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The effect of mindfulness-based nursing support on the psychosocial status of women receiving infertility treatment: a randomized controlled trial

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Abstract

Background This study aimed to evaluate the effect of mindfulness-based support on the psychosocial status of women undergoing infertility treatment.

Method The study was conducted with 34 women who were about to start in vitro fertilization (IVF) and met the inclusion criteria. Participants were randomly assigned to either the experimental group ($n = 17$) or the control group ($n = 17$) using random number sequences generated on "<http://www.random.org>. This process accounted for potential participant loss and was implemented in the order of participation. When cases withdrew, new participants were assigned based on the random sequence. All participants were women over the age of 18, literate, and users of smartphones. The experimental group used the IVFmind mobile application, specially developed for this study to facilitate mindfulness practices for infertility treatment. Psychosocial status was assessed using the Mindfulness Attention Awareness Scale, Infertility Self-Efficacy Scale-Short Form, Infertility Adjustment Scale, and Depression Anxiety Stress Scale. Data were collected through pre-tests and post-tests, and statistical analyses were performed.

Results There were no significant differences between the experimental and control groups in terms of socio-demographic characteristics and infertility-related factors ($p > 0.05$). Mindfulness Attention Awareness Scale: No significant difference was found between groups in the pre-test scores ($U = 120,000$, $p = 0.398$). However, post-test scores of the experimental group were significantly higher than those of the control group ($U = 0.000$, $p < 0.001$). Infertility Self-Efficacy Scale-Short Form: No significant difference was found between groups in the pre-test scores ($U = 125,500$, $p = 0.503$). In the post-test, the experimental group scored significantly higher than the control group ($U = 0.000$, $p < 0.001$). Infertility Adjustment Scale: Pre-test scores showed no significant differences between the groups ($U = 106,500$, $p = 0.184$). In the post-test, the experimental group had significantly lower scores compared to the control group, indicating better adjustment ($U = 3,000$, $p < 0.001$). Depression Anxiety Stress Scale: There was no significant difference between the groups in the pre-test scores ($U = 141,000$, $p = 0.904$). However, post-test scores of the experimental group were significantly lower than those of the control group ($U = 56,500$, $p = 0.002$).

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Conclusions The mindfulness-based mobile application positively impacted the psychosocial status of women undergoing infertility treatment, demonstrating significant improvements. The experimental group showed notable increases in mindfulness, self-efficacy, and adjustment levels, along with significant reductions in depression and anxiety. These results highlight the effectiveness of mindfulness-based interventions in addressing psychological challenges associated with infertility and suggest that mobile applications can be a valuable tool for supporting mental health in this context.

Trial registration The research was registered on <http://clinicaltrials.gov> (ID: NCT05708937). Date of Registration: 01\24\2023.

Keywords Infertility, Woman, Women's health, Nursing care, Depression, Anxiety, Mindfulness

Introduction

Globally, it has been reported that approximately 15% of couples are affected by infertility, which is considered a significant health issue [1]. Infertility is seen as a major public health concern and its prevalence has been reported to be increasing in recent years. The rising rates of infertility worldwide highlight the need for greater attention to this issue from a public health perspective and indicate an additional burden on health systems. This increase is associated with various factors such as lifestyle changes, environmental influences, and aging [2]. The growing prevalence of infertility necessitates the development of effective treatment methods and the enhancement of public awareness.

Infertility is not only an individual problem but also a couple's problem; it is defined as 'the failure to conceive after one year of regular and unprotected intercourse' [3]. Infertility is a process that has social, cultural, and psychological effects as well as physical conditions. Infertility treatment is stressful and threatening for most couples, and it becomes a life crisis because the procedures are physically painful and financially challenging [4, 5]. The stages of infertility diagnosis and treatment contribute to a gradual decline in patients' psychological resilience, affecting their self-confidence, self-esteem, self-efficacy perceptions, and mental health, and leading to disruptions in coping mechanisms with stress [6]. In some cases, confronting infertility has been noted to lead to changes in one's identity as a parent or in self-concept [7–9].

