

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)

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+98 41 1479 6770

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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

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2

Recruitment center

Name of recruitment center

Comprehensive Health Centers of Tabriz

Full name of responsible person

Seida Majidzadeh

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Recruitment center

Name of recruitment center

Private Offices in Tabriz

Full name of responsible person

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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

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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
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Midwifery
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Person responsible for updating data

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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