Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effectiveness of Cognitive Behaviour Therapy on the quality of life and mental fatigue in women with Polycystic Ovarian Syndrome: a randomized controlled clinical trial

Protocol summary

Summary

Objectives: To determine the effect of cognitive behavioral therapy on quality of life and mental fatigue in women with polycystic-ovarian syndrome. Design: Two-armed randomized controlled trial. Conduct: This study will be conducted on 74 women referring to Saqqez gynecology clinic of Imam Khomeini Hospital and private clinics of gynecology. Eligible individuals will be assessed according to the rotterdam criteria and if they have criteria, they will be referred to the research collaborator for final approval. After final diagnosis and person's willingness to participate in the study, baseline evaluations will be conducted. Participants will be randomly assigned to two groups of intervention (receiving cognitive behavior therapy) and control using block randomization with block sizes of 4 and 6 the allocation ratio of 1:1. Participants: Women ages 18-35 years old affected by polycystic ovarian syndrome. Intervention: The intervention group will receive educational counseling according to Cognitive Behavior Therapy (CBT) approach in seven sessions, one session per week for seven sequential weeks. The main outcome variables include quality of life and mental fatigue and the secondary outcome variables include depression and body mass index that will be assessed before and four weeks after the end of intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016111410324N35**
Registration date: **2017-02-02, 1395/11/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-02-02, 1395/11/14

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of Cognitive Behaviour Therapy on the quality of life and mental fatigue in women with Polycystic Ovarian Syndrome: a randomized controlled clinical trial

Public title

The effectiveness of Cognitive Behaviour Therapy on the

quality of life and mental fatigue in women with Polycystic Ovarian Syndrome

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Women ages between 18 to 35 years old; Having at least secondary education; Willingness to participate in the study; Having a contact number for follow-up. Exclusion criteria: Changing of the residential location to another city in the next few months; Uncertainty of being able to participate in counseling sessions; Having cardiovascular diseases, hypertension and liver diseases; Having severe depression (according to Beck questionnaire); Taking of psychiatric or psychotropic drugs; Occurrence of unpleasant events in the last 3 months.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

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 Univercity of Medical Sciences

Street address

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

City

Tabriz

Postal code

Approval date

2017-01-23, 1395/11/04

Ethics committee reference number

IR.TBZMED.REC.1395.1103

Health conditions studied

1

Description of health condition studied

polycystic ovary syndrome

ICD-10 code

E28.2

ICD-10 code description

polycystic ovary syndrome

Primary outcomes

1

Description

Quality of life

Timepoint

Before intervention and 4 weeks after the end of intervention

Method of measurement

Quality-of-life questionnaire (PCOSQ) for women with polycystic ovary syndrome

2

Description

Mental fatigue

Timepoint

Before intervention and 4 weeks after the end of intervention

Method of measurement

Fatigue Impact Scale (FIS)

Secondary outcomes

1

Description

Depression

Timepoint

Before intervention and 4 weeks after the end of intervention

Method of measurement

Beck Depression Inventory (BDI)

2

Description

Body Mass Index

Timepoint

Before intervention and 4 weeks after the end of intervention

Method of measurement

Balance and meter

Intervention groups

1

Description

The intervention group will receive educational

counseling according to Cognitive Behavior Therapy (CBT) approach in seven sessions, one session per week for seven sequential weeks.

Category

Behavior

2

Description

The control will receive no intervention. If the results of research show the positive effect of counseling, the content of counseling as booklet will be provided for control group at the end of study.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Gynecology clinic of Imam Khomeini Hospital

Full name of responsible person

Leila Abdollahi

Street address

Imam Khomeini Hospital, Saqqez city

City

Saqqez

2

Recruitment center

Name of recruitment center

Private clinics of gynecologists

Full name of responsible person

Liela Abdollahi

Street address

Private clinics of gynecologists, Saqqez city

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Reza Rashidi

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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

Vice chancellor for research, Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Leila Abdollahi

Position

MSc Student of conseling in Midwifery

Other areas of specialty/work

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty