

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Developing and evaluating an interventional program based on the needs and strategies for improving the sexual health of women with endometriosis: A mixed method Study

#### Protocol summary

##### Study aim

Designing and evaluating an intervention program based on the needs and strategies for improving the sexual health of women with endometriosis

##### Design

The study has three phases. Phase one: women with endometriosis and experts, sample size in the qualitative study until data saturation is reached. Phase two: sample size of the quantitative part of the study of 70 women with endometriosis (35 in the intervention group) and (35 people in the control group). Sampling of the quantitative phase of the study will be non-random and accessible sampling, and people who have the conditions and completed the online informed consent form to participate in the project will be selected as research units.

##### Settings and conduct

The study is conducted in GYN clinic and 70 women who are willing to participate in the research are invited by telephone and randomly divided into two intervention and control groups, and the intervention group receives the intervention in ETA.

##### Participants/Inclusion and exclusion criteria

Suffering from endometriosis, married, having sex with spouse, Iranian, having informed consent; Pregnancy, participation in an intervention study, addiction, presence of mental disorder, drug use in the last 60 days, suffering from other chronic diseases, stressful events in the last 6 months.

##### Intervention groups

For the intervention group, in addition to providing routine care, the designed intervention (it should be noted that the content of the intervention will be determined based on the findings of the first and second phases of the study, including the solutions obtained from the qualitative study and literature review) will be presented on an authorized virtual network such as ETA.

became. For the control group, an educational booklet about sexual health in endometriosis will be given.

##### Main outcome variables

Quality of sexual life and sexual performance of women

#### General information

##### Reason for update

Greetings and Regards. Due to the fact that the current research is a mixed method study (qualitative phase-quantitative phase), therefore, the start date of the quantitative phase and sampling is from 6/12/2023 to 15/3/2024 and we have not started the intervention yet. Therefore, due to entering the wrong date of sampling and correcting some items, this update is done. Thanks

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220620055229N2**

Registration date: **2023-03-07, 1401/12/16**

Registration timing: **prospective**

Last update: **2023-07-01, 1402/04/10**

Update count: **1**

##### Registration date

2023-03-07, 1401/12/16

##### Registrant information

##### Name

Shahla Mohammadkhani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3724 0171

##### Email address

sh.mohamadkhani76@gmail.com

##### Recruitment status

**Recruitment complete**

## Funding source

### Expected recruitment start date

2023-12-06, 1402/09/15

### Expected recruitment end date

2024-03-15, 1402/12/25

### Actual recruitment start date

empty

### Actual recruitment end date

empty

### Trial completion date

empty

## Scientific title

Developing and evaluating an interventional program based on the needs and strategies for improving the sexual health of women with endometriosis: A mixed method Study

## Public title

The effect of an intervention program on the sexual health of women with endometriosis

## Purpose

Education/Guidance

## Inclusion/Exclusion criteria

### Inclusion criteria:

Women with endometriosis based on the diagnosis of a gynecologist Being Iranian Being married Having sex with your wife Having informed online consent to participate in the study

### Exclusion criteria:

Being pregnant Participating in concurrent sexual health-related intervention studies Having cancer or chronic diseases Existence of various types of severe mental disorders (psychosis, schizophrenia) under medical treatment based on medical record information or statements Drug and alcohol addiction Using any drug or hormone affecting sexual performance within 60 days before the intervention Existence of stressful events during the last 6 months such as immigration, death of relatives, divorce and acute financial problems

## Age

No age limit

## Gender

Female

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 70

## Randomization (investigator's opinion)

Randomized

## Randomization description

First, 70 samples were invited to the study by the third moderator by telephone, and then by using the sequence of random numbers through the online software ([www.Random.org/sequences](http://www.Random.org/sequences)), the women were assigned to two intervention groups (35 people) and control group (35 people).

