

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

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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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

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Person responsible for updating data

Contact

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Latest degree

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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