# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

03 Jul 2026

## Evaluation of Cannabidiol effect as adjunctive therapy on symptoms of patients with Obsessive-Compulsive Disorder

### Protocol summary

**Study aim**
Effectiveness of cannabidiol on the symptoms of patients with obsessive-compulsive disorder

**Design**
The clinical trial has control and intervention groups and it is a two-way blind and randomized block method.

**Settings and conduct**
A total of 40 patients referred to the psychiatric clinic of 22 Bahman Hospital in Qazvin are divided into two groups of intervention and control using the balance block method (Balance block randomization). Patients are asked to complete the Yale-Brown Questionnaire (YBOCS) before entering the study. intervention group received 25 mg of cannabidiol drops daily in addition to standard treatment and thecontrol groupreceived 25 mg of placebo in addition to standard treatment. Then, at weeks 4 and 8, patients are again asked to complete the Yale Brown Questionnaire to assess changes in the course of the disease.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: 1. Age more than 18 years and less than 55 years 2. The patient's physical health 3. Diagnosis of OCD based on DSM-5 criteria 4. Obtain a minimum score of 16 in the Yale-Brown Scale Questionnaire 5. Do not take any psychiatric drugs except SSRIs during the last 4 weeks 6. No previous use of cannabis or other psychotropic drugs Exclusion criteria: 1- Patient dissatisfaction 2- Having other psychiatric disorders, including cognitive disorders, psychotic disorders, drug use, etc. 3. Having physical disorders that increase the risk of side effects of the treatment 4. Pregnancy, desire to conceive and breastfeeding 5. Achieve a score above 17 of the Beck Depression Inventory before starting the project

**Intervention groups**
In the intervention group, in addition to normal treatment, patients are prescribed 25 mg of cannabidiol drops daily, and in the control group, in addition to normal treatment, to patients placebo will be prescribed.

**Main outcome variables**
Obsessive-Compulsive Scale

### General information

**Reason for update**

**Acronym**
OCD

**IRCT registration information**
IRCT registration number: **IRCT20210310050660N1**
Registration date: **2021-04-01, 1400/01/12**
Registration timing: **prospective**

Last update: **2021-04-01, 1400/01/12**
Update count: **0**

**Registration date**
2021-04-01, 1400/01/12

**Registrant information**

**Name**
Mahnaz Majidi

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 28 3355 5054

**Email address**
m.majidi@qums.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2021-04-04, 1400/01/15

**Expected recruitment end date**
2022-03-19, 1400/12/28

**Actual recruitment start date**
empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of Cannabidiol effect as adjunctive therapy on symptoms of patients with Obsessive-Compulsive Disorder

**Public title**

Evaluation of Cannabidiol effect in treatment of patients with Obsessive-Compulsive Disorder

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Being healthy Obssesive compulsive disorder (OCD) diagnosis through DSM-5 criteria ( DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS, 5TH EDITION) Achieving at least score 16 according to YALE BROWN OBSSESIVE COMPLUSIVE SCORE ( YBOS) Being only on SSRIs through recent 4 weeks Do not have history of using cannabis or other ilicit drugs

**Exclusion criteria:**

Unwilling to participate in this study Having history of other psychiatric disorder including psychotic, cognitive and substance use disorder Being medically ill that cause more side effects than usual Pregnancy, expecting to being pregnant and lactation Achieving score more than 17 through completing Beck Depression scale before starting study

**Age**

From **18 years** old to **55 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Data analyser

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients are divided into two treatment groups A and B using the balance block method (Balance block randomization), the size of each block is 6 and the total number of blocks is 10. Balanced randomization allocation method is used for participants in a randomized controlled clinical trial study.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Patients are unaware of their treatment, and medications are given in asymptomatic packages to the clinician who is not aware of the patient's treatment.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of Qazvin University of Medical Sciences

**Street address**

Deputy of research and technology, Vali-asr street

**City**

Qazvin

**Province**

Qazvin

**Postal code**

3415613911

**Approval date**

2021-02-27, 1399/12/09

**Ethics committee reference number**

IR.QUMS.REC.1399.502

## 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**

Intensity of obsessive-compulsive disorder

**Timepoint**

Before entering into study, in week 4 and 8

**Method of measurement**

Yale–Brown Obsessive Compulsive Scale

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**

Intervention group: In addition to standard treatment, 25 mg of cannabidiol drop were administered orally daily for 8 weeks.

**Category**

Treatment - Drugs

**2**

**Description**
Control group: In addition to standard treatment, 25 mg placebo drop were administered orally for 8 weeks.
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
22 Bahman hospital ,Qazvin
**Full name of responsible person**
Mahnaz Majidi
**Street address**
22 Bahman Hospital, Parstar Alley, Rah-ahan street
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Qazvin University of Medical Sciences
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Mohammad Mahdi Emamjomeh
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memamjomeh@qums.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Qazvin 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**
Qazvin University of Medical Sciences
**Full name of responsible person**
Mahnaz Majidi
**Position**
Assistant Professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Psychiatrics
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**
All data will be available.

**When the data will become available and for how long**
Availability will be immediately after the publication of the article.

**To whom data/document is available**
The data will be available to everyone.

**Under which criteria data/document could be used**
All required analyzes can be performed and there will be no special conditions for access.

**From where data/document is obtainable**
For correspondence send Email to Dr. Majidi/ Mahnaz.majidi@yahoo.com

**What processes are involved for a request to access data/document**
It will reach the applicant in the shortest possible time.

**Comments**