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Effects of a short-term mindfulness-based stress reduction program on the quality of life of women with infertility: A randomized controlled clinical trial

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ABSTRACT

Background and purpose: Although some programs based on mindfulness-based stress reduction (MBSR) have been suggested to promote quality of life (QoL) in different conditions, limited studies have addressed their potential effects in women with infertility. In this study, we aimed to determine the effects of an MBSR program on the QoL of women with infertility.

Materials and methods: This randomized controlled clinical trial was conducted on 36 women with infertility, who were selected by consecutive sampling from the Infertility Center of Ahvaz Imam Khomeini Hospital, Iran. Women either participated in the MBSR program or received routine consultation in eight two-hour group sessions once a week. Women's QoL was measured using the 36-item short-form health survey before, immediately after, and one month after the intervention. The intention-to-treat analysis, with multiple imputation for missing data, was also performed.

Results: The mean changes in the total score of QoL and its subscales (except for "social functioning" and "bodily pain") were significant compared to the baseline both at immediately after and one month after the intervention in favor of the experimental group ($P < 0.001$ in most cases). Twenty four and six adverse events were recorded in the experimental and control groups, respectively.

Conclusion: Short-term MBSR program seem to be potentially effective in improving the QoL of women with infertility. Further studies are needed to determine the generalizability of our findings.

1. Introduction

Infertility is one of the most significant global health problems. [1] The one-year prevalence of infertility is estimated at 3.5-16.7% and 6.9%-9.3% in developed and less developed countries, respectively, with an estimated overall median prevalence of 9%. [2] According to the report of the International Committee for Monitoring Assisted Reproductive Technology, primary infertility is defined as the inability to become pregnant within 12 months of unprotected sexual intercourse in women aged 15-49 years, who do not use any birth control methods. [3] In Iran, as a developing country, the prevalence of primary infertility has been reported to be higher than the global average. [4–6] In a community-based survey of Iranian women aged 20-40 years, the prevalence of primary infertility was estimated at 20.2%, 12.8%, and 9.2%, respectively according to the clinical, epidemiological, and demographic definitions of the World Health Organization (WHO). [5]

Infertility negatively affects women's health-related quality of life (QoL) and leads to psychological and marital problems, such as anxiety, depression, frustration, isolation, identity disturbance, lack of attraction, sexual dysfunction, and less sexual and marital satisfaction. [7–9] It

Abbreviations: ACT, acceptance and commitment therapy; IVF, in vitro fertilization; MBIs, mindfulness-based interventions; MBSR, mindfulness-based stress reduction; PGWBI, psychological general well-being inventory; QoL, quality of life; SF-36, 36-item short form health survey

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seems that QoL of women with infertility often decreases due to lack of access to reproductive care, poor organization of health services, and deficient clinical interaction. [10] Therefore, healthcare providers should consider effective interventions to improve the QoL of women with infertility.

The efficacy of mindfulness-based interventions (MBIs), as a component of ancient meditative practices, has been investigated in women with infertility. [11–13] Mindfulness-based stress reduction (MBSR) is a common type of MBI, which aims to relieve stress. It was introduced by Jon Kabat-Zinn and has been used since the 1980's. [14] MBSR aims to cultivate a non-judgmental awareness of whatever is happening at each successive moment of perception. [15] It is an experiential approach to teaching anti-stress skills, which can enable an individual to achieve self-awareness, mindfulness, and self-reflection to engage in self-care activities. [16]

Infertility is an important cause of stress and women with this problem need more professional support to deal with the disease burden, as well as treatment challenges. [17] Therefore, it seems that programs based on MBSR can contribute to the higher QoL of women with infertility. The positive effects of MBSR programs in combination with other MBIs on the QoL of women with infertility have been reported in a non-randomized controlled study [18] and a qualitative study. [19] Moreover, in two pre-post intervention studies, the effect of MBSR program on some aspects of general health was indicated in women with infertility. [3,16] However, to the best of our knowledge, no randomized controlled clinical trial has yet examined the effects of MBSR alone on the QoL of women with infertility. Considering the importance of infertility in most Iranian families [9,20] and the influence of this problem on women's QoL, we aimed to assess the potential effects of such programs on the QoL of Iranian women with infertility in a randomized controlled trial.

