

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Efficacy of sexual counseling on sexual behaviors in women with endometriosis, candidates for laparoscopic surgery.

Protocol summary

Study aim

To determine the effect of sexual counseling on sexual behaviors in women with endometriosis candidate for laparoscopic surgery.

Design

The research is a single-blind randomized clinical trial with two groups: intervention and control. women with endometriosis will be randomly divided into two groups of 30 each using a table of random numbers.

Settings and conduct

The setting of the study is Hazrat-e Rasool Akram affiliated to Iran University of Medical Sciences. Study objectives will be explained to women with endometriosis who is the candidate for laparoscopic surgery and informed written consent will be taken. 60 women with endometriosis will be randomly divided into two groups (intervention and control) by using the computer-generated table of random numbers. Sexual behavior and quality of life questionnaires will be completed in both control and intervention groups, prior to any intervention. In the intervention group, sexual counseling based on the PLISSIT model will be conducting weekly for 3 weeks and, laparoscopic surgery would be performed 4 weeks after the last session. Sexual behavior and quality of life questionnaires in the 3rd and 6th months after laparoscopic surgery will be completed by the patients and the results will be compared.

Participants/Inclusion and exclusion criteria

Women with endometriosis referring to Hazrat-e Rasool Akram will be enrolled according to inclusion criteria.

Intervention groups

In the intervention group, sexual counseling will be done, prior to laparoscopic surgery. They will receive three counseling 45-minute sessions based on the PLISSIT model. Four weeks after counseling sessions women will undergo laparoscopic surgery.

Main outcome variables

Efficacy of sexual counseling on sexual behaviors in

women with endometriosis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180130038567N1**

Registration date: **2018-08-04, 1397/05/13**

Registration timing: **prospective**

Last update: **2018-08-04, 1397/05/13**

Update count: **0**

Registration date

2018-08-04, 1397/05/13

Registrant information

Name

shahla chaichian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6650 9283

Email address

chaichian.sh@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Efficacy of sexual counseling on sexual behaviors in women with endometriosis, candidates for laparoscopic surgery.

Public title
Efficacy of sexual counseling on sexual behaviors in women with endometriosis, candidates for laparoscopic surgery.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Not pregnant Sexually active Heterosexual Sexual dysfunction or dyspareunia during last 6 months
Diagnosis of endometriosis by clinical symptoms (dysmenorrhea, dyspareunia, dysuria, dyschezia, pelvic pain, infertility, hematuria, etc.) clinical examinations examination, and imaging methods(ultrasound, MRI,...), Pelvic pain associated with endometriosis Negative history of hormonal medications (contraceptive pill, gonadotropins, etc.) during the last 3 months. No gynecologic malignancy Negative history of underlying diseases such as cardiovascular, respiratory, renal, hematological, liver, rheumatologic and neurological diseases, psychological disorders in women and spouses Negative history of psychiatric drugs by couple Interested in collaborating in research
Exclusion criteria:
Failure to prove endometriosis by surgery The unwillingness of endometriosis women to participate in the study

Age
From **15 years** old to **50 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Care provider
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, 60 women with endometriosis will be divided into two groups of 30 by a computer-generated table of random numbers.

Blinding (investigator's opinion)
Double blinded

Blinding description
Double-blinding (consisting of outcome assessor and care provider(surgeon)

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway, Tehran

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2017-11-18, 1396/08/27

Ethics committee reference number

IR.IUMS.REC 1396.32134

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

Sexual behaviors

Timepoint

Before intervention, 3 and 6 months after intervention

Method of measurement

Using sexual behavior questionnaires (Female Sexual Function Index, sexual distress, Sexual satisfaction scale for women, Multi- dimensional sexual self-concept).

Secondary outcomes

1

Description

Quality Life

Timepoint

Before and 6 months after intervention.

Method of measurement

The endometriosis health profile questionnaire-30

Intervention groups

1

Description

Intervention group: Intervention group will receive three 45-minute PLISSIT based (the first three stages) individual sexual counseling sessions weekly. Stage1: Permission Stage 2: Limited information Stage3: Specific suggestions. After 4 weeks Laparoscopic surgery will be performed.

Category

Behavior

2

Description

Control group: In the control group, women with endometriosis will only undergo laparoscopic surgery.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram hospital

Full name of responsible person

Shahla Chaichian

Street address

Rasoul Akram Hospital, Satarkhan St, Tehran

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+98 21 6650 9283

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shahlachaichian@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Vice Chancellor for Administration of Iran University of Medical Sciences (IUMS)

Street address

Iran University of Medical Science, Hemmat Highway, Tehran

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Shahla chaichian

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Shahla chaichian

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Shahla chaichian

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address**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