Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Oct 2026

The effect of cognitive-behavioral group counseling on reproductive health and sexual satisfaction in women with endometriosis

Protocol summary

Study aim
Determining the effect of cognitive-behavioral group counseling on reproductive health and sexual satisfaction of women with endometriosis

Design
A controlled clinical trial with parallel, randomized groups on 96 patients with endometriosis used a random number table using www.randomization.com for randomization.

Settings and conduct
Eligible people in the endometriosis clinic of Imam Reza (AS) Hospital will enter the research according to the inclusion criteria. Then the questionnaires will be completed by two groups. Cognitive-behavioral counseling content in the intervention group in 7 sessions and each session for 90-60 minutes with 6 to 8 people, the first and seventh sessions and a month later, in person and the rest of the sessions will be held virtually. The control group will receive routine care.

Participants/Inclusion and exclusion criteria
Inclusion criteria: women of childbearing age (15-49 years), married, no chronic psychiatric disorders, hemorrhage, having sex, diagnosis of endometriosis based on clinical imaging by a doctor, no accidents during the last 6 months, also Tobacco etiquette, no individual suffering from diseases affecting sexual function, no history of pelvic surgery.

Intervention groups
Intervention group Session 1 Discussion about attitude towards reproductive and sexual health, Session 2 Discussion about mental health problems, Session 3 Reconstruction of negative attitude towards infertility, Session 4 Discussion about physical and sexual problems, Session 5 Cognitive reconstruction and change of negative attitude towards sexual issues, Session 6 Discussion The control group receives the routine care of the center.

Main outcome variables
Endometriosis Reproductive Health (ERHQ) , Sexual Satisfaction Score (SSSW)

General information

Reason for update

Acronym
endometriosis

IRCT registration information
IRCT registration number: **IRCT20210919052516N1**
Registration date: **2021-11-15, 1400/08/24**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-15, 1400/08/24**
Update count: **0**

Registration date
2021-11-15, 1400/08/24

Registrant information

Name
maryam nikseresht

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3606 8939

Email address
maryamnik132@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-06, 1400/08/15

Expected recruitment end date
2022-03-06, 1400/12/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of cognitive-behavioral group counseling on reproductive health and sexual satisfaction in women with endometriosis

Public title
The effect of cognitive-behavioral group counseling on reproductive health and sexual satisfaction in women with endometriosis

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Written informed consent to participate in the research Women of childbearing age (15-49 years) Being Iranian and living in Mashhad Have a minimum literacy Getting married and cohabiting Absence of chronic psychiatric disorders and problems in wife and her husband (self-declaration) lack of known chronic diseases in wife and husband Having sex Diagnosis of endometriosis based on history, physical examination and clinical imaging by a physician No accidents during the last 6 months Failure to attend training or cognitive-behavioral counseling classes in the previous 6 months no addiction and alcohol in wife and husband No depression, stress or severe anxiety in a woman and her husband according to the DASS-21 scale Ability to use the Internet and cyberspace if the intervention is done virtually Failure of the person and his wife to get diseases that affect sexual function absence of menopause No history of pelvic surgery Be the only wife of her husband

Exclusion criteria:
Not participating in counseling sessions for more than two sessions and not wanting to continue the intervention Incomplete completion of the questionnaire (answering less than 10% of the questionnaire) Incidence of accidents during the study Receive another training-counseling program during the intervention period.

Age
From **15 years** old to **49 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the permutation block method is used to generate a sequence of random allocation of individuals to the study groups. Random allocation sequence of individuals is done using random allocation software and block size two. The permutation block method is one of the random allocation methods in which each block is selected according to the number of groups studied. In this study, there are two blocks, AB and BA. One of the blocks is selected at random. If the first block, AB, is selected, the first person is assigned to group A and the second person to group B. And this process continues until all the samples are assigned. The characteristic of this method is that the two study groups will have equal numbers.

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
ethics committee of mashhad university of medical sciences

Street address
Ibn sina St, mashhad

City
mashhad

Province
Razavi Khorasan

Postal code
91388-13944

Approval date
2021-10-25, 1400/08/03

Ethics committee reference number
IR.MUMS.NURSE.REC.1400.064

Health conditions studied

1

Description of health condition studied
Endometriosis

ICD-10 code
N80.9

ICD-10 code description
Endometriosis, unspecified

Primary outcomes

1

Description
Reproductive health

Timepoint
Before and immediately one month after the intervention

Method of measurement
Endometriosis Reproductive Health Questionnaire (ERHQ)

2

Description
Sexual satisfaction
Timepoint
Before and immediately one month after the intervention
Method of measurement
Women's Sexual Satisfaction Scale Questionnaire sssw

Secondary outcomes

1

Description
social support
Timepoint
Before and immediately one month after the intervention
Method of measurement
Standard social support questionnaire

2

Description
Stress - Anxiety - Depression
Timepoint
Before and immediately one month after the intervention
Method of measurement
Stress-Anxiety-Depression Inventory DASS-21

3

Description
Intensity of pain
Timepoint
Before and immediately one month after the intervention
Method of measurement
Severity of pain mediated by VAS criteria

Intervention groups

1

Description
Intervention group: The clinical trial study has a pre-test, post-test and control group with the research community of women with endometriosis. To participate in the research, first the control group and then the intervention group are invited. The required information will be collected using available qualified sampling. In both intervention and control groups, after providing the necessary explanations about the objectives of the research, observing the independence of individuals to participate in the research and the confidentiality of information, participants are asked to complete the informed consent form and then take a sample from them. Be. Patients aged 15-49 years in the intervention group participate in 7 group counseling sessions and each session for 90-60 minutes with 6 to 8 people, the first and seventh sessions and a month later, in person and the rest of the sessions will be held virtually. . Women in the same group will be in the same group in the first counseling session and in the next sessions
Category
Behavior

2

Description
Control group: They receive routine care at a medical center. In addition, they complete the questionnaires before, immediately and one month later.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Endometriosis Clinic of Imam Reza Hospital
Full name of responsible person
Leila Hafizi
Street address
Ibn Sina St., Imam Reza Hospital Square, Imam Reza Research and Treatment Center
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 3854 3031
Email
HafiziL@mums.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Fatemeh Erfanian
Street address
Ibn sina St, School of Nursing and Midwifery
City
mashhad
Province
Razavi Khorasan
Postal code
91388-13944
Phone
+98 51 3841 2081
Email
ErfanianF@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Fatemeh Erfanian

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Ibn sina St, Nursing and Midwifery University

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Maryam Nikseresht

Position

student

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available