Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Metacognitive Therapy, Fluvoxamine, or Combination Treatment in Obsessive-Compulsive Disorder: A randomized clinical trial

Protocol summary

Summary

The aim of this study was to compare the effectiveness of metacognitive therapy, fluvoxamine and the combination of metacagnitive therapy with fluvoxamine in treatment of patients with OCD. Inclusion criteria were as follows: (1) diagnosis of OCD according to DSM-IV-TR, (2) age between 18 to 50. Patients were excluded if they had a personality disorder, substance abuse problem and other comorbid axis I disorders. Twenty-one outpatients meeting criteria for OCD without any other axis I and II disorder were randomly assigned to one of three treatment conditions: MCT, fluvoxamine and combined group for 10 weeks of treatment. The demographic Questionnaire, Yale-Brown Obsessive-Compulsive Scale (Y-BOCS), Beck Depression Inventory-II-Second Edition (BDI-II), Beck Anxiety Inventory (BAI), Depression Anxiety Stress Scale-21 (DASS-21), Subjective Units of Distress (SUDs), Global Assessment of Functioning (GAF), Metacognitions Questionnaire-Short Form (MCQ-30), Thought Control Questionnaire (TCQ), and Stop Signals Questionnaire (SSQ) were administered blindly at pre-treatment and post-treatment. Y-BOCS, BDI-II, BAI, DASS-21, SUDs and GAF also were administered after session 2, 4, 6 and 8. Nineteen patients completed this study and two patients dropped out from the study. ANCOVA, repeated measure ANOVA, pre- to post improvement percentage, Kruskal Wallis and mann Withney U-test are used to analyze data.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811303372N1**
Registration date: **2010-04-26, 1389/02/06**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-04-26, 1389/02/06

Registrant information

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Recruitment status

Recruitment complete

Funding source

Research Council of the Iran University of Medical Sciences

Expected recruitment start date

2009-09-06, 1388/06/15

Expected recruitment end date

2009-10-07, 1388/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Metacognitive Therapy, Fluvoxamine, or Combination Treatment in Obsessive-Compulsive Disorder: A randomized clinical trial

Public title

Metacognitive Therapy, Fluvoxamine, or Combination Treatment in Obsessive-Compulsive Disorder: A

randomized clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (1) diagnosis of OCD according to DSM-IV-TR, (2) duration of the illness for at least 1 year, (3) age between 18 to 50. Exclusion criteria: (1) currently suicidal or psychotic, (2)have a personality disorder, neurological disease or substance abuse problem and other comorbid axis I disorders, (3) have been receiving other psychological treatment or pharmacotherapy during the previous month.

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: **19**

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

Ethics Committee of the Mental Health Research Center, Tehran Psychiatric Institute

Street address

Tehran Psychiatric Institute and Mental Health Research Centre, Shahid Mansoori Alley, Niayesh St., Sattarkhan Ave., Tehran, Iran, IR

City

Tehran

Postal code

Approval date

2009-08-31, 1388/06/09

Ethics committee reference number

07/09/06/88

Health conditions studied

1

Description of health condition studied

Obsessive-Compulsive Disorder

ICD-10 code

F42

ICD-10 code description

Obsessive-compulsive disorder

Primary outcomes

1

Description

obsessive-compulsive symptoms severity

Timepoint

before treatment, every two weeks for 3 months, every 6 months for one years in follow up

Method of measurement

scale

2

Description

Depression severity

Timepoint

before treatment, every two weeks for 3 months, every 6 months for one years in follow up

Method of measurement

Inventory

3

Description

Anxiety severity

Timepoint

before treatment, every two weeks for 3 months, every 6 months for one years in follow up

Method of measurement

Inventory

4

Description

Stress severity

Timepoint

before treatment, every two weeks for 3 months, every 6 months for one years in follow up

Method of measurement

Scale

5

Description

Subjective distress

Timepoint

before treatment, every two weeks for 3 months, every 6 months for one years in follow up

Method of measurement

Scale

6

Description
Global functioning
Timepoint
before treatment, every two weeks for 3 months, every 6 months for one years in follow up
Method of measurement
Scale

Secondary outcomes

1

Description
metacognition components
Timepoint
before and after treatment
Method of measurement
inventory

Intervention groups

1

Description
pharmacotherapy(Fluvoxamine 50-300mg, daily, 10 weeks)
Category
Treatment - Drugs

2

Description
Metacognitive Therapy (10 weeks)
Category
Behavior

3

Description
combination of metacognitive therapy and fluvoxamine(50-300ml daily,10 weeks)
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran Psychiatric Institute, Sobhe Sadegh Clinic, Taban Polyclinic, Sokhane Ashena Clinic, Psychiat
Full name of responsible person
Hossein Shareh
Street address
Tehran Psychiatric Institute and Mental Health Research Centre, Shahid Mansoori Alley, Niayesh St.,
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Council of the Iran University of Medical Sciences
Full name of responsible person
Dr. Motevalian
Street address
Iran University of Medical Sciences, Hemmat Exp., Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Council of the Iran University of Medical Sciences
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
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Full name of responsible person
Hossein Shareh
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Web page address

Person responsible for updating data

Contact

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