Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 to12 years with ADHD and their parents in Mashhad. Inclusion criteria included the diagnosis of ADHD and being in the age range of 6 to12 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

Zeynab Abdolahzadeh

Name of organization / entity

Ferdowsi University of Mashhad

Country

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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
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948974
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
Hadi Dehghan
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ferdowsi University of Mashhad

Full name of responsible person
Ahmad Reza Bahrami

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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

Name of organization / entity
Ferdowsi University of Mashhad

Full name of responsible person
Zeynab Abdolahzadeh

Position
Ph.D Studend

Latest degree
Master

Other areas of specialty/work
Psychology

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Ali Mashhadi

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Associate Professor

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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