In the emotional context of this challenging process, it has been observed that infertile women are psychologically more affected compared to infertile men [10, 11]. Infertile women have been reported to experience feelings of hopelessness, depression, pessimism, thoughts of punishment, and questioning their existence due to a perceived loss of control [12–14]. In such a complex psychosocial process, the nursing care provided to women during the prolonged and intricate treatment must encompass more than just physical care. Therefore, individuals, especially women, undergoing infertility diagnosis and treatment require substantial social support [15].

Nurses play a crucial role in supporting the treatment process for infertile women, helping them accept their situation and prepare for re-treatment if the initial treatment is unsuccessful [16, 17]. In this context, according to Watson's Theory, which focuses on human care rather than treatment and intervention, the goal of nursing is to help achieve balance and harmony between the experience of health and illness [18]. A nurse should approach an infertile woman with the same natural and sincere attitude of love that one would have when listening to the problems of a loved one [19]. Watson's Human Caring Theory encompasses a holistic approach to an individual's emotions, thoughts, bodily responses, beliefs, goals, and expectations. It is based on the idea that patients or individuals should receive healing care through their existence as a mind-body-spirit entity [20]. Cognitive (conscious) awareness is a process through which a person learns to focus on the present moment with their holistic state of body, mind, and spirit. Furthermore, cognitive awareness-based care can also be an effective method in fulfilling the functions of "mental-perceptual, values-beliefs, stress-coping, self-concept" from Gordon's Functional Health Patterns model [21]. Nurses can provide emotional support during the infertility process, helping patients manage stress. Especially in the face of the uncertainties and challenges of the IVF process, they can offer counseling services to enhance patients' emotional resilience [22]. Teaching stress management strategies such as mindfulness, yoga, and relaxation techniques can help patients feel more comfortable and at ease during the IVF process [23–26]. Nurses can promote the use of these techniques and guide patients in their application [27].

Mindfulness is a concept that has recently gained popularity and has been defined by Brown and Ryan (2003) as "focusing an individual's attention on the present moment in a non-judgmental and accepting manner" [28]. Although mindfulness has been around for many years, it is only in recent years that it has been the subject of research into its effects on health. There are studies showing that mindfulness helps patients especially to cope with stress, pain or chronic diseases [29–36].

There are also studies in the literature showing that mindfulness-based care is an effective method to improve psychological health such as quality of life, stress, and marital harmony in infertile women [37–39]. In many studies, it has been observed that mindfulness studies are effective on psychosocial problems (anxiety, stress, self-compassion, marital harmony) experienced in infertility [38–45]. In a study where mindfulness-based interventions were implemented, increases in mindfulness levels, self-compassion, and coping strategies among infertile women during their first IVF treatment were observed, leading to improvements in fertility-related quality of life and pregnancy rates [22].

Studies on infertile women have shown that psychosocial support programs involving nurses can enhance individuals' self-efficacy, adjustment levels, and psychosocial well-being [46–48]. The important role of nurses in infertility clinics is to support patients in coping with the effects of infertility [18].

Although research on infertility and mindfulness (cognitive awareness) has been conducted internationally, there are no studies on mindfulness in the context of infertility in Turkey. While research on mindfulness has been conducted with cardiac, psychiatric, and oncology patients in Turkey, no study has been focused on infertility. Despite the positive results of mindfulness research in infertility in other countries, its effects on Turkish women have not yet been measured. Therefore, this study aims to implement a current application designed to promote psychosocial improvement and health in Turkish women undergoing infertility treatment using a modern method. In Europe, numerous cognitive awareness-based mobile applications are available [39]; however, a mobile application specifically developed for infertility is a newer concept. A review of literature reveals the existence of a mobile application called MindfulSpot, which was developed to measure the effectiveness of cognitive awareness (mindfulness) in infertility treatment, although its results have not yet been published [44]. Another study measured the effects of a mobile application called PreLife, designed to facilitate pre-pregnancy lifestyle changes (diet, physical activity, personal health), on infertile women in terms of diet, physical activity, emotional state, body mass index, waist circumference, quality of life, treatment continuation rates, and pregnancy rates. While this study included cognitive awareness-based messages, it did not focus on measuring the effects of cognitive awareness applications specifically aimed at providing psychosocial support to women undergoing infertility treatment through a mobile application [49].

