Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Oct 2026

Efficacy of acceptance and commitment therapy on electroencephalography, psychological flexibility, cognitive fusion, emotion regulation, symptom reduction, and oxytocin blood levels in people with obsessive-compulsive disorder

Protocol summary

Study aim
Determining the effectiveness of Acceptance and commitment therapy on changing the bandwidth of delta, beta 1, beta 2, theta beta coherence, changing the asymmetry of cognitive brain waves of the right hemisphere, cognitive flexibility, cognitive fusion, blood oxytocin level, regulation Excitement in people with obsessive-compulsive disorder

Design
A clinical trial with a control group with a pre-test and post-test with three-month follow-up, single blind, randomly assigning patients to two groups using Excel software.

Settings and conduct
The statistical population includes individuals with OCD in Zanjan province. Patients who will be referred by psychiatrists and meet the inclusion criteria will be examined by the Structured Clinical Interview (SCID-I) and the Yale-Brown scale. Then, in a session before intervention, written consent will be obtained from patients, and demographic characteristics and other questionaairs will be filled. Oxytocin will be sampled subsequently.

Participants/Inclusion and exclusion criteria
Inclusion criteria: symptoms of OCD Comorbidity with other anxiety disorders 18-60 years no severe psychiatric disorders Not using drugs and alcohol in the last three months Not receiving psychological interventions not receive drug therapy in the last month written constent No chronic disease Exit criteria: Absence of more than two sessions Receive other psychological intervention simultaneously using drug at the same time no constent disorder aggreviation

Intervention groups
Intervention group: Acceptance and commitment therapy will be individually during 8 sessions as Dr. Twohing's protocol by two therapists. The aim is mostly reducing anxiety and how to deal with obsessive thoughts and compulsions. Control group: will not receive any special therapy and only use evaluation sessions.

Main outcome variables
Brain waves, OCD symptoms, psychological flexibility

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210727052000N2**
Registration date: **2023-02-07, 1401/11/18**
Registration timing: **prospective**

Last update: **2023-02-07, 1401/11/18**
Update count: **0**

Registration date
2023-02-07, 1401/11/18

Registrant information

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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

2023-02-20, 1401/12/01

Expected recruitment end date

2024-05-19, 1403/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of acceptance and commitment therapy on electroencephalography, psychological flexibility, cognitive fusion, emotion regulation, symptom reduction, and oxytocin blood levels in people with obsessive-compulsive disorder

Public title

The effectiveness of Acceptance and Commitment Therapy on the brain waves of patients with obsessive-compulsive disorder

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Having symptoms of obsessive-compulsive disorder Coexistence with other anxiety disorders (social anxiety disorder, generalized anxiety disorder, panic disorder, specific phobia and transition phobia) Age range between 18-60 years Not suffering from severe psychiatric disorders (psychotic spectrum, bipolar disorder) Not using drugs and alcohol in the last three months Not receiving cognitive-behavioral interventions for at least 8 sessions in the last 5 years Failure to receive drug therapy within a month before the start of the intervention Interest of the participants to participate in the research based on the provisions of the written consent No chronic medical illness

Exclusion criteria:

Absence of more than two sessions Receiving another similar psychological intervention at the same time as the current research Drug therapy at the same time as intervention Lack of consent to continue treatment during the intervention process Aggravation of the person's problems during the intervention and the need to provide another intervention

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: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

People who meet the entry criteria are referred by professors, counseling centers, and psychiatric clinics in Zanjan province and are randomly assigned to the experimental and control groups. 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 46 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)

Not blinded

Blinding description

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

Shahid Beheshti hospital, Ark gate, Zanjan city, Zanjan province

City

Zanjan

Province

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Postal code

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Approval date

2022-11-17, 1401/08/26

Ethics committee reference number

IR.zums.REC.1401.259

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

Sign and symptoms of obsessive-compulsive disorder

Timepoint

pre and post test, after 3 months follow-up

Method of measurement

Yale-Brown Obsessive-Compulsive Scale

2

Description

brain waves

Timepoint

pre, post and 3 months after intervention

Method of measurement

electroeencephalogram

Secondary outcomes

1

Description

cognitive fusion

Timepoint

pre, post and 3 months after intervention

Method of measurement

Cognitive fusion questionnaire

2

Description

cognitive emotion regulation

Timepoint

pre, post and 3 months after intervention

Method of measurement

Cognitive emotion regulation questionnaire

3

Description

psychological flexibility

Timepoint

pre, post and 3 months after intervention

Method of measurement

Acceptance and action questionnaire (II)

Intervention groups

1

Description

Intervention group: Acceptance and Commitment Therapy is third wave psychology therapy, the protocol used by Dr. Twohing was written. The said treatment, during 8 sessions of individual psychotherapy, seeks to increase the acceptance of unpleasant feelings, cognitive breakdown from disturbing annoying thoughts, and also to introduce the values of the patients in order to increase the psychological flexibility of the patients in general.

Category

Treatment - Other

2

Description

Control group: The control group will only benefit from the evaluation sessions, so they will not know whether they will be in the intervention group or the control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid beheshti hospital

Full name of responsible person

Ehsan Saboory

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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?

Yes

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
Seyed Elnaz Mousavi

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Data will be made available to the journal and researchers only if needed, after de-identifying individuals.

When the data will become available and for how long
Researchers start accessing documents and data files after 6 months to a year after the publication of the article.

To whom data/document is available
Only the researchers and reviewers of the journal to which the article is submitted.

Under which criteria data/document could be used
The data will be sent for review studies, where all analyzes must be supervised by one of the authors of the proposal.

From where data/document is obtainable

After publishing the article, researchers can email the responsible author at elnaz48.mousavi@gmail.com to access the data. Or, if you wish, go to Shahid Beheshti Hospital to meet with Dr. Mousavi.

What processes are involved for a request to access data/document

If the reason is scientific and the email is sent after the publication of the article, the requested information will be sent to them at least one week after consultation with other authors.

Comments