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 pelvic endometriosis who use medication

Protocol summary

Study aim
The simultaneous effect of sensate focus technique and position changing on sexual function in under treatment women with pelvic endometriosis

Design
This study is a clinical trial, with control group, with parallel groups, without blinding, randomized, which will be performed on 80 patients.

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

Participants/Inclusion and exclusion criteria
Inclusion criteria: Married women between the ages of 18 and 45 who have undergone medical treatment with an ultrasound diagnosis of endometriosis and have been referred for follow-up and had intercourse in the last 8 weeks.

Intervention groups
Intervention group: includes 40 women with endometriosis who are given a face-to-face training session in the form of a two-hour theory training on sensate focus technique and sexual position with educational slides and a step-by-step guide to sensate focus technique and sexual position will also be provided. The control group included 40 women with pelvic endometriosis who referred to the clinic for follow-up.

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

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200617047812N1**
Registration date: **2020-11-05, 1399/08/15**
Registration timing: **prospective**

Last update: **2020-11-05, 1399/08/15**
Update count: **0**

Registration date
2020-11-05, 1399/08/15

Registrant information

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Name of organization / entity
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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
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The co-effect of sensate focus technique and position changing on sexual function in women with pelvic endometriosis who use medication

Public title
The effect of sensate focus technique and position

changing on sexual function in women with pelvic endometriosis

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 No addiction of couples to drugs and alcohol (according to the research unit and the file) No stressful event during the last month (according to the research unit and the file)

Exclusion criteria:
Not having intercourse Being pregnant Having a mental illness

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Step 1: We will number the people of the community from number 1. This numbering will be done without following any special order. Step 2: We will randomly select a number as the sampling source in the table of random numbers. Step 3: From the beginning of sampling, we will consider rows with the number of sample digits. Step 4: We will read the numbers of the selected rows in order. We will count We will count the recurring number only once. The first selected number will be in the intervention group and the next number in the control group. Sampling will continue until the sample size is completed.

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.1399.089

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
In the intervention group, a 2-hour face-to-face training session will be conducted in the form of theoretical training on the sensate focus technique and sexual positions, along with educational slides, and a step-by-step instruction booklet on sensate focus technique and sexual position will be provided.

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

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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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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