In this study, we measured the effect of a mobile application developed for mindfulness-based psychosocial support in women undergoing infertility treatment on the psychosocial status of infertile women during the

treatment process was measured. The psychosocial variables “depression, anxiety, stress, and low self-efficacy” were chosen to be studied because these are common issues experienced by women undergoing IVF treatment. Additionally, the study aimed to measure the levels of mindfulness before and after the intervention to determine its effect. In this context, depression, anxiety, stress levels, infertility adjustment, and self-efficacy were examined as dependent variables in the study. The effect of the mindfulness application on these variables was measured.

Materials and methods

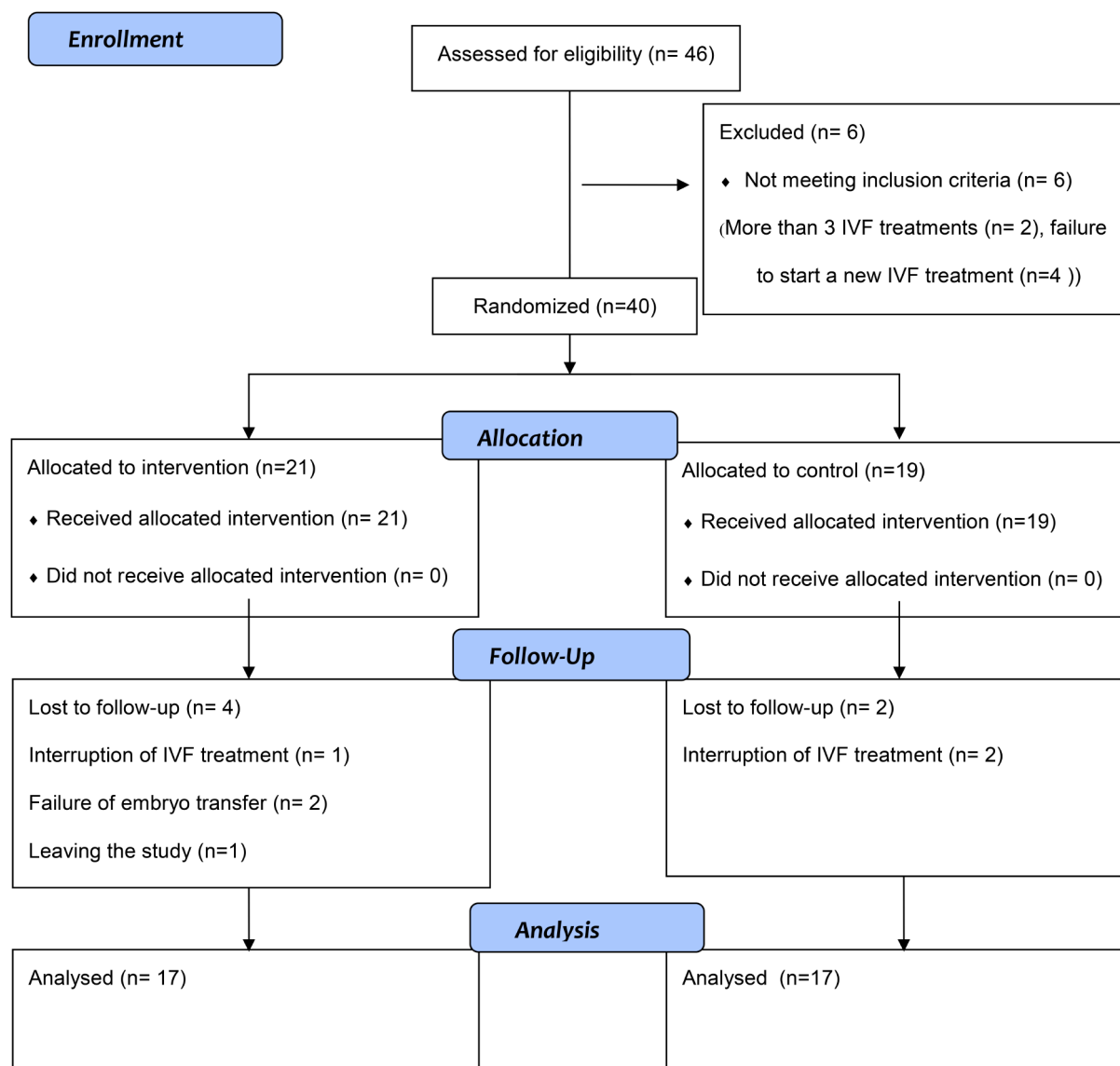
Ethical approval and consent to participate

