

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### Efficacy of psychodrama on reducing the signs and symptoms of obsessive-compulsive disorder, anger and guilt in patients with OCD

#### Protocol summary

##### Study aim

Explaining the effect of psychodrama on reducing the signs and symptoms of obsessive-compulsive disorder, anger and guilt in patients suffering from obsessive-compulsive disorder

##### Design

A single-center, parallel-group, randomized not blinded clinical trial. Sampling was performed by the randomization method. samples were 24 patients who were randomly assigned to experimental (12 patients) and control(12 patients) groups by block randomization. Sampling was performed by the blocking randomization method. Patients who have inclusion criteria will be assessed using randomizer computer software and randomly assigned with 4 and 6 block sizes with 1: 1 allocation to the two groups of intervention and control.

##### Settings and conduct

Sessions were held for 4 weeks , 3 times a week in Nikavin clinic in Isfahan city. Before the intervention, an introductory session was held for the members of the experimental group, in which members received the necessary information and informed consent was obtained from all the participants ,also group psychotherapy norms were conducted and informed to the members of the group. there was no special time limitation for sessions , sessions timeout was almost 5-6 hours,so that every member had the opportunity to play in the role of the protagonist , and psychodrama techniques were used for them.

##### Participants/Inclusion and exclusion criteria

Age:20-35 year-old patients, graduated from high school, no addiction, no personality disorder

##### Intervention groups

Both groups received fluoxetine ,other than that experimental group participated in psychodrama sessions

##### Main outcome variables

Signs and symptoms of obsessive-compulsive disorder, anger, guilt

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200414047068N1**

Registration date: **2020-07-31, 1399/05/10**

Registration timing: **retrospective**

Last update: **2020-07-31, 1399/05/10**

Update count: **0**

##### Registration date

2020-07-31, 1399/05/10

##### Registrant information

##### Name

Melina Shiranibidabadi

##### Name of organization / entity

Islamic Azad University of Shiraz

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3220 7795

##### Email address

melinashirani4@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-05-12, 1399/02/23

##### Expected recruitment end date

2020-05-20, 1399/02/31

##### Actual recruitment start date

2020-05-12, 1399/02/23

##### Actual recruitment end date

2020-05-20, 1399/02/31

##### Trial completion date

2020-06-27, 1399/04/07

## Scientific title

Efficacy of psychodrama on reducing the signs and symptoms of obsessive-compulsive disorder, anger and guilt in patients with OCD

## Public title

Effect of Psychodrama on obsessive-compulsive disorder

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

OCD Graduated from high school

### Exclusion criteria:

addiction, personality disorders, being absent for more than 2 sessions

## Age

From **20 years** old to **35 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **30**

Actual sample size reached: **24**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Sampling was performed by the blocking randomization method. Patients who have inclusion criteria will be assessed using randomizer computer software and randomly assigned with 4 and 6 block sizes with 1: 1 allocation to the two groups of intervention and control.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

A single-center, parallel-group, randomized clinical trial

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Islamic Azad University-Shiraz Branch

##### Street address

Islamic Azad University, Shiraz branch, 5th km of Sadra highway, Shiraz

##### City

Shiraz

##### Province

Fars

## Postal code

71987-74731

## Approval date

2020-05-11, 1399/02/22

## Ethics committee reference number

IR.IAU.SHIRAZ.REC.1399.001

## 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

Signs and symptoms of obsessive-compulsive disorder

#### Timepoint

before intervention and 30 days after starting intervention

#### Method of measurement

Madsley Obsessive-Compulsive Inventory

## Secondary outcomes

### 1

#### Description

Anger in people with Obsessive-Compulsive Disorder

#### Timepoint

Before intervention and 30 days after starting intervention

#### Method of measurement

Novaco anger inventory short-form

### 2

#### Description

Guilt in people with obsessive-compulsive disorder

#### Timepoint

Before intervention and 30 days after starting intervention

#### Method of measurement

Izenc guilt inventory

## Intervention groups

### 1

#### Description

Intervention group: 12 patients suffering from obsessive-compulsive disorder who receive fluoxetine and participate in group psychodrama sessions for one-

month(12 sessions). before and after the intervention , participants answer Maudsley obsessive-compulsive questionnaire, Novaco anger scale(short-form), and Eysenck guilt questionnaire.

**Category**

Treatment - Other

**2**

**Description**

Control group: 12 patients suffering from obsessive-compulsive disorder who receive fluoxetine and do not participate in psychodrama sessions.

**Category**

Treatment - Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

NikAvin Clinic

**Full name of responsible person**

Dr Mohammad Soltanizadeh

**Street address**

NikAvin clinic. Mohtasham Kashani street.Isfahan,Iran

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8136653963

**Phone**

+98 31 3220 7795

**Email**

melinashirani4@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Melina Shirani

**Street address**

Islamic Azad University of Shiraz,Sadra,Shiraz

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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**

Shiraz University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Private

**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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Melina Shirani Bidabadi

**Position**

PHD student

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

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## Person responsible for updating data

### Contact

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**Full name of responsible person**  
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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 documents without private information of participants

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

8 months after the publication of results

### To whom data/document is available

only researchers from universities and scientific institutes

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

using of the documents is allowed just for repetition of the research in other populations and samples.

### From where data/document is obtainable

contact us via gmail address: Melinashirani4@gmail.com

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

delivery of request at first and offering authentication as a researcher who is studying or working in a university or other scientific institutes

### Comments