Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Designing a sexual health promotion program for women with hysterectomy and implementing an intervention based on results: an exploratory sequential mixed method Study

Protocol summary

Study aim

Improving the sexual health of hysterectomized women

Design

The clinical trial has randomized control and intervention groups. The quantitative phase of this study was conducted on 70 patients who were selected through non-random and purposeful sampling and entered the study, then through the online software (www.Random.org/sequences) the patients were divided into two intervention groups (designed intervention) and The control group was assigned.

Settings and conduct

The place of sampling is Baqaeipour Clinic, affiliated to Shahid Sadoughi University of Yazd, and based on the records of women who have undergone hysterectomy, we select people according to the entry criteria, and after entering, they are randomly divided into intervention and control groups from all the participants Informed consent is obtained.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: Women who underwent hysterectomy due to gynecological diseases, sexual dysfunction, must be married and Iranian, have a common bed with their husband, and have informed consent to enter the study.. Exclusion criteria include: Concurrent participation in another study, presence of another chronic disease, presence of mental disorder, smoking and alcohol consumption, use of hormonal drugs that affect sexual function, and having had an oophorectomy.

Intervention groups

The intervention group is a group that receives the sexual health promotion program for hysterectomized women in the form of eight 60-90 minute training sessions as a group using the virtual network. The time of the training sessions is determined according to the plan between the researcher and the clients after prior coordination with the women of this group, and they are given a reminder SMS on the same day.

Main outcome variables

Female sexual function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201222049797N3**
Registration date: **2023-07-31, 1402/05/09**
Registration timing: **prospective**

Last update: **2023-07-31, 1402/05/09**
Update count: **0**

Registration date

2023-07-31, 1402/05/09

Registrant information

Name

fatemeh zahra memar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5227 4486

Email address

memar_fateme@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-09-19, 1403/06/29

Expected recruitment end date

2025-01-18, 1403/10/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Designing a sexual health promotion program for women with hysterectomy and implementing an intervention based on results: an exploratory sequential mixed method Study

Public title

Designing a sexual health promotion program for women with hysterectomy and implementing an intervention based on results

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Women who underwent hysterectomy due to gynecological diseases and obstetric issues (fibroids, adenomyosis, endometrial hyperplasia, postpartum hemorrhages, etc.) and other than women's concerts At least three months and at most three years have passed since the hysterectomy. having sexual dysfunction (getting a score of 28 and above from the questionnaire of women's sexual function) Being Iranian Being married and being the only spouse of a person Having a common bed with your wife Having informed online consent to participate in the study

Exclusion criteria:

Participating in interventional studies related to sexual health at the same time Suffering from chronic diseases such as diabetes, chronic hypertension, heart disease, etc. Existence of various types of severe mental disorders (psychosis, schizophrenia, etc.) under medical treatment based on medical record information or statements Smoking, drugs and alcohol 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 and financial problems Perform oophorectomy

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

Sampling of the quantitative phase of the study will be non-random and purposeful 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. After entering, the participants are randomly assigned to two intervention groups (designated intervention presentation) and control group. Currently, there are three random allocation models, and considering that this intervention is in the form of two groups, the first generation randomization model is used, which uses a sequence of random numbers and through the software on the site (www.Random. org/sequences) is done.The blocks that exist in the desired site, groups A and B are entered in the treatment groups section, and then the number of samples is entered in the number of people in the treatment blocks section, and the software assigns each sample to one of the two groups A and B randomly, which means It is that the allocation of samples to each of the two groups A and B does not happen, but is done in the order that the output of the software is placed.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The sample size of the quantitative part of the study will be determined after completing the qualitative phase of the study and determining the main priority of improving the sexual health of hysterectomized women.Currently, 70 people are expected.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Reproductive Sciences Institute Shahid Sadoughi University of Medical

Street address

Bou Ali Ave

City

yazd

Province

Yazd

Postal code

8916978477

Approval date

2023-07-02, 1402/04/11

Ethics committee reference number

IR.SSU.REC.1402.002

Health conditions studied

1

Description of health condition studied

Hysterectomy women due to gynecological and obstetric problems

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Change in mean scores of sexual function measured by the Female Sexual Function Questionnaire (FSFI).
Timepoint
Female sexual function questionnaires will be completed by the participants before, immediately after the intervention and one month after the intervention
Method of measurement
Female sexual function is based on the FSFI questionnaire of Razon et al., which measures this variable in 6 areas.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: The group whose study intervention included the presentation of sexual health promotion program to hysterectomy women will receive 60-90 minutes of virtual training during 8 sessions.
Category
Rehabilitation

2

Description
Control group: they receive an educational booklet about hysterectomy
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Operating room of Shahid Sadoughi Hospital, Yazd
Full name of responsible person
Dr. Fateme ZareMobini
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Ibn Sina Ave
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
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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
70
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
Dr. Fateme ZareMobini
Position
Assistant Professor, PHD of Reproductive Health
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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