

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Comparing the efficacy of Trans-diagnostic Cognitive Behavior therapy versus pharmacological therapy on reducing symptoms severity of OCD with co-occurring anxiety and mood disorders

Protocol summary

Summary

Objectives: The aim of the study was to comparing the efficacy of transdiagnostic CBT VS pharmacotherapy on reducing severity of OCD patients with co-occurring anxiety and mood disorders. **Design:** Sample of 36 patients recruited from 4 psychiatric and psychological centers from Zanzan, Iran. The participants assigned randomly on three groups (TCBT, Pharmacotherapy, and Control). **Setting and conduct:** Psychological instruments was administrated in four episodes: pretest, midtest, posttest, and a month follow up by two trained professional assistants. The instruments included clinical severity scale from Anxiety Disorders Interview Schedule for DSM-IV (ADIS) and self-reported diagnosis-specific scales. **Participants:** Qualified criteria for the sample included a principal diagnosis of OCD, an age requirement of 18 years or more, and confirm the informed consent. **Exclusion criteria** included the presence of any clinical conditions comprised current DSM-IV diagnosis of psychotic disorders, bipolar disorder, recent history of substance abuse, cognitive and personality disorders and absented in two and more psychotherapeutic sessions and drug cessation across implementing the study. **Intervention:** Psychological interventions was contained 20 session 1 hour based on Barlow UP, and pharmacotherapy was included SSRIs drugs that prescribed by psychiatrist. Control group didn't receive any intervention. **Main outcome measures:** OCD severity, frequency, and dimensions from principle diagnose and anxiety, depression, worry, and social anxiety scores from comorbid diagnosis were included in main outcome measures.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015072523333N1**

Registration date: **2016-02-02, 1394/11/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-02-02, 1394/11/13

Registrant information

Name

Omid Saed

Name of organization / entity

Shahid Beheshti University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Reseacher (Omid Saed)

Expected recruitment start date

2015-04-30, 1394/02/10

Expected recruitment end date

2015-05-30, 1394/03/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the efficacy of Trans-diagnostic Cognitive

Behavior therapy versus pharmacological therapy on reducing symptoms severity of OCD with co-occurring anxiety and mood disorders

SBMU.REC.1394.28

Public title

Comparing the efficacy of Trans-diagnostic Cognitive Behavior therapy versus pharmacological therapy on reducing symptoms severity of OCD with co-occurring anxiety and mood disorders

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria is included: 1. age between 18-45 years 2. presence of one of the anxiety and unipolar mood disorders 3. education at least in 10 years 4. commitment to therapeutic sessions. exclusion criteria: 1. Absence of two or more session 2. presence of other diagnoses such as SUD, cognitive disorders, and somatoform disorders. 3. not participating on one of the four assessments

Age

From **76 years** old to **49 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **36**

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 Shahid Beheshti University of Medical Sciences

Street address

Next to Ayatollah Taleghani Hospital ,Evin

City

Tehran

Postal code

Approval date

2015-05-17, 1394/02/27

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Obsessive Compulsive Disorder

ICD-10 code

F42, F41.9

ICD-10 code description

, Depressive episode unspecified ,Anxiety disorder unspecified, ,Obsessive-compulsive disorder, Social phobias, Generalized anxiety disorder, Recurrent depressive disorder

Primary outcomes

1

Description

disorder severity, OC amount, OC dimension, work and social function

Timepoint

before the intervention, mid test, posttest, a month follow up

Method of measurement

clinical severity rating, obsessive compulsive inventory, dimensional obsessive compulsive scale, work and social adjustment scale

Secondary outcomes

1

Description

anxiety sensitivity

Timepoint

after ending the intervention

Method of measurement

anxiety sensitivity scale

Intervention groups

1

Description

Intervention group 1: Intervention in transdiagnostic cognitive behavior therapy (TCBT group) included 20 one hour sessions of psychotherapy that designed based on Balow's Unified Protocol (2011).

Category

Behavior

2

Description

Intervention 2: Pharmacotherapy intervention included 0.5 mg Haloperidol a time per day, and 50 mg sertraline a time per day to 100 mg two time per day after four weeks that prescribed by professional Psychiatrist.

Category

Treatment - Drugs

3**Description**

Control Group: Participants from control group didn't receive any intervention and they were in wait list.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Zendegi counseling and psychological Service Center

Full name of responsible person

Omid Saed

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Floor 2, Sina Clinin, Shariyar Street, Zanjan, Iran

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Investigator

Full name of responsible person

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Floor 2, Sina Clinic, Shahriyar Street, Zanjan, 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

Investigator

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**

Zanjan University of Medical Sciences

Full name of responsible person

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Web page address

empty

Sharing plan

Informed Consent Form

empty

Deidentified Individual Participant Data Set (IPD)

Clinical Study Report

empty

empty

Study Protocol

Analytic Code

empty

empty

Data Dictionary

Statistical Analysis Plan

empty