

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the effect of cognitive-behavioral therapy and treatment with sildenafil in the treatment of arousal and orgasm disorders, sexual satisfaction and marital satisfaction

Protocol summary

Summary

Present study has been performed with the aim to evaluate the effect of treatment with sildenafil and cognitive-behavioral therapy on female sexual function and to compare these two as well. In this study, 86 married women with arousal and orgasm disorder were randomly divided into two groups of treatment with sildenafil and cognitive-behavioral therapy. One group will be treated with 50 mg oral sildenafil one hour prior to the intercourse and the other group will receive 8 sessions of cognitive-behavioral therapy. Study outcomes including sexual function index, sexual satisfaction and marital satisfaction are evaluated through three questionnaires, before the start of the treatment and at 4, 8 and 12 weeks after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014070318338N1**

Registration date: **2014-08-03, 1393/05/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-08-03, 1393/05/12

Registrant information

Name

Fatemeh Mehrzad

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0021

Email address

fateme_mehrzad@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date

2013-12-22, 1392/10/01

Expected recruitment end date

2014-06-21, 1393/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of cognitive-behavioral therapy and treatment with sildenafil in the treatment of arousal and orgasm disorders, sexual satisfaction and marital satisfaction

Public title

Comparison of the effect of cognitive-behavioral therapy and treatment with sildenafil on sexual function and marital satisfaction in women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Being in a monogamous relationship with only one guy for at least 6 months prior to participation in the study; The presence of sexual functioning disorders diagnosed by a psychiatrist. Exclusion criteria: symptomatic heart diseases; untreated psychiatric disorders; spinal cord injuries;

uncontrolled diabetes mellitus; history of drug abuse; alcohol use; stroke during at least the six previous months; heart attack during at least the six previous months; physical problems of female reproductive tract diagnosed by the gynecologist; those who do not have the willingness to have sex due to familial conflicts

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kashan University of Medical Sciences ethics committee

Street address

Vice chancellor for research, Kashan Medical Sciences complex, Ghotbe Ravandi Blvd.,

City

Kashan

Postal code

Approval date

2013-10-26, 1392/08/04

Ethics committee reference number

29/5/1/460/پ

Health conditions studied

1

Description of health condition studied

female sexual dysfunction

ICD-10 code

F52.8

ICD-10 code description

other sexual dysfunction, not caused by organic disorder

or disease

Primary outcomes

1

Description

Sexual desire

Timepoint

before the intervention/4weeks after the intervention/8weeks after the intervention/12weeks after the intervention(end of intervention)

Method of measurement

FSFI standardized questionnaire

2

Description

Sexual excitement

Timepoint

before the intervention/4weeks after the intervention/8weeks after the intervention/12weeks after the intervention(end of intervention)

Method of measurement

FSFI standardized questionnaire

3

Description

Vaginal lubrication

Timepoint

before the intervention/4weeks after the intervention/8weeks after the intervention/12weeks after the intervention(end of intervention)

Method of measurement

FSFI standardized questionnaire

4

Description

Orgasm

Timepoint

before the intervention/4weeks after the intervention/8weeks after the intervention/12weeks after the intervention(end of intervention)

Method of measurement

FSFI standardized questionnaire

5

Description

Sexual satisfaction

Timepoint

before the intervention/4weeks after the intervention/8weeks after the intervention/12weeks after the intervention(end of intervention)

Method of measurement

FSFI standardized questionnaire

6

Description

Dyspareunia

Timepoint

before the intervention/4weeks after the intervention/8weeks after the intervention/12weeks after the intervention(end of intervention)

Method of measurement

FSFI standardized questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Treatment with 50 mg sildenafil orally one hour before intercourse

Category

Treatment - Drugs

2**Description**

Cognitive-behavioral therapy weekly for 8 sessions was conducted by a female therapist with a PhD in clinical psychology according to the following protocol: from the first to the third session: Introduction, general understanding of different types of sexual disorders and their effect on marital quality, explaining the value and importance of its treatment, determining the main problem, evaluating the method of intercourse, communication skills training, provide sex education and sexual knowledge, identifying irrational thoughts and beliefs and correct assertiveness training/ from the fourth to the sixth session: Cognitive restructuring and changing negative attitudes toward sexual issues, type one sensory concentration, type two sensory concentration, training Kegel exercises, using educational tools, penetration without orgasm, relaxation techniques to minimize everyday-life anxiety/ the seventh and the eighth sessions: the turning point maneuver, intercourse and orgasm, problem solving skills training and its application in everyday-life to minimize the distressing situations, summing up the points made during therapy sessions, elucidating the likelihood of recurrence of symptoms after treatment and responding correctly at the time of symptoms recurrence

Category

Behavior

Recruitment centers**1****Recruitment center****Name of recruitment center**

Kashan Kargarnejad Hospital

Full name of responsible person

Dr.Fatemeh Mehrzad

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

Vice Chancellor for research, Pezeshk Blvd., 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 Mehrzad

Position

Psychiatry resident

Other areas of specialty/work**Street address**

Psychiatry Group, Kargarnejad Hospital, Ghotbe Ravandi Blvd.

City

Kashan

Postal code**Phone**

+98 31 5554 0036

Fax**Email**

Fateme_mehrzad@kaums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr.Fatemeh Mehrzad

Position

Psychiatry resident

Other areas of specialty/work**Street address**

Psychiatry Group, Kargarnejad Hospital, Ghotbe Ravandi Blvd.

City

Kashan

Postal code**Phone**

+98 31 5554 0036

Fax**Email**

Fateme_mehrzad@kaums.ac.ir

Web page address**Position**

Psychiatry resident

Other areas of specialty/work**Street address**

Psychiatry Group, Kargarnejad Hospital, Ghotbe Ravandi Blvd.

City

Kashan

Postal code**Phone**

+98 31 5554 0036

Fax**Email**

Fateme_mehrzad@kaums.ac.ir

Web page address

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

Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr.Fatemeh Mehrzad