Ethical approval was obtained with the permission letter numbered E-74555795-050.01.04-52289 dated 08.02.2021 from Istanbul University Social and Human Sciences Ethics Committee. The “Scientific Research Permit” from the General Directorate of Health Services of the Turkish Ministry of Health was obtained on 19.03.2021 with the form number “2021-03-19T12_06_32”. Informed consent was obtained from the patients whose data would be collected in the study. We acknowledge that the research complies with the Declaration of Helsinki. Patients were contacted between May 2021 and 2022. The study was completed in October 2022.

Sample and sampling method

This study is a randomized controlled experimental type of study. The sample size was calculated using G Power 3.1 software. For the power analysis, previous international studies were referenced [26]. The effect size was determined as 0.754, with a significance level of 0.05, a 95% confidence interval, and a test power of 80%. Based on a two-tailed hypothesis test, the optimal number of female participants per group was determined to be 17. In total, 34 women who met the inclusion criteria were included.

Participants were recruited from both an IVF clinic and through social media platforms to ensure a diverse sample; however, the inclusion criteria remained consistent across both recruitment sources. Women (n:15) receiving treatment at an IVF (in vitro fertilization) Center Clinic in Istanbul and women who used social media and were receiving IVF treatment (n:19) were included in the study. As shown in Fig. 1, the CONSORT 2010 flow diagram illustrates the participant flow in the study. Of the 46 women assessed for eligibility, 6 were excluded due to not meeting the inclusion criteria. A total of 40 participants were randomized, with 21 allocated to the intervention group and 19 to the control group. Final analyses included 17 participants from each group.

**Fig. 1** Consort flow chart**Inclusion criteria**

- Completion of the informed consent form and voluntary participation in the study.
- Not having a psychiatric illness diagnosed by a psychiatrist, such as “schizophrenia, bipolar disorder, major depression, anxiety disorders,” and not receiving treatment for major depression or mood disorders during the treatment process.
- Be at the beginning of IVF treatment (starting ovarian stimulation) or soon to start treatment.
- A maximum of three previous IVF attempts.
- Use a smartphone.
- Speak and understand Turkish.
- Over 18 years of age.

Exclusion criteria

- Termination of treatment at any stage.
- Cancelled prior to embryo transfer.
- Voluntary withdrawal from the study.

Participant recruitment

Participants were recruited from an IVF Center Clinic in Istanbul. The recruitment process involved methods such as referrals from clinic nurses and fertility specialists. The study team contacted potential participants and provided them with detailed information about the study, including its purpose, procedures, and potential benefits and risks. Interested individuals were then screened for eligibility based on the inclusion and exclusion criteria. Those who met the criteria and agreed to participate

were enrolled in the study after communication with the researchers. Additionally, an Instagram account named IVFmind was created by the researcher to announce the study details. Messages were sent to Instagram accounts related to IVF, and women who responded and were interested in the announcement were included in the study if they met the criteria.

Study design

This study is a parallel-group, randomized controlled trial. Participants were randomly allocated to either the experimental group or the control group in a 1:1 ratio. The experimental group received mindfulness meditation training through a mobile application, while the control group did not receive any intervention related to mindfulness.