2. Materials and Methods

2.1. Study design and ethical considerations

This randomized, controlled, parallel-group trial was registered in the Iranian Registry of Clinical Trials (No.: IRCT20180307038993N1). The Regional Ethics Committee of Ahvaz Jundishapur University of Medical Sciences (Ahvaz, Iran) approved the study protocol (No.: IR.AJUMS.REC.1396.907). All research activities were performed according to the ethical considerations of this committee. The trial objectives and methods were explained to potential participants, and a written informed consent was obtained from all women, who met the inclusion criteria. Also, women were informed of their right to withdraw from the study at any time.

2.2. Study sample and setting

Women, who were referred to the Infertility Center of Ahvaz Imam Khomeini Hospital, were invited to participate in the study. Women were included if they met the following criteria: 1) primary infertility for more than three years, confirmed by the assistant gynecologist; 2) a score of 50 or lower (low health-related QoL) on the 36-item short-form health survey (SF-36); 3) being in the age range of 25-40 years; 4) ability to participate in all sessions of the program; and 5) ability to read and write in Persian. On the other hand, the exclusion criteria were physical inability to perform the program practices and becoming pregnant during the study. Moreover, women with confirmed psychological disorders, history of substance abuse or drug/alcohol addiction, experience of regular mind-body practices or psychological interventions in the past six months, or use of anti-psychotic drugs in the past six months were excluded, as these factors could affect their QoL. [21,22]

2.3. Sample size

The sample size was estimated based on the findings of a recent study, [18] which indicated a significant difference in the total QoL between women participating in the MBI program and those receiving routine care. According to the findings of the mentioned study and the following formula, the optimal sample size was estimated to be 15 women per group at a confidence interval of 95% and power of 80%. However, 18 women per group were selected to counteract dropouts. The sample size formula was as follows:

$$n = \frac{\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right)^2 (\delta_1^2 + \delta_2^2)}{(\mu_1 - \mu_2)^2} = \frac{(1.96 + 0.84)^2 [(11.43)^2 + (12.67)^2]}{(71.72 - 59.09)^2}$$

$$= 15$$

2.4. Randomization

Women were selected using consecutive sampling from June to October 2018 by the main researcher (MSH). Women who met the inclusion criteria were randomly allocated into equal experimental (n = 18) and control (n = 18) groups via block randomization method. The randomization sequence was computer-generated using Stat Trek software, and group allocation was conducted by the assistant statistician (MHH), using opaque and sealed envelopes.

2.5. Intervention

In the two groups, women participated in eight two-hour group sessions (groups of six) once a week. Women in the experimental group participated in a program based on MBSR, while women in the control group received routine consultation. The interventions for the two groups were performed in the same center at the same time (from November to December 2018). All women in the two groups were asked to visit the center for participation in the program. For this purpose, women in the experimental group were asked to visit the center on even days, whereas those in the control group were scheduled to visit the center on odd days to avoid contamination between the groups. Most sessions for the two groups were held on weekdays according to the women's opinions. The interventions for the two groups were free of charge, and all participating women were awarded for participation. Moreover, at the end of the study, women in the control group were allowed to participate in the MBCP program for one day at no cost.

The MBSR program was implemented based on the protocol presented by Kabat-Zinn, [23] as well as other valid references 24–26. It was developed by a multidisciplinary research team, including three midwives, a psychologist, and a gynecologist, and was validated by 10 midwifery experts. The program included both theoretical and practical techniques, as well as home practices. The MBSR program and routine consultations were conducted by a master's degree student of midwifery (MSH), who had successfully completed a 10 -h workshop on MBSR and was trained by a fertility specialist about infertility consultation. An overview of the program is presented in Table 1.

At the beginning of the first session, women in the experimental group were encouraged to commit to home practices of each session six days a week. Also, a compact disk was presented to these women in the first session, which consisted of instructions for eight sessions, definition of mindfulness, mindfulness practices, and importance of being in the present moment. After the first session, each MBSR session began by checking the home assignments of the previous week. Moreover, all sessions, except the last session, ended with a review of home practices and goals for the next week. During the MBSR program, all women were contacted via phone calls to address any problems related to home practices. Also, those who missed one session of the program were contacted the next day, and the content of the session, as well as home practices, was reviewed. Women who were absent from more than two

Table 1
An outline of the mindfulness-based stress reduction (MBSR) program developed for women with infertility.

