

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 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**

9137913316

##### **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