Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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)

Phone

+98 71 3627 1531

Email address

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 Siences
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

Shiraz

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

Street address

Psychiatry Department, Hafez Hospital, Abiverdi St, Shiraz

City

Shiraz

Postal code

3478671946

Phone

+98 71 3627 9319

Fax

+98 71 3627 9319

Email

mania@sums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Siences

Full name of responsible person

Arash Mani Ph.D.

Position

Assistant Professor and Member of Shiraz Psychiatric Group

Other areas of specialty/work

Street address

Psychiatry Department, Hafez Hospital, Abiverdi St, Shiraz

City

Shiraz

Postal code

3478671946

Phone

+98 36279319

Fax

+98 71 3627 9319

Email

mania@sums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Samaneh Muosavinasab

Position

Resident of Psychiatry

Other areas of specialty/work

Street address

Psychiatry Department, Hafez Hospital, Abiverdi St, Shiraz

City

Shiraz

Postal code

3478671946

Phone

+98 71 3627 9319

Fax

Email

s_mousavinasab@sums.ac.ir

Web page address

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