Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effectiveness of Mindfulness-Based Cognitive Therapy on Planning, Sustained Attention, and Cognitive Flexibility in Adults with Attention-DeficitHyperactivity Disorder

Protocol summary

Study aim

Evaluate the effectiveness of Mindfulness-Based Cognitive Therapy in improving three core cognitive domains in adults with Attention-Deficit/Hyperactivity Disorder

Design

Randomized clinical trial with parallel groups and waiting list control. After screening, 40 eligible individuals were randomly assigned to either MBCT (8 group sessions; n=20) or wait list control (n=20). Due to the nature of the intervention, blinding of participants and therapists will not possible; however, the outcome assessor (and, where possible, the data analyst) will be blinded to group allocation.

Settings and conduct

The study will conducted at the Counseling Center of Persian Gulf University (Bushehr). Eligible participants will randomized to MBCT or waitlist control and assessed at pretest, posttest, and 2-month follow-up. Although participant/therapist blinding will not feasible, the outcome assessor will blinded via group coding.

Participants/Inclusion and exclusion criteria

Adults with ADHD will recruited from the Persian Gulf University Counseling Center (Bushehr). Inclusion: age 18–40; adult ADHD confirmed via clinical assessment/DSM-5-TR and validated measures (Barkley); written consent; able to attend sessions and complete assessments; no active psychosis or neurological disorder. Exclusion: >2 absences; major medication/psychotherapy changes; acute episodes (e.g., mania/psychosis); withdrawal or incomplete posttest/follow-up.

Intervention groups

Intervention group: Mindfulness-based cognitive therapy, control group receives no intervention.

Main outcome variables

Planning; sustained attention; cognitive flexibility

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250927067383N2**
Registration date: **2026-01-04, 1404/10/14**
Registration timing: **prospective**

Last update: **2026-01-04, 1404/10/14**
Update count: **0**

Registration date

2026-01-04, 1404/10/14

Registrant information

Name

leila kamran

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 917 001 8657

Email address

l.kamran92@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-02-16, 1404/11/27

Expected recruitment end date

2026-03-12, 1404/12/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Mindfulness-Based Cognitive Therapy on Planning, Sustained Attention, and Cognitive Flexibility in Adults with Attention-DeficitHyperactivity Disorder

Public title

Effectiveness of Mindfulness-Based Cognitive Therapy on Planning, Sustained Attention, and Cognitive Flexibility in Adults with Attention-DeficitHyperactivity Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18–40 years and Provision of written informed consent Willingness to attend sessions regularly Absence of active psychotic disorders or neurological conditions ADHD eligibility was established via clinical interview and DSM-5-TR criteria (American Psychiatric Association, 2022) and a Barkley-based diagnostic procedure, such that the presence of ≥3 symptoms in either the inattention domain or the hyperactivity–impulsivity domain, and ≥5 symptoms on the total ADHD index will consider clinically meaningful.

Exclusion criteria:

Missing more than two treatment sessions Initiation of, or substantial change in, concurrent pharmacotherapy or psychotherapy during the study period; Emergence of acute clinical conditions (e.g., manic episode or psychotic symptoms) that interfered with continuing the intervention Withdrawal from the study or failure to complete post-test or follow-up assessments.

