

ORIGINAL ARTICLE

Efficacy of Dry Cupping versus Counselling with Mindfulness-based Cognitive Therapy Approach on Fertility Quality of Life and Conception Success in Infertile Women due to Polycystic Ovary Syndrome: A Pilot Randomized Clinical Trial

Fahimeh Baghbani¹, Ms; Katayoun Alidousti², Ms; Mohammad Mahdi Parvizi^{3,4}, MD, PhD, MPH; Atefeh Ahmadi^{5,6}, PhD; Shaghayegh Moradi Alamdarloo⁷, MD; Amir Mohammad Jaladat^{4,8}, MD, PhD; Fatemeh Atarzadeh⁴, MD, PhD

¹Student Research Committee, Razi Faculty of Nursing and Midwifery, Kerman University of Medical Sciences, Kerman, Iran;

²Nursing Research Center, Kerman University of Medical Sciences, Kerman, Iran;

³Molecular Dermatology Research Center, Shiraz University of Medical Sciences, Shiraz, Iran;

⁴Research Center for Traditional Medicine and History of Medicine, Shiraz University of Medical Sciences, Shiraz, Iran;

⁵Reproductive Health, Family and Population Research Center, Kerman University of Medical Sciences, Kerman, Iran;

⁶Department of Counselling in Midwifery, Razi Faculty of Nursing and Midwifery, Kerman University of Medical Sciences, Kerman, Iran;

⁷Maternal-fetal Medicine Research Center, Department of Obstetrics and Gynecology, School of Medicine, Shiraz University of Medical Sciences, Shiraz, Iran;

⁸Department of Iranian Medicine, School of Medicine, Shiraz University of Medical Sciences, Shiraz, Iran

Corresponding Author:

Atefeh Ahmadi, PhD; Reproductive Health, Family and Population Research Center, Haft Bagh Alavi City, Postal code: 76169-13555, Kerman, Iran

Tel: +98 34 31325220; Fax: +98 34 31325218; Email: atefeahmadi59@gmail.com

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ABSTRACT

Background: Physical and psychological interventions could affect the quality of life (QoL) of women with infertility. The purpose of this study was to compare the effectiveness of dry cupping and counselling with the mindfulness-based cognitive therapy (MBCT) approach on fertility QoL and conception success in infertile women due to polycystic ovary syndrome (PCOS).

Methods: This was a two-arm pilot randomized clinical trial from first January 2021 to the end of November 2022. In this regard, 19 women with infertility who were referred to the health centers affiliated with Shiraz University of Medical Sciences and met the inclusion criteria were enrolled in the study. Participants were randomly divided into two groups (10 in the virtual MBCT group and 9 in the cupping group). All participants completed the fertility quality of life (FertiQoL) tool before the intervention and three months after the end of the intervention. In addition, after the end of the intervention, a human chorionic gonadotropin test was performed monthly for three months, too. We used ANOVA/ANCOVA and its related effect sizes, including mean difference (MD) and standard mean difference (SMD: Hedges's *g*), and chi-square tests to compare the study group outcomes in Stata 14.2. P-values equal to or less than 0.10 were considered significant.

Results: The intervention resulted in significant differences in the mean overall scores of FertiQoL between the counseling and cupping groups (61.76±14.28 and 50.65±12.53, respectively) [P=0.091, MD=11.11 (90% CI: 0.33 to 21.89), SMD=1.07 (90% CI: 0.279 to 1.84)]. No significant difference was found in conception rates between the groups after the intervention.

Conclusion: This pilot study found that MBCT improved the fertility QoL in PCOS-related infertility patients better than cupping therapy.

Trial registration: IRCT201706110334452N13

Keywords: Cognitive behavioral therapy, Cupping therapy, Infertility, Polycystic ovary syndrome, Quality of life

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INTRODUCTION

Infertility is a universal health issue and the number of infertile couples around the world is increasing.¹ All around the world, 15% of couples in reproductive age suffer from infertility. The prevalence of infertility in Iran has been estimated at 2-5%.² Infertility is a complex disorder with medical, psychological, social, and economic aspects.³ The presence of psychiatric disorders in infertile women can affect the efficacy of their treatment,⁴ while the main goal of treatment is to increase the pregnancy rate.⁵ Polycystic ovary syndrome (PCOS), which is the most common endocrine and metabolic disorder among women of reproductive age, is one of the causes of infertility.⁶ The prevalence of this syndrome varies from 6 to 12% worldwide and from 13.6 to 19.4 in Iran.⁷

The World Health Organization defines quality of life (QoL) as: "individuals' perceptions of their position in life in the context of the culture and value systems in which they live". QoL is a complex concept that is defined in several ways within and between various disciplines.⁸ Thus, QoL encompasses medical and psychosocial factors including daily living activities, instrumental activities, psychological well-being, social functioning, health status, pain, and life satisfaction.⁹ On the other hand, nowadays, QoL has been increasingly utilized as a parameter for the evaluation of various treatment outcomes.¹⁰ Infertility could activate a physiological stress response, and increasing anxiety and psychological distress are related to a decrease in pregnancy rates.¹¹ A study has shown that PCOS can significantly reduce QoL and mental health.¹² The evidence demonstrated that exercise is effective in improving health-related QoL and decreasing PCOS symptom distress; it can also improve symptoms and the prevalence of depression and anxiety in women with PCOS.¹³

There is no definitive treatment for PCOS infertility. Current treatment methods are time-consuming, complicated, or not cost-effective, while evidence has revealed that

treating PCOS requires a holistic therapeutic approach from considering mental health to physical health.¹⁴ It has been revealed that complementary medicine can have a positive effect on the QoL of infertile women and the pregnancy rate.¹⁵ On the other hand, research showed that many patients with chronic conditions, especially those who did not receive acceptable responses from conventional and modern medicine such as patients with infertility, were attracted to the use of complementary and alternative remedies in the hope of increasing their QoL although they did not have enough information in this field and the effectiveness of these methods has not been fully confirmed yet.¹⁶

Infertile women's QoL is an important and challenging issue.¹⁷ It has been suggested that populations with higher levels of mindfulness perform better in terms of psychological well-being which can be considered in infertility counseling.¹⁸ Less attention is paid to negative infertility consequences on sexual relations, self-confidence, social relations, and more holistic treatment. In this regard, a study showed that cognitive behavior therapy that included stress management interventions and mindfulness-based stress reduction (MBSR) reduced worries in women with PCOS¹⁹ and had positive effects on QoL in women with infertility.¹⁵

Mindfulness-based cognitive therapy (MBCT) involves cognitive and mindfulness skills that engage the participants in various stress management techniques, including relaxation, yoga, and self-care.²⁰ Psychological interventions on the mind and body reduce anxiety and depression which can increase pregnancy chances.³

Cupping is a thousand-year-old practice in some communities around the world. This ancient practice dates back to 3300 BC and is still used in Europe, Asia, and the Middle East, despite the advancement of modern medicine. Dry cupping involves creating a vacuum inside a cup placed on the surface of the skin using local negative pressure to promote blood flow.²¹ The function of the

ovary and uterus is improved by performing dry cupping, and it is a safe method for the management of oligomenorrhea. On the other hand, cupping therapy is commonly observed in therapeutic settings to alleviate pain and enhance the overall sense of well-being in patients.²² Additionally, it seems that dry cupping can improve the health and overall QoL of the people by positively influencing their physical and psychological health perceptions.²³

To the best of our knowledge, there was not enough evidence about the effectiveness of counselling with the MBCT approach and cupping therapy on fertility QoL and conception rate in women with PCOS-related infertility. Therefore, this pilot study aimed to compare the efficacy of dry cupping and counseling with the MBCT approach on the fertility QoL and conception success in women with PCOS-related infertility.

MATERIALS AND METHODS

This is a two-arm pilot randomized clinical trial among women with PCOS-related infertility who were referred to health centers affiliated with Shiraz University of Medical Science, Shiraz, Iran from the first of January 2021 to the end of November 2022. Because this was a pilot and feasibility study, according to the rule of thumb, we estimated approximately 20 patients in the study (including 10 patients in each study group) as a minimum sample size.²⁴

The eligibility criteria for patients were as follows: 18- to 40-year-old Iranian married women with infertility problems with a definite diagnosis of PCOS based on the Rotterdam criteria by the gynecologist of the research team; ability to read, write, and speak the Persian language; couples' agreement to have vaginal intercourse (two to three times per week) around the time of ovulation (11th to 17th days of the menstrual cycle) at the time of the study; no history of deep vein thrombosis or pulmonary embolism; women who were under assistant reproductive therapy (ART) and should be

in the resting period (without any chemical or procedural treatment); passage of more than one year from their infertility; lack of other endocrine and internal diseases or any chronic conditions affecting the conception rate; lack of well-known mental illnesses; not consumption of psychoactive drugs and narcotics; lack of endometrial cancer or cervical cancer; no breast cancer or ovarian cancer, and willingness to participate in the study. The exclusion criteria of the study included patients with a major anxiety-causing incident during the study; patients who did not implement the treatment plan, participated in other related intervention programs during the trial, and voluntarily withdrew from the study; skin sensitivity following the application of dry cupping; absence in more than one cupping therapy session; and lack of doing the home exercises related to counseling for more than two days.

