Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of education based on family centered empowerment model on social support and quality of life of women with endometriosis

Protocol summary

Study aim

Determining the effect of education based on family-centered empowerment model on social support and quality of life of women with endometriosis

Design

The clinical trial has a control group with parallel groups, randomized on 64 women with endometriosis. Sampling by the available method, randomization using the site.

Settings and conduct

This study is a randomized clinical trial with pre-test, post-test and control group. Sampling will be done using the available method from women with endometriosis referring to the women's clinic of Imam Reza (AS) Mashhad Hospital who meet the entry criteria. The intervention will be done only for the test group and according to the steps of the family-centered empowerment model

Participants/Inclusion and exclusion criteria

Age between 18-50 years, having at least basic literacy, patients who have endometriosis diagnosed by a gynecologist with the help of sonography and are candidates for medical treatment, the onset of endometriosis symptoms at least in the last 6 months, not taking antidepressants and sedatives in the last 3 months, and satisfaction The patient and his wife, no history of malignant diseases, no unpleasant events such as the death of relatives in the last three months, living with his wife.

Intervention groups

The intervention group is all women with confirmed endometriosis who will receive 5 training sessions and 1 final assessment session of 45-60 minutes based on the family-centered empowerment model during two weeks (one day in between) at the women's clinic by the researcher.

Main outcome variables

The main outcome of quality of life score, social support score, and family-centered empowerment model structures score in women with endometriosis before and 1.5 months after the intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220720055505N1**
Registration date: **2022-07-31, 1401/05/09**
Registration timing: **prospective**

Last update: **2022-07-31, 1401/05/09**
Update count: **0**

Registration date

2022-07-31, 1401/05/09

Registrant information

Name

Maryam Armaghan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3765 4407

Email address

armaghanm992@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of education based on family centered empowerment model on social support and quality of life of women with endometriosis

Public title
The effect of education based on family centered empowerment model on social support and quality of life of women with endometriosis
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18-50 years, having at least basic literacy patients who have endometriosis diagnosed by a gynecologist with the help of sonography and are candidates for medical treatment the onset of endometriosis symptoms at least in the last 6 months not taking antidepressants and sedatives in the last 3 months satisfaction the patient and her husband not history of malignant diseases no unpleasant events such as the death of relatives in the last three months living with his husband
Exclusion criteria:
The patient's unwillingness to participate in the research, the person's pregnancy, the malignant diseases, patients who are candidates for surgical treatment, patients with other chronic diseases, patients who do not have the conditions to participate in training sessions.
Age
From **18 years** old to **50 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, patients are randomly assigned to two control and intervention groups using the random permutation block method with blocks of size 4. For this purpose, 16 blocks that have 4, were randomly selected from the website https://www.sealedenvelope.com.
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 Mashhad University of Medical Sciences
Street address
No. 32, Yas 8, Ferdowsi 5, Ferdowsi Blvd
City
Mashhad
Province
Razavi Khorasan
Postal code
9197614661
Approval date
2022-07-05, 1401/04/14
Ethics committee reference number
IR.MUMS.NURSE.REC.1401.032

Health conditions studied

1

Description of health condition studied
Endometriosis
ICD-10 code
N80
ICD-10 code description
Endometriosis

Primary outcomes

1

Description
Quality of life score
Timepoint
At the beginning of the study and 1.5 months after the end of the intervention
Method of measurement
Specific endometriosis quality of life questionnaire(EHP30)

2

Description
Social support score
Timepoint
At the beginning of the study and 1.5 months after the end of the intervention
Method of measurement
Sherbon Stewart Social Support Questionnaire

3

Description
Questionnaire score of family-centered empowerment model structures
Timepoint
At the beginning of the study and 1.5 months after the

end of the intervention

Method of measurement

Questionnaire made by the researcher

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: People with endometriosis in the intervention group will receive 5 training sessions based on the family-centered empowerment model during two weeks (every other day) at the women's clinic by the researcher. Each session will be held for 45 to 60 minutes. The training sessions will be held in groups of 6-7 people. The intervention will be done only for the test group and it will last for eight weeks (2 weeks of training sessions and 6 weeks for practice sessions and then evaluation).The intervention is designed based on the structures of the family-centered empowerment model and includes: the first step (perceived threat): this step is conducted during two 60-minute sessions by the researcher and with the method of speech and group discussion for the patient, with the aim of increasing knowledge and understanding and in The result of understanding the threat by becoming aware of the nature and symptoms of endometriosis and important issues regarding nutrition, exercise and other effective factors in controlling the disease will be implemented in Imam Reza Hospital.The second step (self-efficacy): this stage will be carried out by means of group discussion and during 2 sessions of 60 minutes, in which people will use each other's experiences for better control of the disease, they will get to know the problems and the process of solving the problem, and their proposed solutions. will present and then the best solution will be chosen. Also, the ability to recognize drugs, dosage of drugs and their side effects will be discussed in group discussion and expression of experiences. The third step of self-belief and self-esteem is through educational participation. In this step, the researcher provides educational pamphlets to the patients and asks them to teach their wives what they have learned.And then, during a virtual session, the researcher completes the learned material for the spouses of the patients and solves the ambiguities. The researcher will follow up the implementation of the programs through phone calls. The fourth step (evaluation): includes the evaluation of the process, which is obtained during the intervention process and in each session by asking oral questions from learning the contents of the previous sessions, and then the final evaluation will be done 1.5 months after the intervention by completing the questionnaires again. became. During this 1.5 month, the researcher will follow the implementation of the program through phone calls

Category

Lifestyle

2

Description

Control group: Control group: The control group also receives only the usual measures of the endometriosis clinic. In terms of respecting the ethical issues of the research, the patients and their spouses in the control group will be given educational pamphlets.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Dr. Azam PourHOseini

Street address

Imam Reza (AS) Educational Research and Treatment Center, Imam Reza (AS) Hospital Square, Ibn Sina Street

City

Mashhad

Province

Razavi Khorasan

Postal code

۹۱۳۷۹۱۳۳۱۶

Phone

+98 51 3854 3031

Email

pourhoseinia@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr.Mohamad Ali Kiani

Street address

University St, Khorasan Razavi, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

13944-91388

Phone

+98 51 3841 2081

Email

presidentoffice@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Kobra Mirzakhani

Position

science Committee

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Faculty of Nursing and Midwifery, Ibn Sina Street, University Street, Doctor's Crossroad

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

0098 51 3-38591511

Email

MirzakhaniK@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Kobra Mirzakhani

Position

science Committee

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Faculty of Nursing and Midwifery, Ibn Sina Street,University Street, Doctor's Crossroad

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

0098 51 3-38591511

Email

MirzakhaniK@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Maryam Armaghan

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

No.32, Yas8, Ferdowsi 5, Blvd Ferdowsi

City

Mashhad

Province

Razavi Khorasan

Postal code

9197614661

Phone

009 51 37654407

Email

ArmaghanM992@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available