Week	Summary of the program	
One	Theoretical work	- Introduction and foundation of the program: greetings; program preparation and orientation (aims, contents, and structure); an introduction to mindfulness and MBSR and its effects; infertility complications; and common treatments of infertility - Automatic pilot: awareness of emotions, thoughts, bodily sensations, and behavioral being mode and doing mode; and mind wandering and its acceptance
	Practical work	Body scan practice; sitting meditation practice; eating meditation practice
	Home practice	Body scan (at least 6 hours per week or 45 min daily); sitting meditation (10 min daily in different times of body scan); eating meditation (raisin or other meals at least 4 times per week)
Two	Theoretical work	- Awareness and be present: mind rumination; from unawareness to awareness (observer or witness); the power of breathing; interruption of behavioral habits; attention without judgment; direct experience of psychical feelings and internal experiences; and mindfulness in activities of daily living
	Practical work	Body scan practice and sitting meditation practice
	Home practice	Body scan (at least 45 min daily); sitting meditation (10 min daily in different times of body scan); mindfulness in activities of daily living; and awareness of a pleasant event that had happened in lives in the past couple of days and recording of its related feelings and thoughts in daily calendar
Three	Theoretical work	- Attention: being non-judgmental; identification of behavioral patterns; self-thinking and self-observation; and being non-reactive
	Practical work	Body scan practice; sitting meditation practice; mindfulness yoga practice; and expanded awareness practice
	Home practice	Body scan and mindfulness yoga (at least 45 min daily in every other one manner); sitting meditation (15-30 min daily in different times of body scan and mindfulness yoga); and awareness of an unpleasant event that had happened in lives in the past couple of days and recording of its related feelings and thoughts in daily calendar
Four	Theoretical work	- Acceptance: direct experience of external experiences and events; goals and objectives, values, barriers, and commitment
	Practical work	Body scan practice; sitting meditation practice; mindfulness yoga practice; and expanded awareness practice
	Home practice	Body scan and mindfulness yoga (at least 45 min daily in every other one manner); sitting meditation (20 min daily in different times of body scan and mindfulness yoga); and loving-kindness (attention to any stressful events during a week and being kindness toward it instead of any efforts to change it)
Five	Theoretical work	- Stress: stuck in stress reactivity; responding to stress instead of reactivity; working with symptoms, physical pain, and emotional pain; sleep and sleep stress
	Practical work	Body scan practice; sitting meditation practice; mindfulness yoga practice; and walking meditation practice
	Home practice	Body scan; mindfulness yoga; and sitting meditation (at least 45 min daily alternately); walking meditation; responding to stress instead of reactivity; and awareness of a stressful relationship and recording of its related patterns in daily calendar
Six	Theoretical work	- Non-sexual meditation: self-communication; communication with others; feelings and beliefs about infertility - Sexual meditation: psychological differences of male and female; and sexual beliefs of couples
	Practical work	Body scan practice or mindfulness yoga practice; sitting meditation practice; walking meditation practice; and walking meditation yoga practice
	Home practice	Body scan; mindfulness yoga; and sitting meditation (at least 45 min daily alternately); walking meditation; responding to stress instead of reactivity; awareness of a stressful relationship and recording of its related patterns in daily calendar; and walking meditation yoga
Seven	Theoretical work	- Sexual information: gynecology anatomy; sexual reaction cycle; sexual stimulators; sexual differences; intercourse sections and positions - Common sexual problems
	Practical work	Sitting meditation practice; and one of previous weeks practices
	Home practice	Sitting meditation (at least 45 min daily); one of previous weeks practices (at least 45 min daily); self-observation at the end of each day in bed and in laying position, and loving-kindness (attention of loving to others)
Eight	Theoretical work	- Additional meditation information - Ending of program and conclusion
	Practical work	Body scan practice; sitting meditation practice; mindfulness yoga practice; and walking meditation practice
	Home practice	Body scan (at least 2 times per week), sitting meditation or mindfulness yoga or other selected practices; and walking meditation

The program developed by the protocol presented by Kabat-Zinn [23] as well as other valid references [24–26].

sessions of the program were not followed-up and were excluded from the study.

