Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

Phone
+98 31 5748 8268

Email address
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
Yazd

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 Ḍiabetes Polyclinic

Full name of responsible person

Dr,M. Rahmanian

Street address

Bahonar Ave

City

Yazd

Province

Yazd

Postal code

8915878818

Phone

+98 35 3728 0226

Email

Ghadiriam@yahoo.com

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.

City

Yazd

Province

Yazd

Postal code

8915173143

Phone

+98 35 3726 3733

Email

info@ssu.ac.ir

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

Person responsible for general inquiries

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr.Tahmineh Farajkhoda
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Boali ave
City
Yazd
Province
Yazd
Postal code
8915878818
Phone
+98 35 3725 8770
Email
Farajkhoda_t@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr.Tahmineh Farajkhoda
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Boali Ave
City
Yazd
Province
Yazd
Postal code
8915878818
Phone
+98 35 3725 8770
Email
Farajkhoda_t@Yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr.Tahmineh Farajkhoda
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Boali Ave
City
Yazd
Province
Yazd
Postal code
8915878818
Phone
+98 35 3725 8770
Email
farajkhoda_t@yahoo.com

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