Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The comparison of hypnotherapy and routine care on the resilience of women with polycystic ovary syndrome

Protocol summary

Study aim
Determining of the effect of hypnotherapy on resilience of patients with polycystic ovary syndrome (PCOS)

Design
In this clinical trial with a control group and parallel design, blindness will be done at the level of assessor and statistician. Random allocation will be done on 56 patients in two groups. The blocking process will be done. The samples will be placed in 28 blocks of 2 persons.

Settings and conduct
The research setting is midwifery and gynecology offices and health centers in Tehran. At first, patients with PCOS will be admitted to the study according to the researchers inclusion checklist with the initial diagnosis of PCOS based on Rotterdam criteria and definitive diagnosis by a gynecologist and based on the purpose of the study. After obtaining informed written consent, the questionnaires will be completed by the participants in the presence of the researcher. After that, patients in both groups will be visited and treated by a gynecologist to receive standard treatments for women with PCOS (including a combined OCP, spironolactone and metformin). In the intervention group, in addition to the above treatment, hypnotherapy will be performed.

Participants/Inclusion and exclusion criteria
Single or married women aged 18 to 45 with PCOS who can read and write Persian and are not suffering from other endocrine diseases.

Intervention groups
Six sessions of hypnotherapy will be done in the intervention group. Routine care will done in control care.

Main outcome variables
The primary outcome includes resilience and the secondary outcomes include quality of life and anxiety and depression.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20161126031117N12**
Registration date: **2022-05-04, 1401/02/14**
Registration timing: **registered_while_recruiting**

Last update: **2022-05-04, 1401/02/14**
Update count: **0**

Registration date
2022-05-04, 1401/02/14

Registrant information

Name
Soghra Khani

Name of organization / entity
Mazandaran University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-03-25, 1401/01/05

Expected recruitment end date
2022-05-22, 1401/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The comparison of hypnotherapy and routine care on the resilience of women with polycystic ovary syndrome

Public title
Evaluation of the effectiveness of hypnotherapy on polycystic ovary syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
single or married women with confirmed polycystic ovarian syndrome according to Rotterdam criteria Have come to visit for the first time because of this disease being able to read and write or speak in Persian have Iranian nationality being satisfied to participate in the research

Exclusion criteria:
Occurrence of any kind of acute complication affecting the quality of life and resilience during the intervention, such as the death of important people in a person's life. being suffering from other endocrine diseases or any other chronic diseases which affect patient`s quality of life such as Chronic debilitating liver and kidney disease being psychotic and having serious thoughts of harm to oneself and others (recognized by a psychiatrist) being Infertile and undergoing assisted reproductive therapy history of seizures using psychotropic drugs and any kind of drug abuse participating in similar training sessions

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **56**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, random blocking method will be used for random allocation of samples in the intervention and control groups, based on marital status (single and married) and BMI (<20, 20-25 and> 25). For this purpose, double blocks will be considered. The two possible blocks are TC and CT, that T stands for the intervention group and C stands for the control group. Numbers will be generated randomly (with the RANDBETWEEN command in Excel software and in ranges 1 and 2) and according to the production values of one of the blocks (for production number 1 CT block, for production number 2 TC blocks) will be selected and samples will be allocated. For example, two married people with a body mass index of 20-25 have been referred, one to be included in the intervention group and the other one in the control group. In Excel software, between number one and two, assuming the number two is selected randomly. Therefore, these two people are assigned to the TC block. Accordingly, these two people are assigned to refer to this block in order. In fact, the first person enters the intervention group and the second person enters the control group. Now, if the number one is chosen, these two people will be assigned to the CT block.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Blinding will be done at the assessor level. In this way, after finishing the work, The colleague hands over the questionnaires to the samples and after completing the questionnaire by them, a box will be placed there and the samples will insert the completed questionnaire in the box and groups are named A and B. The statistical analyst is also blinded and at the end of the analysis, the coded groups are identified.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mazandaran University of Medical Sciences

Street address
Moalem square, Moalem street

City
sari

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Mazandaran

Postal code
4816715793

Approval date
2022-04-13, 1401/01/24

Ethics committee reference number
IR.MAZUMS.REC.1401.024

Health conditions studied

1

Description of health condition studied
polycystic ovarian syndrome

ICD-10 code
E28.2

ICD-10 code description
Polycystic ovarian syndrome

Primary outcomes

1

Description

resilience

Timepoint

before intervention, 6 weeks after starting the intervention, 4 weeks after ending the intervention.

Method of measurement

Connor-Davidson Resilience Scale

Secondary outcomes

1

Description

quality of life

Timepoint

before intervention, 6 weeks after starting the intervention, 4 weeks after ending the intervention.

Method of measurement

PCOS Health-Related Quality of Life Questionnaire

2

Description

anxiety and depression

Timepoint

before intervention, 6 weeks after starting the intervention, 4 weeks after ending the intervention.

Method of measurement

Hospital Anxiety and Depression Scale

Intervention groups

1

Description

Intervention group: In the intervention group, hypnotherapy is performed by a trained researcher who is trained in the Iranian Association of Clinical Hypnosis and has a valid certificate. For each subject in the intervention group, 6 weekly sessions of hypnotherapy will be held for 40 to 60 minutes. 1. During the first session, the biography, a full explanation of how to do the work and educating and preparing the patient, eliminating the misunderstanding of hypnosis and completing the questionnaire will be done. Patients are also asked to describe a place in the real world that gives them a sense of safety and comfort. 2. In the second session, induction and deepening and direct instincts to increase relaxation and conditioning for rapid hypnosis will be done. 3.In the third session, the ego will be strengthened to increase self-esteem and increase the endurance and resilience of life issues by the individual. 4.During the fourth session, age regression and dealing with negative emotions and then increasing calmness will be done. 6.In the sixth session, the previous sessions will be reviewed and then the mental experience of ideal body image and focusing on increasing relaxation in the whole body and mind will be done. Then the questionnaires are completed again.

Category

Treatment - Other

2

Description

Control group: For the control group routine care will be done (Routine care means receiving standard treatments by a gynecologist and balanced physical activity and diet). Questionnaires will be completed simultaneously with the intervention group at all stages.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

health centers, gynecologist and obstetrician and midwifery offices

Full name of responsible person

Dr. Soghra Khani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Mahtab Hajimohammadreza

Position

Master's student

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Research-related information is shared with the aim of keeping individuals' names and identities confidential and adhering to the 31 Code of Ethics.

When the data will become available and for how long

from 2023

To whom data/document is available

All researchers and research enthusiasts

Under which criteria data/document could be used

For reviewing and supplementary research and in order to use by therapists of polycystic ovarian syndrome

From where data/document is obtainable

To access data and documents, you can contact to the responsible author whose e-mail is:

khanisog343@gmail.com and the e-mail of the midwifery student which is mw.mahtabhmr@gmail.com. If the article is published, you can refer to it according to the address of the magazine.

What processes are involved for a request to access data/document

they should first send an email to the author of the article and submit their request, and if the author and the research team deem it appropriate, the documents and files will be provided in a short time.

Comments