

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Comparison between the effect of counseling based on Rational-Emotive-Behaviour Theory (REBT) and Mindfulness-Based Art therapy (MBAT) on the body image of women with polycystic ovary syndrome (PCOS)

Protocol summary

Study aim

Determining the effect of counseling based on Rational-Emotive-Behaviour Theory with Mindfulness-Based Art therapy on the body image of women with polycystic ovary syndrome in Kerman city, 2019

Design

The present study is a quasi-experimental study of clinical trial type with intervention and control group and pre-test and post-test. The sample size was 90 (30 in each of the intervention groups and 30 in the control group) of women with polycystic ovary syndrome in Kerman city. A targeted sampling method is used. At the beginning of the study, they are randomly divided into three groups (one control group and two intervention groups).

Settings and conduct

The implementation area is the consultation room of each center. The mentioned consultations is done in two separate groups. Data collection is performed by questionnaires immediately after the intervention and one month after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion: Gynecologist diagnoses poly cystic ovary syndrome, Exclusion: Do not attend two or more counseling sessions. Not willing to continue participating in the study while doing research.

Intervention groups

Intervention is used to Rational Emotive Behaviour counseling is conducted twice a week for 90 minute for 8 weeks and Mindfulness Based Art therapy counseling is conducted twice a week for 90 to 120 minute for 8 weeks in the intervention group.

Main outcome variables

Body image

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170611034452N9**

Registration date: **2020-01-25, 1398/11/05**

Registration timing: **prospective**

Last update: **2020-01-25, 1398/11/05**

Update count: **0**

Registration date

2020-01-25, 1398/11/05

Registrant information

Name

Atefeh Ahmadi

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 5205

Email address

a.ahmadi@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-20, 1399/01/01

Expected recruitment end date

2020-06-21, 1399/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	Secondary Ids
Scientific title Comparison between the effect of counseling based on Rational-Emotive-Behaviour Theory (REBT) and Mindfulness-Based Art therapy (MBAT) on the body image of women with polycystic ovary syndrome (PCOS)	empty
Public title Comparison between the effect of counseling based on Rational-Emotive-Behaviour Theory and Mindfulness-Based Art therapy on the body image in polycystic ovary syndrome	Ethics committees
Purpose Education/Guidance	<u>1</u>
Inclusion/Exclusion criteria Inclusion criteria: Gynecologist diagnoses poly cystic ovary syndrome. Women aged 18 to 45 years. Not getting pregnant or breastfeeding or not wanting to get pregnant. Do not use any type of psychiatric medication during the 60 days prior to the intervention. No other physical or mental illness is recorded in the patient's medical record. Do not use alcohol or psychotropic substances. Ability to read, write or speak Persian. Willing to attend counseling sessions. has not participated in other consultation sessions. Exclusion criteria: Do not attend two or more counseling sessions. Not willing to continue participating in the study while doing research. Any acute stressful event occurs during the intervention for the individual.	Ethics committee Name of ethics committee Ethics committee of Kerman University of Medical Sciences and Health Services Street address Kerman - first of Haft Bagh Alavi - Pardis of Kerman University of Medical Sciences City kerman Province Kerman Postal code 7616913555 Approval date 2020-01-08, 1398/10/18 Ethics committee reference number IR.KMU.REC.1398.485
Age From 18 years old to 45 years old	Health conditions studied
Gender Female	<u>1</u>
Phase N/A	Description of health condition studied Polycystic ovary syndrome ICD-10 code ICD-10 code description
Groups that have been masked <i>No information</i>	<u>2</u>
Sample size Target sample size: 90	Description of health condition studied Body image ICD-10 code ICD-10 code description
Randomization (investigator's opinion) Randomized	Primary outcomes
Randomization description How to randomize will be through random table. To use the random number table, each sample is given a code or machine number, the researcher randomly starts from a table point in a row or column, selecting the point by blindfolding and placing Finger or pen tip on the table. Moves in the direction of a row or column.	<u>1</u>
Blinding (investigator's opinion) Not blinded	Description body image of women with polycystic ovary syndrome Timepoint Before intervention and after the sessions are completed and one month after the intervention Method of measurement Multidimensional Body-Self Relations Questionnaire
Blinding description	Secondary outcomes
Placebo Not used	empty
Assignment Parallel	Intervention groups
Other design features	

1

Description

Intervention group: Intervention is used to Rational Emotive Behaviour counseling in women with polycystic ovary syndrome is conducted once a week for 90 minute for 8 weeks in the intervention group.

Category

Lifestyle

2

Description

Intervention group: Intervention is used to Mindfulness Based Art therapy counseling in women with polycystic ovary syndrome is conducted once a week for 90 to 120 minute for 8 weeks in the intervention group.

Category

Lifestyle

3

Description

Control group: There is no intervention for the control group.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

public call

Full name of responsible person

Firoozeh Mirzaee

Street address

Address of holding the sessions: Tahmasbabad intersection, deputy of research, Kerman University of Medical Sciences

City

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7619813159

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Atefeh Ahmadi

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kmsrc@googlegroups.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Atefeh Ahmadi

Position

proffessor asistant

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

Contact

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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

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

Statistical Analysis Plan

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

Informed Consent Form

Undecided - It is not yet known if there will be 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

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

Data Dictionary

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

Title and more details about the data/document

Data on the main outcomes of the research after the completion of research work can be published.

When the data will become available and for how long

Starting access to the data above is immediately after publishing the results.

To whom data/document is available

Researchers in academia and scientific institute are able to access research data.

Under which criteria data/document could be used

In case of supplementary research, using data is permitted.

From where data/document is obtainable

The applicant can contact the researcher to receive information via email. atefeahmadi59@gmail.com
ramazanianzahra@gmail.com

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

After submitting a written request from the applicant, the data will be provided to him/her as soon as possible.

Comments