

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

A comparative study of the effectiveness of cognitive behavioral interventions and sildenafil on sexual function in methadone patients

Protocol summary

Study aim

1) Determining and comparing the mean score of sexual function before and one month after the intervention in the two groups 2) Determining and comparing the mean score of quality of sexual life before and one month after the intervention in the two groups 3) Determining and comparing the mean score of sexual self-efficacy before and one month after the intervention in the two groups

Design

A two-group, single-blind, randomized, phase-3, parallel clinical trial on 70 methadone-treated patients. Excel software (rand function) will be used for randomization.

Settings and conduct

People with drug abuse who have been on methadone treatment for at least three months will be selected by convenience method. These people are selected from Navid Salamat Addiction Treatment Center located in Motahhari St., Isfahan. A trained physician and sex therapist psychologist will explain the purpose of the study to patients treated with methadone in a private environment and taking into account the patient's comfort individually

Participants/Inclusion and exclusion criteria

Methadone treatment for at least three months, not receiving psychotherapy and medication before Entry into research, willingness to participate in research, age over 18 years, literacy, not having acute mental disorders such as psychosis, bipolar disorder, physically approved schizophrenia, being married and having sex with a regular sexual partner for at least 3 years Month, erection performance questionnaire score less than 21

Intervention groups

Sildenafil tablets (25 mg) will be given daily for one month in the intervention group. In the psychological intervention group, the cognitive-behavioral approach will be held by a trained physician in 4 sessions of 90 minutes per week for 4 weeks.

Main outcome variables

Male sexual function; The quality of men's sexual life;

Sexual self-efficacy - erectile dysfunction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191224045887N1**

Registration date: **2021-08-28, 1400/06/06**

Registration timing: **prospective**

Last update: **2021-08-28, 1400/06/06**

Update count: **0**

Registration date

2021-08-28, 1400/06/06

Registrant information

Name

zahra amini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3669 3657

Email address

z.amini@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-07, 1400/07/15

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	A comparative study of the effectiveness of cognitive behavioral interventions and sildenafil on sexual function in methadone patients
Public title	Comparison of the effect of sildenafil and education on sexual activity of methadone users
Purpose	Supportive
Inclusion/Exclusion criteria	Inclusion criteria: Methadone treatment for at least three months Willingness to participate in research Age over 18 years ability to read and write Married and having sex with a regular sexual partner for at least 3 months Erection performance index questionnaire score less than 21 Exclusion criteria: Receive psychotherapy and medication within three months before entering the study Acute mental disorder such as psychosis, bipolar disorder, schizophrenia approved by a doctor Having hypertension Patients with anatomical problems in the penis and other sexual disorders
Age	From 18 years old
Gender	Male
Phase	3
Groups that have been masked	No information
Sample size	Target sample size: 70
Randomization (investigator's opinion)	Randomized
Randomization description	A list of eligible people will be created for randomization. Then people will be individually divided into two groups using Excel software. Group 1, drug group and group 2 will be educational intervention group.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	People in the intervention group of sildenafil tablets (25 mg) will be prescribed daily for one month. In the psychological intervention group, the cognitive-behavioral approach will be held by a trained physician in 4 sessions of 90 minutes per week for 4 weeks.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Headquarters of the Ministry of Health, Treatment and Medical Education, Ghods Town (West), between South Flamek and Zarafshan, Tehran, Iran

City

Isfahan

Province

Isfahan

Postal code

8167933461

Approval date

2021-08-23, 1400/06/01

Ethics committee reference number

IR.MUI.MED.REC.1400.404

Health conditions studied

1

Description of health condition studied

sexual dysfunction

ICD-10 code

F11.281

ICD-10 code description

Opioid dependence with opioid-induced sexual dysfunction

Primary outcomes

1

Description

Sexual function score in the Male Sexual health Questionnaire

Timepoint

Before the intervention and 30 days after the intervention

Method of measurement

Men's Sexual Health Questionnaire

2

Description

Men's sexual quality of life score from the sexual quality of life questionnaire

Timepoint

Before the intervention and 30 days after the intervention

Method of measurement

Sexual Quality of Life questionnaire

3

Description

Score of sexual self-efficacy scale - erectile dysfunction

Timepoint
Before the intervention and 30 days after the intervention

Method of measurement
Sexual Self Efficacy Scale-Erectile Functioning (SSES-E)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Sildenafil tablets (25 mg) once daily for one month from Marham Daroo Company

Category

Rehabilitation

2

Description

Second intervention group: Psychological intervention group with a cognitive-behavioral approach will be held by a trained physician in 4 sessions of 90 minutes per week for 4 weeks.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Navid Salamat Addiction Treatment Center

Full name of responsible person

Mostafa Rezaie

Street address

first floor, Motahhari Boulevard, Imam Khomeini Square, North Vesal Street, Parmis Complex,

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z.amini@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Shaghayegh Haghjoo

Street address

Third floor, building number 4, Isfahan University of Medical Sciences, Hezar Jerib St., Isfahan

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8167933461

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zahraamini63@gmail.com

Grant name

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

Zahra Amini

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Public Health/Community Medicine

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inquiries

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data can be published after deleting the identification details

When the data will become available and for how long

Access starts three months after the results are published

To whom data/document is available

All people will be able to access it with an official letter from a reputable center

Under which criteria data/document could be used

If data is needed for meta-analysis, the data will be provided to the applicant

From where data/document is obtainable

By email to Dr. Zahra Amini at z.amini@med.mui.ac.ir

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

The applicant must receive the data by an official letter from the Vice Chancellor for Research of Isfahan University of Medical Sciences

Comments