimental and control groups, randomly. Participants including major eligibility criteria: At least primary education (6th class) ; Co-therapy sessions; Agreement to participate in research; The diagnosis of Attention Deficit Hyperactivity Disorder in their children should be confirmed by a psychiatrist in at least the past 3 years and who are unwilling to participate in therapy sessions and whom with other psychiatric or medical problems or chronic diseases in themselves or their children should be excluded from this study. Intervention: All participants completed GHQ-28, SF-36 and SDQ parent form, three times as, pre-test, post-test and follow-up. Experimental group participate in eight, 45 min sections of group therapy base on Mindfulness Based Stress Reduction therapy (MBCT) .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016112231021N1**

Registration date: **2017-03-13, 1395/12/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-03-13, 1395/12/23

Registrant information

Name

Samaneh Muosavinasab

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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s_mousavinasab@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of group mindfulness based stress reduction on parents of children with Attention Deficit Hyperactivity Disorder on mental health, quality of life and child behavioral problems, a randomized controlled

clinical trial

Public title

Effectiveness of stress reduction on parents of children with Attention Deficit Hyperactivity Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1.At least primary education (6th class) ; 2.Co-therapy sessions; 3.Agreement to participate in research; 4.The diagnosis of Attention Deficit Hyperactivity Disorder should be confirmed by a psychiatrist in at least the past 3 years Exclusion criteria: 1.Unwillingness to participate in therapy sessions; 2.Other psychiatric or medical problems or chronic diseases in children or their parents

Age

From **8 years** old to **16 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

random number table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Ethic Comittee, 7th floor, Medical School, Zand St.

City

Shiraz

Postal code

7134814336

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

IR.SUMS.MED.REC.1394.76

Health conditions studied

1

Description of health condition studied

ADHD

ICD-10 code

F90.0

ICD-10 code description

Attention deficit:disorder with hyperactivity

Primary outcomes

1

Description

Mental health of mothers of children with ADHD

Timepoint

Before intervention- immediately after intervention- 3 months after intervention

Method of measurement

GHQ-28 inventory

2

Description

Quality of life of mothers of children with ADHD

Timepoint

Before intervention- immediately after intervention- 3 months after intervention

Method of measurement

SF-36 inventory

3

Description

Behavioral problems in child with ADHD

Timepoint

Before intervention- immediately after intervention- 3 months after intervention

Method of measurement

SDQ inventory, parent form

Secondary outcomes

1

Description

level of stress

Timepoint

In sessions

Method of measurement

Observation and self report

Intervention groups

1

Description

The experimental group will participate in therapy sessions. (8 sessions, once a week, for 45 minutes) and in these groups using mindfulness stress reduction

techniques are taught

Category

Behavior

2

Description

Control group with no intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hafez Training and Medical Center

Full name of responsible person

Mani Arash M.D.

Street address

Psychiatry clinic, Hafez Hospital, Abiverdi St, Shiraz
mran blvd

City

Shiraz

2

Recruitment center

Name of recruitment center

Imam Reza Medical Clinic

Full name of responsible person

Mani Arash M.D.

Street address

Psychiatry department, 4th floor, Imam Reza Medical
Clinic, Nemazee SQ, Shiraz, Iran

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor of Shiraz University of Medical School

Full name of responsible person

Hashemi Seyed Basir

Street address

Vice chancellor for research, 6th floor, Shiraz
University of Medical Sciences, Zand St.A

City

Shiraz

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice chancellor of Shiraz University of Medical School

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

Shiraz University of Medical Sciences

Full name of responsible person

Arash Mani Ph.D.

Position

Assistant Professor and Member of Shiraz Psychiatric
Group

Other areas of specialty/work

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Assistant Professor and Member of Shiraz Psychiatric
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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