

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Evaluation of the effect of oral traditional Persian medicine product of silk (*Bombyx mori* L. Cocoon), on sexual dysfunction and Quality of Life in women of reproductive age, compare with placebo. a triple-blind randomized clinical trial

#### Protocol summary

##### Study aim

The main goal: Determining the effect of the oral product of traditional Persian medicine product of silk (*Bombyx mori* L. Cocoon), on sexual dysfunction and Quality of Life in women of reproductive age, compare with placebo.

##### Design

Clinical trial with control group, parallel groups, triple blind, randomized by epidemiologist, on 74 patients.

##### Settings and conduct

Patients with sexual dysfunction referred to Health College of Persian Medicine in Qom and medical science clinics in Qom, including Rayhane Infertility Center of Nekoui Hospital, who meet the study entry criteria, are selected by the researcher, then the details of the study will be explained by the researcher, then the questionnaire Demographic characteristics and disease information are adjusted and patients are randomly assigned to one of two treatment groups.

##### Participants/Inclusion and exclusion criteria

1. Women aged 18-50 years 2. The woman being married and her husband being monogamous 3. FSFI women's sexual function index score < 28 in the initial evaluation 4. Patients with BMI less than 30 5. Having informed consent to participate in the study

##### Intervention groups

Intervention group: The patients will be given traditional Persian medicine products containing silk. Silk syrup is taken three times a day for 3 weeks and 10 cc each time. Control group: patients will be given a placebo product. Placebo syrup is taken 10 cc three times a day for 3 weeks.

##### Main outcome variables

female sexual function, quality of life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221017056213N1**

Registration date: **2022-12-04, 1401/09/13**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-12-04, 1401/09/13**

Update count: **0**

##### Registration date

2022-12-04, 1401/09/13

##### Registrant information

##### Name

fatemeh jahani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 25 3776 4075

##### Email address

fjahani@muq.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-11-22, 1401/09/01

##### Expected recruitment end date

2023-09-21, 1402/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Evaluation of the effect of oral traditional Persian medicine product of silk (*Bombyx mori* L. Cocoon), on sexual dysfunction and Quality of Life in women of reproductive age, compare with placebo. a triple-blind randomized clinical trial

### Public title

Evaluation of the effect of oral product of silk (*Bombyx mori* L. Cocoon), on sexual dysfunction and Quality of Life in women of reproductive age

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Women aged 18-50 years The woman being married and her husband being monogamous FSFI women's sexual function index score < 28 in the initial evaluation Ability to read, understand and complete the questionnaire People with BMI less than 30 Having informed consent to enter the study

#### Exclusion criteria:

pregnancy and breastfeeding delaying menstruation for 2 months or more significant clinical findings in physical examination, screening tests or other findings that prevent safe participation in the study, including the presence of any organic, anatomical disease (such as malformation of the anatomy of the external genitalia, spinal cord injuries or related surgery), hormonal in the study group such as diabetes, cerebrovascular disease, liver and kidney function damage, heart disease, hypothyroidism, cancers in history and medical history of psychiatric diseases that are under drug treatment. receiving psychotherapy or other treatments for sexual dysfunction using tobacco, alcohol, drug abuse using any chemical and herbal medicine known to affect libido being participate in another clinical trial study major changes in recent relationships, ongoing or unforeseeable disorder or disturbance that is not related to his sexual dysfunction.

### Age

From **18 years** old to **50 years** old

### Gender

Female

### Phase

3

### Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

### Sample size

Target sample size: **74**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Patients are divided into two groups using the

randomized balanced block method with block sizes of 4 and 6. The random sequence is generated by an epidemiologist by running an online program on the website (<https://www.sealedenvelope.com>). Allocation concealment is also guaranteed due to the use of special codes generated by the website.

