

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Effectiveness Comparison of Body- Mind Intervention in Virtual and Face to Face Method on Quality of Life in Polycystic Ovary Syndrome

Protocol summary

Study aim

Determining and Comparing the Effectiveness of Mind-Body Intervention in Two Virtual-in-person Methods on Quality of Life in Women with Polycystic Ovary Syndrome

Design

Clinical trial of control group, with randomized double-blind randomized parallel groups on 60 patients. Use of random number table for randomization

Settings and conduct

After obtaining informed consent from women undergoing polycystic ovary syndrome, they were then randomly assigned to two groups of virtual mind-body intervention (n = 30) and control group (n = 30). The two groups of 15 people are divided. The intervention group received 8 sessions of 2-hour counseling with physical therapy approach. Also, fasting blood glucose was measured in the laboratory of the Diabetes Polyclinic twice for the beginning of the study and at the end of week 8 in both groups for free. Yazd Diabetes Clinic Study Place

Participants/Inclusion and exclusion criteria

Married women of childbearing age, Iranian, literate, for both intervention groups, virtual and mobile, and Internet or iPhone Operating System (ios) for both groups, Polycystic Ovary Syndrome based on Rotterdam criteria and treated Being in a diabetes clinic. Willingness to have a fasting blood sugar test before the study and after the end of week 8. Exclusion: Participation in another study, self-reported history of other chronic mental and physical illnesses, use of other medications

Intervention groups

Intervention group: Virtual physical counseling group.
Control group: Physical Mental Counseling (8 sessions of two-hour physical counseling) before and after the eighth and twelfth week of quality of life in women with polycystic ovary syndrome

Main outcome variables

Quality of Life, Satisfaction with the virtual and face-to-face counseling method, Fasting blood sugar

General information

Reason for update

Restriction of words and failure to include a blood sugar test

Acronym

IRCT registration information

IRCT registration number: **IRCT20190916044783N1**

Registration date: **2020-04-19, 1399/01/31**

Registration timing: **prospective**

Last update: **2021-01-03, 1399/10/14**

Update count: **1**

Registration date

2020-04-19, 1399/01/31

Registrant information

Name

maryam javanbakht

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 5748 8268

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m.javanbakht@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2019-12-24, 1398/10/03

Actual recruitment start date

2020-04-27, 1399/02/08

Actual recruitment end date

2020-06-23, 1399/04/03

Trial completion date

2020-09-23, 1399/07/02

Scientific title

Effectiveness Comparison of Body- Mind Intervention in Virtual and Face to Face Method on Quality of Life in Polycystic Ovary Syndrome

Public title

Effectiveness of Body- Mind Intervention in Virtual and Face to Face Method on Quality of Life in Polycystic Ovary Syndrome

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Married women of childbearing age Iranian ethnicity Literacy for reading and writing Internet literacy and android or i o s mobile phone for both group Having a pco case based on Rotterdam criteria and being treated at a diabetes clinic Having a tendency to do FBS test before study and after 8 week Willingness to participate in the study

Exclusion criteria:

pregnancy

Age

From **15 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Using computer random number table The researcher will begin to provide you with a framework for your statistical community, and you can guide yourself to 60 people who are known and invited as an official source. The researcher used to schedule tables for the visible sample of his eyes in the form of tables and fingers or the tip of a pen. Move between different levels or columns using this and employers to request funding. The selected number is actually the personality code of the budget community that is chosen by the sample. Each code, for example, was assigned to members of a virtual counseling group or face-to-face counseling so that you could arrange your samples in each group of 30 people. The final samples were called to a specific location, the purpose and method of work, and the right to freely participate or not to participate in the research were explained to them. Samples that did not wish to attend the sessions were excluded from the study. Then the required number of samples (30 people for each group) was selected. We again divided the members of each group by throwing coins into two groups of fifteen (B and A) so that if the milk procedure was visible, it belonged to group A, and if the line procedure appeared, it would belong to group B.

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 Yazd University of Medical Sciences

Street address

Negin complex, Shahid Ghandi Ave

City

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Province

Yazd

Postal code

8915878818

Approval date

2019-04-24, 1398/02/04

Ethics committee reference number

IR.SSU.REC.1398.004

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**

Quality of Life in Patients with Polycystic Ovary Syndrome

Timepoint

Evaluation of quality of life in patients with polycystic ovary syndrome before study and after 8 and 12 weeks

Method of measurement

Iranian Amini et al. Quality of Life Questionnaire

Secondary outcomes**1****Description**

Fasting blood sugar

Timepoint
At the beginning of the study and after the end of week 8

Method of measurement
Glucometer device

Intervention groups

1

Description

Intervention group:virtual counseling of body-mind intervention on quality of life in polycystic ovary syndrome . For the virtual consulting team after forming a channel in the WhatsApp Virtual Network Software (Consultation protocol over 8 sessions of 2-hour counseling with mind-body-based therapeutic approach and techniques of this method include mindfulness, meditation, breathing techniques, creative visualization and exposure.) Is done. This study is performed as pre-test, post-test (week 8 and week 12 after intervention). At the beginning of the study, women completed eight weeks, twelve weeks in addition to demographic questions, a questionnaire of Iranian quality of life, as well as acceptance and satisfaction of a counseling approach and method of self-reporting. Reminds people via SMS.Also, fasting blood sugar measurement in the laboratory of Diabetes Polyclinic is measured twice at the beginning of the study and at the end of week 8 in both groups for free.

Category

N/A

2

Description

control group:face to face counseling of body-mind intervention on quality of life in polycystic ovary syndrome . In-person group sessions (eight two-hour sessions) In-person counseling is provided for two groups of 15 in the Yazd Diabetes Clinic due to lack of facilities and space. This study is a pre-test, post-test(Consultation protocol over 8 sessions of 2-hour counseling with mind-body-based therapeutic approach and techniques of this method include mindfulness, meditation, breathing techniques, creative visualization and exposure.). Thus, women completed in-person counseling at the beginning of the study, completion of week 8, completion of twelve weeks in addition to demographic questions, Iranian quality of life questionnaire, and acceptance and satisfaction of the counseling approach and method of self-reporting and homework assignments. People were reminded daily via SMS.Also, fasting blood sugar measurement in the laboratory of Diabetes Polyclinic is measured twice at the beginning of the study and at the end of week 8 in both groups for free.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Diabetes Polyclinic

Full name of responsible person

Dr,M. Rahmanian

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Bahonar Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Yazd University of Medical Sciences

Full name of responsible person

Dr. Massoud Mirzaei

Street address

Shahid Sadoughi University of Medical Sciences, Yazd Bahonar Square,Yazd, Iran.

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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

Vice chancellor for research, Yazd University of Medical Sciences

Proportion provided by this source

60

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

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Person responsible for general inquiries**Contact****Name of organization / entity**

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Postal code**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable