Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
mirghafourvandm@tbzmed.ac.ir

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
City
Tabriz
Province
East Azarbaijan
Postal code
5138947977
Phone
+98 41 3479 6969
Email
fatemehshabani7697@gmail.com

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
City
Tabriz
Province
East Azarbaijan
Postal code
5138947979
Phone
+98 41 3479 6969
Email
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
Street address
Faculty of Nursing & Midwifery, South Shariati Street
City
Tabriz
Province
East Azarbaijan
Postal code

5138947979
Phone
+98 41 3177 2048
Email
fatemehshabani7697@gmail.com

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
Street address
Faculty of Nursing & Midwifery, South Shariati Street
City
Tabriz
Province
East Azarbaijan
Postal code
5138947979
Phone
+98 41 3177 2048
Email
mirghafourvandm@tbzmed.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mojgan Mirghafourvand
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Faculty of Nursing & Midwifery, South Shariati Street
City
Tabriz
Province
East Azarbaijan
Postal code
5138947979
Phone
+98 41 3177 2048
Email
mirghafourvandm@tbzmed.ac.ir

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