

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

The Effect of Cognitive-Behavioral Therapy on Stress and Anxiety of Women with Premature Ovarian Insufficiency: A Randomized Controlled Trial

Protocol summary

Study aim

To determine the effect of cognitive-behavioral counseling on stress and anxiety in women with premature ovarian failure

Design

Randomized controlled trial with two parallel arms

Settings and conduct

This study will be performed in Al-Zahra educational and therapeutic center in Tabriz on 48 women with confirmed premature ovarian failure. In the study, informed written consent will be obtained and initial evaluations will be performed. Participants will be assigned to the intervention and control groups using a block randomization method with block sizes of 4 and 6 and with a 1:1 allocation ratio.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women under 40 years with confirmed premature ovarian failure based on the information recorded in the patient file, Anxiety score 35-65 in Spielberger Anxiety Questionnaire and score above 21.8 in the perceived stress questionnaire, Verbal and auditory ability. Exclusion criteria: History of mental illness according to the patient declaration, History of participating in training sessions related to premature menopause, Mental and motor disability

Intervention groups

For the intervention group, 8 counseling sessions of 45-60 minutes with cognitive-behavioral approach once a week will be held. The control group will receive routine care.

Main outcome variables

Mean scores of anxiety and stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120718010324N64**

Registration date: **2021-02-14, 1399/11/26**

Registration timing: **prospective**

Last update: **2021-02-14, 1399/11/26**

Update count: **0**

Registration date

2021-02-14, 1399/11/26

Registrant information

Name

Mojgan Mirghafourvand

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1479 6969

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-17, 1399/11/29

Expected recruitment end date

2021-05-19, 1400/02/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Cognitive-Behavioral Therapy on Stress and

Anxiety of Women with Premature Ovarian Insufficiency:
A Randomized Controlled Trial

Public title

The Effect of Cognitive-Behavioral Therapy on Stress and Anxiety

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age under 40 years Confirmation of premature ovarian failure with necessary tests Moderate Anxiety Based on Spielberger Index Moderate stress based on perceived stress index Listening and speaking ability

Exclusion criteria:

History of a specific mental illness Previous participation in sessions related to premature menopause Mental and motor disability

Age

From **15 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be assigned to the two groups including Intervention group (Recipient of cognitive-behavioral counseling) and control group by the block randomization method with block sizes of 4 and 6 and with a 1: 1 allocation ratio. In order to hide the allocation (Allocation Concealment), the type of intervention is written on paper and sealed in opaque envelopes. The envelopes will be opened based on the order of the participants entering to the study and the type of group will be determined. Random allocation and preparation of envelopes will be done by a person not involved in sampling and data collection.

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

Reaserch department, third floor, headquarters number 2, Tabriz University of Medical Sciences, Golgasht street, Azadi avenue

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Approval date

2021-01-23, 1399/11/04

Ethics committee reference number

IR.TBZMED.REC.1399.964

Health conditions studied

1

Description of health condition studied

Stress

ICD-10 code

Z73.3

ICD-10 code description

Stress, not elsewhere classified

2

Description of health condition studied

Anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes

1

Description

Stress

Timepoint

Before and after intervention

Method of measurement

Perceived stress questionnaire

2

Description

Anxiety

Timepoint

Before and after intervention

Method of measurement

Spielberger Anxiety Inventory

Secondary outcomes

1

Description

Depression
Timepoint
Before and after intervention
Method of measurement
Beck Depression Inventory

2

Description
Self-esteem
Timepoint
Before and after intervention
Method of measurement
Rosenberg Self-Esteem Questionnaire

Intervention groups

1

Description
Intervention group: 8 sessions of counseling with cognitive-behavioral approach will be held for 45-60 minutes once a week in a calm environment and in groups (5 to 7 people in each group). The content of these sessions includes initial psychological assessment, reorganization of concepts, use of clinical skills, strengthening skills and how to use them, generalization and maintenance, follow-up and evaluation after intervention.

Category
Behavior

2

Description
Control group: Participants in the control group will receive routine care.

Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra educational and medical center
Full name of responsible person
Fatemeh Shabani
Street address
Nursing and Midwifery faculty, South Shariati street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Samiei
Street address
Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz
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iro@tbzmed.ac.ir
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
Tabriz University of Medical Sciences
Full name of responsible person
Fatemeh Shabani
Position
MSc student of Counseling in Midwifery
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mojgan Mirghafourvand

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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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

Participant data is confidential.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available