Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The efficacy of Group Metacognitive therapy on self-esteem & mental health of the patients suffering from major depression disorder

Protocol summary

Summary

The present research aimed to analyze the efficacy of Metacognitive group therapy (MCT) on self-esteem and Mental Health of those who suffer from Major depressive Disorder (MDD). The study population is MDD patients who refer to Ibn-e-Sina and Ghaem hospital of Mashhad. In a clinical trial, available Sampling method was taken to choose 30 patients randomly allocated in two groups (experiment and Control). Two groups took SSRIs (Citalopram or Sertraline) as standard treatment. Experiment group patients went under MCT Treatment. Eysenck Self-esteem and Mental Health Checklist (MHC) were used in pre-test, post-test and 2-month follow-up as the study instrument.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201162611N3**
Registration date: **2012-02-10, 1390/11/21**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-02-10, 1390/11/21

Registrant information

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Mohammad Reza Fayyazi Bordbar
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Recruitment status

Recruitment complete

Funding source

Islamic Azad University Sari Branch

Expected recruitment start date

2011-05-22, 1390/03/01

Expected recruitment end date

2011-10-15, 1390/07/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of Group Metacognitive therapy on self-esteem & mental health of the patients suffering from major depression disorder

Public title

The efficacy of Group Metacognitive therapy on self-esteem & mental health of the patients suffering from major depression disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Meeting DSM-IV-TR criteria's of MDD; informed consent; Diploma or higher education; No any other psychological therapy at least during the 2 previous years. Exclusion criteria: borderline personality disorder; receiving any other simultaneous psychological intervention; psychosis; drug abuse or dependency.

Age

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

Gender

Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
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
Islamic Azad University Sari Branch
Street address
Islamic Azad University Sari Branch, 25 kilometers sea street
City
Sari
Postal code
Approval date
2010-08-20, 1389/05/29
Ethics committee reference number
25/05/1389

Health conditions studied

1

Description of health condition studied
Major Depressive Disorder
ICD-10 code
F32.2
ICD-10 code description
Severe depressive episode without psychotic symptoms

Primary outcomes

1

Description
Self esteem
Timepoint
Before the intervention, after intervention, 2 months after of intervention
Method of measurement
Eysenck Self esteem Test

2

Description
Mental health
Timepoint
Before the intervention, after of intervention, 2 months after of intervention
Method of measurement
Mental health Checklist

Secondary outcomes

empty

Intervention groups

1

Description
Pharmacotherapy (Citalopram: starting dose of 10 mg and increased to the maximum 40 mg per day, and sertraline: starting dose 50 mg and increased to a maximum of 150 mg.)
Category
Treatment - Drugs

2

Description
Metacognitive Group therapy (5 weeks)
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Ibn-e-Sina Hospital
Full name of responsible person
Vahid Farahmand
Street address
Ibn-e-Sina Hospital, Hor-e-Ameli Blvd.
City
Mashhad

2

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
Vahid Farahmand
Street address
Ghaem Hospital, Ahmedabad AV.
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University Sari Branch
Full name of responsible person
Vahid Farahmand
Street address
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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
Islamic Azad University Sari Branch
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
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Person responsible for updating data

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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