

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Comparison of the effectiveness of exposure and response prevention method and acceptance and commitment therapy on recovery of patients with obsessive-compulsive disorder receiving sertraline.

#### Protocol summary

##### Summary

The purpose of the study: Comparative effects of exposure and response prevention and acceptance and commitment therapy among patients with obsessive-compulsive disorder receiving sertraline. Design of the study: An experimental design using pre and post-test and a three-month follow up was used. The study population: all patients referred to private and public institutions at Sanandaj city who are being diagnosed by obsessive-compulsive psychiatrists and are under medical treatment for this disorder. The sample includes 45 people. The sampling method is purposeful in a manner accessible, and random allocation based on block redundancy is carried out on 15 individuals per block and three blocks. The random allocation will be as follows: Persons who get the Yale Brown score of 16 or higher will enter Form 1 and will be entered in the same form if they have the exit criteria. If they do not have the exit criteria, they will be transferred to Form 2. Setting and conduct: After arranging patients in the three groups and taking written consent for entering to the research, pre-test is carried out and after that, both groups will be treated. Intervention group 1: Exposure and response prevention therapy that will be delivered through 12 sessions. Each session will take 45 minutes and will be held once a week. The patients will be treated by sertraline (50-200 mg/d) by the psychiatrist at the same time prescribed for 12 weeks. Intervention group 2: Acceptance and Commitment therapy that will be delivered through 12 sessions. Each session will take 45 minutes and will be held once a week. The patients will be treated by sertraline (50-200 mg/d) by the psychiatrist at the same time prescribed for 12 weeks. Control group: The patients in this group will receive one sertraline tablet (50-200 mg/d) under the supervision of psychiatrist for 12 weeks, then post-test will be carried out at the end of therapy and 3 months later after the

end of the therapy. Inclusion criteria: age between 18 and 60 years old; minimum level of the third grade at primary school; satisfaction with the company in the research; diagnosis OCD according to DSM5 criteria; receiving the drug under the supervision of a psychiatrist; earn score 16 and over at Yale-Brown Obsessive Scale. Exclusion criteria: having severe personality disorder; psychotic symptoms (hallucination, delusions); having a physical illness; intellectual disability; Substance abuse. Intervention: Intervention included two groups of exposure and response prevention and acceptance and commitment therapy. Main outcome measures: Primary outcome measures will be OCD signs and symptoms. Secondary outcome measures will be subjective distress; obsessive rituals; control unwanted thoughts.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017081335675N1**

Registration date: **2017-11-02, 1396/08/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-11-02, 1396/08/11

##### Registrant information

##### Name

Mojgan Salavati

##### Name of organization / entity

Kurdistan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 87 3346 2102

**Email address**

m.salavati@hum.uok.ac.ir

**Recruitment status**

Recruitment complete

**Funding source**

Vice chancellor for research, Kurdistan University of Medical Sciences and University of Kurdistan.

**Expected recruitment start date**

2017-07-23, 1396/05/01

**Expected recruitment end date**

2017-10-23, 1396/08/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effectiveness of exposure and response prevention method and acceptance and commitment therapy on recovery of patients with obsessive-compulsive disorder receiving sertraline.

**Public title**

Comparison of psychological and therapeutic treatment on obsessive-compulsive disorder.

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: age between 18 and 60 years old; minimum level of the third grade primary school; satisfaction with the company in the research; diagnosis OCD according to DSM5 criteria; receive the drug under the supervision of a psychiatrist; getting score 16 and over in Yale-Brown Obsessive Scale. Exclusion criteria: having severe personality disorder; psychotic symptoms (hallucination, delusions); having a physical illness; intellectual disability; Substance abuse.

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size:

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Random allocation based on block redundancy is carried out on 15 individuals per block and three blocks.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Kurdistan University of Medical Sciences

**Street address**

Kurdistan University of Medical Sciences, Pasdaran Blvd

**City**

Sanandaj

**Postal code**

66141-18665

**Approval date**

2017-07-10, 1396/04/19

**Ethics committee reference number**

IR.MUK.REC.1396/77

**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

**Timepoint**

Before the intervention, after the intervention and 3 months after intervention

**Method of measurement**

The Yale Brown Obsessive-Compulsive Scale (Y-BOCS)

**Secondary outcomes****1****Description**

Subjective distress

**Timepoint**

Before the intervention, after the intervention and 3 months after intervention

**Method of measurement**

Subjective Unit Distress(SUD)

## 2

### **Description**

Obsessive rituals

### **Timepoint**

Before the intervention, after the intervention and 3 months after intervention

### **Method of measurement**

Stop Signal Questionnaire (SSQ)

## 3

### **Description**

Control unwanted thoughts

### **Timepoint**

Before the intervention, after the intervention and 3 months after intervention

### **Method of measurement**

Thought Control Questionnaire (TCQ)

## **Intervention groups**

### 1

#### **Description**

Intervention group 1: Exposure and response prevention therapy that will be delivered through 12 sessions. Each session will take 45 minutes and will be held once a week. The patients will be treated by sertraline (50-200 mg/d) by the psychiatrist at the same time prescribed for 12 weeks.

#### **Category**

Behavior

### 2

#### **Description**

Intervention group 2: Acceptance and Commitment therapy that will be delivered through 12 sessions. Each session will take 45 minutes and will be held once a week. The patients will be treated by sertraline (50-200 mg/d) by the psychiatrist at the same time prescribed for 12 weeks.

#### **Category**

Behavior

### 3

#### **Description**

Control group: The patients in this group will receive one sertraline tablet (50-200 mg/d) under the supervision of psychiatrist for 12 weeks.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

**Name of recruitment center**

Family Psychiatry Clinic

**Full name of responsible person**

Dr Asrin Seyydoshohadayi

#### **Street address**

Family Psychiatry Clinic, Adab Street

#### **City**

Sanandaj

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Vice chancellor for research, Kurdistan University of Medical Sciences

##### **Full name of responsible person**

Dr Farzin Rezaei

##### **Street address**

Kurdistan University of Medical Sciences, Pasdaran Blvd

##### **City**

Sanandaj

#### **Grant name**

-

#### **Grant code / Reference number**

-

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Vice chancellor for research, Kurdistan University of Medical Sciences

#### **Proportion provided by this source**

#### **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*

### 2

#### **Sponsor**

##### **Name of organization / entity**

University of Kurdistan

##### **Full name of responsible person**

Dr Mehdi Zemestani

##### **Street address**

University of Kurdistan, Pasdaran Blvd

##### **City**

Sanandaj

#### **Grant name**

-

#### **Grant code / Reference number**

-

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

University of Kurdistan

**Proportion provided by this source**  
**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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**Position**

Master student

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## Person responsible for scientific inquiries

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**Full name of responsible person**

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**Other areas of specialty/work**

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**City**

## 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*