Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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)

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

Purpose
Education/Guidance

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.

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

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

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.

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 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

Health conditions studied

1

Description of health condition studied
Polycystic ovary syndrome

ICD-10 code

ICD-10 code description

2

Description of health condition studied
Body image

ICD-10 code

ICD-10 code description

Primary outcomes

1

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

Secondary outcomes

empty

Intervention groups

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
Kerman
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Postal code
7619813159
Phone
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Email
kmu_research@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Atefeh Ahmadi
Street address
Kerman-first element of the Haft Bagh Allavi-Pardis of Kerman University of Medical Sciences
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7616913555
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Email
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
Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person
Atefeh Ahmadi

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

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Person responsible for updating data

Contact

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Atefeh ahmadi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
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Email
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Web page address

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