### Blinding (investigator's opinion)

Triple blinded

### Blinding description

In this study, the patient, the researcher (project manager (doctor)) and the statistical consultant will not know about the syrup content and they will be blinded. Only the traditional medicine pharmacist who is responsible for the preparation of Iranian traditional medicine syrup and placebo syrup will know about the content of medicinal syrups. People who meet the inclusion criteria, if they want to participate in the study, after obtaining written informed consent, they will be given the traditional Iranian medicine syrup and placebo, which are in the same packaging and completely similar in terms of appearance, color and aroma. They receive a random face. A special code will be considered for each syrup and will be recorded on the syrup label. Only the pharmacist consultant will know about the drug codes. Medicines will be provided to the doctor and plan administrator and the patient. The code of each syrup specific to each patient will be entered in the patient's file and checklist by the administrator. At the end of the study, the information and checklist form of the patients will be provided to the statistics consultant for statistical analysis, and after the data analysis, the code of syrups will be provided to the administrator and statistics consultant for the final analysis by the pharmaceutical expert.

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committees of Qom University of Medical Sciences

##### Street address

No. 83, Shahid Lotfi Niaser, Shahid Lotfi Niaser, Safashehr St., No. 83

##### City

Qom

##### Province

Ghous

##### Postal code

3716993456

### Approval date

2022-07-04, 1401/04/13

**Ethics committee reference number**

IR.MUQ.REC.1401.093

**Health conditions studied**

1

**Description of health condition studied**

sexual dysfunction

**ICD-10 code**

F52

**ICD-10 code description**

Sexual dysfunction not due to a substance or known physiological condition

**Primary outcomes**

1

**Description**

sexual dysfunction

**Timepoint**

The beginning of the study, the end of the fourth week from the beginning of the intervention, one month after the end of the intervention

**Method of measurement**

female sexual function index Questionnaire

2

**Description**

Quality of Life

**Timepoint**

The beginning and end of the study

**Method of measurement**

Quality of life questionnaire with 36 questions

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Intervention group: Patients will be given traditional Persian medicine products containing silk. Silk syrup is taken three times a day for 3 weeks and 10 cc each time.

**Category**

Treatment - Drugs

2

**Description**

Control group: Patients will be given a placebo product. Placebo syrup is taken 10 cc three times a day for 3 weeks.

**Category**

Placebo

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Health College of Persian Medicine in Qom and Medical Sciences Clinics in Qom, including Reihaneh In

**Full name of responsible person**

fatemeh jahani

**Street address**

Qom Faculty of Persian Traditional Medicine , next to Alley 44, 15 Khordad Blvd

**City**

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**Postal code**

3714848350

**Phone**

+98 25 3777 3466

**Email**

fatima.jahani1370@gmail.com

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Ghous University of Medical Sciences

**Full name of responsible person**

Dr. Alireza Kohpaei

**Street address**

No. 8 , Shahid Lotfi Niasser (alley no. 4) , Jihad Danighi Alley , Safashehr St

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research@muq.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Ghous 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**

Ghous University of Medical Sciences

**Full name of responsible person**

fatemeh jahani

**Position**

PhD student of traditional medicine

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Traditional Medicine

**Street address**

Faculty of Traditional Persian Medicine of Qom  
University of Medical Sciences, corner of Alley 44, 15  
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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**

Dr. fatemeh nojavan

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

PhD student of traditional medicine

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Traditional Medicine

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

### Title and more details about the data/document

Data will be sent by researchers upon request. All potential data can be shared after de-identifying individuals.

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

After printing the results of the study

### To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions.

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

The data will be used only for use in published research

articles and will not be made available to the public in any other way.

**From where data/document is obtainable**

To receive the desired documents and data, please refer to the Faculty of Traditional Medicine of Qom University of Medical Sciences.

**What processes are involved for a request to access**

**data/document**

The data will be accessible from the time of announcing the request to the responsible person and proving the scientific documents of the applicant that they are working researchers at the university, as well as reviewing the relevant study and research.

**Comments**