The hypothesis of the study was that mindfulness meditation through a mobile application would improve levels of mindfulness and reduce symptoms of depression, anxiety, and stress among women undergoing IVF treatment, compared to those who did not receive the mindfulness intervention.

Important changes to methods after trial commencement

No significant changes to the methods were made after the trial commenced. The eligibility criteria remained the same throughout the study period.

Settings and locations

Data were collected at an IVF Center Clinic in Istanbul. The mindfulness application was used by participants in their own time and location.

Intervention procedure

- The experimental group engaged in mindfulness meditation exercises through a mobile application. The intervention consisted of daily guided mindfulness practices, each lasting approximately 20 min, over a period of 8 weeks.
- The control group received no specific intervention related to mindfulness during the study period.
- Both groups were instructed to continue their standard IVF treatment protocols as prescribed by their fertility specialists.

Pre-specified primary and secondary outcome measures

Primary outcomes

Mindfulness, measured using the Mindful Attention Awareness Scale (MAAS). This was assessed at baseline and after 8 weeks of intervention.

Secondary outcomes

Levels of depression, anxiety, and stress measured using the Depression Anxiety Stress Scale (DASS 21). This was assessed at baseline and after 8 weeks of intervention. Self-efficacy related to infertility measured using the Infertility Self-Efficacy Scale - Short Form, assessed at baseline and after 8 weeks of intervention. Adjustment to infertility measured using the Fertility Adjustment Scale, assessed at baseline and after 8 weeks of intervention. No changes to the trial outcomes were made after the trial commenced.

Randomization/group assignment

Simple randomization was performed for a total of 40 participants using random number sequences generated on www.random.org, without blocking or restriction. Participants meeting the inclusion criteria were assigned to either the experimental or control group according to this sequence in the order of their enrollment. Due to participant attrition, new participants were allocated to the corresponding group based on the sequence. The study was ultimately conducted with 34 participants: 17 in the experimental group and 17 in the control group. The experimental group practiced mindfulness meditation via a mobile application, while the control group received no mindfulness-related intervention. All participants completed both pre-tests and post-tests. Blinding was not applicable for participants or care providers due to the nature of the intervention.

Measurements

Personal information form

The 21-item form was developed by the researchers. It consists of socio-demographic information and questions about infertility and obstetric history.

Mindful attention awareness scale (MAAS)

This scale, which was developed by Brown and Ryan in 2003, aims to measure mindfulness and attention to momentary experiences in daily life. The scale contains 15 items and is responded to as a 6-point Likert scale. The higher the score on the scale, the higher the level of mindfulness. The Mindful Attention Awareness Scale has a single-factor structure and a single total score. The internal consistency coefficient of the Turkish version of the scale is Cronbach Alpha (α) = 0.80 [50]. The consistency of the scale in our study was found to have a good degree of reliability, with the Cronbach's Alpha coefficient being 0.872 in the pre-test and 0.957 in the post-test.

The depression anxiety stress scale (DASS 21)

This is the abbreviation of the Depression Anxiety Stress Scale (DASS 21), which is used to measure the level of depression, anxiety and stress. The long version of the

scale (DASS 42) was developed by Lovibond and Lovibond (1995) [51]. The 4-point Likert-type scale, which aims to measure the level of “depression, anxiety and stress” under three headings, consists of a total of 21 items. Scoring 5 points in the depression subdimension, 4 or more points in anxiety and 8 or more points in stress indicates that the individual has a relevant problem. The internal consistency coefficient of the Turkish version of the scale is $\alpha = 0.808$ for anxiety, 0.819 for depression, and 0.756 for stress [52]. When the scale reliability of our study was examined, the Cronbach alpha coefficient of the DASS 21 Scale in the pre-test was 0.870, while the Cronbach alpha coefficients of the subdimensions were 0.576 for anxiety, 0.838 for depression, and 0.587 for stress. As a result of the analysis, it was determined that the DASS 21 scale and its sub-dimensions were found to have good reliability.

