Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Impact of Mindfulness-Based Cognitive Therapy (MBCT) on the Executive Functions of adults with Cognitive Disengagement Syndrome

Protocol summary

Study aim
Investigating the effectiveness of mindfulness cognitive therapy on improving executive functions in adults with cds

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
Participants were adults with cognitive disinhibition syndrome, screened through the Persian Gulf University Counseling Center. Inclusion criteria included age 18–40 years, diagnosis based on clinical assessment and validated instruments (including the ACI questionnaire), written informed consent, ability to attend regularly and complete assessments at three times, and no active psychotic disorder or neurological disease. Inclusion criteria included missing more than two sessions, initiating/majorly changing concurrent medication or psychotherapy during the study, developing an acute clinical condition (such as mania or psychotic symptoms), and withdrawing or failing to complete posttest/follow-up assessments.

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

Main outcome variables
Planning; sustained attention; cognitive flexibility, Inhibition

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250927067383N3**
Registration date: **2026-01-19, 1404/10/29**
Registration timing: **retrospective**

Last update: **2026-01-19, 1404/10/29**
Update count: **0**

Registration date
2026-01-19, 1404/10/29

Registrant information

Name
leila kamran

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 917 001 8657

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-01-10, 1404/10/20

Expected recruitment end date
2026-01-15, 1404/10/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Impact of Mindfulness-Based Cognitive Therapy (MBCT) on the Executive Functions of adults with Cognitive Disengagement Syndrome

Public title
The Impact of Mindfulness-Based Cognitive Therapy (MBCT) on the Executive Functions of adults with Cognitive Disengagement Syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
age 18–40 years willingness to attend sessions regularly absence of neurological disorders or active psychotic conditions normal intellectual functioning based on student health records
Exclusion criteria:
color blindness lack of basic computer skills concurrent psychotropic medication or psychological treatment comorbid attention-deficit/hyperactivity disorder

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

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **40**

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. 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)
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

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Bahmani street

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Bushehr

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۷۵۱۶۹۱۳۸۱۷

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
Cognitive Disengagement Syndrome
ICD-10 code
ICD-10 code description

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)

4

Description
Stroop test
Timepoint
Pre-test, post-test, follow-up
Method of measurement
Interference score

Secondary outcomes

empty

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

Sponsor

Name of organization / entity
Persian gulf university

Full name of responsible person
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golestaneh@pgu.ac.ir

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)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Privacy

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

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

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