

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Comparison the Effectiveness of Child Mindfulness Therapy, Mindful Parenting and Combination Therapy of These Two Interventions in Attention Deficit / Hyperactivity Disorder: A Outcome-Based Study

Protocol summary

Study aim

The main objective was to compare the effectiveness of child mindfulness therapy, mindful parenting, and combination therapy of these two interventions on the primary and secondary outcomes of ADHD in children with this disorder and their parents.

Design

The present study includes three treatment groups. Subjects are assigned to groups using the simple random . The sample size of each group is 20. This is a clinical trial with parallel and randomized groups, which will be performed on 60 subjects.

Settings and conduct

The intervention of groups 1, 2, and 3 will be held twice a week in a counseling center. Participants come to the center two days a week, at different times to attend meetings. The intervention will be performed by people trained in the field of mindfulness. In the first and last session, questionnaires are completed.

Participants/Inclusion and exclusion criteria

Participants consisted of children aged 6 to 12 years with ADHD and their parents in Mashhad. Inclusion criteria included the diagnosis of ADHD and being in the age range of 6 to 12 years. Exclusion criteria included suffering from other mental disorders.

Intervention groups

Group 1 consists of children with ADHD who receive mindfulness intervention that consists of eight sessions and each session lasts for 45 minutes. The content of the sessions includes mindfulness of the environment, objects, self and body, and breathing meditation. Content includes formal and daily mindfulness exercises. Group 2 includes parents of affected children who receive mindful parenting intervention. This course consists of eight 45-minute sessions. Content includes automatic and mindful parenting, stress response, compassion meditation. Group 3 is a combination of intervention 1 for

children and intervention 2 for their parents that consists of 16 sessions and lasts two months.

Main outcome variables

core symptoms of ADHD; executive function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190622043972N1**

Registration date: **2020-11-13, 1399/08/23**

Registration timing: **retrospective**

Last update: **2020-11-13, 1399/08/23**

Update count: **0**

Registration date

2020-11-13, 1399/08/23

Registrant information

Name

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Name of organization / entity

Ferdowsi University of Mashhad

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-31, 1398/10/10

Expected recruitment end date

2020-06-19, 1399/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the Effectiveness of Child Mindfulness Therapy, Mindful Parenting and Combination Therapy of These Two Interventions in Attention Deficit / Hyperactivity Disorder: A Outcome-Based Study

Public title

The Effect of Mindfulness-Based Therapies in Attention Deficit / Hyperactivity Disorder

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Receiving a diagnosis of Attention-Deficit/Hyperactivity Disorder (ADHD) Being between the age range of 6 to 12 years The presence of the children and parents in at least six sessions of treatment

Exclusion criteria:

Children afflicted with other mental disorders Having an IQ below 80 Receiving simultaneous psychological treatment Patients without caretakers/attendants or with irresponsible parents/surrogates Illiteracy of parents Parents afflicted with mental disorders

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Mashhad Education Department includes 10 districts. The name of each district is recorded on a piece of paper. The pieces of paper are then thrown in a bag. The researcher will put his/her hand in the bag and take out a piece of paper to randomly select the education district. Once the education district has been identified, a list of the district's primary schools will be obtained from the Department of Education, and 10 schools will be selected through a process similar to how the district is selected. Using the SNAP questionnaire, the screening will be done to identify students with suspected ADHD. After screening and conducting a clinical interview, the names of students receiving a definitive diagnosis of ADHD will be written separately on a piece of paper. The names are then poured into a bag. Each time the researcher puts his or her hand in the bag and pulls out a piece of paper. The first 20 people who get out of the bag in this way will be placed in group one, the next 20 people in group two, and the third 20 people in group three. In the next step,

the names of the groups will be written separately on three pieces of paper and thrown into the bag. The first piece of paper to come out of the bag after the researcher's hand is inserted into the bag will be group one, the second piece of paper will be group two, and the third piece of paper will be group three.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Factorial

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Ferdowsi University of Mashhad

Street address

Bioethics Committee, Room 414, Third Floor, Central Organization, Ferdowsi University of Mashhad, Azadi Square

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Approval date

2019-07-03, 1398/04/12

Ethics committee reference number

IR.UM.REC.1398.098

Health conditions studied**1****Description of health condition studied**

Attention deficit hyperactivity disorder

ICD-10 code

F90

ICD-10 code description

Attention-deficit hyperactivity disorders

Primary outcomes**1****Description**

The Main Symptoms of Attention Deficit Hyperactivity Disorder

Timepoint

Before the intervention, after the intervention, three months after the intervention

Method of measurement

Swanson, Nolan and Pelham Rating scale

2**Description**

Executive Function

Timepoint

Before the intervention, after the intervention, three months after the intervention

Method of measurement

Barkley Deficits in Executive Functioning

Secondary outcomes**1****Description**

Behavior Problems

Timepoint

Before the intervention, after the intervention, three months after the intervention

Method of measurement

Achenbach Child Behavior Checklist

2**Description**

Sleep Quality

Timepoint

Before the intervention, after the intervention, three months after the intervention

Method of measurement

Child's Sleep Habits Questionnaire

3**Description**

Parenting Stress

Timepoint

Before the intervention, after the intervention, three months after the intervention

Method of measurement

Parenting Stress Index

4**Description**

Interactive style of child parent

Timepoint

Before the intervention, after the intervention, three months after the intervention

Method of measurement

Parent child relationship scale

Intervention groups**1****Description**

The intervention group No. 1 includes children with attention-deficit/ hyperactivity disorder (ADHD) who are

subjected to the mindfulness therapy for eight sessions during one month. Treatment sessions are held twice each week. The duration of each session lasts for 45 minutes. The intervention is achieved from the combination of mindfulness-based cognitive therapy and mindfulness-based stress reduction and includes training of increased concentration on the present moment and accepting of experiences through knowledge of the environment, objects, body, and body movements.

Category

Behavior

2**Description**

The intervention group No. 2 includes parents of children with attention-deficit/ hyperactivity disorder (ADHD) who are subjected to the treatment for one month. The sessions are held weekly and two sessions per week for 45 minutes. This intervention is obtained from two therapeutic protocols of mindfulness-based cognitive therapy and mindfulness-based stress reduction. The contents of the treatment sessions including listening with full attention, acceptance without judgment of oneself and the child, emotional awareness of oneself and the child, self-regulation in parenting relationships, and compassion for oneself and the child.

Category

Behavior

3**Description**

The intervention No. 3 includes children with attention-deficit/ hyperactivity disorder (ADHD) and their parents. This intervention is a combination intervention that includes mindfulness for afflicted children and mindfulness parenting for parents of these children. Overall, the number of sessions is 16 sessions that eight sessions will be held for children and eight sessions for their parents. The sessions of children and parents will be held in a day, twice a week. The content of the children's and parents' sessions will be similar to the content of the sessions in interventions Nos. 1 and 2.

Category

Behavior

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tabadkan Education Counseling Center

Full name of responsible person

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Sponsors / Funding sources

1

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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
Ferdowsi University of Mashhad
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

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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

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

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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