2.6. Data collection

2.6.1. Demographic and clinical data

The demographic and clinical characteristics of the participants were collected based on their clinical records and interviews, using a checklist including items on the age, educational level, and occupational status of women and their partners, duration of marriage, monthly income, residence status, family history of infertility, type of infertility, duration of infertility treatment, and type of infertility treatment.

2.6.2. Health-related QoL

Women's health-related QoL was evaluated using the Persian version of SF-36. This instrument is composed of eight subscales: 1) physical functioning (10 items); 2) social functioning (2 items); 3) role limitations due to physical problems (4 items); 4) role limitations due to emotional problems (3 items); 5) bodily pain (2 items); 6) general health (5 items); 7) vitality (4 items); and 8) mental health (5 items). The items of this self-rated survey are rated on a five-point Likert scale (score range = 0-4) or a three-point Likert scale (score range = 0-2). The negative items are inversely scored. The items are summed up to determine the total score, ranging from 0 to 100 for each subscale, as well as the total scale. Higher scores indicate higher QoL. [27] The validity and reliability of the Persian version of SF-36 have been confirmed by the Institute for Health Sciences Research. [28]

In the current trial, the primary outcome was total QoL, and the eight subscales were considered as the secondary outcomes. The survey of each group was completed by women at baseline (T1), immediately after the intervention (T2), and one month after the intervention (T3).

2.6.3. Safety data

The occurrence of adverse events was evaluated by recording all observed or volunteered adverse events. For this purpose, any adverse events were monitored by a fertility specialist's examinations at the end of each program or consultation session. Also the attribution of adverse events was specified by the specialist. To increase the reporting rate of the event, all patients were informed to the possibility of adverse events in the consent form. In the case of adverse events, the discontinuation was determined by either the patients or specialist. For patients who withdrew or lost to follow-up, adverse events were obtained by telephone. Due to the non-pharmacological nature of the interventions and also short treatment period, the laboratory monitoring were not planned. Moreover, we considered only descriptive statistics to report adverse events, because no explicit prespecified harms-related hypotheses were determined. [29]

2.7. Statistical analysis

The intention-to-treat analysis, with multiple imputation for missing data, was performed using SPSS version 22. Chi-square test was used to assess the homogeneity of the groups for demographic and clinical characteristics. The normal distribution of variables was confirmed using Kolmogorov–Smirnov test. Since the baseline values were significantly different between the groups in terms of the total score of QoL and also the subscales of "role limitations due to emotional problems" and "mental health", analysis of covariance (ANCOVA) was used to compare the mean changes between the groups (baseline values as covariates). In all analyses, *P*-value less than 0.05 was considered to be significant.

3. Results

3.1. Follow-up

There were no withdrawals due to harms with the allocated intervention; however, of 36 randomized women, three from the experimental group and three from the control group did not complete the study due to the absence in more than two sessions of the program (n = 4), pregnancy (n = 1), and dissatisfaction with intervention (n = 1) (Fig. 1).

3.2. Demographic and clinical characteristics

No significant differences were found between the groups in terms of the demographic characteristics and clinical data (Table 2).

3.3. Primary outcome

Based on the inter-group comparisons using ANCOVA test, the mean changes of QoL were significant compared to the baseline both at T2 ($P < 0.001$) and T3 ($P < 0.001$) in favor of the experimental group (Table 3).

3.4. Secondary outcomes

Based on the ANCOVA results, the mean changes in all subscales, except for "social functioning" and "bodily pain", were significantly different compared to the baseline both at T2 and T3 in favor of the experimental group (Table 3).