Using Random Allocation Software version 1, we randomly allocated the recruited women who suffered from PCOS-related infertility with the permutation block method to two intervention groups including "counseling with the MBCT approach" and "dry cupping". Moreover, dark-colored envelopes were also used for random allocation concealment.

Because of the nature of the intervention methods, we could not blind the participants and researchers; however, to reduce the risk of bias, the outcomes assessor and statistician were blinded. In this regard, we defined the study groups as A (cupping group) and B (MBCT) for a statistician.

Overall, 350 infertile women were referred to health centers and initially assessed. The gynecologist on the research team could identify PCOS as the only cause of infertility in 23 of them. Three of them did not agree to participate in the study despite fulfilling the inclusion criteria, and one of them became pregnant before the start of the study. Finally, 19 subjects were included in the study (10 in the counseling group and 9 in the cupping group). The trial CONSORT flow diagram is shown in Figure 1.

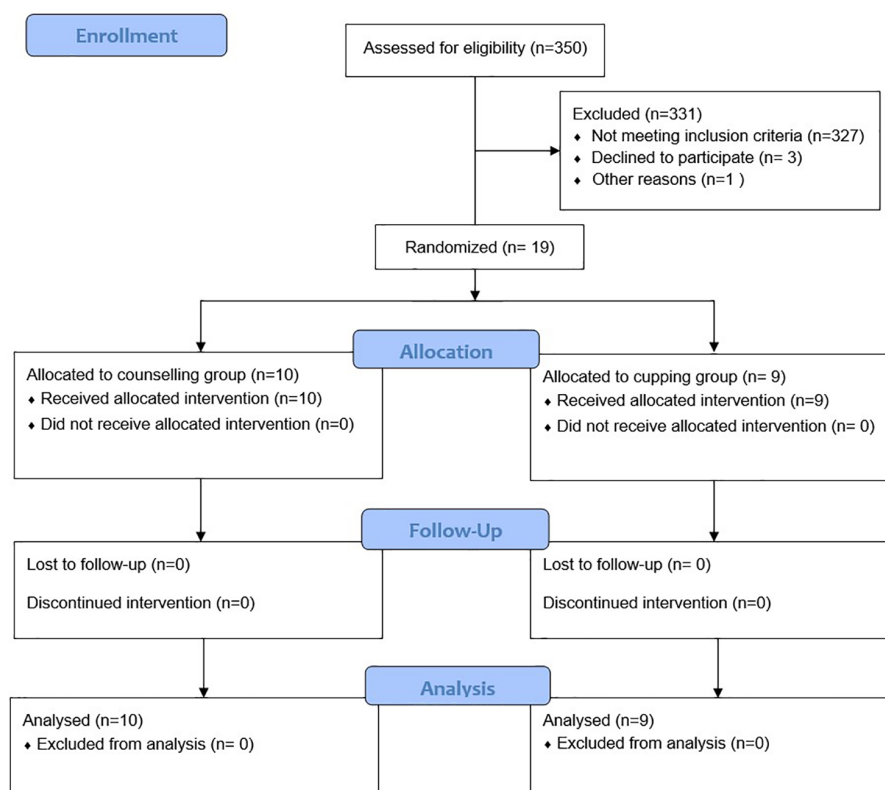


Figure 1: Flow diagram of participant recruitment

Both groups of participants received two months of related treatment and were followed up three months after the interventions finished. In the dry cupping treatment group, the intervention was started for all participants after the end of a menstrual period. For cupping therapy, the patients were referred to the Traditional Persian Medicine Clinic affiliated with Shiraz University of Medical Sciences, Shiraz, Iran. The treatment sessions were conducted twice a week during non-menstrual days for two months by the traditional medicine specialist. Three glass cups were used, which were proportional to the body size. The location of the cups was greased with chamomile oil; then, the first cup was placed above the symphysis pubis, and two other cups were placed on the right and left sides of the first one at 2.5 centimeters. They were placed according to the patient’s tolerance for up to 20 minutes. Then, they were slowly removed.

In the MBCT group, the time of the counseling sessions was scheduled on a specific day of the week with the coordination of the participants. The weekly sessions were

held virtually in eight 90-minute sessions due to the COVID-19 pandemic. Participants were engaged in various exercises that ranged in form from lying to sitting and walking mindfully. In the first four sessions, the focus was on mindfulness of inner experiences, and in the second half, on life challenges. All sessions began with a formal practice (body scan, mindful movement, or mindful sitting practice). Short mindfulness exercises, such as three-minute breathing and mindful walking, poems, and stories, were related to the topic of the session, and at the end of each session, there was a short mindfulness exercise. Home exercises were provided at the end of each session.²⁵ The context and homework of the sessions are shown in Table 1.

