

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### The Study of the Effectiveness of Acceptance and Commitment Therapy (ACT) and drug intervention on Severity of Symptom and Quality of Life in Obsessive Compulsive Patients

#### Protocol summary

##### Study aim

Determining and Comparing the Effectiveness of Acceptance and Commitment-Based Therapy (ACT) and Medication Therapy (SSRIs) on Symptom Severity and Quality of Life in Patients with Obsessive-Compulsive Disorder

##### Design

The study design is a randomized controlled clinical trial with parallel groups and single-blind .

##### Settings and conduct

Study place is Specialty Clinic of OCD, Isfahan University of Medical Sciences. Patients are first visited by a psychiatrist to make a definitive diagnosis of obsessive-compulsive disorder, Eligible patients are randomly assigned to groups I and II by a non-therapist. Pre-test and post-test carry out by a psychologist that is unaware of the type of the groups. ACT intervention is administered by a psychologist in group 1 and drug administration by a psychiatrist in group 2. Therapists and evaluators are also unaware of the work.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of Obsessive-Compulsive Disorder based on DSM-5 criteria 2. Ages from 18 to 65 years 3. Education 9 years and up 4. Signing informed consent Exclusion criteria: 1. Existence of Psychosis , bipolar disorder or mental retardation 2. Serious suicidal thoughts

##### Intervention groups

The first group receives Acceptance and Commitment Therapy (ACT) . The second group receives routine drug treatment of patients with obsessive-compulsive SSRIs according to the protocol will be Prescribed by the psychiatrist.

##### Main outcome variables

Decreased severity of obsessive-compulsive symptoms, increased quality of life, reduced symptoms of depression, anxiety and stress.

#### General information

##### Reason for update

##### Acronym

ACT

##### IRCT registration information

IRCT registration number: **IRCT20110815007339N3**

Registration date: **2020-04-07, 1399/01/19**

Registration timing: **retrospective**

Last update: **2020-04-07, 1399/01/19**

Update count: **0**

##### Registration date

2020-04-07, 1399/01/19

##### Registrant information

##### Name

Amrollah Ebrahimi

##### Name of organization / entity

Isfahan University of Medical Sciences, Isfahan, Iran

##### Country

Iran (Islamic Republic of)

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-05-31, 1398/03/10

##### Expected recruitment end date

2019-07-01, 1398/04/10

##### Actual recruitment start date

2019-06-07, 1398/03/17

##### Actual recruitment end date

2019-07-19, 1398/04/28

**Trial completion date**

2019-09-06, 1398/06/15

**Scientific title**

The Study of the Effectiveness of Acceptance and Commitment Therapy (ACT) and drug intervention on Severity of Symptom and Quality of Life in Obsessive Compulsive Patients

**Public title**

Effectiveness of Acceptance and Commitment Therapy (ACT) in Obsessive Compulsive Patients

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

patients with OCD according to DSM-5 criteria, age between 18 to 65 years consenting to participate in research, without underlying specific physical and other psychological treatments until 30 days before participating in the study

**Exclusion criteria:**

The presence of psychosis, bipolar disorder or mental retardation Serious suicidal thoughts Absolute illiteracy

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Care provider
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **30**

Actual sample size reached: **28**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization is simply performed by using a random number table via someone other than the treatment team. Eligible patients will be randomly assigned to one of groups A, B, and C.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Evaluators and therapists are unaware of what other procedures and what patients are doing. Evaluators evaluate the treatment several times without knowing the treatment.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

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department of Health psychology, Isfahan University of medical Sciences, Hezarjirib Avn. Isfahan, Iran

**City**

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**Province**

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**Postal code**

8173955174

**Approval date**

2015-05-24, 1394/03/03

**Ethics committee reference number**

IR.MUI.REC.1394.3.103

**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**

Quality of life, severity of obsessive-compulsive symptoms, severity of symptoms of depression, anxiety, stress

**Timepoint**

Study start, after study completion, and three months later (follow-up three months)

**Method of measurement**

By valid questionnaires: quality of life, severity of symptoms. Depression, Anxiety and Stress Questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group will Receive the standard protocol of Acceptance and Commitment Treatment (ACT) which developed by Steven Hayes. Treatment is offered in 8 sessions of 90 minutes and twice a week. Before, after, and after 3 months follow-up evaluation.

**Category**  
Behavior

2

**Description**

Control group: This group will receive SSRIs in accordance with the standard and routine pattern prescribed for patients with obsessive-compulsive disorder. The drug is prescribed by a psychiatrist with an obsessive-compulsive research line. The dose of the drug is determined by the patient status and the physician's evaluation.

**Category**  
Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**  
Obsessive-compulsiveness clinic in Isfahan University of Medical Sciences

**Full name of responsible person**  
Amrollah Ebrahimi

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Western Shariati Ave., Psychosomatic Research Center

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**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**  
Esfahan University of Medical Sciences

**Full name of responsible person**  
معاونت پژوهشی دانشگاه علوم پزشکی اصفهان

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**Email**  
research@mui.ac.ir

**Grant name**  
research

**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**  
Esfahan 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**  
Esfahan University of Medical Sciences

**Full name of responsible person**  
Amrollah Ebrahimi

**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)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no justification for publishing raw data. The trial results are published in scientific paper

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Results will be published in the form of a Final report and a scientific paper

**When the data will become available and for how long**

After the publication in the Journal

**To whom data/document is available**

Health Researchers

**Under which criteria data/document could be used**

Preparation of scientific paper

**From where data/document is obtainable**

To the responsible author

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

direct contact

**Comments**