Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparing the Efficacy and Mechanisms of Change of Meta-Inner Humor Therapy (MIHT) versus Mindfulness-Based Cognitive Therapy (MBCT) for Generalized Anxiety Disorder with or without Major Depressive Disorder: A Multilevel Longitudinal Randomized Controlled Trial

Protocol summary

Study aim

Comparing the Efficacy and Mechanisms of Change of Meta-Inner Humor Therapy (MIHT) versus Mindfulness-Based Cognitive Therapy (MBCT) for Generalized Anxiety Disorder with or without Major Depressive Disorder:

Design

This study is a two-arm randomized controlled trial (RCT) designed in accordance with the CONSORT 2010 and SPIRIT guidelines. Participants, stratified by diagnostic status (GAD alone vs. GAD + MDD), will be randomly allocated to either MMIH or MBCT using stratified block randomization. The study aims to evaluate the clinical efficacy and underlying psychological mechanisms of both interventions by assessing outcomes at four time points: baseline, post-treatment (week 10), and 3- and 6-month follow-ups.

Settings and conduct

Participants will be recruited from June 20, 2026, to August 21, 2026, through a multi-stage referral and announcement strategy to enhance sample representativeness and reduce self-selection bias. Following random assignment into two intervention groups, participants in each arm will receive their respective treatments at university counseling centers and outpatient clinics in Tehran

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Primary diagnosis of GAD (with or without comorbid MDD), confirmed via SCID-5; age 18 or older; and written informed consent. Exclusion Criteria: Current or lifetime history of psychotic, bipolar, severe personality, or substance use disorders; debilitating medical conditions; or active suicidality.

Intervention groups

Intervention Group 1: Meta-Inner Humor Therapy (MIHT), consisting of 10 weekly 90-minute group therapy sessions. Intervention Group 2: Mindfulness-Based Cognitive Therapy (MBCT), consisting of 10 weekly 90-minute group therapy sessions.

Main outcome variables

Severity of Generalized Anxiety Disorder and Major Depressive Disorder symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130904014564N3**
Registration date: **2026-05-30, 1405/03/09**
Registration timing: **prospective**

Last update: **2026-05-30, 1405/03/09**
Update count: **0**

Registration date

2026-05-30, 1405/03/09

Registrant information

Name

Mehdi Akbari

Name of organization / entity

Kharazmi University

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-06-20, 1405/03/30

Expected recruitment end date

2026-08-21, 1405/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Efficacy and Mechanisms of Change of Meta-Inner Humor Therapy (MIHT) versus Mindfulness-Based Cognitive Therapy (MBCT) for Generalized Anxiety Disorder with or without Major Depressive Disorder: A Multilevel Longitudinal Randomized Controlled Trial

Public title

Comparing the Efficacy of Meta-Inner Humor Therapy (MIHT) versus Mindfulness-Based Cognitive Therapy (MBCT) for Generalized Anxiety Disorder with or without Major Depressive Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion Criteria:a) Participants must have Generalized Anxiety Disorder (GAD) as their primary diagnosis, which may present either in isolation or with comorbid Major Depressive Disorder (MDD). Other comorbid disorders, if present, will be recorded and included as covariates in the analyses. Diagnoses will be established based on the DSM-5 using the Structured Clinical Interview for DSM-5 (SCID-5) to ensure diagnostic accuracy and consistency in sample selection. Consequently, the study sample will consist of adults with GAD (with or without depressive comorbidity) who meet the required eligibility criteria.b) Age 18 years or older.c) Provision of written informed consent.Exclusion Criteria:a) Current or lifetime diagnosis of any psychotic disorder, bipolar disorder, severe personality disorders, substance use disorder, or any debilitating medical condition (such as an uncontrolled chronic illness).b) Presence of active suicidal ideation or behavior.Stable psychiatric medication use (e.g., SSRIs, SNRIs, benzodiazepines) is permitted, provided that the dosage has remained unchanged for the past 6 months and remains stable throughout the course of the treatment.

Exclusion criteria:

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Sample Size and Randomization The sample size will be estimated using Monte Carlo simulations within the simr package in R, ensuring that the Group × Time interaction is detectable with a minimum power of 90% at a significance level of 0.05. Accounting for a 15% attrition rate, the target sample size is set at 90 participants, with 45 participants per treatment arm. Participants will be stratified by diagnostic status (GAD alone vs. GAD + MDD), and other comorbidities will be included as covariates in the analyses. Subsequently, participants will be allocated to one of the two treatment groups—MMIH or MBCT-GAD—using block randomization with a block size of 6. The randomization process will be managed by the REDCap randomizer algorithm to ensure a complete audit trail of the randomization procedure.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding and Allocation The allocation process will be double-blind for outcome assessors, therapist, and data analysts. An independent researcher, who has no involvement in participant interaction, will manage the allocation using sequentially numbered, opaque, sealed envelopes. Outcome assessors and statistical analysts will remain completely blinded to the assigned treatment groups. Therapeutic effects will be compared between the two groups at four time points: pre-treatment (baseline), post-treatment (week 10), and at 3-month and 6-month follow-ups.

Placebo

Not 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

City

Tehran

Province

Tehran

Postal code

15719-14911

Approval date

2026-05-13, 1405/02/23

Ethics committee reference number
IR.KHU.REC.1405.023

Health conditions studied

1

Description of health condition studied
Generalized Anxiety Disorder with or without Major Depressive Disorder
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Severity of generalized anxiety disorder symptoms with or without major depressive disorder
Timepoint
Baseline, post-treatment (week 10), 3-month follow-up, and 6-month follow-up
Method of measurement
The Generalized Anxiety Disorder symptoms questionnaire to assess generalized anxiety disorder symptoms, and the Patient Health Questionnaire-9 (PHQ-9) to assess major depressive disorder symptoms

Secondary outcomes

1

Description
Worry
Timepoint
Baseline, post-treatment (week 10), 3-month follow-up, and 6-month follow-up
Method of measurement
Penn State Worry Questionnaire (PSWQ)

2

Description
Satisfaction With Life
Timepoint
Baseline, post-treatment (week 10), 3-month follow-up, and 6-month follow-up
Method of measurement
Satisfaction With Life Scale (SWLS)

3

Description
Meta-Inner Humor Beliefs
Timepoint
Baseline, post-treatment (week 10), 3-month follow-up, and 6-month follow-up
Method of measurement
Meta-Inner Humor Beliefs Scale

4

Description
Mindfulness
Timepoint
Baseline, post-treatment (week 10), 3-month follow-up, and 6-month follow-up
Method of measurement
Five Facet Mindfulness Questionnaire – 15 (FFMQ-15)

5

Description
Repetitive Negative Thinking
Timepoint
Baseline, post-treatment (week 10), 3-month follow-up, and 6-month follow-up
Method of measurement
Repetitive Thinking Questionnaire – 10-item version (RTQ-10)

6

Description
State-Trait Anxiety
Timepoint
Baseline, post-treatment (week 10), 3-month follow-up, and 6-month follow-up
Method of measurement
Spielberger State-Trait Anxiety Inventory (STAI)

Intervention groups

1

Description
Intervention group: Meta-Inner Humor Therapy (MMIH)
Category
Treatment - Other

2

Description
Intervention group: Mindfulness-Based Cognitive Therapy (MBCT)
Category
Treatment - 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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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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No.43, South Mofateh St, Kharazmi University, Tehran, Iran
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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