Infertility self-efficacy scale-short form

It was developed in 2006 to assess individuals' self-efficacy perceptions of the strength of their emotional, cognitive, and behavioral skills in relation to infertility [53]. The nine-point Likert-type scale consists of a total of 16 items and the short form consists of 10 items. The internal consistency coefficient of the Turkish version of the scale is $\alpha:0.78$ [54]. The scale is unidimensional, and the scores are between 8 and 32. The higher the score, the higher the perceived self-efficacy. The Cronbach alpha coefficient of the scale used in our study was 0.733 in the pre-test. As a result of the analysis, the scale was found to have a good level of reliability.

Fertility adjustment scale

It was developed by Glover et al. in 1999 to standardize the measurement of psychological adjustment in infertility [55]. The scale is a 12-item, six-point Likert scale. The minimum scale score is 12 and the maximum score is 72. A high score on the Infertility Adjustment Scale indicates inadequate adjustment. The internal consistency coefficient of the Turkish version of the scale is $\alpha:0.77$ [54]. In our study, the Cronbach alpha coefficient in the pretest of the scale was 0.689. The scale and its sub-dimensions were found to have good reliability.

Data analysis

SPSS (Statistical Package for Social Sciences) for Windows 25.0 program was used for the statistical analysis of the data. Descriptive statistics (mean, standard deviation, median, quads, percentage) and chi-square analysis for homogeneity were used to evaluate the data. The Kolmogorov-Smirnov-Shapiro-Wilk method was used to test for normal distribution of quantitative data, and the Mann-Whitney U analysis was used to test for differences between two independent groups when comparing

data that were not normally distributed. The Wilcoxon signed-ranks test was used for within-group comparisons of non-normally distributed quantitative variables. A p-value less than 0.05 was considered statistically significant. Confidence intervals (CI) of 95% were used for estimates.

Statistical assumptions and data distribution normality

To ensure the validity of the study results, it is crucial to address various statistical assumptions, including the normality of data distribution. In this study, we employed SPSS (Statistical Package for Social Sciences) for Windows 25.0 for data analysis. The descriptive statistics of the study data were assessed using methods such as mean, standard deviation, median, quartiles, percentages, minimum, and maximum values.

The homogeneity of the experimental and control groups was tested using the Chi-square analysis. Normality tests for quantitative data were conducted using the Kolmogorov-Smirnov and Shapiro-Wilk methods.

For quantitative data that did not meet normal distribution assumptions, differences between independent groups were analyzed using the Mann-Whitney U test. To evaluate whether there were statistically significant differences in the scores of pre-test and post-test measures (Cognitive Awareness, DASS 21, Infertility Adaptation, and Infertility Self-Efficacy) between the experimental and control groups, the Mann-Whitney U test was applied.

In cases where the quantitative data did not follow a normal distribution, Wilcoxon (Signed-Ranks) test was used for within-group comparisons. The statistical significance of differences in scores from pre-test and post-test measures for participants in both the experimental and control groups was assessed using the Wilcoxon (Signed-Ranks) test.

For examining the relationships between the scales used in the study with non-normally distributed measurements, Spearman correlation analysis was performed. Reliability of the scales and their sub-dimensions was tested using Cronbach's Alpha.

Customization of the mindfulness application for infertility treatment

A mindfulness-based intervention was applied to the experimental group participants through a mobile application designed to provide psychosocial support during the infertility treatment process. This mindfulness intervention is based on established mindfulness practices and principles. Specifically, the protocol includes daily mindfulness messages and audio recordings focused on mindfulness breathing and body awareness exercises. During an approximately 120-minute training session,

participants were introduced to the concept of mindfulness, its benefits, and practical techniques.

This approach is grounded in Kabat-Zinn's (1990) foundational work on mindfulness-based stress reduction (MBSR) and has been adapted to fit the context of infertility [56]. It is inspired by studies demonstrating the effectiveness of mindfulness in improving psychological health in women undergoing infertility treatment [23, 57, 58]. Participants were instructed to regularly engage in mindfulness exercises throughout the treatment process and to reinforce these skills.

