

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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

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Ibn Sina St., Imam Reza Hospital Square, Imam Reza Research and Treatment Center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Fatemeh Erfanian

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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

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
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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