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

After entering the screening and entry conditions, participants will be randomly assigned to two groups: "Mindfulness-Based Cognitive Therapy (MBCT)" and "Waiting List Control". The randomization method is simple randomization (simple randomization) and the randomization unit is considered to be individual (individual level). This means that each participant will be independently placed in one of the two groups. The allocation sequence will be created using SPSS software and the Random Number Generator function. The final list of allocations will be prepared by an independent researcher who has no intervention in the evaluation process. For allocation concealment, the group codes (A and B) will be placed in opaque and sealed envelopes and the envelopes will be opened in order based on the sequence of companies' arrival to minimize the possibility of bias in allocation. The assessors of the tests (TOL, CPT, WCST) will be blinded to the company grouping. Stratified randomization (stratified randomization) is not used in this study because the sample size was limited and population characteristics (gender, age) are matched between groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Due to the nature of the group-based psychological intervention (MBCT) and the inclusion of a waitlist control group, blinding of participants and the therapist to group allocation will not be feasible. Participants will be directly aware of whether they are receiving the therapeutic sessions or are assigned to the waitlist, and the therapist will naturally be aware of delivering the intervention. However, to minimize assessment bias, blinding will be implemented at the level of outcome assessors and/or data analysts. Participants: Prior to enrollment, all participants will be provided with a full explanation of the study objectives, procedures, group conditions (MBCT intervention versus waitlist control), and the assessment schedule. Written informed consent will be obtained. Therefore, participants will not be blinded. Interventionist/Therapist: MBCT sessions will be delivered by a licensed therapist. Given the therapist's direct role in administering the intervention, blinding will not be possible. Principal Investigator and Research Team: The principal investigator will be involved in study processes (e.g., study design, supervision of implementation, coordination of sessions) and, due to the operational nature of the trial, will be aware of group allocation. To reduce potential bias, the principal investigator will not be directly involved in outcome assessments. Data Collectors and Outcome Assessors: Cognitive assessments, including the Tower of London (TOL), Continuous Performance Test (CPT), and Wisconsin Card Sorting Test (WCST), will be administered at all three time points (pre-test, post-test, and follow-up) by trained assessors who will be blinded to group allocation. To maintain blinding, group assignment will not be recorded on assessment forms, and participants will be instructed to refrain from disclosing their treatment status during testing.

Placebo

Not used

Assignment

Factorial

Other design features

no

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Bushehr University of Medical Sciences
Street address
Bahmani street
City
Bushehr
Province
Boushehr
Postal code
1234567890
Approval date
2025-08-12, 1404/05/21
Ethics committee reference number
IR.BPUMS.REC.1404.255

Health conditions studied

1

Description of health condition studied
Attention-deficit hyperactivity disorders
ICD-10 code
F90
ICD-10 code description
Attention-deficit hyperactivity disorders

Primary outcomes

1

Description
Planning
Timepoint
Pre-test, post-test, immediately after treatment, follow-up 2 months after treatment
Method of measurement
Final score on the Tower of London benchmark test

2

Description
Sustained attention
Timepoint
Pre-test, post-test, follow-up
Method of measurement
Omission errors in CPT

3

Description
Wisconsin Card Sorting
Timepoint
Pre-test, post-test, follow-up
Method of measurement
Number of categories completed on the Wisconsin Card Sorting Test (WCST)

Secondary outcomes

1

Description
NO
Timepoint
NO
Method of measurement
NO

Intervention groups

1

Description
Intervention Group: Mindfulness-Based Cognitive Therapy (MBCT)Participants assigned to the intervention group will receive Mindfulness-Based Cognitive Therapy (MBCT) in a group format. The intervention will be delivered by a trained and licensed therapist in accordance with the standard MBCT protocol. The program will consist of eight in-person group sessions, each lasting approximately 90 minutes, and will be conducted on a weekly basis.Each session will include the following components:Instruction in core mindfulness concepts, with an emphasis on awareness of the present moment.Formal mindfulness practices, including body scan, focused breathing, and mindfulness of movement (e.g., simple stretching exercises).Brief daily-life practices aimed at increasing awareness of thoughts, emotions, and bodily sensations in real-world situations.Cognitive components targeting the identification of automatic thoughts, nonjudgmental observation of thoughts, and reduction of engagement with ruminative thinking.Training in strategies for managing distraction and redirecting attention back to the target stimulus.Participants will be assigned homework exercises, consisting of daily mindfulness practice lasting 20–30 minutes, with completion documented using structured practice logs. Attendance and active participation will be monitored throughout the intervention period, and the intervention will be delivered in a standardized and uniform manner to all participants in this group.
Category
Treatment - Other

2

Description
Control group: Waitlist control group without any intervention
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Persian Gulf University consultant center
Full name of responsible person
Leila Kamran
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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
Persian gulf 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
Persian Gulf University
Full name of responsible person
Leila Kamran
Position
Consultant,
Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Confidentiality
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable