

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### The efficacy of cognitive behavioral therapy with and without Sertraline in patients with obsessive compulsive disorder

#### Protocol summary

##### Study aim

The efficacy of cognitive behavioral therapy with and without Sertraline in patients with obsessive-compulsive disorder

##### Design

Clinical trial with two arm parallel groups without control group, without randomization and blindness with sample size of 20 for each group and the whole sample size of 40

##### Settings and conduct

Participants were recruited through self referrals, professional and clinic referrals, and advertisements in hospital and networks. Patients were divided into two groups , CBT with and without Sertraline. Study duration is 12 weeks in all groups. In the CBT group the sessions would be twice a week during the first month and the duration of every session is 2 hours.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: diagnosis of disorder; age between 18 to 65 ; education at least grade 7 Yale brown obsessive compulsive scale total scores equal and more than 16  
Exclusion criteria;History or current bipolar disorder and psychotic disorders; current major depressive episode and suicidal ideation ; substance or alcohol dependency in the 6 past months.

##### Intervention groups

This study consists of two interventional groups. One is cognitive behavior therapy and the other is cognitive behavior therapy plus Sertraline. the duration of the study is twelve weeks. psychotherapy is going to be once a week and sertraline initiates by 25 milligram up to 200 milligram as needed. the study dose not have any control group.

##### Main outcome variables

Severity of obsessive compulsive disorder measured by Yale Brown Scale

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200126046273N1**

Registration date: **2020-05-02, 1399/02/13**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-05-02, 1399/02/13**

Update count: **0**

##### Registration date

2020-05-02, 1399/02/13

##### Registrant information

##### Name

marzieh effatpanah

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 3271 3571

##### Email address

hosseiniyamin88@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-09-23, 1398/07/01

##### Expected recruitment end date

2020-09-22, 1399/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The efficacy of cognitive behavioral therapy with and without Sertraline in patients with obsessive compulsive disorder

#### Public title

The efficacy of cognitive behavioral therapy with and without Sertraline in patients with obsessive compulsive disorder

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

diagnosis of disorder age between 18 to 65 education at least grade 7 yale brown obsessive compulsives scale total score >= 16

##### Exclusion criteria:

History or current bipolar disorder History psychotic disorders Current major depressive episode and suicidal ideation Substance or alcohol dependency in 6 past months. History of adequate treatment with sertraline (200 mg in 8 weeks) History of adequate treatment with CBT( more than 3 sessions in week during more than 2 weeks )

#### Age

From **18 years** old to **65 years** old

#### Gender

Both

#### Phase

2

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **40**

#### Randomization (investigator's opinion)

Not 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 ebne sina University of Medical Sciences

###### Street address

Farshchian hospital Honarestan Blvd., HamedanTown.

###### City

hamedan

###### Province

Hamadan

###### Postal code

6514757694

###### Approval date

2019-09-15, 1398/06/24

###### Ethics committee reference number

IR.UMSHA.REC.1398.462

### 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

yale brown scale number

##### Timepoint

onset of study. week 8. week16

##### Method of measurement

yale brown scale

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Intervention group 1 is cognitive behavior therapy. Cognitive behavioral sessions are once a week for a while of one hour in Sina Hospital in Hamedan City. the duration of the study is twelve weeks. During the study patients will be assessed by yale Brown scale three times in the baseline, the mid treatment and after treatment.

##### Category

Treatment - Other

#### 2

##### Description

Intervention group 2 is cognitive behavioral therapy plus sertraline. Cognitive behavioral therapy in this group is exactly the same as intervention group 1. In addition Sertraline will be administered by 25 mg daily and according to each patients need gradually get to 200 mg daily in the first 4 weeks. the duration of the study is twelve weeks. During the study patients will be assessed by yale Brown scale three times in the baseline, the mid treatment and after treatment.

##### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Farshchian Hospital and Social networks

**Full name of responsible person**

Marzieh Effat Panah

**Street address**

No. 16, Balal Ave., Jafar Tayar Blvd.

**City**

Hamedan

**Province**

Hamadan

**Postal code**

6514757694

**Phone**

+98 81 3271 3571

**Email**

hoseiniyamin88@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Saeed Bashirian

**Street address**

Medical University of Hamedan .Ahmadi Roshan Blvd

**City**

Hamedan

**Province**

Hamadan

**Postal code**

6517838736

**Phone**

+98 81 3838 0717

**Email**

s\_bashirian@yahoo.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Hamedan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

Academic

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Marzieh Effat Panah

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Psychiatrics

**Street address**

No. 16, Balal Ave., Jafar Tayar Blvd.,

**City**

Hamedan

**Province**

Hamadan

**Postal code**

6514757694

**Phone**

+98 81 3271 3571

**Email**

hosseiniyamin88@gmail.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Latif Moradveisi

**Position**

Consultant

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

**Street address**

Farshchian Hospital. Honarestan Blvd

**City**

Hamedan

**Province**

Hamadan

**Postal code**

6517838736

**Phone**

+98 81 3827 4184

**Email**

latif.moradveisi@gmail.com

## Person responsible for updating data

#### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Marzieh Effat Panah

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Psychiatrics

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available