Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the Effectiveness of Cognitive-Behavioral Therapy and Mindfulness-Based Stress Reduction on Quality of Life, Perceived Stress, Attention and Working Memory in Individuals with Mild Cognitive Impairments.

Protocol summary

Study aim

The aim of this study is to investigate and compare the effectiveness of Cognitive Behavioral Therapy (CBT) and Mindfulness-Based Stress Reduction (MBSR) on quality of life, perceived stress, attention, and working memory in patients with Mild Cognitive Impairment (MCI).

Design

A controlled clinical trial with parallel groups, conducted in a single-blind design using random allocation, involving 45 participants diagnosed with MCI, with 15 participants assigned to each group.Participants will complete computer-based tests and self-report questionnaires. The intervention protocols will be applied to the experimental groups, followed by a post-test and a three-month follow-up. For ethical reasons, the control group may receive one of the interventions after the study.

Settings and conduct

Forty-five eligible participants with MCI will be purposefully selected from the Yadman Clinic in Tehran. After obtaining informed consent, they will be randomly assigned to three equal groups, including two experimental groups and one control group (15 participants in each group).

Participants/Inclusion and exclusion criteria

The main inclusion criteria include: a confirmed diagnosis of MCI by a neurology specialist, being between 60 and 80 years of age, fluency in Persian, having at least eight years of formal education, and the ability to attend treatment sessions and regularly perform the exercises related to each intervention. The main exclusion criteria include: a confirmed diagnosis of any type of progressive dementia, the presence of progressive neurological disorders, absence from more than four sessions, and uncontrolled internal medical conditions.

Intervention groups

1.Cognitive Behavioral Therapy (CBT) ,2.Mindfulness-Based Stress Reduction (MBSR) and 3. Control group

Main outcome variables

Quality of Life, Perceived Stress, Attention and Working Memory

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251024067740N1**
Registration date: **2025-11-04, 1404/08/13**
Registration timing: **prospective**

Last update: **2025-11-04, 1404/08/13**
Update count: **0**

Registration date

2025-11-04, 1404/08/13

Registrant information

Name

Anahita Tarki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 930 620 6392

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-11-08, 1404/08/17

Expected recruitment end date
2026-03-07, 1404/12/16
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the Effectiveness of Cognitive-Behavioral Therapy and Mindfulness-Based Stress Reduction on Quality of Life, Perceived Stress, Attention and Working Memory in Individuals with Mild Cognitive Impairments.

Public title
Comparing the Effectiveness of Cognitive-Behavioral Therapy and Mindfulness-Based Stress Reduction in people with Mild Cognitive Impairments
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Receiving a confirmed diagnosis of Mild Cognitive Impairment (MCI) by a neurology specialist. Being between 60 and 80 years of age. Fluency in Persian language and having at least 8 years of formal education. The participant’s ability to attend treatment sessions as scheduled according to the therapeutic protocols and to regularly perform the exercises related to each intervention. The ability to write and fully complete the questions of self-report instruments and computer-based tools across the three stages of implementation.
Exclusion criteria:
A confirmed diagnosis of any type of progressive dementia. Having progressive neurological disorders, or a diagnosed cognitive impairment resulting from conditions such as COVID-19 infection, brain injury, stroke, multiple sclerosis (MS), Parkinson’s disease, or other similar causes. Absence from more than four sessions in any of the intervention programs. Exacerbation of symptoms, hospitalization, or undergoing anesthesia and surgery during the implementation of the protocols. Presence of severe visual or hearing impairments, history of stroke, transient ischemic attack (TIA), or head injury with a history of loss of consciousness. History of internal medical conditions such as uncontrolled diabetes, uncontrolled hypertension, uncontrolled hyperlipidemia, obstructive sleep apnea, or a history of HIV infection. Presence of major neurological or psychiatric disorders, including stroke, epilepsy, seizures, Parkinson’s disease, multiple sclerosis (MS), brain injuries, diagnosed schizophrenia, adult attention-deficit/hyperactivity disorder (ADHD), or any condition requiring frequent hospital visits or hospitalizations. Dependence on or abuse of substances or specific medications.
Age
From **60 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients diagnosed with Mild Cognitive Impairment (MCI) will be randomly assigned to the intervention and control groups using a lot-drawing randomization method. Each participant was assigned a unique number, and the sample numbers were then randomly selected using the Excel software to determine group allocation.
Blinding (investigator's opinion)
Single blinded
Blinding description
participants are unaware of the intervention identity. Allocation uses neutral codes (A/B).
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Islamic azad University - Karaj Branch
Street address
Islamic Azad University, Karaj Branch, Shahid Chamran Boulevard, Karaj, Alborz Province, Iran
City
karaj
Province
Alborz
Postal code
3149968111
Approval date
2024-04-23, 1403/02/04
Ethics committee reference number
IR.IAU.K.REC.1403.030

