Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Randomized Controlled Trial of a Novel Mindfulness based on Meta-Inner Humor for Co-occurrence of Anxiety, OCD, and Depressive Disorders

Protocol summary

Study aim

The primary hypotheses test whether MMIH reduces emotional distress (depression, anxiety, OCI-R) and increases life satisfaction. Secondary hypotheses focus on the effects of MMIH on reducing RNT, maladaptive meta-beliefs, psychological inflexibility, and enhancing mindfulness. The mechanism of change hypothesis examines whether changes in meta-beliefs predict improvements in symptoms and broader processes beyond mindfulness.

Design

This study was a three-arm randomized controlled trial (RCT) following CONSORT 2010 and longitudinal measurement at three time points: baseline, post-treatment, and 6-month follow-up .

Settings and conduct

Participants were recruited from September 3 to May 17, 2025, using a multi-tiered referral and outreach strategy to enhance representativeness and reduce self-selection bias.

Participants/Inclusion and exclusion criteria

Eligibility criteria included: (a) meeting DSM-5 diagnostic criteria for at least one disorder in anxiety disorders, depressive disorders, and obsessive-compulsive and related disorders; (b) age 18 or older; and (c) provision of written informed consent. Exclusion criteria included: (a) current or past diagnosis of psychotic disorders, bipolar disorders, severe personality disorders, substance use disorders, or any debilitating medical condition (e.g., uncontrolled chronic illness); and (b) current suicidality.

Intervention groups

MMIH is a 10-week manualized group therapy (90 minutes/week), delivered by certified clinicians trained in the MMIH protocol.

Main outcome variables

Obsessive–Compulsive Inventory–Revised; Satisfaction with Life Scale; Meta-Inner Humor Scale; Mindful Attention Awareness Scale; Repetitive Thinking Questionnaire – 10 ' Acceptance and Action Questionnaire–II; Metacognitions Questionnaire–30; Self-Compassion Scale – Short Form; Patient Health Questionnaire – 9 item; State–Trait Anxiety Inventory

General information

Reason for update

Acronym

MMIH Protocol

IRCT registration information

IRCT registration number: **IRCT20130904014564N2**
Registration date: **2025-09-04, 1404/06/13**
Registration timing: **retrospective**

Last update: **2025-09-04, 1404/06/13**
Update count: **0**

Registration date

2025-09-04, 1404/06/13

Registrant information

Name

Mehdi Akbari

Name of organization / entity

Kharazmi University

Country

Iran (Islamic Republic of)

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Email address

akbari.psy@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-07-03, 1403/04/13

Expected recruitment end date

2024-09-17, 1403/06/27

Actual recruitment start date

2024-09-03, 1403/06/13

Actual recruitment end date

2025-05-17, 1404/02/27

Trial completion date

empty

Scientific title

Randomized Controlled Trial of a Novel Mindfulness based on Meta-Inner Humor for Co-occurrence of Anxiety, OCD, and Depressive Disorders

Public title

Mindfulness based on Meta-Inner Humor

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

(a) Meeting DSM-5 diagnostic criteria for at least one disorder in each of the following categories—anxiety disorders, depressive disorders, and obsessive-compulsive and related disorders—as determined by the Structured Clinical Interview for DSM-5 (SCID-5); (b) Age 18 years or older; (c) Provision of written informed consent.

Exclusion criteria:

Exclusion criteria were: (a) current or past diagnosis of psychotic disorders, bipolar disorders, severe personality disorders, substance use disorders, or any debilitating medical condition (e.g., uncontrolled chronic illness); (b) Current suicidality. Use of stable pharmacotherapy (e.g., SSRIs, SNRIs, benzodiazepines) was permitted if dosage remained unchanged during the six months prior to enrollment and throughout the intervention.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **101**
More than 1 sample in each individual
Number of samples in each individual: **31**
Experimental group (MMIH intervention; n = 31), Placebo-control group (n = 31), and Waitlist control group (n = 31).
Actual sample size reached: **93**
More than 1 sample in each individual
Actual sample size in each individual: **93**
Experimental group (MMIH intervention; n = 31), Placebo-control group (n = 31), and Waitlist control group (n = 31).

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be stratified based on diagnosis severity (high/low) and gender, and will then be randomized using permuted block randomization (block size = 6). Randomization will be implemented through an independent and concealed sequence using the REDCap randomizer with a full audit trail. Group assignment will be double-blinded for both outcome assessors and participants. After confirming eligibility, participants will be randomly assigned to one of three study arms: Experimental group (MMIH intervention; n = 31), Placebo-control group (n = 31), and Waitlist control group (n = 31). An independent researcher, not involved in participant recruitment or intervention, will generate the randomization sequence and will oversee allocation concealment using Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE). Researchers responsible for outcome assessment and statistical analysis will remain blinded to group assignments.

