

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of marital relationship enrichment counseling compared to usual treatment on the quality of life, performance and sexual satisfaction of women with endometriosis

Protocol summary

Study aim

Investigating the impact of marital relationship enrichment counseling on the quality of life, performance and sexual satisfaction of women with endometriosis

Design

A clinical trial with a control group, with parallel groups, single blind, randomized using a card, will be conducted on 44 patients.

Settings and conduct

1- Location of the study: Endometriosis clinic of the hospital affiliated to Qom University of Medical Sciences is the research environment of this study. 2- Study population: women with endometriosis 3- Type of blinding: only blinding of the statistician will be done.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age over 18 years; married; Diagnosis of endometriosis by a gynecologist; At least two years of living together have passed; At least six months have passed since the diagnosis, treatment and stabilization of the disease. Exclusion criteria: history of severe marital disputes and going to court; couple's addiction to drugs; Experiencing recent crises in life; history of psychiatric disorders; History of participating in psychological training classes with the aim of improving sexual problems

Intervention groups

Intervention group: The intervention to enrich couples' relationships will take place during six 90-minute sessions in the form of couple counseling with the presence of the patient and his wife. Control group: The control group will receive only regular programs.

Main outcome variables

Sexual performance; Sexual satisfaction; Sexual life quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231229060565N1**

Registration date: **2024-02-18, 1402/11/29**

Registration timing: **prospective**

Last update: **2024-02-18, 1402/11/29**

Update count: **0**

Registration date

2024-02-18, 1402/11/29

Registrant information

Name

Zohre Momenimovahed

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3662 6132

Email address

zmomeni@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-08-22, 1403/06/01

Expected recruitment end date

2024-10-22, 1403/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of marital relationship enrichment counseling compared to usual treatment on the quality of life, performance and sexual satisfaction of women with endometriosis

Public title

Effect of counseling on Sexual life quality, sexual function and sexual satisfaction in patient with endometriosis

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Over 18 years of age married diagnosed with endometriosis by a gynecologist at least two years of cohabitation at least six months of diagnosis, treatment and stabilization of the disease

Exclusion criteria:

Simultaneous participation in another study History of participating in psychological training classes with the aim of improving sexual problems History of psychiatric disorders Experiencing recent crises in life Addiction of couples to drugs History of severe marital disputes and going to court

Age

From **18 years** old

Gender

Female

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, people are randomly assigned to two intervention and control groups. In this method, a number of cards are considered as the first group and the same number of cards for the next groups; Then, by mixing the cards together, one card is issued and its allocation is recorded, and that card is returned to the box containing other cards after being issued. Then the cards are mixed again and another card is taken out. This process continues until reaching a random sequence according to the sample size.

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 Qom University of Medical Sciences

Street address

School of Nursing and Midwifery; East No. 2 Alley; Moalem Blvd; Qom

City

Qom

Province

Ghoum

Postal code

3715835155

Approval date

2023-10-16, 1402/07/24

Ethics committee reference number

IR.MUQ.REC.1402.190

Health conditions studied

1

Description of health condition studied

Endometriosis

ICD-10 code

N80

ICD-10 code description

Endometriosis

Primary outcomes

1

Description

Quality of sexual life

Timepoint

Before, immediately and three months after participating in the meetings in two intervention and control groups

Method of measurement

women's sexual life quality questionnaire

2

Description

Sexual performance

Timepoint

Before, immediately and three months after participating in the meetings in two intervention and control groups

Method of measurement

women's sexual performance scale

3

Description

sexual satisfaction

Timepoint

Before, immediately and three months after participating in the meetings in two intervention and control groups

Method of measurement

Larson's sexual satisfaction questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Couples relationship enrichment intervention will take place during six 90-minute sessions. The executive protocol of marital relationship enrichment sessions (RET) will be conducted in the form of couple counseling and in the presence of husband and wife, and the enrichment package will be based on similar interventions taken from two treatment books based on communication enrichment and the book of sex education sessions taken from my wife's book with comments from Specialists will be specially designed.

Category

Lifestyle

2**Description**

Control group: The control group receives only the usual treatments.

Category

Lifestyle

Recruitment centers**1****Recruitment center****Name of recruitment center**

Endometriosis Clinic of Women's Hospital affiliated to Qom University of Medical Sciences

Full name of responsible person

Zohre Khalajinia

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School of Nursing and Midwifery; East No. 2 Alley; Moalem Blvd; Qom

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ghoum 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

Ghoum 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**

Ghoum University of Medical Sciences

Full name of responsible person

Zohre Momenimovahed

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ghoum University of Medical Sciences

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Position

Associate Professor

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Person responsible for updating data

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Position

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Latest degree

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Other areas of specialty/work

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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 further information

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

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Still undecided - no release schedule yet

When the data will become available and for how long

Still undecided - no release schedule yet

To whom data/document is available

People working in scientific and research institutions

Under which criteria data/document could be used

If all group members agree, the file can be accessed

From where data/document is obtainable

Dr Zohre Khalajinia

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

The applicant should send an email to Dr. Khalajinia. It will be sent if agreed

Comments