It should be noted that if participants in this group did not send their feedback to the researcher within 24 hours after sending the content of a session, it was considered as the person’s absence from the counselling session. The outcomes in both study groups were assessed both before starting interventions and three months after the end of the interventions.

Table 1: Context and homework of counselling sessions (at least 45 minutes /day)

Session	Context	Homework
1: Mind Autopilot	Basic introduction, statement of the purpose of forming the group, statement of the rules and topics of the meetings/ definition of research techniques, raisin technique/body scanning technique.	Body-scanning meditation focusing on a daily task and a meal.
2: Dealing with obstacles	Body-scanning meditation, ten minutes of conscious mind breathing, mindfulness technique on thoughts and feelings.	Body awareness meditation, ten minutes of mindful breathing, and mindfulness of another daily task, daily recording of the experience of a pleasant event.
3: Mindfulness on breathing and on the body during movement	Mindful movement technique, Practice seeing and listening consciously, Stretching and breathing, sitting meditation with an awareness of the body and breathing, Three-minute breathing space technique, Exploring the calendar of pleasant experiences (from week 4 onwards, it can be combined with the calendar of unpleasant experiences).	Stretching and breathing exercises on the first, third, and fifth days, mindful movement exercises on the second, fourth, and sixth days, recording a pleasant event, and three-minute breathing space technique three / day.
4: Stay in the present	5 minutes mindfulness of seeing or hearing, sitting meditation (awareness of breath, body, sounds, thoughts, and non-choice awareness), three-minute breathing space technique and use it as a coping skill when you feel life Going hard, walking consciously, exploring the calendar of unpleasant experiences along with defining the realm of stress.	Sitting meditation, the three-minute breathing space technique, and considering it as a coping skill for unpleasant feelings.
5: acceptance and permission	Sitting meditation with awareness of breathing and body, emphasis on paying attention to 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 poem based on mindfulness and exploring its themes in a group, exploring habitual patterns of response and the potential of using mindfulness skills to facilitate greater responsiveness to the experience of the present and at the moment.	The three-minute breathing space technique along with considering it as a coping skill for any unpleasant feelings) and opening door technique.
6: Thoughts are not reality	Sitting meditation with awareness of breathing and body along with the introduction of problems in mindfulness exercises and exploring its effects on body and mind, three-minute breathing space, training of moods, thoughts, and alternative perspective, starting to formulate an action plan and individual validation on Mindfulness on Stress.	Working with different combinations of the three basic exercises; Using short exercises, exercises with or without a CD, three-minute breathing space (three times/day), three-minute breathing space, open in thinking, reflect and work more on preventing the recurrence of stress, action plan.
7: How can I best take care of myself?	Sitting meditation with awareness of breathing and body, sounds, thoughts, and feelings, the three-minute breathing space of the body along with the introduction of problems in mindfulness exercises and exploring its effects on the body and mind, exploring the relationship between behavior and mood, preparing a list of activities daily and checking which activity creates a feeling of emptiness and which one creates a feeling of empowerment and vitality and mastery. Trying to increase reinforcing activities. Identifying the signs of stress symptoms relapse to deal with a possible relapse.	Doing one of the activities that the person can continue after the sessions. Breathing-Regular and Coping Space: After practicing exploring the choice to open up in skillful performance, consider and create a warning system to identify the recurrence of stress and an action plan for times when mood drops.
8: Applying what has been learned to face the future	Body-scanning meditation, final Meditation, review of early warning systems and action plan for relapse prevention, whole course review - the most valuable things in your life that mindfulness practice has helped you face in times of crisis, slow down, discuss how to carry the formal and informal practices learned into life.	Planning to continue homework in the follow-up period.

Fertility QoL was the primary outcome, assessed by the FertiQol questionnaire. All participants filled out this questionnaire before the interventions and three months after the last intervention session. They filled out the questionnaire sent to them by WhatsApp application. The FertiQol tool is a questionnaire that is specifically designed for infertile patients to assess their QoL developed by the European Society of Human Reproduction and Embryology and the American Society for Reproductive Medicine in 2011. Two main modules formed the FertiQol tool: the Core FertiQol module and the Treatment module. There are 24 items in the Core FertiQol module and 10 in the Treatment FertiQol module. The 24 items from the Core FertiQol are categorized into four domains, including the emotional, mind/body, relational, and social domains. The emotional domain evaluates the impact of infertility on emotions, such as sadness, resentment, or grief. The mind/body domain refers to the influence of infertility on physical health, cognition, and behavior. The relational domain and social domain are used to quantify the impact of infertility on partnership and social aspects (e.g., social inclusion, expectation, and support), respectively. The optional treatment module consists of two domains that are used to assess the environment and tolerability of infertility treatment.²⁶

