Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison between Effectiveness of Dry Cupping and Counselling with Mindfulness-based Cognitive Therapy Approach (MBCT) on Fertility Quality of Life and Conception Success in Infertile Women due to Polycystic Ovarian Syndrome: a randomized pilot clinical trial

Protocol summary

Study aim
Comparative Investigation between Effectiveness of Dry Cupping and Counselling with Mindfulness-based Cognitive Therapy Approach (MBCT) on Fertility Quality of Life and Conception Success in Infertile Women due to Polycystic Ovarian Syndrome

Design
A pilot clinical trial consisting of two intervention groups, on 19 patients. Premuted block was used for randomization.

Settings and conduct
intervention group with dry cupping: they were referred to Parsian Medical Center in Shiraz. counseling group with a mindfulness-based cognitive therapy approach: eight sessions of 90 minutes of counseling held by the researcher. This study has no blinding.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- Married infertile women with a definitive diagnosis of PCOS based on Rotterdam criteria that were diagnosed by the gynecologists 2- Patients should be between 18 to 40 years old 3- Being married 4- Ability to read, write and speak Persian 5- agreement of couples to have vaginal quietus (for example, 2-3 times per week) around the time of ovulation during the study. Criteria for not entering: 1- Endometrial, cervical, breast or ovarian cancers 2- History of deep vein thrombosis or pulmonary embolism 3- Having known mental illnesses under treatment 4- Using psychotropic drugs and narcotics 5- Having another endocrine, internal or chronic diseases affecting conception rate

Intervention groups
1- Dry cupping treatment group: Dry cupping under the abdomen in the upper pubic area is done with three special glasses in clean days, twice a week for two months 2- Counselling group with a mindfulness-based cognitive therapy approach including eight sessions of 90 minutes per week

Main outcome variables
Fertility Quality of Life

General information

Reason for update
According to the study's results, based on the decision of the research team, the fertility quality of life was considered as the primary outcome and the rate of fertilization success as the secondary outcome. Also, due to some reasons like the time limitation, the small number of patients who met the inclusion criteria, and not reaching the sample size which has been estimated before the start of the study so the study was conducted as a pilot clinical trial. It should be noted that in the interventions section, according to the conducted research, the explanations related to the interventions were recorded in detail.

Acronym

IRCT registration information
IRCT registration number: **IRCT20170611034452N13**
Registration date: **2021-11-05, 1400/08/14**
Registration timing: **prospective**

Last update: **2022-12-19, 1401/09/28**
Update count: **1**

Registration date
2021-11-05, 1400/08/14

Registrant information

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Name of organization / entity
Kerman University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-11-06, 1400/08/15
Expected recruitment end date
2021-11-21, 1400/08/30
Actual recruitment start date
2021-12-21, 1400/09/30
Actual recruitment end date
2022-04-19, 1401/01/30
Trial completion date
2022-09-21, 1401/06/30

Scientific title
Comparison between Effectiveness of Dry Cupping and Counselling with Mindfulness-based Cognitive Therapy Approach (MBCT) on Fertility Quality of Life and Conception Success in Infertile Women due to Polycystic Ovarian Syndrome: a randomized pilot clinical trial

Public title
Comparison between Effectiveness of Dry Cupping and Counselling on Fertility Quality of Life and Pregnancy Rate in Infertile Women due to Polycystic Ovarian Syndrome
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Married women with infertility with definitive diagnosis of polycystic ovary syndrome based on Rotterdam criteria by gynecologists Lack of known mental illnesses under treatment Do not use psychotropic drugs and narcotics Married women Ability to read, write and speak Persian Do not attend counseling sessions or medication for fertility Couples agree to have vaginal sex (for example, two to three times a week) around the time of ovulation during the time of the study No endometrial cancer or cervical cancer The subject should not have a history of deep vein thrombosis or pulmonary embolism
Exclusion criteria:
Endocrine, endogenous or any chronic diseases affecting the rate of fertilization
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **20**
Actual sample size reached: **19**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible patients were selected by the Convenience sampling method and continued until reaching the desired sample size (at least 9 people in each group). Using random allocation software version 1, patients with the permutation blocks method (including 5 blocks of four) were randomly allocated to two intervention groups including a counselling and cupping group. Dark-coloured envelopes were also used for allocation concealment.
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
Research Ethics Committees of Kerman University of Medical Sciences
Street address
Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran
City
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Province
Kerman
Postal code
7616913555
Approval date
2021-08-30, 1400/06/08
Ethics committee reference number
IR.KMU.REC.1400.290

Health conditions studied

1

Description of health condition studied
infertile women due to poly cystic ovary syndrome
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Fertility Quality of Life
Timepoint
participants completed the FertiQol questionnaire before

the intervention and three months after the end of the intervention.

