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), 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

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8916877443

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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
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Other areas of specialty/work
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Person responsible for updating data

Contact

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Full name of responsible person
Fatemeh ZareMobini

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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
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