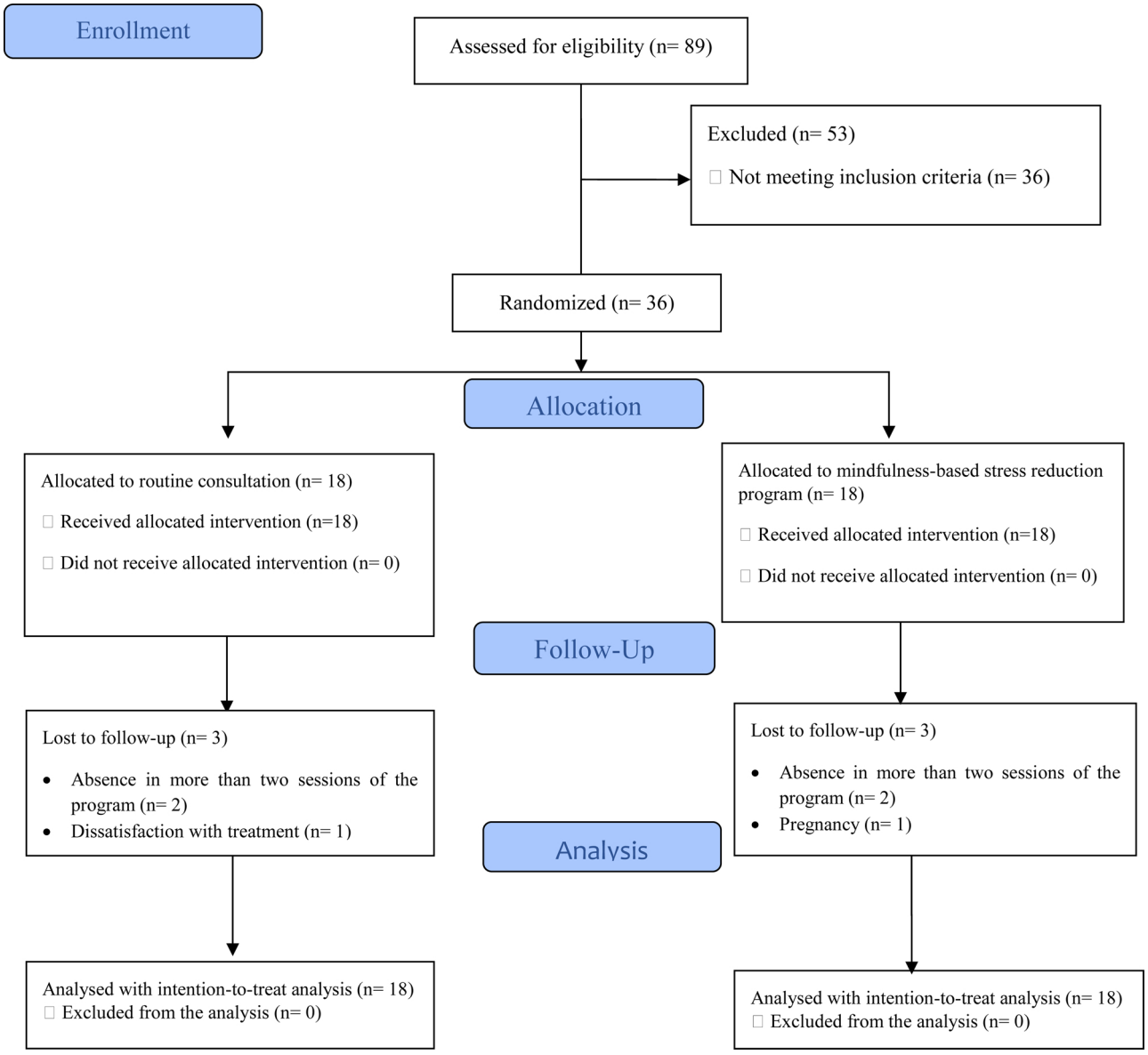

Fig. 1. CONSORT flow diagram of the groups' enrollment, allocation, intervention, follow-up, and analysis.

Table 2
Demographic and clinical characteristics of the experimental and control groups.