Health conditions studied

1

Description of health condition studied
Mild Cognitive Impairment
ICD-10 code
G31.84
ICD-10 code description

Mild cognitive impairment, so stated

Primary outcomes

1

Description
Quality of Life
Timepoint
Before the intervention – Immediately after the intervention – Three-month follow-up after the intervention
Method of measurement
world health organization- quality of life questionnaire (WHOQOL-100)

2

Description
Perceived Stress
Timepoint
Before the intervention – Immediately after the intervention – Three-month follow-up after the intervention
Method of measurement
percieved stress scale-14 (PSS-14)

3

Description
Attention
Timepoint
Before the intervention – Immediately after the intervention – Three-month follow-up after the intervention
Method of measurement
Cambridge Neuropsychological Test Automated Battery (CANTAB) will be used in the subtests of Rapid Visual Information Processing (RVP) and Match to Sample Visual Search (MTS).

4

Description
Working Memory
Timepoint
Before the intervention – Immediately after the intervention – Three-month follow-up after the intervention
Method of measurement
Cambridge Neuropsychological Test Automated Battery (CANTAB) in the Spatial Working Memory (SWM) subtest.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Cognitive-Behavioral Therapy, Cognitive Behavioral Therapy (CBT), based on the classical cognitive-behavioral approach, will be conducted with the aim of improving the cognitive, behavioral, and emotional states of participants in the experimental group through nine group therapy sessions, held once a week, each lasting 90 minutes.
Category
Treatment - Other

2

Description
Intervention group:Mindfulness-Based Stress Reduction, The Mindfulness-Based Stress Reduction (MBSR) program will be conducted in eight weekly sessions. Each session will typically last for two and a half hours and will follow a structured program.
Category
Treatment - Other

3

Description
Control group:No intervention، They were included in the study for comparison with the intervention groups and did not receive any medication, placebo, or treatment.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Yadman Clinic
Full name of responsible person
Anahita Tarki
Street address
3rd Floor، No. 1, Nakhoda Mohtaj Alley, Paknezhad Boulevard, Sanat Square, Shahrak-e Gharb, Tehran, Iran
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Web page address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University

Full name of responsible person
شیدا سوداگر
Street address
Islamic Azad University, Karaj Branch (Amir al-Momenin Academic Complex), Moazen Blvd. and Esteghlal Blvd. Intersection, end of Rajaee Shahr, Karaj, Alborz Province, Iran
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info@kiau.ac.ir
Web page address
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Islamic Azad University, Karaj Branch

Proportion provided by this source
1

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
Anahita Tarki
Position
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Person responsible for updating data

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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

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

Yes - There is 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

Title and more details about the data/document

The findings will be reported in scientific articles after the completion of the interventions.

When the data will become available and for how long

It is anticipated to occur within 1 to 6 months after the intervention.

To whom data/document is available

Researchers, Research Students

Under which criteria data/document could be used

Use of information with proper citation

From where data/document is obtainable

Accessible through reputable journals, scientific publications, and the researcher’s personal email address

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

The requester should briefly and clearly state their request so that it can be responded to in the shortest possible time.

Comments