

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)

Phone

+98 31 3625 8818

Email address

a_ebrahimi@med.mui.ac.ir

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

Street address

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

City

Isfahan

Province

Isfahan

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

Street address
Western Shariati Ave., Psychosomatic Research Center

City
Isfahan

Province
Isfahan

Postal code
8173948763

Phone
+98 31 3628 9966

Fax
+98 31 3628 9966

Email
psrc@mui.ac.ir

Web page address
<https://psrc.mui.ac.ir/>

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

Street address
Isfahan University of Medical Sciences, Hezarjirib

City
Isfahan

Province
Isfahan

Postal code
73461-81746

Phone

+98 31 3668 0042

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

Street address
West Shariati Ave, Varpashti, Niloofar Building

City
Isfahan

Province
Isfahan

Postal code
8173955174

Phone
+98 31 3625 8818

Email
a_ebrahimi@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Amrollah Ebrahimi

Position
associate professor of Psychology

Latest degree
Ph.D.

Other areas of specialty/work

Psychology

Street address

West Shariati Ave, Varpashti, Niloofar Building

City

Isfahan

Province

Isfahan

Postal code

8173955174

Phone

+98 31 3625 8818

Email

a_brahim@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

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Amrollah Ebrahimi

Position

Associate professor

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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