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.

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.

Public title

Study of cognitive therapy and mindfulness on children with hyperactivity

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
City
GHAHAVAND
Province
Hamadan
Postal code
6515643356
Phone
+98 918 018 1774
Email
MAHSHADGORJIAN1995@GMAIL.COM

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
REZA RADFAR
Street address
IAU HESARAK TOWN
City
TEHRAN
Province
Tehran
Postal code
۱۴۷۷۸۹۳۸۵۵
Phone
+98 21 4486 5239
Email
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

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

Street address
NO 10, FARAHANI AVE., AGHAJANI BEIG CENTER, ARAMGAH SQURE

City
HAMADAN

Province
Hamadan

Postal code
6515643356

Phone
+98 918 018 1774

Email
MAHSHADGORJIAN1995@GMAIL.COM

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Mojtaba Habibi Asgarabad

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

Street address
NO 10, FARAHANI AVE., MADANI BLVD.

City
hamedan

Province
Hamadan

Postal code
6515643356

Phone
+98 912 238 7577

Email
Babakhabibius@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Mahshad Gorjian

Position
Teaching assistant

Latest degree
Master

Other areas of specialty/work
Psychology

Street address
No 10, farahani ave., madani blvd.

City
Hamedan

Province
Hamadan

Postal code
6515643356

Phone
+98 81 3251 0280

Fax

Email
mahshadgorjian1995@gmail.com

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