Characteristics		Experimental group (n = 18)	Control group (n = 18)	*P-value*[†]
Woman' age (year)	25-30	7 (38.88)	7 (38.88)	0.917
	31-35	9 (50.00)	7 (38.88)	
	36-40	2 (11.12)	4 (22.24)	
Partner's age (year)	26-30	4 (22.24)	7 (38.88)	0.510
	31-35	6 (33.32)	4 (22.24)	
	36-40	8 (44.44)	7 (38.88)	
Duration of marriage (year)	3-5	4 (22.24)	5 (27.79)	0.061
	6-10	5 (27.77)	6 (33.33)	
	11-15	8 (44.44)	1 (5.55)	
	16-25	1 (5.55)	6 (33.33)	
Woman' education	Less than diploma	7 (38.88)	9 (50.00)	0.731
	Diploma	9 (50.00)	7 (38.88)	
	Collegiate	2 (11.12)	2 (11.12)	
Partner' education	Illiterate	1 (5.52)	0 (0.0)	0.151
	Less than diploma	4 (22.24)	11 (61.11)	
	Diploma	9 (50.00)	5 (27.77)	
	Collegiate	4 (22.24)	2 (11.12)	
Woman' occupational status	Employee	1 (5.55)	2 (11.12)	0.597
	Homemaker	17 (94.45)	16 (88.88)	
Partner's occupational status	Unemployed	2 (11.12)	2 (11.12)	0.062
	Self-employed	6 (33.32)	13 (72.23)	
	Laborer	6 (33.32)	1 (5.55)	
	Employee	4 (22.24)	1 (5.55)	
	Retired	0 (0.0)	1 (5.55)	
Monthly income	Good	0 (0.0)	2 (11.12)	0.144
	Moderate	13 (72.23)	8 (44.44)	
	Weak	5 (27.77)	8 (44.44)	
Residence status	Personal	3 (16.66)	4 (22.24)	0.120
	Rental	15 (83.34)	14 (77.76)	
Family history of infertility	Yes	5 (27.77)	5 (27.77)	1.000
	No	13 (72.23)	13 (72.23)	
Type of infertility	Feminine	9 (50.00)	2 (11.12)	0.071
	Masculine	5 (27.78)	11 (61.11)	
	Both feminine and masculine	3 (16.67)	3 (16.65)	
	Unknown	1 (5.55)	2 (11.12)	
Duration of infertility (year)	3-5	4 (22.23)	5 (27.78)	0.278
	6-10	5 (27.78)	5 (27.78)	
	11-15	7 (38.88)	6 (33.32)	
	16-25	2 (11.11)	2 (11.12)	
Duration of infertility treatment (year)	1-5	6 (33.32)	7 (38.88)	0.311
	6-10	3 (16.66)	2 (11.12)	
	11-15	3 (16.66)	3 (16.66)	
	More then 16	3 (16.66)	6 (33.34)	
Type of infertility treatment	Drug use	6 (33.33)	3 (16.66)	0.307
	Intrauterine insemination	7 (38.88)	5 (27.79)	
	Other	5 (27.79)	10 (55.55)	

Data are presented as number (percentage).
[†] Chi-square test

3.5. Safety data

In the experimental group, some adverse events with minor severity were occurred during the MBSR sessions as the result of fertility drugs. These adverse events included fatigue (n = 6), headache (n = 1), dizziness (n = 2), abdominal discomfort (n = 2), nausea (n = 3), cramps (n = 4), and breast tenderness (n = 3). Most reported adverse events disappeared within few hours after the home practice and/or practical work. Moreover, two women reported ovarian hyperstimulation syndrome lasted for a maximum of three day. In addition, one pregnancy was reported in a woman who lost to follow-up. In the control group also women reported some minor adverse events with similar severity to the experimental group, such as vomiting (n = 1), headaches (n = 3), abdominal discomfort (n = 1), and cramps (n = 1). Due to experience of abdominal discomfort, one woman in the control group decided to withdraw from the study.

4. Discussion

In this study, we investigated the potential effectiveness of an eight-week MBSR program in improving the QoL of Iranian women with infertility. Based on the findings, total QoL and subscales of "physical functioning", "role limitations due to physical problems", "role limitations due to emotional problems", "general health", "vitality", and "mental health" significantly increased after the intervention among women participating in the MBSR program, compared to women who received routine consultation. However, no significant difference was found between the groups regarding "social functioning" and "bodily pain".

The present study provided initial evidence supporting the effect of MBIs on improving the QoL of women with infertility. In a study conducted on Chinese women subjected to their first in vitro fertilization (IVF), a significant increase was observed in all fertility-related QoL domains in women who attended a mindfulness-based program, including MBSR components in combination with mindfulness-based cognitive therapy, mindfulness-based childbirth and parenting, and acceptance and commitment therapy (ACT). [18] It was found that women with experience of participation in the aforesaid intervention had experienced an improved infertility-related QoL. [19]

Furthermore, in a pre-post intervention study on infertile women waiting for IVF, it was found that a 12-week MBSR program (mindfulness meditation, relaxation, autogenic training, biofeedback, and guided imagery) significantly improved the total score of general well-being, as well as all subscales of the Psychological General Well-Being Index (PGWBI). [16] Similarly, a randomized controlled trial indicated that an eight-session MBSR program (two hours per session) significantly increased the general well-being of women, as measured by PGWBI. [30] Although our findings are in line with the mentioned studies on the effects of MBIs on the QoL of women with infertility, differences in the study design, MBI program, women's characteristics, and measures of QoL should be considered.

