Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effectiveness of emotion regulation-based play therapy with child-centered mindfulness-based intervention on adjustment, emotion management, and executive functions of children with attention deficit hyperactivity disorder (ADHD)

Protocol summary

Study aim

To compare the effectiveness of emotion regulation-based play therapy and child-centered mindfulness intervention on adjustment, emotion management, and executive functions in children with attention-deficit/hyperactivity disorder.

Design

This is a randomized, three-arm, controlled, pretest–posttest quasi-experimental trial involving 45 participants, randomly allocated to two intervention groups and one control group using sealed-envelope randomization.

Settings and conduct

The study will be conducted in counseling centers in Yasuj, Iran, among children with ADHD. A total of 45 eligible participants will be selected using purposive sampling and randomly allocated to two intervention groups and one control group. Data will be analyzed using SPSS software.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Children aged 6–12 years with a DSM-5 diagnosis of ADHD. Written parental informed consent and child assent. No related pharmacological or psychological treatment within the previous 6 months. Exclusion Criteria: Severe psychiatric comorbidities or learning disabilities. Current use of psychiatric medications. Withdrawal from the study or absence from more than two intervention sessions.

Intervention groups

Intervention Group 1: Participants will receive emotion-based play therapy in eight face-to-face group sessions, each lasting 90 minutes, delivered by the researcher according to the study protocol. Intervention Group 2: Participants will receive child-centered mindfulness training in eight face-to-face group sessions, each lasting 90 minutes. Control Group: Participants will receive no intervention during the study period and will continue with routine care. Outcome assessments will be performed at the same time points as in the intervention groups.

Main outcome variables

Adaptability, Emotion regulation, Executive functions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251121068065N13**
Registration date: **2026-07-10, 1405/04/19**
Registration timing: **prospective**

Last update: **2026-07-10, 1405/04/19**
Update count: **0**

Registration date

2026-07-10, 1405/04/19

Registrant information

Name
kavoushgaran kavoushgaran
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 915 718 4680
Email address
atiye.hesary@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-08-01, 1405/05/10

Expected recruitment end date

2026-10-07, 1405/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of emotion regulation-based play therapy with child-centered mindfulness-based intervention on adjustment, emotion management, and executive functions of children with attention deficit hyperactivity disorder (ADHD)

Public title

Comparing the effectiveness of emotion-focused and child-centered mindfulness play therapy on children's adjustment, emotion regulation, and executive functioning

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children aged 6–12 years. Diagnosis of attention-deficit/hyperactivity disorder (ADHD) according to DSM-5 criteria. Written informed consent provided by parents or legal guardians. Child's assent to participate in the study. No pharmacological or non-pharmacological interventions targeting executive functions or emotion regulation within the previous 6 months.

Exclusion criteria:

Comorbid autism spectrum disorder, intellectual disability, or other severe psychiatric disorders. Severe learning disabilities interfering with participation in the intervention. Current use of psychiatric medications that may affect study outcomes. Withdrawal of parental consent or child assent during the study. Absence from more than two intervention sessions.

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: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible participants will be selected through purposive sampling and randomly allocated in a 1:1:1 ratio to two intervention groups and one control group using simple randomization. The random allocation sequence will be generated before participant enrollment using the RAND function in Microsoft Excel. Allocation concealment will be ensured using sequentially numbered, sealed, opaque envelopes prepared by an independent researcher not involved in participant recruitment or outcome assessment. After completion of the baseline assessment, each participant will be assigned to the next available envelope, which will determine group allocation.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Islamic Azad University - Yasuj Branch

Street address

Islamic Azad University, Yasuj Branch, 4th km., Si Sakht Road,Yasuj.

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7591493686

Approval date

2025-12-11, 1404/09/20

Ethics committee reference number

IR.IAU.YASOOJ.REC.1404.055

Health conditions studied

1

Description of health condition studied

Children with attention-deficit/hyperactivity disorder (ADHD)

ICD-10 code

F90.0

ICD-10 code description

Attention-deficit hyperactivity disorder, predominantly inattentive type

Primary outcomes

1

Description

Adaptability

Timepoint

Adaptability will be assessed at baseline, immediately after the intervention, and at the 2-month follow-up.

Method of measurement
Adaptability will be assessed using the Children's Adaptation Questionnaire developed by Dokhanchi (1998), consisting of 37 items rated on a 4-point Likert scale (0–3). Total scores range from 0 to 111, with higher scores indicating greater adaptability. Certain items are reverse-scored according to the questionnaire guidelines.

2

Description
Emotion management
Timepoint
Emotion management will be assessed at baseline, immediately after the intervention, and at the 2-month follow-up.
Method of measurement
Emotion management will be assessed using the Child Emotion Management Questionnaire (Zeman et al., 2001). This 38-item instrument is rated on a 3-point Likert scale (rarely, sometimes, often) and includes three subscales: anger, sadness, and worry. The total score is calculated by summing all item scores, with higher scores indicating greater emotion management difficulties.

3

Description
Executive functions
Timepoint
Executive functions will be assessed at baseline, immediately after the intervention, and at the 2-month follow-up.
Method of measurement
Executive functions will be assessed using the Executive Function Scale developed by Barclay (2012) for children and adolescents. The scale consists of 70 items rated on a 4-point Likert scale (never to always) and includes five subscales: time management, organization/problem solving, inhibition/self-control, self-motivation, and emotional regulation. The total score is calculated as the sum of all items, with higher scores indicating greater executive dysfunction.

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Participants will receive no intervention during the study period and will continue with routine care. Outcome assessments will be performed at the same time points as in the intervention groups.
Category
Treatment - Other

2

Description
Intervention group: Participants will receive emotion-based play therapy in eight face-to-face group sessions, each lasting 90 minutes, delivered by the researcher according to the study protocol.
Category
Treatment - Other

3

Description
Intervention group: Participants will receive child-centered mindfulness training in eight face-to-face group sessions, each lasting 90 minutes, delivered by the researcher according to the study protocol.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Khard-consultation center
Full name of responsible person
Saham Fazli
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Sponsors / Funding sources

1

Sponsor
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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
Islamic Azad University, Yasuj Branch
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
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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