Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The co-effect of sensate focus technique and position changing on sexual function in women with deep-infiltrating endometriosis three to six months after surgery

Protocol summary

Study aim
The co-effect of sensate focus technique and position changing on sexual function in women with deep-infiltrating endometriosis three to six months after surgery

Design
Phase 3 clinical trial, with control group, without blinding, randomized

Settings and conduct
Random clinical trial with control group,Endometriosis Clinic in Avicenna Research Institute, and simple randomization and evaluation of interventions one and two months after intervention training

Participants/Inclusion and exclusion criteria
Married women aged 18 to 45 years who underwent laparoscopic diagnosis and pathology with deep endometriosis and underwent surgery and referred for follow-up three to six months after surgery and have intercourse in the last 8 weeks.

Intervention groups
Intervention group: includes 40 women who have referred for follow-up 3 to 6 months after surgery and are taught sensate focus technique and position changing in a two-hour session. Control group: includes 40 women with deep endometriosis who have undergone surgery.

Main outcome variables
sexual function; Sensate focus technique; Position changing

General information

Reason for update
Recording the exact time of the start and end of the sampling of the study (the start of the sampling was postponed due to the coronavirus outbreak)

Acronym

IRCT registration information
IRCT registration number: **IRCT20200617047813N1**
Registration date: **2020-10-13, 1399/07/22**
Registration timing: **prospective**

Last update: **2023-01-28, 1401/11/08**
Update count: **1**

Registration date
2020-10-13, 1399/07/22

Registrant information

Name
Parisa Tajik

Name of organization / entity
Tarbiat Modares University

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-30, 1399/09/10

Expected recruitment end date
2021-12-01, 1400/09/10

Actual recruitment start date
2021-01-06, 1399/10/17

Actual recruitment end date
2021-09-02, 1400/06/11

Trial completion date
2021-09-02, 1400/06/11

Scientific title
The co-effect of sensate focus technique and position changing on sexual function in women with deep-

infiltrating endometriosis three to six months after surgery

Public title
The effect of sensate focus technique and positioning changing on sexual function after endometriosis surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Married women aged 18-45 years Having intercourse in the last 8 weeks No known underlying disease other than endometriosis (according to the research unit and the file) No mental illness (according to the research unit and the file) Husband monogamy and living with the spouse now and during the study Literacy of Persian language Being Iranian and living in Tehran Non-addiction of couples to drugs and alcohol (according to the research unit and the file) No stressful incident during the last month (according to the research unit and the file)
Exclusion criteria:
The couple's unwillingness to stay in the study Getting pregnant while studying Failure to perform a regular intervention program Remaining severe surgical complications (according to the research unit and the file)
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **80**
Actual sample size reached: **76**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple random sampling; using Random number table; Even numbers for the intervention group and odd numbers for the control group
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 Tarbiat Modares university
Street address
Jalal Al-Ahmad Highway, Faculty of Medical Sciences, Tarbiat Modares University, Tehran
City
Tehran
Province
Tehran
Postal code
1411713116
Approval date
2020-10-10, 1399/07/19
Ethics committee reference number
IR.MODARES.REC.1399.090

Health conditions studied

1

Description of health condition studied
Sexual function
ICD-10 code
F52
ICD-10 code description
Sexual dysfunction not due to a substance or known physiological condition

Primary outcomes

1

Description
Improve sexual function
Timepoint
At the beginning of the study and 1 and 2 months after the intervention
Method of measurement
FSFI (female sexual function index), VAS (visual analogue scale)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: A face-to-face training session is conducted in the form of theoretical training about sensate focus technique and position changing ; with the presentation of training slides. This two-hour workshop will be held individually with spouse in a private and quiet environment
Category
Treatment - Other

2

Description
Control group: no intervention; and at the end of the

evaluation period, a training booklet will be provided to the control group.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Avicenna Research Institute

Full name of responsible person
Shadab Shahali

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No. 97, Corner of Yakhchal St, Shariati St,Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tarbiat Modares university

Full name of responsible person
Mohammad Taghi Ahmadi

Street address
Jalal Al-Ahmad Highway, Nasr Bridge, Faculty of Medical Sciences, Tarbiat Modares University

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http://www.modares.ac.ir/en

Grant name

Grant code / Reference number
0

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tarbiat Modares university

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
Tarbiat Modares university

Full name of responsible person
Shadab Shahali

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Web page 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

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

Only part of the data, including information about the main outcome, can be shared

When the data will become available and for how long

Access efficiency starts from 1401

To whom data/document is available

The data will only be available to field researchers

Under which criteria data/document could be used

For further research, researchers can send a written request to the responsible author.

From where data/document is obtainable

Corresponding Author, Tarbiat Modares University, Faculty of Medical Sciences, Department of Midwifery and Reproductive Health

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

After a written request from the responsible author, the request will be sent to the research unit of Tarbiat Modares University and if the rules are complied with, the analyzed data will be provided to the researchers.

Comments