

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### The effect of self-regulation training on reducing the symptoms of patients with obsessive-compulsive disorder

#### Protocol summary

##### Study aim

A study of effect of self-regulation training on reducing the symptoms of patients with obsessive-compulsive disorder

##### Design

Clinical trials with control group, parallel groups, Not blinded, randomized, phase 3, on 30 patients, Randomization was centralized and computerized with concealed randomization sequence carried out at an external site.

##### Settings and conduct

This study is a not blinded trial. The study sample population is consists of all patients with obsessive-compulsive disorder referring to Farabi Hospital in Kermanshah, that 30 persons will be selected randomly method and randomly will be divided into two groups, intervention group (self-regulation training) and control group. All subjects in all two groups will be re-evaluated by completing questionnaires at baseline, 5 weeks and 2 months after the end of the study (follow-up), will be assessed.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of obsessive-compulsive disorder according to the DSM-5 by psychiatrist; Age range 18-55 years; Having complete patient satisfaction to participate in research; Low self-regulation score; Minimum level of high school education; Do not use psychotherapy in the last 6 months and when using this treatment. Non-inclusion criteria: Disagreement to participate in the study.

##### Intervention groups

Intervention group: In addition to standard drug treatment, the intervention group will participate in self-regulation training sessions. These treatment sessions are for 10 sessions (twice a week) and each session is 45 minutes. Control group: The control group will receive only standard drug treatment.

##### Main outcome variables

Severity of symptoms of obsessive-compulsive disorder

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150822023705N15**

Registration date: **2022-03-05, 1400/12/14**

Registration timing: **prospective**

Last update: **2022-03-05, 1400/12/14**

Update count: **0**

##### Registration date

2022-03-05, 1400/12/14

##### Registrant information

##### Name

Mostafa Alikhani

##### Name of organization / entity

Kermanshah University of Medical Sciences -  
Substance Abuse Prevention Research Center

##### Country

Iran (Islamic Republic of)

##### Phone

+98 838264513

##### Email address

mo.alikhani@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-04-03, 1401/01/14

##### Expected recruitment end date

2022-07-05, 1401/04/14

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The effect of self-regulation training on reducing the symptoms of patients with obsessive-compulsive disorder

## Public title

The effect of self-regulation training in patients with obsessive-compulsive disorder

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Diagnosis of obsessive-compulsive disorder according to the DSM-5 by psychiatrist Age range 18-55 years Having complete patient satisfaction to participate in research Low self-regulation score Minimum level of high school education Do not use psychotherapy in the last 6 months and when using this treatment

### Exclusion criteria:

Disagreement to participate in the study

## Age

From **18 years** old to **55 years** old

## Gender

Both

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **30**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Patients will be divided into two equal groups (A and B) based on a randomized size 6-block design using random allocation software. To randomly assign 30 patients to the intervention and control groups, 5 different blocks of 6 different letters A and B, which indicate self-regulation training and control groups respectively, will be initially created. These blocks will be numbered from one to five. In the next step, each of these blocks will be randomly selected by performing lottery using 5 cards with numbers 1 to 5 on them. Thus, in each lottery, by selecting a block, a combination of 6 letters of the letters A (Self-regulation training group) and B (control group) will be obtained. At the end of the 5 drawings, after selecting 5 blocks, a total of 30 letters A and B will be obtained

## 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

Kermanshah University of Medical Sciences

##### Street address

Vice Chancellor for Research Affairs, Building No.2, Kermanshah University of Medical Sciences, Shahid Beheshti boulevard

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6719851115

##### Approval date

2021-08-10, 1400/05/19

##### Ethics committee reference number

IR.KUMS.REC.1400.340

## 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

Severity of symptoms of obsessive-compulsive disorder

#### Timepoint

The beginning of the study (baseline), week five and 2 months after the end of the study (follow-up)

#### Method of measurement

Obsessive-Compulsive Inventory-Revised (OCI-R)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: In addition to standard drug treatment, the intervention group will participate in self-regulation training sessions. These treatment sessions are for 10 sessions (twice a week) and each session is 45 minutes. self-regulation training sessions will be conducted in groups by a psychologist.

#### Category

Behavior

## 2

### Description

Control group: The control group will receive only standard drug treatment.

### Category

Other

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Farabi Hospital

**Full name of responsible person**

Payam Mohammadi

**Street address**

Farabi Hospital; Isar square

**City**

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Koroush Hamzehee

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

No

**Title of funding source**

Kermanshah 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**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Farnaz Radmehr

**Position**

Research Assistant

**Latest degree**

Master

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Razi University of Kermanshah

**Full name of responsible person**

Khodamorad Momeni

**Position**

Associate Professor

**Latest degree**

Ph.D.

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## Person responsible for updating data

### Contact

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Kermanshah University of Medical Sciences

**Full name of responsible person**

Mostafa Alikhani

**Position**

Research Assistant

**Latest degree**

Master

**Other areas of specialty/work**

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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