Moreover, the findings of the present study substantiate the available data regarding the effects of MBIs on other health-related outcomes of women with infertility. In a non-randomized controlled clinical trial among Portuguese women with infertility, a 10-week mindfulness-based program (developed based on MBSR, mind/body program for infertility, and basic principles of ACT) significantly decreased depressive symptoms, internal and external shame, entrapment, and defeat. It also inversely improved the subjects' mindfulness skills and self-efficacy to deal with infertility. [13] In another randomized controlled trial on women undergoing IVF or intracytoplasmic sperm injection, women in the brief mindfulness group (four sessions including guided mindfulness breathing and body scan) showed decreased depression and improved sleep quality, compared to the control group receiving routine care. [11] All of the mentioned psychological measures are predictors of QoL; therefore, it seems that the present study can support the reviewed research.

Although a growing body of literature has indicated the importance of mind-body connection and infertility, [31,32] the mechanism through which MBSR programs can affect the QoL of infertile women has not been fully addressed. In a previous qualitative study, it was found that participation in MBSR programs could be beneficial for women with infertility in several ways through improving the mind-body connection, self-discovery, learning, and stress relief. Overall, MBSR programs make infertility-related stress more manageable, enhance women's

Table 3
Comparison of the quality of life of the experimental and control groups on different times.

Quality of life*	Experimental (n = 18)	Control (n = 18)	Changes compared with T1		
	Mean ± SD	Mean ± SD	Experimental group Mean ± SE	Control group Mean ± SE	*P*-value†
Physical functioning					
T1	56.66 ± 10.28	54.44 ± 5.65	-	-	-
T2	70.83 ± 11.14	56.11 ± 5.05	14.71 ± 1.81	1.11 ± 1.81	< 0.001
T3	68.33 ± 10.28	56.11 ± 6.54	12.28 ± 1.87	1.04 ± 1.87	< 0.001
Social functioning					
T1	43.88 ± 12.28	45.83 ± 7.42	-	-	-
T2	58.47 ± 14.68	51.38 ± 13.48	13.71 ± 3.77	6.42 ± 14.36	0.137
T3	58.47 ± 10.25	56.25 ± 16.74	13.77 ± 3.30	11.22 ± 3.30	0.591
Role limitations due to physical problems					
T1	40.27 ± 19.43	40.27 ± 12.54	-	-	-
T2	70.83 ± 17.67	44.44 ± 10.69	30.55 ± 2.44	4.16 ± 2.44	< 0.001
T3	73.61 ± 15.97	47.22 ± 16.90	33.33 ± 2.64	6.94 ± 2.64	< 0.001
Role limitations due to emotional problems					
T1	20.35 ± 16.70	37.00 ± 19.74	-	-	-
T2	66.62 ± 21.87	37.00 ± 15.69	46.34 ± 5.39	−0.07 ± 5.39	< 0.001
T3	62.92 ± 27.74	42.55 ± 19.13	42.06 ± 6.17	6.06 ± 6.17	0.001
Bodily pain					
T1	45.69 ± 16.06	48.88 ± 10.64	-	-	-
T2	60.97 ± 17.51	52.50 ± 12.87	13.97 ± 3.63	4.91 ± 3.63	0.088
T3	60.41 ± 15.10	60.00 ± 9.39	13.34 ± 2.98	12.48 ± 2.98	0.840
General health					
T1	40.66 ± 5.34	39.32 ± 4.33	-	-	-
T2	61.32 ± 9.12	40.25 ± 5.34	20.96 ± 1.68	0.62 ± 1.68	< 0.001
T3	63.62 ± 8.18	43.49 ± 6.27	23.18 ± 1.57	3.94 ± 1.57	< 0.001
Vitality					
T1	35.00 ± 10.28	40.00 ± 10.43	-	-	-
T2	56.11 ± 9.16	41.11 ± 9.32	20.13 ± 1.64	2.08 ± 1.64	< 0.001
T3	54.16 ± 9.27	45.27 ± 9.62	18.25 ± 1.64	6.18 ± 1.64	< 0.001
Mental health					
T1	22.77 ± 10.55	36.66 ± 9.43	-	-	-
T2	58.00 ± 8.14	37.77 ± 9.32	32.52 ± 2.20	4.81 ± 2.20	< 0.001
T3	57.11 ± 7.10	39.55 ± 9.39	32.23 ± 2.30	5.98 ± 2.30	< 0.001
Total					
T1	38.07 ± 3.06	42.86 ± 3.67	-	-	-
T2	62.89 ± 8.65	45.06 ± 4.72	23.60 ± 1.83	3.41 ± 1.82	< 0.001
T3	62.32 ± 7.58	48.66 ± 7.03	23.01 ± 1.91	7.04 ± 1.91	< 0.001

