

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

The effect of self-care counseling on depression and anxiety in women with Endometriosis: a randomized controlled trial.

Protocol summary

Study aim

To determine the Effect of self-care counseling on depression and anxiety in women with Endometriosis.

Design

Randomized controlled Clinical Trial

Settings and conduct

The study will be conducted in Alzahra Medical Educational center of Tabriz city on 76 of 15-45 years old women who have Endometriosis diagnosed with laparoscopy and treated in the last 1-3 years. Women who meet the study criteria will be selected using convenience sampling method and if they would like to participating in the study, informed consent will be obtained. Then, the social and demographic characteristics questionnaire, Beck Depression questionnaire, The Splineberger State-Trait Anxiety questionnaire, and the quality of life scale will be completed by the researcher through interview. The participants will be divided into intervention and control groups by a person who is not involved in the sampling using randomized block design according to their history of infertility with a ratio of 1:1 and a block size of 4 and 6.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Detected Endometriosis with laparoscopy in the last 1-3 years Being in reproductive age 15-45 year. Exclusion Criteria: Presence of any conditions that increase the risk of anxiety and depression. Having high depression and very severe anxiety score.

Intervention groups

For the intervention group self-care group counselling will be conducted at seven sessions of 60-90 min with one week interval. The controls will receive only the routine care.

Main outcome variables

The main outcome is depression and anxiety, which will be measured before the intervention, and 4 weeks after intervention, using the Beck depression Inventory and

the Splineberger State-Trait Anxiety Inventory.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111219008459N13**

Registration date: **2019-02-10, 1397/11/21**

Registration timing: **prospective**

Last update: **2019-02-10, 1397/11/21**

Update count: **0**

Registration date

2019-02-10, 1397/11/21

Registrant information

Name

Shirin Hasanpoor

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 41 1479 6770

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-05-20, 1398/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of self-care counseling on depression and anxiety in women with Endometriosis: a randomized controlled trial.

Public title

The effect of counseling on depression and anxiety in women with Endometriosis

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Residence in Tabriz city Having at least guidance literacy
Detected Endometriosis with laparoscopy in the last 1-3
years Being in reproductive age 15-45 year Having a
home and mobile phone number

Exclusion criteria:

Presence of any conditions that increase the risk of
anxiety and depression such as Irritable Bowel Syndrome
Use of anti-anxiety and antidepressant drugs over the
past 3 months Self-reported malignant diseases Having
high depression and very severe anxiety score Recent
disastrous events such as death of relatives or divorce
that disrupts the mental health of individual Speech and
hearing impairments that prevent communication with
researcher The self-reported history or having
psychological problems or history of hospitalization in
mental health hospitals

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: **38**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants are divided into intervention and control
groups using randomized block design according to their
history of infertility with ratio 1:1 and a block size of 4
and 6 by a person not involved in the sampling. In order
to allocation concealment, the type of intervention will
be written on paper and placed in numbered, matte and
packed envelopes. The envelopes will be opened in the
order of participation of the participants and the type of
group will be determined.

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 Tabriz University of Medical
Sciences

Street address

Research department, third floor, central construction
number 2, Tabriz University of Medical Sciences,
Golgash Street, Azadi Avenue, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5168743953

Approval date

2019-01-20, 1397/10/30

Ethics committee reference number

1397.788

Health conditions studied**1****Description of health condition studied**

Depression

ICD-10 code

F32.0

ICD-10 code description

Major depressive disorder, single episode, mild

2**Description of health condition studied**

Anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes**1****Description**

Depression

Timepoint

Before the intervention and four weeks after the
intervention

Method of measurement

Beck Depression Inventory

2**Description**

Anxiety
Timepoint
Before the intervention and four weeks after the intervention
Method of measurement
Spilnberger State-Trait Anxiety Inventory

Secondary outcomes

1
Description
Quality of life
Timepoint
Before the intervention and four weeks after the intervention
Method of measurement
The 36 items Quality of Life questionnaire.

Intervention groups

1
Description
For the intervention group (n=38) self-care group counselling will be conducted at seven sessions of 60-90 min, with one week interval by researcher.
Category
Other

2
Description
The control group (n=38) will receive the routine care.
Category
Other

Recruitment centers

1
Recruitment center
Name of recruitment center
Alzahra Medical Educational Center
Full name of responsible person
Nooshin Farshi
Street address
Baghshomal crossroad, South Artesh Street, Tabriz
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Sponsors / Funding sources

1
Sponsor
Name of organization / entity
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Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz
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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
Tabriz 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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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 further 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