Items from these domains are presented in the questionnaire randomly and rated on a scale of 0 to 4. The subscale and total FertiQol scores are computed and transformed to achieve a range of 0 to 100, where higher scores indicate better QoL. Cronbach reliability statistics for the Core and Treatment FertiQol (and subscales) were satisfactory, in the range of 0.72 and 0.92.²⁷ Studies indicated adequate reliability in the overall scale ($\alpha=0.43-0.92$), as well as the core Emotional, Mind/Body, Social, and Relational scales ($\alpha=0.43-0.92$) and two optional Tolerability and Environment fertility treatment subscales ($\alpha=0.67-0.92$).²⁸ In a cross-sectional study, Hekmatzadeh et al.

(2018) evaluated the psychometric properties of the Iranian version of FertiQol. The reliability of the Iranian version of FertiQol is satisfactory in all domains (0.77-0.83) and is valid and reliable for evaluating self-report infertility and its treatment problems.²⁹

Conception success was assessed by a pregnancy test as a secondary outcome. In the present study, the human chorionic gonadotropin (β hCG) test was performed qualitatively with blood samples by Omega β hCG Kit Serum (Lot: s1908254fa25) to assess the conception success. In the qualitative type, depending on the presence or absence of hCG in the sample, a positive or negative result is reported.³⁰ The test was performed monthly for three months.

Stata software version 14.2 was used for the statistical analysis of data. Quantitative data were described with mean and standard deviation, and the classified data were described with frequency and percentage. The Shapiro-Wilk statistical test was also used to check the normality of data distribution. ANOVA/ANCOVA statistical test was also used to check the effect of the interventions. Fisher's exact test was used to compare the outcome of successful conception in the patients of the two study groups, and the Risk Ratio (RR) was also calculated. We used mean difference and standard mean difference, including Hedge's g , to express the effect size of the interventions (negligible: 0-0.19, poor: 0.20-0.49, moderate: 0.5-0.79, strong: 0.8-1).³¹ Given the small sample size and the pilot nature of this study, the significance level of the P value was considered equal to or less than 0.1 ($P \leq 0.1$). Confidence Intervals (CI) were calculated at 90%.³¹

The study power was assessed following data analysis, with the fertility QoL score of infertile women as the primary outcome variable. G-power software version 3.1.9.2 was utilized for this purpose.

The present article was extracted from the thesis supported by Kerman University of Medical Sciences, Kerman, Iran. The study was approved by the Ethics Committee

of Kerman University of Medical Sciences (No. IR.KMU.REC.1400.290). Patients signed informed consent to participate in the study. Informed consent was obtained to enter the study, and participants could withdraw from the study whenever they were willing without any changes in their treatment. The anonymity of all participants was preserved. All methods were performed based on the guidelines and principles of declaration of Helsinki.

RESULTS

The mean age of the patients in the counseling and cupping group and mean duration of infertility of patients in the counseling and cupping groups were reported (Table 2). Table 3 shows the medical underlying information. The two groups had no differences in baseline scores except for the educational level of the spouse. The statistical analysis resulting from the data collection of the FertiQol questionnaire in the two groups is reported in Table 4. After the interventions, the overall mean scores which showed the fertility QOL in the counseling group were significantly higher than those of the cupping group (P=0.091).

Also, the total mean scores in the counseling group were significantly higher than those of the cupping group, after the base-line-score adjusting of the results (P=0.030). The total score of core-FertiQol, after the interventions in the counselling group was significantly higher than the cupping group (P=0.058); also, after adjusting the results, the score in the counseling group was higher than the cupping group after the intervention (P=0.012). In the Treatment FertiQol score, there was no statistically significant difference between the two groups after the interventions in both crude (P=0.608) and base-line adjusted analysis (P=0.731). Furthermore, in both subscales of Treatment FertiQol, environment, and tolerability, there was no statistically significant difference between the two groups following the interventions. In each group, only one participant had a positive pregnancy test during the study period, which was not statistically significant. According to the Pearson correlation coefficient, the correlation of the fertility QOL score before and after the study was equal to 0.57; given the effect size of 0.525 and the type 1 error (alpha)=0.1, the power of the study was estimated to be equal to 0.80.

