Clinical Trial Protocol
Iranian Registry of Clinical Trials
25 Oct 2022

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
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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
Research 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

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### Self-esteem

**Timepoint**
Before and after intervention

**Method of measurement**
Rosenberg Self-Esteem Questionnaire

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### 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

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### 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
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   **Full name of responsible person**
   Dr. Mohammad Samiei

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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
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**
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Tabriz

**Province**
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**Postal code**
Person responsible for scientific inquiries

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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