

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Dec 2023

### The effect of cognitive-behavioral counseling on depression and anxiety in women with polycystic ovary syndrome: a randomized controlled trial

#### Protocol summary

##### Study aim

Determining the effect of cognitive-behavioral counseling on depression and anxiety in women with polycystic ovaries

##### Design

A randomized controlled clinical trial with two parallel arms. The final sample size was 42 people in each group

##### Settings and conduct

This study will be performed on 42 women with approved polycystic ovary syndrome in Al-Zahra Educational and Medical Centers in Tabriz. Participants will be assigned to the intervention and control groups using a random blocking method with the size of 4 and 6 blocks with a 1:1 allocation ratio.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Minimum secondary education, 2- Diagnosis of polycystic ovary syndrome by a gynecologist and having a medical record due to polycystic ovary syndrome Exclusion criteria: 1- Having a history of mental illness according to the person 2 Having a history of chronic physical illnesses (heart disease, hypertension, lung disease, iron deficiency anemia, diabetes, thyroid disease, epilepsy) according to the person's experience 3- Experiencing a severe mental crisis during the last 3 months Such as the death of relatives according to the self-declaration 4- Pregnant and childbirth women 5- Women with severe depression

##### Intervention groups

For the intervention group, group counseling with a cognitive-behavioral approach will be held in 8 sessions of 45 to 60 minutes, once a week. An educational booklet is provided for the control group.

##### Main outcome variables

Average score of anxiety and depression Average score of anxiety and depression

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20110826007418N7**  
Registration date: **2021-10-25, 1400/08/03**  
Registration timing: **registered\_while\_recruiting**

Last update: **2021-10-25, 1400/08/03**

Update count: **0**

##### Registration date

2021-10-25, 1400/08/03

##### Registrant information

##### Name

Parisa Yavarikia

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1479 6770

##### Email address

yavarikiap@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-07-11, 1400/04/20

##### Expected recruitment end date

2021-11-11, 1400/08/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of cognitive-behavioral counseling on depression and anxiety in women with polycystic ovary

syndrome: a randomized controlled trial

### Public title

The effect of cognitive-behavioral counseling on depression and anxiety in women with polycystic ovary syndrome

### Purpose

Education/Guidance

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Women with polycystic ovary syndrome, based on information recorded in the patient's file A score of 35-65 in the Spielberger Anxiety Questionnaire and a score above 20 in depression Minimum secondary education

#### Exclusion criteria:

Having a history of mental illness according to the individual Having a history of chronic physical diseases (heart disease, hypertension, lung diseases, iron deficiency anemia, diabetes, thyroid diseases, epilepsy) according to the individual According to the individual Experiencing a severe psychological crisis during the last 3 months, such as the death of relatives Pregnant and postpartum women Women with severe depression

### Age

No age limit

### Gender

Female

### Phase

N/A

### Groups that have been masked

No information

### Sample size

Target sample size: 84

### Randomization (investigator's opinion)

Randomized

### Randomization description

Participants will be assigned to two intervention groups (receiving cognitive-behavioral counseling) and the control group by random blocking method with 4 and 6 block sizes and 1: 1 allocation ratio. To hide the type of intervention, it will be written on a piece of paper and numbered in a matte envelope. The envelopes will be opened in the order in which the participants enter 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

### 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

South Shariati St. - School of Nursing and Midwifery, Tabriz

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

5138947977

### Approval date

2021-06-09, 1400/03/19

### Ethics committee reference number

IR.TBZMED.REC.1400.229

## Health conditions studied

## 1

### Description of health condition studied

Anxiety in women with polycystic ovary syndrome

### ICD-10 code

F41.9

### ICD-10 code description

Anxiety disorder, unspecified

## 2

### Description of health condition studied

Depression in women with polycystic ovary syndrome

### ICD-10 code

F32

### ICD-10 code description

Major depressive disorder, single episode

## Primary outcomes

## 1

### Description

Depression

### Timepoint

Before and after the intervention

### Method of measurement

Beck Depression Inventory

## 2

### Description

Anxiety

### Timepoint

Before and after the intervention

### Method of measurement

Spielberger Anxiety Inventory

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

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

Sheida Majidzadeh

##### Street address

South Shariati St., School of Nursing and Midwifery

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

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##### Phone

+98 41 3479 6969

##### Email

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### 2

#### Recruitment center

##### Name of recruitment center

Comprehensive Health Centers of Tabriz

##### Full name of responsible person

Seida Majidzadeh

##### Street address

South Shariati St., School of Nursing and Midwifery

##### City

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##### Province

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##### Postal code

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### 3

#### Recruitment center

##### Name of recruitment center

Private Offices in Tabriz

##### Full name of responsible person

Seida Majidzadeh

##### Street address

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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

Golgasht St., Tabriz University of Medical Sciences, Central Building No. 2, Research Deputy

##### City

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##### Email

iro@tbzmed.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

No

#### 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**  
Parisa Yavari Kia  
**Position**  
Master  
**Latest degree**  
Master  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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Tabriz University of Medical Sciences  
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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