Method of measurement

FertiQol questionnaire

Secondary outcomes

1

Description

conception success

Timepoint

At four times: immediately after the end of treatment, one month, two months, three months after the end of treatment in case of delay in menstruation

Method of measurement

Quality Beta-HCG by blood sample

Intervention groups

1

Description

Intervention group1:In dry cupping group, treatment session were conducted twice a week during cleansing period for two months by a traditional medicine specialist. Three glass cups were used and selection of their sizes according to the size of the individual. The person was placed on the bed lying on her back so the area of cupping was exposed. The placement of cups was greased with chamomile oil. The first cup was placed on the top of the symphysis pubis. two other cups were placed on the right and left sides of the first one at a distance of 2.5 centimeters. the amount of suction created was such that the skin of the area was sucked to the top of the cup and became red and profuse. the cups were placed according to the patient's tolerance for up to 20 minutes, then they were slowly removed.

Category

Treatment - Other

2

Description

Intervention group2: Counseling group with Mindfulness-Based Cognitive Therapy approach (MBCT):In this group, eight sessions held for 90 minutes with 45 minutes a day of exercise, which can be accompanied by a one-day mind-guided program in 6th week. In the first 4 sessions, the focus is on inner experiences and in the second half is on life challenges. All sessions begin with a formal exercise (body checking, mindfulness movement, or sitting meditation practice).Short mindfulness exercises, such as three-minute breathing and conscious walking, are poems and stories related to the topic of the session, and there will also be a short mindfulness exercise at the end of each session. Due to prevalence of Covid19 , counseling sessions held on-line. The summary of counseling protocol with mindfulness-based cognitive therapy approach to increase pregnancy rate in patients with polycystic ovary syndrome is as follows: session1: Mind autopilot: basic acquaintance, stating the purpose of group formation, stating the rules and restrictions of the sessions / defining research variables, raisin technique / body meditation. Homework: 45 minute body meditation, and mindfulness on a daily task And a meal. session2: Overcoming Obstacles: Body Check Meditation, Ten Minutes of Mindful Breathing, Mindfulness Techniques on Thoughts and Feelings Homework: 45-Minute Body Check Meditation, Ten Minutes of Mindful Breathing, and Mindfulness of Another Daily Task, Daily Record of One Experience Pleasant event.session3:Mindfulness of breathing and body while moving: Conscious movement technique, conscious seeing and hearing practice, then stretching and breathing practice and then sitting meditation with body and breathing awareness, three-minute breathing space technique Explore the calendar of pleasant experiences (from week 4) Then it can be accompanied by a calendar of unpleasant experiences.) Homework: Practice stretching and breathing on the first, third and fifth days, practice mindful movement on the second, fourth and sixth days, record an unpleasant event, three-minute breathing space technique Times a day.session4: Session 4: Staying in the present: 5 minutes mind awareness of seeing or hearing, sitting meditation (awareness of breathing, body, sounds, thoughts and consciousness without choice), three-minute breathing space technique and using it when a coping skill when you feel like life is going hard, conscious walking, exploring the calendar of unpleasant experiences with defining the realm of stress Homework: sitting meditation, three-minute breathing space technique with regard to it as a coping skill In any unpleasant feeling.session5: Acceptance and permission. Sitting meditation with awareness on breathing and body, emphasizing how we react to thoughts, feelings, five senses when they occur, introducing problems in mindfulness exercises and exploring its effects on body and mind, three-minute breathing space , Reading a mindfulness-based poem and exploring its themes in the group, exploring habitual patterns of reaction and the potential to use mindfulness skills to facilitate more responsiveness to the experience of the present and the moment of homework: a three-minute breathing space technique with consideration Take it as a coping skill in any unpleasant feeling) and then explore the choice of opening the body gate. session6:Thoughts are not reality: sitting meditation with awareness on breathing and body along with introducing problems in mindfulness exercises and exploring its effects on body and mind, three-minute breathing space, practicing moods, alternative thoughts and perspectives, starting to develop an action plan and Individual validation of mindfulness on home stress-solving: forty-minute exercises a day, working with different combinations of the three main bases of exercises; Use short exercises, exercises with or without CDs, three-minute breathing space (regular three times a day), three-minute breathing space (adaptation during each unpleasant event) and in the first stage, creating a wider view of thoughts, practice Open in thinking, reflection and more work on preventing stress recurrence, action plan.session7:How can I best take care of myself? Sitting meditation with awareness on breathing and body,

sounds, thoughts and feelings, three-minute breathing space of the body with the introduction of problems in mindfulness exercises and exploring its effects on body and mind, exploring the relationship between behavior and mood, preparing a list of activities Daily and check which activity creates a feeling of emptiness and which a feeling of strengthening and vitality and dominance. Efforts to increase strengthening activities. Identify signs of recurrence of stress symptoms to deal with possible recurrence. Homework: Perform one of the activities that the person can continue after the sessions. Breathing-Regular and Coping Space: After practicing exploring the choice of opening in skillful performance, consider and create a warning system to detect the recurrence of stress as well as an action plan in times when mood swings. session8: Apply the fact learned in the face of the future: Examining body care, final care, reviewing early warning systems and planning for use at times of high recurrence, reviewing the entire course - the most valuable things in your life that mindfulness exercises do to you in times of encounter Help them continue with the formal and informal exercises they have learned in life .Homework: Plan to continue the exercises in the follow-up period

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Motahari Specialized and Sub-Specialized Clinic

Full name of responsible person
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Sponsors / Funding sources

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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
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
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Full name of responsible person
Atefeh Ahmadi

Position
Assistant professor

Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available