Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of education based on planned behavior Theory on the promotion of sexual & reproductive health of women with endometriosis

Protocol summary

Study aim

Determining the effect of education based on the theory of planned behavior on promoting reproductive and sexual health of women with endometriosis

Design

Two arm parallel group randomised trial on 76 patients with endometriosis. randomization will performed by quadruple block.

Settings and conduct

Eligible individuals in the infertility clinic of Imam Khomeini Hospital, according to the inclusion criteria, will enter the research. Then, the questionnaires will be completed by two groups. Educational content based on the theory of planned behavior, which has the structures of attitude, abstract norm and perceived control, which is taught in the form of lectures, questions and answers. The control group will receive routine care.

Participants/Inclusion and exclusion criteria

Inclusion criteria : 1- Women with endometriosis based on medical tests or medical diagnosis and clinical signs 2- Age between 15 to 45 years 3- Having the ability to read and write 4- No chronic psychiatric disorders (self-reported) 5- Ability to use the Internet and cyberspace Exclusion criteria: 1- Having genital or reproductive infections at the same time as endometriosis 2- single 3- Not being able to use cyberspace and smart phone

Intervention groups

The intervention group, in addition to get routine activities, 4 training sessions for 120-190 minutes per week for four weeks in the form of educational slides, educational posters, short educational videos compiled by the researcher and educational booklets in PDF format (PDF) Will be held. The control group will not receive any intervention

Main outcome variables

sexual & reproductive health

General information

Reason for update

Acronym

PBT

IRCT registration information

IRCT registration number: **IRCT20120414009463N64**
Registration date: **2021-06-21, 1400/03/31**
Registration timing: **retrospective**

Last update: **2021-06-21, 1400/03/31**
Update count: **0**

Registration date

2021-06-21, 1400/03/31

Registrant information

Name

Zahra Behboodi Moghadam

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6692 7171

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-19, 1399/10/30

Expected recruitment end date

2021-05-30, 1400/03/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of education based on planned behavior Theory on the promotion of sexual & reproductive health of women with endometriosis

Public title
The effect of education on promoting sexual health and fertility in women with endometriosis

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
1- Women with endometriosis based on medical tests or medical diagnosis and clinical signs 2- No history of participating in training or counseling classes 3- Having Iranian nationality 4- Age between 15 to 45 years 5- Having the ability to read and write 6- Non-addiction (based on patient file information available at the center) 7- Do not consume alcohol 8- No known chronic diseases 9- No chronic psychiatric disorders and known malignant diseases (self-reported) 10. Being married or living with a spouse 11- Ability to use the Internet and cyberspace if the intervention is done virtually

Exclusion criteria:
1-Having genital or reproductive infections at the same time as endometriosis 2- Having underlying diseases 3- single 4- Not being able to use cyberspace and smart phone

Age
From **15 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **76**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be performed by randomized block design of two treatments with quadruple blocks. The letter A is for the intervention group and the letter B is for the control group. Then we write all the permutation compounds, which are 6 different compounds, on 6 cards as follows: 1. AABB, 2. ABBA, 3. ABAB, 4. BAAB, 5. BABA, 6. BBAA, Then we will choose a digit from numbers 1 to 6 by drawing. For example, if the number 2 is selected, it means that the first person in the intervention group will be the next two people in the control group and the fourth person in the intervention 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 Tehran University of Medical Sciences

Street address
Gods Ave, Keshavaz Blvd, Tehran

City
Tehran

Province
Tehran

Postal code
۸۶۵۳۲۴۰۹۷۲

Approval date
2020-12-28, 1399/10/08

Ethics committee reference number
IR.TUMS.FNM.REC.1399.148

Health conditions studied

1

Description of health condition studied
endometriosis

ICD-10 code
N80

ICD-10 code description
Endometriosis

Primary outcomes

1

Description
sexual & reproductive health

Timepoint
Before the study, 4 weeks after the intervention, eight weeks after the intervention

Method of measurement
Endometriosis Reproductive Health Specific Questionnaire(ESHQ)

Secondary outcomes

empty

Intervention groups

1

Description
The present intervention is based on the model of the theory of planned behavior, which is a suitable theory for changing behavior. This model is defined based on the four elements of knowledge, attitude, mental norms and

perceived behavioral control, and in this study, educational content will be designed based on this element. Intervention group: In addition to routine actions, the intervention group will receive training sessions. These sessions are held online in person as much as possible and in severe cases of illness. 4 training sessions for 120-190 minutes per week will be performed for the participants for four weeks. The content of the sessions includes educational videos, posters, slides, Virtual and video conversations and online tests. Training activities based on this model for women with endometriosis in the structures of the model of the theory of planned behavior will be summarized as follows: first session: Educational content of this session includes: History of endometriosis in Iran and the world, latest global and national statistics Related to endometriosis will be the importance of endometriosis, the definition of endometriosis, the causes of endometriosis, age groups at risk, and ways to prevent endometriosis. At the end of the session, after summarizing the topic, their questions will be answered. Second session: The content of the training program of the second session including: the effect of endometriosis on vital body function, symptoms and clinical course of endometriosis, disease stages, diagnostic methods, referral time To the doctor and midwife before and after the diagnosis, what to do after the diagnosis of endometriosis, treatment of endometriosis, misconceptions about endometriosis and the importance of nutrition in patients. Third session: The content of the educational program of the third session includes: costs related to treatment and follow-up for communities, social, psychological and psychological damage to endometriosis, sexual health and its dimensions, reproductive health, fertility concerns, misconceptions about Pregnancy, the importance of improving sexual health, sexual function and reproductive health in patients, the importance of obtaining accurate information about endometriosis, using and transmitting this information to others to increase their awareness and knowledge to help improve sexual health And their fertility. fourth session: At the beginning of the fourth session, a review of the issues raised in the previous session will be done and the questions and ambiguities of the people will be answered. During this session, misconceptions about not being pregnant, positive and negative attitudes toward endometriosis, mental beliefs, knowledge and attitudes about the disease, motivation to follow influential people and mental norms will be examined in a group discussion. At the end, a summary of what has been taught during the previous sessions will be presented to the people and their questions will be answered.

Category

Behavior

2

Description

Control group: The control group does not receive any intervention and receives routine care by the clinic

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility Clinic of Imam Khomeini Hospital in Tehran

Full name of responsible person

Niyosh Zandi

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Tohid Squre, Imam Khomeini Hospital Complex

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Zahra Behboodi Moghadam

Position
Professor

Latest degree
Ph.D.

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Midwifery

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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
No - There is not 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
No - There is not 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