

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Oct 2026

The Effectiveness of Combined Acceptance and Commitment Therapy and Exposure and Response Prevention on OCD Symptom Reduction and Related Psychological Factors in Patients with Obsessive-Compulsive Disorder

Protocol summary

Study aim

Determining the effectiveness of the combined treatment of acceptance and commitment and exposure and response prevention on reducing obsessive symptoms and related psychological factors in patients with obsessive-compulsive disorder.

Design

Clinical trial with control group, with parallel group, single-blind (outcome assessment blinding), with randomization, the rand function of Excel software will be used for randomization.

Settings and conduct

The combined protocol of ACT and ERP for patients with obsessive compulsive disorder at Dr. Beheshti Psychiatric Hospital in Zanjan city will be conducted individually and in 16 treatment sessions, and the patients will be evaluated by a person other than the therapist who does not know about the people in the study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: having symptoms of obsessive-compulsive disorder based on the interview (SCID-I, II) and obtaining a score of at least 21 in the OCI-R questionnaire; age range between 18-60 years; having a diploma or higher education; Participants' interest to participate in the research based on the provisions of the written consent. Exclusion criteria: not suffering from severe depression (score ≥ 24 in the Hamilton Depression Inventory), bipolar disorder spectrum, psychotic disorder spectrum, or borderline or schizotypal personality disorder; not consuming drugs and alcohol in the last three months; not participating in previous formal ERP or ACT trials for OCD; Not receiving psychiatric drugs.

Intervention groups

The combined ACT and ERP treatment protocol will be implemented on the intervention group and will be

evaluated in three phases. The control group will be evaluated in three phases without treatment. After completing the research, the control group will also receive the mentioned treatment.

Main outcome variables

Severity of obsessive-compulsive disorder symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230719058848N1**

Registration date: **2023-08-28, 1402/06/06**

Registration timing: **prospective**

Last update: **2023-08-28, 1402/06/06**

Update count: **0**

Registration date

2023-08-28, 1402/06/06

Registrant information

Name

Zahra Nejadebrahim Soumee

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-20, 1402/06/29
Expected recruitment end date
 2023-10-21, 1402/07/29
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 The Effectiveness of Combined Acceptance and Commitment Therapy and Exposure and Response Prevention on OCD Symptom Reduction and Related Psychological Factors in Patients with Obsessive-Compulsive Disorder

Public title
 The Effectiveness of Combined Acceptance and Commitment Therapy and Exposure and Response Prevention on Obsessive-Compulsive Disorder

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 having symptoms of obsessive-compulsive disorder based on the interview (SCID-I, II) and obtaining a score of at least 21 in the OCI-R questionnaire. Age range between 18-60 years. Having a diploma or higher education. Participants` interest to participate in the research based on the provisions of the written consent.
Exclusion criteria:
 Suffering from severe depression (score ≥ 24 on the Hamilton Depression Inventory), bipolar disorder spectrum, psychotic spectrum disorder, or borderline or schizotypal personality disorder. Drug and alcohol consumption in the last three months. Participation in previous formal ERP or ACT trials for OCD. Taking psychiatric drugs.

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

Gender
 Both

Phase
 N/A

Groups that have been masked

- Outcome assessor

Sample size
 Target sample size: **40**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Random allocation is done using Excel software. For this, in the first column, we enter 20 numbers 1 and 20 numbers 2 (representing the test and control group, respectively). Then, in the second column, we generate 40 random numbers using the (RAND) function. We sort the data based on column values containing random numbers (ascending or descending). With this sorting, the order of placement of numbers 1 and 2 will also change and be placed randomly. Based on the order of

appearance of numbers 1 and 2, the samples are assigned to two groups.

Blinding (investigator's opinion)
 Single blinded

Blinding description
 In the implementation of this study, blinding will be done in such a way that the therapist and the evaluator are two different people, the therapist is the student, and the evaluator will be a clinical psychology graduate who will not know about the people of both groups in the process of evaluating the occurrence of consequences and reduction of symptoms before and after treatment and also during the follow-up period.

Placebo
 Not used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zanjan University of Medical Sciences

Street address

Dr. Beheshti Psychiatric Hospital, Ark Square

City

Zanjan

Province

Zanjan

Postal code

4513615788

Approval date

2023-07-18, 1402/04/27

Ethics committee reference number

IR.ZUMS.REC.1402.093

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 disorder score in OCI-R questionnaire

Timepoint

Before the start of the intervention, after the end of the intervention, 3 months after the end of the intervention

Method of measurement

Obsessive-Compulsive Inventory-Revised (OCI-R)

Secondary outcomes

1

Description

Psychological flexibility score

Timepoint

Before the start of the intervention, after the end of the intervention, 3 months after the end of the intervention

Method of measurement

Acceptance and Action Questionnaire-II (AAQ-II)

2

Description

Experiential avoidance score

Timepoint

Before the start of the intervention, after the end of the intervention, 3 months after the end of the intervention

Method of measurement

Acceptance and Action Questionnaire-II (AAQ-II)

3

Description

Cognitive fusion score

Timepoint

Before the start of the intervention, after the end of the intervention, 3 months after the end of the intervention

Method of measurement

Cognitive Fusion Questionnaire-7 (CFQ)

4

Description

Interpretation of intrusions score

Timepoint

Before the start of the intervention, after the end of the intervention, 3 months after the end of the intervention

Method of measurement

Interpretation of Intrusions Inventory-31 (III-31)

Intervention groups

1

Description

Intervention group: Including 20 patients with obsessive-compulsive disorder who will receive the combined treatment protocol of ACT and ERP written by Twohig et al. (2011) twice a week for 16 sessions and each session for 120 minutes. And they are evaluated before the start of the intervention, after its completion and 3 months after its completion. The aforementioned treatment protocol combines the two treatments of acceptance and commitment and exposure and response prevention in

order to improve the symptoms of obsessive-compulsive disorder and requires that people attend the treatment until the end of 16 sessions in order to achieve therapeutic effects. The tools needed in this treatment are the homework worksheets, which clients are expected to do the exercises at home in addition to doing the exercises in the treatment session and write in the worksheets. Acceptance and commitment therapy includes 6 components: acceptance, living in the present moment, cognitive diffusion, self as context, values, and committed action, these 6 components are the basis of the structure of a main component called psychological flexibility, and the goal of this treatment is to achieve psychological flexibility. In Exposure and response prevention, people are exposed to the anxiety-provoking stimuli according to the pre-determined hierarchy, and they are also prevented from wanting to engage in their past avoidant or additional behaviors in response to these stimuli. The process continues and repeats until the person's anxiety is reduced when exposing the said stimuli.

Category

Treatment - Other

2

Description

Control group: Including 20 patients with obsessive-compulsive disorder who do not receive any intervention during the study and are placed on the waiting list to receive the combined ACT and ERP treatment protocol written by Twohig et al. (2011) twice a week for 16 sessions and each session for 120 minutes after the research completion.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Beheshti Psychiatric Hospital

Full name of responsible person

Seyyede Elnaz Mousavi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

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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

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Seyyede Elnaz Mousavi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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Full name of responsible person

Dr. Seyyede Elnaz Mousavi

Position

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Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Name of organization / entity

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Full name of responsible person

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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