Table 2: Demographic characteristics of patients in the counselling and cupping groups

Variable	Counselling Group (N=10) Mean±SD	Cupping Group (N=9) Mean±SD	P value*
Age (year)	28.6±3.71	32.11±5.9	0.135
Spouse's Age (year)	35.9±3.17	35.11±5.01	0.684
Age of marriage (year)	20.6±2.87	24±5.63	0.111
Marriage duration (year)	7.8±4.04	7.88±3.72	0.961
Infertility duration (year)	6.1±2.60	5.33±1.41	0.444
	N (%)	N (%)	P value**
Education			
Academic	5 (50)	4 (44.44)	>0.99
Non-academic	5 (50)	5 (55.55)	
Spouse's education			
Academic	7 (70)	1 (11.11)	0.020
Non-academic	3 (30)	8 (88.88)	
Occupation			
Housewife	9 (90)	7 (77.77)	0.334
Employee	1 (10)	0 (0)	
Freelance	0 (0)	2 (22.22)	
Spouse's occupation			
Employee	3 (30)	0 (0)	0.211
Freelance	7 (70)	9 (100)	

*Independent t-test; **Fisher's exact test

Table 3: Medical underlying information of patients in the counselling and cupping groups

Variable	Counselling Group (N=10) N (%)	Cupping Group (N=9) N (%)	P value*
Infertility Type			
Primary	6 (60)	8 (88.88)	0.303
Secondary	4 (40)	1 (11.11)	
Menstrual regularity			
Regular	1 (10)	1 (11.11)	>0.99
Irregular	9 (90)	8 (88.88)	
Menstrual cycle (day)			
21-35	1 (10)	1 (11.11)	>0.99
>35	9 (90)	8 (88.88)	
Disease history except for infertility			
Yes	3 (30)	0 (0)	0.211
No	7 (70)	9 (100)	
Spouse's disease history			
Yes	5 (50)	4 (44.44)	>0.99
No	5 (50)	5 (55.55)	
Gravida			
0	6 (60)	8 (88.88)	0.325
1	2 (20)	0 (0)	
2	0 (0)	1 (11.11)	
3	1 (10)	0 (0)	
4	1 (10)	0 (0)	
Para			
0	8 (80)	9 (100)	>0.99
2	1 (10)	0 (0)	
3	1 (10)	0 (0)	
Abortion			
0	7 (70)	8 (88.88)	0.721
1	2 (20)	0 (0)	
2	1 (10)	1 (11.11)	
Live			
0	9 (90)	9 (100)	>0.99
1	1 (10)	0 (0)	
Death			
0	8 (80)	9 (100)	0.747
2	2 (20)	0 (0)	

*Fisher's exact test

DISCUSSION

In this study, MBCT could be significantly effective in improving the fertility QOL and core FertiQol (emotional, mind-body, and social subscales). The results of this research show the impact of interventions to promote fertility QOL by using counseling-based methods in infertile women due to PCOS. Before the interventions, there was no significant difference in all subscales of FertiQol scores. Three months after the interventions in both groups, the participants in the counselling group showed significant improvement, approximately increasing more

than 11.66 scores in the mean difference of overall scores of FertiQol compared to the cupping group. On the other hand, although the value of the standard mean difference (*Hedge's g*) of this score was in the strong area of interpretation, the widening of the 90% CI of this variable indicated that this result was inconclusive and might be related to the small sample size of the study. Moreover, the effect of MBCT was strong on the scores of several subscales of the FertiQol questionnaire, including the total score of the Core FertiQol scale, the emotional sub-scale, and the social sub-scale, but this effect was not conclusive.

Table 4: Fertility quality of life and its subscales score (using FertiQoL tool) in pre and post-interventions by study arms (counselling vs. cupping) according to different models

