

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of pharmacotherapy with Fluoxetine and Cognitive- Behavior Therapy on sexual function of females with Obsessive-Compulsive Disorder

Protocol summary

Summary

The aim of this study was to compare the effects of pharmacotherapy and Cognitive Behavior Therapy (CBT) on sexual function of females with Obsessive Compulsive Disorder (OCD). Inclusion criteria: 18-52 years old married female patients who were diagnosed with OCD based on DSM- IV-TR. Exclusion criteria: comorbid axis I and axis II disorders according to clinical interview, past history of sexual dysfunction before the recent episode and other diseases or factors effecting on sexual function except OCD. A total of 58 patients were selected and with permuted block randomization divided into two groups of twenty nine patients for CBT and pharmacotherapy. This study was a single blind clinical trial and blinding was done for the patients. The patients of pharmacotherapy group received 60 mg of capsule Fluoxetine twice a day, whereas the patients of CBT group had ten CBT sessions of forty five minutes long per week done by a clinical psychologist. The obsessions and compulsions and their severity, sexual function, marital satisfaction and sexual satisfaction of patients were assessed both before the interventions and three months after drug intervention and after ten sessions of CBT using the Obsessive Compulsive Yale Brown Scale, Female Sexual Function Index, Marital Satisfaction Scale of Enrich and Sexual Satisfaction Scale, respectively.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013091014619N1**

Registration date: **2015-05-19, 1394/02/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-05-19, 1394/02/29

Registrant information

Name

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Name of organization / entity

Kasahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2013-09-11, 1392/06/20

Expected recruitment end date

2014-06-10, 1393/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of pharmacotherapy with Fluoxetine and Cognitive- Behavior Therapy on sexual function of females with Obsessive-Compulsive Disorder

Public title

The effect of Fluoxetine and Cognitive- Behavior Therapy on sexual function

Purpose

Treatment

Inclusion/Exclusion criteria
 Inclusion criteria: 18-52 years old married female patients with Obsessive-Compulsive Disorder according to DSM IV-TR criteria Exclusion criteria: Comorbid axis I and axis II disorders according to clinical interview; psychotic symptoms; past history of sexual dysfunction before recent episode; endocrine disorders (thyroid dysfunction and Diabetes Mellitus); local genitalia problems (vaginitis, pelvic infections); hypogonadism; cardiovascular disorders (angina, Myocardial Infarction); renal dysfunction; neurologic disorders (Cerebrovascular accident, spinal injuries, autonomic pelvic neuropathy); history of abdominal and pelvic surgeries causing sexual dysfunction (oophorectomy, surgery for prolaps); psychiatric drug reception during last month; using other drug causing sexual dysfunction

Age
 From **18 years** old to **52 years** old

Gender
 Female

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **58**

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Single blinded

Blinding description

Placebo
 Not used

Assignment
 Parallel

Other design features
 The blinding is for the patients.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
 Ethics committee of Kashan University of Medical Sciences

Street address
 5th kilometer of Ghotbe Ravandi Blvd.

City
 Kashan

Postal code

Approval date
 2013-08-22, 1392/05/31

Ethics committee reference number
 2049/1/5/29/پ

Health conditions studied

1

Description of health condition studied

Sexual dysfunction, Obsessive- compulsive disorder

ICD-10 code

F52, F42

ICD-10 code description

Sexual dysfunction, not caused by organic disorder or disease, Obsessive-compulsive disorder

Primary outcomes

1

Description

Kind and severity of obsessions and compulsions

Timepoint

Before the onset of intervention, three months after the onset of intervention

Method of measurement

Obsessive- Compulsive Yale Brown Scale

Secondary outcomes

1

Description

Sexual function

Timepoint

Before the onset of intervention,three months after the onset of intervention

Method of measurement

Female Sexual Function Index

2

Description

Sexual satisfaction

Timepoint

Before the onset of intervention, three months after the onset of intervention

Method of measurement

Sexual Satisfaction Scale

3

Description

Marital satisfaction

Timepoint

Before the onset of intervention,three months after the onset of intervention

Method of measurement

Marital Satisfaction of Enrich Scale

Intervention groups

1

Description

Drug intervention: 60 mg capsule Fluoxetine daily (twice

daily) for 3 months.

Category

Treatment - Drugs

2

Description

Nondrug intervention group: Cognitive- Behavior Therapy done by clinical psychologist during 10 forty five minutes sessions weekly.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Karegarnejad Psychiatric Hospital

Full name of responsible person

Dr. Fatemeh Assarian.The specialty of Psychiatrist Children and Adolescent

Street address

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kashan University of Medical Sciences

Full name of responsible person

Dr. Gholam Ali Hamidi

Street address

5th Kilometer Ghotbe Ravandi Blvd.

City

kashan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Kashan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr. Fatemeh Assarian

Position

The specialty of Psychiatrist Children and Adolescent

Other areas of specialty/work

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Position

Psychiatric Resident

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty

Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty