

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 2026

### The comparison of the effectiveness of unified transdiagnostic treatment and mindfulness based cognitive therapy (MBCT) in cognitive avoidance ,emotional regulation and rumination in depression disorder: a double-blind randomized clinical trial

#### Protocol summary

##### Study aim

Comparing the effectiveness of integrated transdiagnostic therapy and mindfulness therapy on cognitive avoidance, emotion regulation and rumination in depressive disorder

##### Design

A clinical trial with a control group with two parallel treatment groups on 45 patients

##### Settings and conduct

Background: depression disorder, location: Jihad Counseling Center, Mashhad University. Clinical interviews and depression questionnaires were taken from people who referred to the center with depression complaints, and then, if they were eligible, they were randomly divided into three groups of 15 The subjects were divided into (metadiagnostic therapy group, mindfulness therapy group and control group).

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of depressive disorder in structured clinical interview based on SCID-5 Beck depression questionnaire Exclusion criteria: Existence of psychiatric disorders (schizophrenic spectrum disorders and other psychotic disorders and bipolar disorder) Receiving other psychological treatments at the same time

##### Intervention groups

The first experimental group with integrated metadiagnostic therapeutic intervention, the second experimental group with cognitive therapy intervention based on mindfulness and the control group.

##### Main outcome variables

Rumination Cognitive avoidance Emotion Regulation

#### General information

##### Reason for update

##### Acronym

UM

##### IRCT registration information

IRCT registration number: **IRCT20231107059985N1**

Registration date: **2023-11-14, 1402/08/23**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-11-14, 1402/08/23**

Update count: **0**

##### Registration date

2023-11-14, 1402/08/23

##### Registrant information

###### Name

Somayeh Afshar

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3766 9496

###### Email address

afshar.so@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-11-09, 1402/08/18

##### Expected recruitment end date

2024-03-10, 1402/12/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The comparison of the effectiveness of unified transdiagnostic treatment and mindfulness based cognitive therapy (MBCT) in cognitive avoidance ,emotional regulation and rumination in depression disorder: a double-blind randomized clinical trial

## Public title

Investigating the effect of integrated transdiagnostic therapy and cognitive therapy based on mindfulness in depression

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Diagnosing depression disorder in a structured clinical interview based on SCID-5 Beck Depression Questionnaire not receiving drug treatment (physical and psychological medication) receiving other psychological treatments not having severe psychiatric disorders absence of addiction

### Exclusion criteria:

Being less than 18 years old and more than 50 years old having absence of more than 3 sessions having an addiction having a psychiatric disorder receiving drug treatment (physical and psychological medication) receiving Other psychological treatments

## Age

From **18 years** old to **50 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Data analyser

## Sample size

Target sample size: **45**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Simple randomization method Randomization unit: individual Randomization tool: sealed envelope Explanation about concealment: In order to prevent selection distortion, a number of envelopes are prepared with aluminum foil (in order to make the contents of the envelopes unclear), and each of the random sequences created is recorded on a card and the cards are placed inside the envelopes in order. In order to preserve the random sequence, the outer surface of the envelope is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box in order. At the time of the registration of the participants, according to the order of entry of the eligible participants into the study, one of the letter envelopes will be opened and the assigned group of that participant will be revealed.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

After selecting the sample, none of the people in the sample will know about randomization and the process of

allocation to groups. The data analyst will be chosen outside the study and all the data will be provided to him in a coded form.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Faculty of Medicine, Islamic Azad University, Mashhad Medical Sciences Unit

##### Street address

Mashhad ,Faramarz abbasi Blv,faramarz 15 Avenue, resalat 29,45 No

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9197964916

#### Approval date

2023-11-07, 1402/08/16

#### Ethics committee reference number

IR.IAU.MSHD.REC.1402.128

## Health conditions studied

### 1

#### Description of health condition studied

Major depressive disorder

#### ICD-10 code

F33.0

#### ICD-10 code description

Major depressive disorder, recurrent, mild

## Primary outcomes

### 1

#### Description

depression

#### Timepoint

A pre-test, post-test and then follow-up after 3 months.

#### Method of measurement

Clinical interview(SCID-5), Beck Depression Questionnaire (2nd edition)

## Secondary outcomes

### 1

**Description**

ruminatation

**Timepoint**

pre-test, post-test and follow-up (two months after the post-test)

**Method of measurement**

Rumination response style scale

### 2

**Description**

Cognitive avoidance

**Timepoint**

pre-test, post-test and follow-up (two months after the post-test)

**Method of measurement**

Cognitive avoidance questionnaire(CAQ)

### 3

**Description**

Emotion Regulation

**Timepoint**

pre-test, post-test and follow-up (two months after the post-test)

**Method of measurement**

emotion regulation questionnaire (ERQ)

## Intervention groups

### 1

**Description**

The first intervention group: integrated metadiagnostic treatment based on the treatment protocol of David Barlow et al. (2009)

**Category**

Behavior

### 2

**Description**

Intervention group 2: cognitive therapy based on mindfulness based on the therapeutic protocol of Segal et al. (2002)

**Category**

Behavior

### 3

**Description**

Control group: no intervention

**Category**

N/A

## Recruitment centers

### 1

**Recruitment center**

Name of recruitment center

Mashhad Academic Jihad Counseling Center

**Full name of responsible person**

Dr.moghadaszadeh

**Street address**

serah adabiat Ave

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845623919

**Phone**

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**Email**

afshar.so@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Dr Gholamreza Kazemi

**Street address**

Daneshgah Ave,Defae Moghadas Square,Bojnourd

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**Province**

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vahed@bojnourdiau.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Islamic Azad University Of Bojnourd

**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

Islamic Azad University  
**Full name of responsible person**  
Negar Asgharipour zahmati  
**Position**  
Associate Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Psychology  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Islamic Azad University  
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Somayeh Afshar  
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Phd Student  
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Master  
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## Person responsible for updating data

### Contact

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**Full name of responsible person**  
Somayeh Afshar  
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Phd Student

### Latest degree

Master

### Other areas of specialty/work

Psychology

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### City

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### Province

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### Postal code

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### Phone

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### Email

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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

Yes - There is 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

All information related to the main outcome or similar will be published.

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

Since 1403

### To whom data/document is available

Researchers working in academic and scientific institutions

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

It is possible to access the documents for the information of other researchers.

### From where data/document is obtainable

Mashhad Academic Jihad Counseling Center, Samia Afshar 09151070883

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

Only by stating the reason for the request via email or phone, the required documents will be shared.

### Comments