

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Oct 2026

The effectiveness of cognitive therapy on mindfulness on cognitive dissociation syndrome, inhibitory control, and behavioral problems in children with symptoms on the verge of attention deficit/hyperactivity disorder.

Protocol summary

Study aim

Studying the prevalence of subthreshold symptoms of attention deficit/hyperactivity disorder in Iranian children aged 8 to 13 years. Determining the effectiveness of mindfulness-based cognitive therapy (child version) on cognitive dissonance syndrome and on inhibitory control and behavioral problems in children with subthreshold symptoms of attention deficit/hyperactivity disorder.

Design

This study was designed as a randomized, controlled, parallel-group clinical trial involving 80 patients. Random allocation was performed using the RAND function in Microsoft Excel."

Settings and conduct

Two sessions (each 45 min) were chosen and will be held in the Hamedan Province School Counseling Room every week. Accordingly, 24 sessions of 45 min will be held during the same 12 weeks. During the implementation of mindfulness-based cognitive therapy - child version, the treatment sessions will be repeatedly reviewed by the supervisors and counselors. Also, the content of the sessions will be recorded randomly and monitored by the supervising clinical psychologist with continuous feedback to the facilitator.

Participants/Inclusion and exclusion criteria

Age 10-13 years Willingness of the child to participate in the study Absence of chronic psychiatric disorders (schizophrenia spectrum, bipolar spectrum, and neurotic disorders). Receive a diagnosis of subthreshold symptoms of attention deficit/hyperactivity disorder by a clinical psychologist or psychiatrist with at least 5

Intervention groups

1: will receive mindfulness-based cognitive therapy (child version). 2: will receive a mindfulness framework without mindfulness content.

Main outcome variables

Child and Adolescent Mindfulness Questionnaire The Child and Adolescent Behavioral Problems Scale was used to measure externalizing symptoms. Cognitive Dissociation Syndrome Inhibitory Control

General information

Reason for update

The study was initially designed as a **crossover randomized controlled trial (RCT)** because this design has been employed in certain intervention studies to enhance statistical efficiency, reduce inter-individual variability, and ensure that all participants eventually receive the intervention. However, following a more thorough methodological review and expert feedback on the design of pediatric psychological trials, it became evident that a crossover design presents important limitations for mindfulness-based interventions, particularly **Mindfulness-Based Cognitive Therapy for Children (MBCT-C)**. A fundamental assumption of a crossover design is that the effects of the intervention are reversible or can be eliminated after the treatment phase, allowing participants to return to their baseline state following an adequate washout period. This assumption is not applicable to MBCT-C, as the intervention is specifically intended to produce enduring improvements in attentional regulation, emotional awareness, self-regulation, and behavioral control. The skills acquired during treatment are expected to persist beyond the intervention period and may even become further consolidated over time. Consequently, the likelihood of **carryover effects** is substantial, making it difficult to interpret post-crossover comparisons and potentially compromising the internal validity of the study. Accordingly, the study design was revised to a **parallel-group randomized controlled trial**. In this design, participants remain in their originally assigned groups following randomization, and the effectiveness of

MBCT-C is evaluated by comparing the intervention group with the waitlist control group at the post-intervention assessment. This approach enables a clearer and more valid evaluation of the intervention by eliminating the risk of contamination resulting from prior exposure to treatment. Furthermore, adopting a parallel-group design simplifies the statistical analysis by eliminating the need to model **sequence effects**, **period effects**, and **carryover effects**, thereby improving the clarity and interpretability of the analytical strategy. This modification is also more consistent with the theoretical and clinical foundations of MBCT-C, in which the maintenance and consolidation of learned mindfulness skills are considered integral components of the therapeutic mechanism rather than factors that can be fully removed or controlled. Therefore, from both methodological and clinical perspectives, a parallel-group randomized controlled trial represents a more appropriate and scientifically rigorous design for evaluating the effectiveness of MBCT-C.		Public title Study of cognitive therapy and mindfulness on children with hyperactivity
Acronym IRCT registration information IRCT registration number: IRCT20241008063301N1 Registration date: 2025-08-19, 1404/05/28 Registration timing: prospective Last update: 2026-07-30, 1405/05/08 Update count: 1 Registration date 2025-08-19, 1404/05/28 Registrant information Name mahshad gorjian Name of organization / entity Country Iran (Islamic Republic of) Phone +98 81 3251 0280 Email address mahshadgorjian1995@gmail.com Recruitment status Recruitment complete Funding source Expected recruitment start date 2025-09-23, 1404/07/01 Expected recruitment end date 2025-12-22, 1404/10/01 Actual recruitment start date empty Actual recruitment end date empty Trial completion date empty Scientific title The effectiveness of cognitive therapy on mindfulness on cognitive dissociation syndrome, inhibitory control, and behavioral problems in children with symptoms on the verge of attention deficit/hyperactivity disorder.		Purpose Education/Guidance
		Inclusion/Exclusion criteria Inclusion criteria: Cognitive Disengagement Syndrome, Inhibitory Control Behavioral Problems in Children Diagnosed with Subthreshold Attention-Deficit/Hyperactivity Disorder Exclusion criteria:
		Age From 8 years old to 13 years old
		Gender Both
		Phase N/A
		Groups that have been masked No information
		Sample size Target sample size: 80
		Randomization (investigator's opinion) Randomized
		Randomization description 80 children will be randomly selected from the eligible participants. Their selection will be based on the number assigned to each child and will be done using the random number function in Excel. They will then be divided into groups one and two.
		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 Ethics Committee of the Science and Research Unit Street address HESARAK BLVD, AZAD UNIVERSITY Science and research BRANCH City TEHRAN Province Tehran Postal code ۱۴۷۷۸۹۳۸۵۵
		Approval date 2025-02-20, 1403/12/02
		Ethics committee reference number IR.IAU.SRB.REC.1404.039

Health conditions studied

1

Description of health condition studied

Cognitive Disengagement Syndrome, Inhibitory Control, and Behavioral Problems in Children Diagnosed with Subthreshold Attention-Deficit/Hyperactivity Disorder

ICD-10 code

ICD-10 code description

Disengagement

Primary outcomes

1

Description

Cognitive Disengagement Syndrome as mbct

Timepoint

3 month

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: will receive mindfulness-based cognitive therapy (child version). In this study, a 12-week group intervention will be conducted, consisting of 24 sessions of 45 minutes each. Each session will be held with the aim of teaching mindfulness techniques to enhance attention self-management, intentional focus, emotion self-regulation, and emotional resilience. During the implementation of this intervention, the treatment sessions will be monitored and evaluated by the supervisors and counselors. Also, the content of the sessions will be randomly recorded and monitored by a supervising clinical psychologist with continuous feedback to ensure the quality of the content and interventions.

Category

Behavior

2

Description

Intervention group 2: The mindfulness framework will receive no mindfulness content. Both types of treatment will be equal in duration and number of sessions to reduce the role of confounding variables related to the length and timing of treatment.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

GHAHAVAND SCHOOLS

Full name of responsible person

MAHSHAD GORJIAN

Street address

IMAM KHOMAINI

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GHAHAVAND

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Hamadan

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Phone

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

REZA RADFAR

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IAU HESARAK TOWN

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TEHRAN

Province

Tehran

Postal code

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R.RADFAR@SRBIAU.AC.IR

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

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

Babakhabibius@yahoo.com

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

MAHSHAD GORJIAN

Position

PHD STUDENT

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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Iran University of Medical Sciences

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Mojtaba Habibi Asgarabad

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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