

# 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 questionnaires 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 consent No chronic disease Exit criteria: Absence of more than two sessions Receive other psychological intervention simultaneously using drug at the same time no constant disorder aggravation

##### 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

##### Name

Fatemeh Hassani alimolk

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 3566 1160

##### Email address

fatima.hassani75@yahoo.com

##### 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**

Zanjan

##### **Postal code**

7531974143

##### **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**

electroencephalogram

## 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

**Street address**

Shahid Beheshti Hospital, Zanjan City, Ark Square

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fatima.hassani75@yahoo.com

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Samad Nadri

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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**

**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](mailto: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**