Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Nov 2026

The Study of the Effectiveness of Acceptance and Commitment Therapy (ACT) and drug intervention on Severity of Symptom and Quality ofLife 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 cary 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 ofLife 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 Univrsity of medical Sciences, Hezarjirib Avn. Isfahan, Iran

City
Isfahan

Province
Isfehan

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
Isfehan
Postal code
۸۱۷۳۹۴۸۷۶۳
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
Isfehan
Postal code
۷۳۴۶۱-۸۱۷۴۶
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
Isfehan
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

Isfehan

Postal code

8173955174

Phone

+98 31 3625 8818

Email

a_ebrahimi@med.mui.ac.ir

Person responsible for updating data

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

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Province

Isfehan

Postal code

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+98 31 3625 8818

Email

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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