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
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Name of organization / entity

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Iran (Islamic Republic of)

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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 stimuluses 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 stimuluses. The process continues and repeats until the person's anxiety is reduced when exposing the said stimuluses.
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
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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
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Full name of responsible person
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Position
Associate professor
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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