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

Registration timing: prospective

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

Registrant information
Name
Maryam Tajik
Name of organization / entity
Tarbiat Modares University
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Iran (Islamic Republic of)
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m.tajjik@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 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**
Not used

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

**Secondary Ids**
empty

**Ethics committees**

<table>
<thead>
<tr>
<th>#</th>
<th>Ethics committee</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

**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**

<table>
<thead>
<tr>
<th>#</th>
<th>Description of health condition studied</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Sexual function</td>
</tr>
</tbody>
</table>

**ICD-10 code**
F52

**ICD-10 code description**
Sexual dysfunction not due to a substance or known physiological condition

**Primary outcomes**

<table>
<thead>
<tr>
<th>#</th>
<th>Description</th>
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<tbody>
<tr>
<td>1</td>
<td>Improve sexual function</td>
</tr>
</tbody>
</table>

**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**

<table>
<thead>
<tr>
<th>#</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>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.</td>
</tr>
</tbody>
</table>
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
Street address
No. 97, corner of Yakhchal St, Shariati St, Tehran
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Tehran
Postal code
1941913114
Phone
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Fax
+98 21 2264 4754
Email
maryam.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
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Email
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Web page address
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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Jalal Al-Ahmad Highway, Faculty of Medical Sciences, Tarbiat Modares University
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14115-111
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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
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Jalal Al-Ahmad Highway, Faculty of Medical Sciences, Tarbiat Modares University
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Tehran
Province
Tehran
Postal code
14115-111
Phone
+98 21 8288 3811
Email
shadab.shahali@modares.ac.ir
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