T1: before the intervention (baseline), T2: immediately after the intervention, and T3: one month after the intervention.
Values are expressed as mean ± standard deviation.
* Measured by the 36-item short-form health survey (higher scores indicate higher quality of life).
† Analysis of covariance (baseline values as covariates)

awareness, offer opportunities for self-care, and improve the sense of community and social support. [16] Moreover, it was found that improvement of mindfulness skills can help infertile women experience negative inner feelings in new ways. It also decreases their entanglement with these negative feelings and reduces their psychological distress. [13] The MBSR programs seem to be effective in minimizing the suffering and negative consequences of infertility and its treatment. They also help women pay less attention to their infertility problem and live a more vital, flexible, and value-based life. [13] Future studies need to determine the mechanisms of MBSR programs in order to develop more effective programs, especially for infertile women.

Although the present findings improved our understanding of the value of MBSR programs in promoting QoL, they should be interpreted with caution due to some limitations. Even though the intention-to-treat analysis was performed for the missing data, the small sample size can limit the generalizability of our findings. In addition, generalization of the present findings may be limited as only women with infertility were recruited in the study. Moreover, this study had a non-blind design, as women could not be blinded due to the nature of the intervention. We provided routine consultation for women in the control group at the same time as the experimental group participating in the program and with the same instructor. However, the beneficial effects of MBSR program could be related to the higher level of researcher's attention to women in the experimental group, compared to the control group. In addition, the observed changes in QoL after the MBSR program may be attributed to demand characteristics, expectations, therapist support, and group support.

Despite the aforesaid limitations, the findings of the present study could provide valuable evidence regarding the usefulness of MBSR programs for women with infertility. Overall, both interventions were safe, but some women reported side effects at the end of some session of MBSR program due to fertility drug use. Hence, considering low cost, easy usage, and safety, MBSR program can be used as appropriate strategy, along with other routine care programs for infertile women.

5. Conclusion

The short-term MBSR program, which included eight two-hour group sessions per week, was effective in improving the QoL of women with infertility. We recommend further rigorous studies with a larger sample size and an active control group (i.e., group therapy and support group program) to assess the effects of similar interventions on QoL and other related outcomes, such as self-care and response to treatment. In addition, it is useful to determine if the benefits of MBSR programs can be sustained in women's partners. Also, data triangulation can be beneficial for a reliable analysis of QoL after MBSR programs. Finally, it is recommended to determine the cost-effectiveness and mechanisms of MBSR programs in women with infertility.

Declaration of Competing Interest

The authors declare that they have no conflict of interests.

Authors' contribution

MSH: Study conception and design, data collection, data analysis and interpretation, and manuscript preparation; PM: supervision (midwife), study conception and design, data interpretation, and critical revision of the paper; KH: supervision (midwife), study conception and design, data interpretation, and critical revision of the paper; MHH: supervision (statistician), study conception and design, data analysis, and critical revision of the paper; EJF: supervision (psychologist), study conception and design, and critical revision of the paper; EMJ: supervision (gynecologist), study conception and design, data analysis, and critical revision of the paper. All the authors read and approved the final manuscript.

Ethical approval

The Ethics Committee of Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran, approved this trial (Reference No. IR.AJUMS.REC.1396.907).

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.ctim.2020.102403.

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