Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Design and evaluation the effect of Educational mobile Application on sexual function and sexual quality of life in women with endometriosis under medical treatment

Protocol summary

Study aim
Design and evaluation the effect of Educational mobile Application on sexual function and sexual quality of life in women with endometriosis under medical treatment

Design
Clinical trial with 100 people in two groups of intervention and control with parallel groups, randomized by random number table

Settings and conduct
n the first stage, the literature was reviewed by searching Persian and English articles in 5 databases, PubMed, Scopus, web of science, Cochran library, Google scholar, with keywords including endometriosis in the title and keywords sexual function, sexual activity, sexual satisfaction, sexual quality of life, sexual dysfunction, sex disorder, dyspareunia, sex education, sex counseling is done in the title or abstract to prepare the content of the application. Then the application is designed by a software engineer and to evaluate the effectiveness of the application, 100 people suffering from endometriosis under medical treatment referring to private offices of endometriosis specialists in Tehran are randomly assigned to the intervention and control groups, and the application is used on the mobile phones of the members. The intervention group is installed and the pamphlet with sex education content is given to the control group

Participants/Inclusion and exclusion criteria
Women between the ages of 18 and 45 with endometriosis diagnosed by ultrasound by a gynecologist who don't have been sexually active during the past month and have a known infertility problem, sexual dysfunction, a known underlying disease, or the use of drugs affecting sexual function in them

Intervention groups
The installation of the educational mobile application for 2 months is done on the mobile phones of the intervention group. The members of the control group are given a pamphlet with the content of sex education

Main outcome variables
sexual function and sexual quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230820059202N1**
Registration date: **2024-05-09, 1403/02/20**
Registration timing: **prospective**

Last update: **2024-05-09, 1403/02/20**
Update count: **0**

Registration date
2024-05-09, 1403/02/20

Registrant information

Name
Mobina Khorrami

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8865 5366

Email address
mobinaakhorrami1143@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-05-30, 1403/03/10

Expected recruitment end date
2024-08-31, 1403/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Design and evaluation the effect of Educational mobile Application on sexual function and sexual quality of life in women with endometriosis under medical treatment

Public title

Design and evaluation the effect of Educational mobile Application on sexual function and sexual quality of life in women with endometriosis under medical treatment

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Endometriosis has been diagnosed in them by a gynecologist through ultrasound To be sexually active during the last month There is no known infertility problem in any of the couples There should be no known sexual dysfunction in the male partner such as erectile dysfunction, ejaculation disorder Does not have any known underlying diseases such as mental illness, cardiovascular disease, kidney disease, diabetes, excretory disease, pelvic inflammatory disease and other women's diseases Absence of urinary tract infection, vaginitis, cervical inflammation, active wounds or genital lesions that interfere with sexual intercourse, or a history of sexual assault Women have not used any drugs affecting sexual function such as antidepressants, beta blockers, antihistamines, antipsychotics, benzodiazepines, antiepileptic drugs Couples should not consume cigarettes, alcohol and drugs Not experiencing stressful events (death of a child or a close relative, severe illness of a close relative, imprisonment of a family member, depression, etc.) in the last 3 months The couple has not taken various sex education classes or courses

Exclusion criteria:

Failure to fully complete research questionnaires

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: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

First, the number of members of the research sample (100 people) is determined. Then study samples are selected through available sampling and a 3-digit sample code is assigned to each of the selected members. Then a table containing 10 rows and 10 columns is prepared in which sample codes are written. In the next step, a row and a column from the table of random numbers are randomly selected as the starting point. Then we start moving in the column or row direction. According to the sample number of 50 people, which is two digits, we select the first two digits of each code, and numbers smaller than the number of the population are selected as the code of the intervention group. This work continues until 50 people are selected as samples and then the remaining people are selected as members of 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 in Research Faculty of Pharmacy, Nursing and Midwifery, Shahid Beheshti University

Street address

Faculty of Nursing and Midwifery, Vali Asr Street, Intersection of Ayatollah Hashemi Rafsanjani Highway, Tehran

City

Tehran

Province

Tehran

Postal code

1996835119

Approval date

2023-08-01, 1402/05/10

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1402.071

Health conditions studied

1

Description of health condition studied

endometriosis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

female sexual function

Timepoint

Before starting the intervention

Method of measurement

female sexual performance questionnaire

2

Description

female sexual quality of life

Timepoint

Before starting the intervention

Method of measurement

Questionnaire of the quality of women's sexual life

Secondary outcomes

1

Description

female sexual function

Timepoint

One month and two months after the intervention

Method of measurement

female sexual function questioner

2

Description

female sexual quality of life

Timepoint

One month and two months after the intervention

Method of measurement

female sexual quality of life questioner

Intervention groups

1

Description

Intervention group: In 50 women with endometriosis under medical treatment in the intervention group, an educational application will be installed on the mobile phone and will be available to them for two months and they will be taught to watch the different educational parts of the program in the time order announced

Category

Treatment - Devices

2

Description

Control group: A pamphlet with the content of sex education is given to 50 women with endometriosis under medical treatment in the control group

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Private practice of endometriosis specialists

Full name of responsible person

Khadijah Shadjo

Street address

Unit 14, Plate 5, Veera Alley, Shariati St

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Phone

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

sepideh hajian

Street address

Faculty of Nursing and Midwifery, Vali Asr Street, Intersection of Ayatollah Hashemi Rafsanjani Highway, Tehran

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s-hajian@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person
mobina khorrami

Position
Master's degree student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
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Position
Master's degree student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All the information about the samples can be shared in the Excel file after de-identifying the people

When the data will become available and for how long
3 months after printing the results

To whom data/document is available
Access to study documents is free for the public

Under which criteria data/document could be used
The use of study documents is allowed in scientific studies by mentioning the main researcher

From where data/document is obtainable
Send request to email mobinaakhorrami1143@gmail.com

What processes are involved for a request to access data/document
The applicant should send his academic information, the place of use of the study documents, the title of his research or industrial work and the form containing the commitment to mention the main researcher of the documents in his research or industrial work to the email of the main researcher and after checking the eligibility of the information sent, the original researcher will provide them with the documents via email after a week

Comments