Outcome	Model	Time point	Counselling Group n=10	Cupping group n=9	Mean Difference (90% CI)	Hedges's g (90% CI)	P value*
Total Score of FertiQoL	Crude	Pre	47.94±13.30	48.86±15.87	-0.92 (-12.56 to 10.72)	-	0.091**
		Post	61.76±14.28	50.65±12.53	11.11 (0.33 to 21.89)	1.07 (0.279 to 1.84)	
	Adjusted ^a	Pre	47.94±13.30	48.86±15.87	-	-	0.030**
		Post	62.02±10.61	50.37±10.61	11.66 (3.14 to 20.18)	1.05 (0.26 to 1.82)	
Total score of Core FertiQoL scale	Crude	Pre	50.31±15.12	51.97±20.01	-1.66 (-15.71 to 12.40)	-	0.058**
		Post	64.58±15.46	50.12±15.46	14.47 (2.11 to 26.83)	0.89 (0.12 to 1.65)	
	Adjusted ^a	Pre	50.31±15.12	51.97±20.01	-	-	0.012**
		Post	65.05±11.84	49.60±11.84	15.44 (5.940 to 24.95)	1.25 (0.43 to 2.03)	
Total score of Treatment FertiQoL scale	Crude	Pre	48.5±14.54	46.11±10.83	2.39 (-7.95 to 12.72)	-	0.608
		Post	55.00±12.71	51.94±12.71	3.06 (-7.16 to 13.22)	0.23 (-0.50 to 0.95)	
	Adjusted ^a	Pre	48.5±14.54	46.11±10.83	-	-	0.731
		Post	54.39±10.99	52.62±10.99	1.77 (-7.07 to 10.60)	0.15 (-0.57 to 0.88)	
Score of Emotional sub-scale	Crude	Pre	41.25±23.85	38.43±22.80	2.82 (-15.85 to 21.50)	-	0.027**
		Post	58.33±19.14	37.04±19.14	21.30 (5.99 to 36.60)	1.06 (0.12 to 1.98)	
	Adjusted ^a	Pre	41.25±23.85	38.43±22.80	-	-	0.015**
		Post	57.68±15.89	37.76±15.89	19.92 (7.16 to 32.68)	1.20 (0.39 to 1.98)	
Score of Mind-body sub-scale	Crude	Pre	51.67±26.80	56.94±26.35	-5.28 (-26.33 to 15.98)	-	0.330
		Post	65.00±21.48	55.09±21.48	9.91(-7.26 to 27.08)	0.44 (-0.30 to 1.17)	
	Adjusted ^a	Pre	51.67±26.80	56.94±26.35	-	-	0.089**
		Post	66.45±15.47	53.48±15.47	12.97 (0.520 to 25.41)	0.80 (0.03 to 1.55)	
Score of Relational sub-scale	Crude	Pre	58.33±4.73	62.5±6.17	-4.17 (-17.54 to 9.20)	-	0.617
		Post	66.67±13.84	63.43±13.84	3.24± (-7.82 to 14.30)	0.22 (-0.50 to 0.94)	
	Adjusted ^a	Pre	58.33±4.75	62.5±6.17	-	-	0.227
		Post	67.85±9.89	62.11±9.89	5.73 (-2.23 to 13.70)	0.55 (-0.19 to 1.28)	
Score of Social sub-scale	Crude	Pre	50.00±5.41	50.00±7.25	0.00 (-15.53 to 15.53)	-	0.006**
		Post	68.33±16.23	44.91±16.23	23.42 (10.45 to 36.40)	1.38 (0.39 to 2.34)	
	Adjusted ^a	Pre	50.00±5.41	50.00±7.25	-	-	0.002**
		Post	68.93±14.14	44.91±14.14	23.43 (12.08 to 34.77)	1.58 (0.72 to 2.41)	
Score of Environment sub-scale	Crude	Pre	47.08±13.18	46.30±11.68	4.79 (-10.09 to 19.68)	-	0.581
		Post	54.58±14.16	50.93±14.16	3.66 (-7.66 to 14.98)	0.25 (-0.62 to 1.11)	
	Adjusted ^a	Pre	47.08±13.18	46.30±11.68	-	-	0.568
		Post	54.33±11.65	51.21±11.65	3.12 (-6.23 to 12.47)	0.26 (-0.47 to 0.98)	
Score of Tolerability sub-scale	Crude	Pre	50.63±20.72	45.83±15.93	4.79 (-10.09 to 19.66)	-	0.806
		Post	55.63±18.76	53.47±18.76	2.15 (-12.84 to 17.15)	0.11 (-0.61 to 0.83)	
	Adjusted ^a	Pre	50.63±20.72	45±8315.93	-	-	0.975
		Post	45.73±17.87	54.47±17.88	0.27 (-14.14 to 14.67)	0.00 (-0.72 to 0.72)	

*Calculated based on one-way ANOVA/ANCOVA; **Significant (P≤0.1); ^aAdjusted for baseline Pre-treatment Fertility quality of life score (calculated based on Oneway ANOVA / ANCOVA model)

A study showed that mindfulness-based therapies could enhance the fertility QOL and its subscales in infertile women undergoing in-vitro fertilization (IVF) by managing their physiological symptoms, which could result in reducing their stress and anxiety level.¹⁸ However, our study revealed that MBCT did not have a favorable effect on the fertility

QOL in the subscales of “treatment” and “relation”. The effect of face-to-face cognitive-behavioral counselling is much more effective than virtual or Internet counselling,³² while in this study, counselling was virtual.

