

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of Metacognitive Therapy (MCT) Effectiveness and Cognitive-Behavioral Therapy (CBT) in Patients with Major Depressive Disorder (MDD)

Protocol summary

Summary

The aim of this study was to compare the efficacy of metacognitive therapy (MCT) and Cognitive-Behavior therapy in treating Iranian patients with MDD. Method: Thirty-Three outpatients meeting DSM-IV-TR criteria for MDD without any other axis I and II disorder will randomly assigned to one of three treatment conditions: MCT, CBT and Pharmacotherapy treatment. The Beck Depression Inventory-II-Second Edition (BDI-II), Beck Anxiety Inventory (BAI), Metacognitions Questionnaire-Short Form (MCQ-30), Ruminative Response Scale (RRS) and Dysfunctional Attitude Scale (DAS) will administered at pre-treatment, post-treatment and Follow-up. Data were analyzed by repeated measure ANOVA

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108147328N1**

Registration date: **2011-12-24, 1390/10/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-12-24, 1390/10/03

Registrant information

Name

Ahmad Ashouri

Name of organization / entity

Tehran University of Medical Science

Country

Iran (Islamic Republic of)

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+98 21 6655 1585

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Recruitment status

Recruitment complete

Funding source

Tehran university of medical science-Tehran psychiatric institute and ,mental health research center

Expected recruitment start date

2010-05-22, 1389/03/01

Expected recruitment end date

2010-10-23, 1389/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Metacognitive Therapy (MCT) Effectiveness and Cognitive-Behavioral Therapy (CBT) in Patients with Major Depressive Disorder (MDD)

Public title

Comparison of Metacognitive Therapy (MCT) Effectiveness and Cognitive-Behavioral Therapy (CBT) in Patients with Major Depressive Disorder (MDD)

Purpose

Treatment

Inclusion/Exclusion criteria

]Inclusion criteria: Having diagnosis criteria for MDD based on the psychiatrist and psychologist ;diagnoses through diagnostic interview and results of the SCID-I/CV test;Receiving no psychological therapies during six months before participation in the study; Being at least 18 aged to 50; Having at least third level of guidance school; Signing the letter of satisfaction by the patients for participating in the study; Exclusion criteria: Having

psychotic symptoms; drug abuse and other psychological disorders placed at Axis I plus having serious suicidal thought as they could not receive and maintain medications; Having complete criteria of personality disorder at Axis II by psychiatrist and psychologist diagnoses through diagnostic interview and results of the SCID-II test.

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **33**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Science/Ethics Committee

Street address

Ghods St, Keshavarz Bvd, Tehran, Iran, I. R.

City

Tehran

Postal code

Approval date

2011-07-02, 1390/04/11

Ethics committee reference number

130/727/90/D

Health conditions studied

1

Description of health condition studied

Major Depression Disorder

ICD-10 code

F32.2

ICD-10 code description

Severe depressive episode without psychotic symptoms

Primary outcomes

1

Description

Depression Severity

Timepoint

pre-test-post-test-follow-up

Method of measurement

BDI-II

2

Description

Anxiety

Timepoint

pre-test-post-test-follow-up

Method of measurement

BAI

3

Description

Rumination

Timepoint

pre-test-post-test-follow-up

Method of measurement

ruminative response scale (RRS)

4

Description

Metacognitive Beliefs

Timepoint

pre-test-post-test-follow-up

Method of measurement

Metacognitions Questionnaire-Short Form (MCQ-30),

5

Description

Dysfunctional Attitde

Timepoint

pre-test-post-test-follow-up

Method of measurement

Dysfunctional Attitude Scale (DAS)

Secondary outcomes

empty

Intervention groups

1

Description

exprimental groups 1- metacognitive therapy 8 session

Category

Treatment - Other

2

Description

control : pharmacotherapy

Category

Treatment - Drugs

3

Description

Experimental Group 2 Cognitive Behavior Therapy

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Psychiatric Institute

Full name of responsible person

Maryam AliMohammadi

Street address

Tehran Psychiatric Institute, Niayesh St, Sattarkhan Ave, Tehran, Iran

City

Tehran

2

Recruitment center

Name of recruitment center

Taban Health & Diabet Clinic

Full name of responsible person

Street address

Taban Health & Diabet Clinics, Derakhti Blvd, Tehran, Iran

City

Tehran

3

Recruitment center

Name of recruitment center

Private Office of Psychiatry and Clinical Psychology

Full name of responsible person

Street address

Psychiatry & Clinical Psychology Clinic, 14 th Alley, Mofatteh St, Shahid Beheshti Ave, Tehran, Iran

City

Tehran

4

Recruitment center

Name of recruitment center

Oil Company Hospital

Full name of responsible person

Street address

Oil Company Hospital, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Science, Tehran Psychiatric Institute and Mental Health Research Center

Full name of responsible person

Taban

Street address

Tehran Psychiatric Institute

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Science, Tehran Psychiatric Institute and Mental Health Research Center

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Science, Tehran Psychiatric institute

Full name of responsible person

Ahmad Ashouri

Position

PhD Student

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Position**Other areas of specialty/work****Street address****City****Postal code****Phone****Fax****Email****Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty

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