Clinical Trial Protocol
Iranian Registry of Clinical Trials
27 Dec 2022

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

Last update: 2020-10-13, 1399/07/22
Update count: 0
Registration date
2020-10-13, 1399/07/22

Registrant information
Name
Parisa Tajik
Name of organization / entity
Tarbiat Modares University
Country
Iran (Islamic Republic of)
Phone
+98 21 5596 6271
Email address
p.tajik@modares.ac.ir

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 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

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
Behavior

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
Behavior
Recruitment centers

1

Recruitment center
Name of recruitment center
Avicenna Research Institute
Full name of responsible person
Shadab Shahali
Street address
No. 97, Corner of Yakhchal St, Shariati St, Tehran
City
Tehran
Province
Tehran
Postal code
1941913114
Phone
+98 21 23519
Fax
+98 21 2264 4754
Email
Parisa.rasuli2014@gmail.com

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
City
Tehran
Province
Tehran
Postal code
14115-111
Phone
+98 21 8288 3326
Fax
+98 21 8288 3326
Email
parisa.rasuli2014@gmail.com
Web page address
http://www.modares.ac.ir/en

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
Street address
Jalal Al-Ahmad Highway, Faculty of Medical Sciences, Tarbiat Modares University
City
Tehran
Province
Tehran
Postal code
14115-111
Phone
+98 21 8288 3811
Email
shadab.shahali@modares.ac.ir

Person responsible for scientific 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
Street address
Jalal Al-Ahmad Highway, Faculty of Medical Sciences, Tarbiat Modares University
City
Tehran
Province
Tehran
Postal code
14115-111
Phone
+98 21 8288 3811
Email
shadab.shahali@modares.ac.ir
Person responsible for updating data

Contact
Name of organization / entity
Tarbiat Modares university
Full name of responsible person
Shadab Shahali
Position
Associate professor
Latest degree
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Other areas of specialty/work
Reproductive Health
Street address
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14115-111
Phone
+98 21 8288 3811
Email
shadab.shahali@modares.ac.ir
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