

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2303 1548

###### Email address

o.saed@sbmu.ac.ir

##### 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 Behesti 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

**Street address**

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

**City**

Zanjan

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

Investigator

**Full name of responsible person**

Omid Saed

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Floor 2, Sina Clinic, Shahriyar Street, Zanjan, Iran

**City**

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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**

Dr Farhad Taremian

**Position**

assistant professor

**Other areas of specialty/work****Street address**

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Shahid Beheshti University of Medical Sciences

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## **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*