

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Comparative Effectiveness of Cognitive Behavioral Therapy and Mindfulness-Based Cognitive Therapy on Executive Functions, Cognitive Disengagement Syndrome, Stress Management, and Quality of Life in Adults with ADHD

#### Protocol summary

##### Study aim

To investigate the effectiveness of cognitive-behavioral therapy (CBT) and mindfulness-based cognitive therapy (MBCT) on reducing attention deficit hyperactivity disorder (ADHD) symptoms, cognitive disengagement syndrome, improving executive functions, quality of life, and stress management in adults with ADHD.

##### Design

This study is a randomized clinical trial with parallel groups, which includes two intervention groups and a control group. The sample size for epidemiology was 1000 girls and boys. Random allocation was performed. The sample size was 60 people (each group about 20 people).

##### Settings and conduct

The study was conducted at Persian Gulf University and affiliated counseling centers. After screening 1000 students, 60 eligible participants were randomly assigned to CBT, MBCT, or control groups. Standardized executive function tests and questionnaires were administered, followed by group therapy sessions, posttest, and two-month follow-up.

##### Participants/Inclusion and exclusion criteria

Diagnosis of ADHD in adulthood based on clinical interview and DSM-5 criteria. Age 18 to 40 years; Having a severe psychiatric disorder (such as schizophrenia or bipolar disorder). Substance dependence or active substance abuse. Receiving concomitant psychological treatment or taking a cognitive-altering medication during the study period.

##### Intervention groups

CBT group: Group cognitive-behavioral therapy. MBCT group: Group mindfulness-based cognitive therapy. Control group: Placed on a waiting list and did not receive the intervention.

##### Main outcome variables

Reduction of symptoms of ADHD (attention, hyperactivity, impulsivity); reduction of CDS; improvement of executive functions; improvement of quality of life; improvement of stress management

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20250927067383N1**

Registration date: **2025-10-07, 1404/07/15**

Registration timing: **retrospective**

Last update: **2025-10-07, 1404/07/15**

Update count: **0**

##### Registration date

2025-10-07, 1404/07/15

##### 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

2024-09-22, 1403/07/01

##### Expected recruitment end date

2024-12-21, 1403/10/01

**Actual recruitment start date**  
empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Comparative Effectiveness of Cognitive Behavioral Therapy and Mindfulness-Based Cognitive Therapy on Executive Functions, Cognitive Disengagement Syndrome, Stress Management, and Quality of Life in Adults with ADHD

**Public title**  
Effectiveness of Cognitive-Behavioral and Mindfulness-Based Therapies in Adults with Attention-Deficit/Hyperactivity Disorder

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Age 18- 40 years old Sufficient motivation  
**Exclusion criteria:**  
History of neurological disorders Color blindness Lack of computer knowledge

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

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant

**Sample size**  
Target sample size: **60**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The sampling method of this study is multi-stage cluster random sampling, and the assignment of subjects to groups is also random.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
Participants: Individuals enrolled in the study were aware of the type of treatment they were receiving (cognitive-behavioral or cognitive-mindfulness), but were not accurately informed of the existence of a control group and between-group comparisons to reduce the expectation effect. Principal Investigator: The principal investigator, who was responsible for data analysis, was not aware of the coding of groups (A, B, and C) until the end of data collection, and analyses were conducted as anonymous data. Therapists: Due to the nature of psychological interventions, therapists were aware of the type of intervention they were implementing and there was no possibility of blinding them. Healthcare personnel: Because the intervention was implemented in an academic setting and by a trained researcher, clinical

personnel had no involvement in the treatment and care of participants. Data collectors and outcome assessors: The individuals who collected and scored the questionnaires were unaware of the type of intervention and the grouping of participants. The questionnaires were delivered and analyzed with only the participants' anonymous codes (without mentioning the treatment group). Authors of the final report: The initial writing of the article was done based on the coded data (without disclosing the groups) and only after the statistical analyses were completed, the group codes were opened and the results were interpreted accordingly.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

## Ethics committees

### 1

#### Ethics committee

**Name of ethics committee**

Bushehr University of Medical Sciences

**Street address**

Asadabadi Street, Alley 3, Parsam Building, Unit 8

**City**

Shiraz

**Province**

Fars

**Postal code**

7134944323

#### 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 disorder

#### ICD-10 code

F90

#### ICD-10 code description

Attention-deficit hyperactivity disorders

## Primary outcomes

### 1

#### Description

Inattention score measured by the Barkley Adult ADHD Rating Scale-IV (BAARS-IV).Hyperactivity score measured by the BAARS-IV.Impulsivity score measured by the BAARS-IV.Sluggish Cognitive Tempo (SCT) score

measured by the BAARS-IV and performance-based tests. Cold executive functions (cognitive flexibility, sustained attention, response inhibition, planning) measured by the Wisconsin Card Sorting Test (WCST), Stroop Test, Tower of London, and Continuous Performance Test (CPT). Hot executive functions (emotion regulation and decision-making) measured by related questionnaires and decision-making tasks. Quality of life measured by the Adult ADHD Quality of Life Questionnaire (AAQoL). Stress management measured by the Depression Anxiety Stress Scales (DASS-21).

#### **Timepoint**

Pre-test before the intervention begins, post-test immediately after the end of the treatment sessions, and follow-up 2 months after the end of treatment.

#### **Method of measurement**

Barclay Adult Attention-Deficit Hyperactivity Disorder Rating Scale, Adult ADHD Quality of Life Scale (AAQoL), Depression-Anxiety-Stress Scale (DASS), Stroop test, Wisconsin Card Sorting Test, Tower of London Test, Continuous Performance Test (CPT)

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: Cognitive-behavioral therapy

#### **Category**

Treatment - Other

### 2

#### **Description**

Control group: No intervention was performed.

#### **Category**

Treatment - Other

### 3

#### **Description**

Intervention group: Mindfulness-based cognitive therapy

#### **Category**

Treatment - Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Persian gulf university

##### **Full name of responsible person**

Leila Kamran

##### **Street address**

Bushehr, Persian Gulf Street, Persian Gulf University

##### **City**

Bushehr

#### **Province**

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#### **Postal code**

7516913817

#### **Phone**

+98 917 001 8657

#### **Email**

l.kamran92@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Persian Gulf University

##### **Full name of responsible person**

Leila Kamran

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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**

psychologist

##### **Latest degree**

Master

##### **Other areas of specialty/work**

Psychology

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Position**

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**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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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**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All data is potentially shareable after de-identifying individuals.

**When the data will become available and for how long**

From the time of defense for 6 months

**To whom data/document is available**

Researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

No analysis or use is permitted.

**From where data/document is obtainable**

To receive data/documents, please contact your supervisor, Dr. Golestaneh, at the email address [golestaneh@pgu.ac.ir](mailto:golestaneh@pgu.ac.ir).

**What processes are involved for a request to access data/document**

Approval from researcher, supervisors and advisors

**Comments**