Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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

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Sponsors / Funding sources

1

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Full name of responsible person

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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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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.
What processes are involved for a request to access data/document
Approval from researcher, supervisors and advisors
Comments