Blinding (investigator's opinion)

Double blinded

Blinding description

While participants will be blinded to intervention type, outcome assessors will remain blind to group allocation. Therapists and facilitators will be instructed to avoid disclosing any information related to group identity. Participants will be informed that they may receive one of three structured interventions as part of a mental health trial.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kharazmi University

Street address

No.43, South Mofateh St, Kharazmi University, Tehran, Iran

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Postal code

15719-14911

Approval date

2025-08-31, 1404/06/09

Ethics committee reference number

IR.KHU.REC.1404.081

Health conditions studied

1

Description of health condition studied

Generalized Anxiety Disorder

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

2

Description of health condition studied

Social Anxiety Disorder

ICD-10 code

F40.1

ICD-10 code description

Social phobias

3

Description of health condition studied

Panic Disorder

ICD-10 code

F41.0

ICD-10 code description

Panic disorder [episodic paroxysmal anxiety] without agoraphobia

4

Description of health condition studied

Specific Phobia

ICD-10 code

F40.2

ICD-10 code description

Specific (isolated) phobias

5

Description of health condition studied

Major Depressive Disorder

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

6

Description of health condition studied

Dysthymia

ICD-10 code

F34.1

ICD-10 code description

Dysthymic disorder

7

Description of health condition studied

Obsessive-compulsive disorder

ICD-10 code

F42

ICD-10 code description

Obsessive-compulsive disorder

8

Description of health condition studied

Body dysmorphic disorder

ICD-10 code

F45.22

ICD-10 code description

Body dysmorphic disorder

9

Description of health condition studied

Hoarding disorder

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Obsessive compulsive symptoms

Timepoint

Pre-treatment (baseline), post-treatment (end of week 10), and at 6-month follow-up

Method of measurement

The Obsessive-Compulsive Inventory-Revised (OCI-R)

2

Description

Depressive symptom

Timepoint

Pre-treatment (baseline), post-treatment (end of week 10), and at 6-month follow-up

Method of measurement

Patient Health Questionnaire–9 (PHQ-9)

3

Description

Trait anxiety

Timepoint

Pre-treatment (baseline), post-treatment (end of week 10), and at 6-month follow-up

Method of measurement

State-Trait Anxiety Inventory (STAI)

4

Description

Life satisfaction

Timepoint

Pre-treatment (baseline), post-treatment (end of week 10), and at 6-month follow-up

Method of measurement

Satisfaction with Life Scale (SWLS)

Secondary outcomes

1

Description

Mindfulness

Timepoint

Pre-treatment (baseline), post-treatment (end of week 10), and a six-month follow-up

Method of measurement

The Mindfulness Attention Awareness Scale (MAAS)

2

Description

Psychological inflexibility

Timepoint

Pre-treatment (baseline), post-treatment (end of week 10), and a six-month follow-up

Method of measurement

Acceptance and Action Questionnaire–II (AAQ-II)

3

Description

Repetitive negative thoughts

Timepoint

Pre-treatment (baseline), post-treatment (end of week 10), and a six-month follow-up

Method of measurement

Repetitive Thinking Questionnaire–10 (RTQ-10)

4

Description

Positive and negative metacognitions

Timepoint

Pre-treatment (baseline), post-treatment (end of week 10), and a six-month follow-up

Method of measurement

Metacognitions Questionnaire–30 (MCQ-30)

5

Description

Self-Compassion

Timepoint

Pre-treatment (baseline), post-treatment (end of week 10), and a six-month follow-up

Method of measurement

Self-Compassion Scale–Short Form (SCS-SF)

Intervention groups

1

Description

Intervention group: Mindfulness based on Meta-Inner Humor

Category

Behavior

2

Description

Intervention group: Placebo-Control Intervention (Attention-Matched Psychoeducational Control)

Category

Placebo

3

Description

Control group: Waitlist control group

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Academic counseling centers, psychiatric outpatient clinics, and private clinics in Tehran

Full name of responsible person

Dr. Mehdi Solimani

Street address

South Kargar Street, Below the Lashgar, Roozbeh Psychiatric Hospital, Tehran, Iran

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m.akbari@khu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research and Technology, Kharazmi University

Full name of responsible person

Dr. Alireza Harifi

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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

Vice-chancellor for Research and Technology, Kharazmi 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
Kharazmi University

Full name of responsible person
Mehdi Akbari

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Information on the main outcome of the research will be shared.

When the data will become available and for how long
Access begins 6 months after results are published.

To whom data/document is available
Data and other scientific documentation can be made available to any person who requests it.

Under which criteria data/document could be used
There are no specific restrictions.

From where data/document is obtainable

To access the data, you can send a message to Dr. Mehdi Akbari's email address: Akbari.psy@gmail.com or m.akbari@khu.ac.ir

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

One month after the requester sends a message to one of the two emails mentioned in the previous section, individuals can receive the requested information.

Comments