## Blinding (investigator's opinion)

Not blinded

## Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics committees of Reproductive Sciences - Shahid Sadoughi University of Medical Sciences

##### Street address

Bou Ali Ave

##### City

Yazd

##### Province

Yazd

##### Postal code

8916877443

#### Approval date

2023-02-19, 1401/11/30

#### Ethics committee reference number

IR.SSU.RSI.REC.1401.018

## Health conditions studied

### 1

#### Description of health condition studied

endometriosis

#### ICD-10 code

N80.0

#### ICD-10 code description

Endometriosis of uterus

## Primary outcomes

### 1

#### Description

Quality of sex life

#### Timepoint

Before the intervention, immediately and two months after the intervention

#### Method of measurement

Questionnaire of the quality of sexual life of Simond women

## Secondary outcomes

### 1

#### Description

Women's sexual performance

#### **Timepoint**

Before the intervention, immediately and two months after the intervention

#### **Method of measurement**

Rozen Women's Sexual Performance Questionnaire

### **Intervention groups**

#### **1**

##### **Description**

Intervention group: For the intervention group, in addition to providing routine treatment for endometriosis, an intervention was designed (it should be noted that the content of the intervention will be determined based on the findings of the first and second phases of the study, including the solutions obtained from the qualitative study and literature review) on the virtual network. Authorized as it will be provided.

##### **Category**

Behavior

#### **2**

##### **Description**

Control group: For the control group, an educational booklet about sexual health in endometriosis will be given

##### **Category**

Behavior

### **Recruitment centers**

#### **1**

##### **Recruitment center**

###### **Name of recruitment center**

GYN Clinic of Shahid Sadoughi Hospital, Yazd

###### **Full name of responsible person**

Fatemeh Zare Mobini

###### **Street address**

Bo Ali St, Faculty of Nursing and Midwifery

###### **City**

Yazd

###### **Province**

Yazd

###### **Postal code**

8916877443

###### **Phone**

+98 35 3824 1751

###### **Email**

fatemehzaremobini@yahoo.com

### **Sponsors / Funding sources**

#### **1**

##### **Sponsor**

###### **Name of organization / entity**

Yazd University of Medical Sciences

###### **Full name of responsible person**

Alireza Moradi

##### **Street address**

Yazd, Bahnar Square, Central Organization of Yazd University of Medical Sciences

##### **City**

Yazd

##### **Province**

Yazd

##### **Postal code**

8916978477

##### **Phone**

+98 35 3726 3733

##### **Email**

alirezampr@gmail.com

##### **Grant name**

##### **Grant code / Reference number**

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

Yes

##### **Title of funding source**

Yazd 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**

Yazd University of Medical Sciences

###### **Full name of responsible person**

Fatemeh ZareMobini

###### **Position**

Assistant Professor

###### **Latest degree**

Ph.D.

###### **Other areas of specialty/work**

Reproductive Health

###### **Street address**

Bou Ali Ave

###### **City**

Yazd

###### **Province**

Yazd

###### **Postal code**

8916877443

###### **Phone**

+98 35 2438 1751

###### **Email**

fatemehzaremobini@yahoo.com

### **Person responsible for scientific**

## **inquiries**

### **Contact**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Fatemeh ZareMobini

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Reproductive Health

**Street address**

Bou Ali Ave

**City**

Yazd

**Province**

Yazd

**Postal code**

8916877443

**Phone**

+98 35 2438 1751

**Email**

fatemehzaremobini@yahoo.com

## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Fatemeh ZareMobini

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Reproductive Health

**Street address**

Bou Ali Ave

**City**

Yazd

**Province**

Yazd

**Postal code**

8916877443

**Phone**

+98 35 2438 1751

**Email**

fatemehzaremobini@yahoo.com

## **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**

Not applicable

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

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

**Data Dictionary**

Not applicable

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

All personal data of participants can be shared after de-identification.

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

After printing the results

**To whom data/document is available**

The data will be available for researchers working in academic and scientific institutions, and people who are busy can apply to receive them.

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

Scientific use

**From where data/document is obtainable**

fatemehzaremobini@yahoo.com

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

One week after receiving the applicant's email

**Comments**