Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of group counseling based on Leventhal's self-regulation theory on the illness perception and quality of life of women with endometriosis.

Protocol summary

Study aim

Determining the effect of group counseling based on Leventhal's self-regulation theory on the illness Perception and quality of life of women with endometriosis.

Design

Clinical trial with control group, with parallel groups, randomized, on 64 patients. Random Allocation Software and block size of four were used for randomization.

Settings and conduct

The environment of this research: Clinic of Imam Reza Hospital in Mashhad. The research sample includes 64 women with endometriosis who will be randomly assigned to two counseling and control groups. The counseling group participates in 5 face-to-face group counseling sessions based on Leventhal's self-regulation model, while the control group does not receive counseling.

Participants/Inclusion and exclusion criteria

women of reproductive age 15-49 years old and married, not pregnant and not breastfeeding, diagnosed with endometriosis (symptoms, ultrasound, MRI, or surgery by gynecologist) ≥1 year prior, no history of receiving advice from another source, absence of psychiatric disorders through self-report and absence of systemic diseases such as diabetes, hypertension, polycystic ovary syndrome, systemic lupus erythematosus, irritable bowel syndrome and inflammatory bowel disease. Exclusion criteria: the participant's unwillingness to continue the study, participate in training sessions or counseling outside the scope of the study during the implementation of the study. Accidents during the study or the last 6 months.

Intervention groups

The intervention group: the group counseling group based on Leventhal's theory, and the control group will not receive the intervention during the study. the content of the sessions will be provided to the control group.

Main outcome variables

illness perception and quality of life.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260421069119N1**
Registration date: **2026-05-11, 1405/02/21**
Registration timing: **prospective**

Last update: **2026-05-11, 1405/02/21**
Update count: **0**

Registration date

2026-05-11, 1405/02/21

Registrant information

Name

Mahdiye Yaghoubi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5231 2232

Email address

yaghoubimh4022@mums.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-05-22, 1405/03/01

Expected recruitment end date

2026-11-22, 1405/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of group counseling based on Leventhal's self-regulation theory on the illness perception and quality of life of women with endometriosis.

Public title

The effect of group counseling on endometriosis.

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Women of reproductive age 15-49 years old and married non-pregnant and non-lactating diagnosed with endometriosis by a doctor based on symptoms, ultrasound, MRI, or surgery by a gynecologist one year past the onset of the disease No history of receiving advice from another source Absence of psychiatric disorder by self-report no addiction no systemic disease such as diabetes, hypertension, polycystic ovary syndrome, systemic lupus erythematosus, irritable bowel syndrome, and inflammatory bowel disease.

Exclusion criteria:

Participant's unwillingness to continue the study Participating in educational or counseling sessions outside of the study concept during the study period Accidents during the study or in the last 6 months

Age

From **15 years** old to **49 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, block randomization and sample selection method are available. Permutation blocks method was used to generate the sequence of random assignment of people to the studied groups. Random allocation sequence of people was done using Random Allocation Software and block size of four. The permutation block method is one of the random allocation methods in which each block is selected according to the number of studied groups. Sealed envelopes are used to hide the assignment. Based on the order of arrival of the research units, the envelopes will be opened in order and the assigned group will be revealed.

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

Shahid Dr. Kharazmi Educational Complex, University Campus, East Gate of Ferdowsi University of Mashhad, Azadi Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2025-12-23, 1404/10/02

Ethics committee reference number

IR.MUMS.NURSE.REC.1404.118

Health conditions studied

1

Description of health condition studied

endometriosis

ICD-10 code

(N80-N98)

ICD-10 code description

Endometriosis (with ICD-10 code: N80) is a non-inflammatory disorder of the female reproductive system characterized by the growth of tissue similar to the endometrium (inner lining of the uterus) outside the uterine cavity. These tissues are usually foun

Primary outcomes

1

Description

illness perception score in the Broadbent illness Perception Questionnaire

Timepoint

Measuring illness perception at the beginning of the study (before the start of the intervention) and one month and two months after the study

Method of measurement

Broadbent illness Perception Questionnaire

2

Description
Quality of life score in the WHO Quality Of Life -BREF (WHOQOL-BREF)
Timepoint
Measuring quality of life at the beginning of the study (before the start of the intervention) and one month and two months after the study
Method of measurement
WHOQOL-BREF

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:
Category
Rehabilitation

2

Description
Control group:
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Endometriosis Clinic, Imam Reza Hospital, Mashhad
Full name of responsible person
Dr. Mahboube Firoozi
Street address
Imam Reza Educational Research and Treatment Center, Imam Reza Hospital Square, Ibn Sina Street
City
Mashhad
Province
Razavi Khorasan
Postal code
۹۱۳۷۹۱۳۳۱۶
Phone
+98 51 3854 3031
Email
emamreza@mums.ac.ir
Web page address
https://emamreza.mums.ac.ir/

2

Recruitment center
Name of recruitment center
Dr. Azam Pourhosseini's office
Full name of responsible person
Dr. Azam Pourhosseini
Street address
1st floor, No. 35/1, 8 Mollasadra St. (7 Dadgar St.), Ahmad Abad St.
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Phone
+98 51 3800 2000
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. Mohsen Tafaghodi
Street address
University Research and Technology Vice-Chancellor, University of Medical Sciences, 3rd floor, next to Hoveizeh Cinema, University Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 1538
Email
TafaghodiM@mums.ac.ir
Web page address
https://v-research.mums.ac.ir/moavenat/2021-04-06-05-57-55
Grant name
Research executive grant
Grant code / Reference number
4040158
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
Dr Mahboube Firoozi

Position
assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

Street address
Shahid Dr. Kharazmi Educational Complex, University Campus, East Gate of Ferdowsi University of Mashhad, Azadi Square

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913199

Phone
+98 51 3884 6730

Fax

Email
firoozim@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr Mahboube Firoozi

Position
assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

Street address
Shahid Dr. Kharazmi Educational Complex, University Campus, East Gate of Ferdowsi University of Mashhad, Azadi Square

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913199

Phone
+98 51 3884 6730

Fax

Email
firoozim@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Mahdiye Yaghoubi

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Shahid Dr. Kharazmi Educational Complex, University Campus, East Gate of Ferdowsi University of Mashhad, Azadi Square

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913199

Phone
+98 51 3884 6730

Fax

Email
YaghoubiMH4022@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
Undecided - It is not yet known if there will be a plan to make this available

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