It has been demonstrated that cognitive-behavioral therapy and mind-body interventions can be useful to reduce stress,

anxiety, and depression in infertile women.³³ The most psychological interventions were effective in reducing the depression score of women with PCOS.¹² In addition, mindfulness-based yoga sessions improved QOL and reduced anxiety and stress in women with PCOS.³⁴ Being fully aware of the present moment without judgment about the events and thoughts seems to help women relate their life, infertility and treatment in a new point of view.¹⁸ In MBCT, a person learns to focus on attention to the present moment and control his/her thoughts and opinions. This cognitive skill can be a reason for increasing the level of the fertility QoL.³⁵

Exploring the background of the studies, we found no research about the effect of dry cupping on the QoL in infertile women with PCOS. It seems that this study, for the first time, investigated the impact of this treatment on the PCOS fertility QoL in a pilot way. A study showed that wet cupping could improve the health and overall QoL of people by positively influencing their physical and psychological health perception;¹⁰ it was also revealed that dry cupping in people without chronic diseases could improve their well-being and physical and mental health.²³ Acupuncture decreased testosterone and luteinizing hormone (LH) and improved menstrual cycles in PCOS and consequently and indirectly improved the fertility and QoL.¹² The difference in findings in this pilot might be related to low sample size and effect of other confounding factors on the QoL. However, scientifically, the duration and number of sessions of this traditional therapy were enough.

The conception rate was evaluated as a secondary outcome in both groups. In this study, the two interventions did not increase the fertility success. Moreover, the result of our study in this part was in line with that of a similar study that indicated no efficacy of cupping therapy on conception.³⁶ It seems that we can expect to achieve better results by increasing the length of the follow-up and continuing psychological and traditional

interventions along with modern medical interventions.

Infertility risk factors are not limited to medical factors but extend to psychological variables. The emotional stress of women can lead to tubal spasms and lack of ovulation. Therefore, psychological interventions for infertile couples led to a significant increase in pregnancy rates.³⁷ In confirmation of this point, women who receive some kind of psychological intervention during infertility treatment are almost twice as likely to become pregnant compared to women who receive only routine care.³⁸ Mindfulness-based interventions showed a positive effect on pregnancy rates.¹⁸ An explanation for such observations may be related to the fact that the hypothalamus-pituitary-adrenal axis plays an undeniable role in controlling the excretion of some hormones such as cortisol, which affects the clinical pregnancy rate. Mind-body and psycho-social interventions can increase fertility rates by improving the performance of this axis.¹¹

Previously, no study has been directly related to the effect of dry cupping on the pregnancy rate of PCOS infertility, whereas a study states that cupping therapy has a positive effect on women of reproductive age in treating menstrual disorders and infertility,³⁹ and cupping therapy can be considered a safe and effective complementary intervention for metabolic disorders.⁴⁰ On the other hand, acupuncture, which has the same mechanism as cupping, has been widely used in the treatment of PCOS. Acupuncture regulates LH secretion and improves insulin resistance and hyperandrogenism. Furthermore, it inhibits the excessive activity of sympathetic nervous system and regulates the neural activity of the ovarian glands by regulating the sympathetic activity. Acupuncture can be used as a pre-chemical treatment for infertile women due to PCOS to regulate menstrual cycles and correct LH hormone levels during ARTs such as IVF. However, one study did not find its effect on the rate of pregnancy and ovulation,⁴¹ and another one mentioned the

effectiveness of acupuncture on the ovulation rate in PCOS.⁴²

This study very carefully selected pure infertility only related to PCOs among a significant number of women referred to infertility clinics. Both interventions were done professionally with a three-month follow up for pregnancy. Several studies have compared these two methods on PCO-related infertility. This study checked the participants precisely to be only PCOs. Even their Anti-Mullerian hormone was checked to rule out the other reasons of infertility of the patients.

This study had some limitations. The small sample size affected the statistical significance of the findings. The wide range of confidence interval values of the estimated effect sizes indicate inconclusive results. Second, the duration of interventions and follow-up was short, and it can affect assessment of the conception rate. Next, due to the Covid-19 pandemic, virtual counselling sessions were held. Furthermore, this study did not have a control group.

CONCLUSION

In the present study, it was concluded that MBCT could improve fertility QoL in infertile women due to PCOS; however, because of the inconclusiveness of the results, further studies are recommended. There was no significant difference in the conception rate between the counselling and cupping groups in our pilot study, so further studies are required to generalize the conclusions with a larger sample size, long term follow-up, and with a control group. In clinical practice, more attention and intervention on the infertile patients' QoL by using counselling and traditional medicine are recommended.

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