

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

anahita.tarki@iau.ac.ir

##### 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

Perceived 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

##### City

Tehran

##### Province

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##### Postal code

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##### Phone

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##### Email

anahita.tarki@iau.ac.ir

##### Web page address

<https://drmaryamnoroosian.com/services>

## 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 Rajae Shahr, Karaj, Alborz Province, Iran

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**Province**

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**Postal code**

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info@kiau.ac.ir

**Web page address**

https://karaj.iau.ir/fa

**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**

Ph.D. Candidate

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

**Street address**

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**Position**

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**Latest degree**

Master

**Other areas of specialty/work**

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

Islamic Azad University

**Full name of responsible person**

Anahita Tarki

**Position**

Ph.D. Candidate

**Latest degree**

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**Other areas of specialty/work**

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+98 21 2670 0944

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anahitatarki2013@gmail.com

**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**