The customization of the mindfulness application for infertility involved basing the content on the stages of the IVF treatment process. Audio recordings were created for specific stages such as oocyte retrieval and embryo transfer. For example, mindfulness body scans were tailored to focus on the woman's uterus and ovaries, and visualizations of the uterine lining (endometrium). Cognitive awareness exercises were diversified and customized with input from experts in women's health, psychiatric nursing, psychology, and linguistics. Unique messages were provided, such as focusing on the ovaries and uterus

during body scans and on the embryo and uterine wall after embryo transfer.

Mindfulness audio therapy content specific to infertility

The mindfulness meditation content for infertility treatment was prepared by reviewing national and international sources. Expert opinions were sought from academic personnel in the fields of women's health nursing, psychiatric nursing, psychology, and linguistics specializing in mindfulness. As a result, six different meditation contents were developed:

- (1) Breath Awareness.
- (2) Body Scan (specific to IVF treatment).
- (3) Drug Administration and Ovarian Awareness.
- (4) Diaphragm Breath before Oocyte Pick up (OPU).
- (5) Uterine Awareness Before Embryo Transfer.
- (6) Post-Transfer Embryo and Uterine Awareness.

The contents were recorded in a quiet environment, and background music was added to enhance their effect. The mindfulness intervention protocol is shown in Table 1. Interventions in the experimental and control groups and data collection.

After obtaining the necessary permissions for the research, including ethical permissions and permission from the Provincial Health Directorate, the data collection phase began.

Face-to-face interviews were conducted with patients reached through IVF centers (n:15), and pre-test forms were filled out by hand. For patients reached through social media (n:19), a phone interview was conducted, and pre-tests were then sent via Google Forms. Participants were informed about the purpose, scope, content, and procedure of the study before all tests were administered.

In the experimental group

After filling out the "Personal Information Form," pre-tests were administered. A WhatsApp group named IVF-Mind was created for the experimental group. The group was informed about meeting dates through this group, where the administrator could send one-way messages, and a daily mindfulness message was sent every morning. When the number of women in the experimental group reached 4 to 5, an online meeting was arranged at a mutually agreed date and time. New meeting dates were planned for each new participant group. At the meeting, after the researcher introduced herself, information was given about "the IVF treatment process, physical and mental changes during infertility treatment, the purpose of the study, and how it would be conducted." This was followed by training on "mindfulness and mobile application." The training lasted approximately 120 min. At

Table 1 Mindfulness intervention protocol for IVF treatment

Mindfulness Meditation	Target	When to Practice
<i>Breath Awareness</i>	Aims to focus on breathing and sensations in the body. Develops diaphragmatic breathing.	Twice a day, can be done when stressed. 14 minutes
<i>Body & Uterus Awareness</i>	Aims to develop mindful awareness of different body parts, specifically the uterus and ovaries for IVF treatment.	Twice a day, suitable for every stage of the treatment. 13 + 15 minutes (two parts)
<i>Injection Therapy and Ovary Awareness</i>	Aims to develop awareness and reduce stress during hormone injections administered daily before oocyte retrieval.	Before and after injection application. 18 minutes
<i>Pre-Oocyte Retrieval (OPU) Diaphragmatic Breathing</i>	Aims to reduce anxiety and stress before oocyte retrieval, focusing on ovarian and oocyte awareness.	3-4 days before the procedure and during the waiting period before oocyte retrieval. 13 minutes
<i>Pre-Embryo Transfer Uterus Awareness</i>	Aims to cope with ambivalent feelings before embryo transfer, promoting awareness of emotions and the new situation. Provides mental preparation with uterus awareness.	3-4 days before the embryo transfer procedure and during the waiting period in the room. 20 minutes
<i>Embryo and Uterine Awareness Post-Transfer</i>	Aims to reduce stress and anxiety during the waiting period after embryo transfer, fostering body acceptance of the new situation. Provides uterus and embryo awareness with mind-body harmony.	During the waiting period after embryo transfer until the pregnancy test. 23 minutes

It is implemented with the audio recordings available in the mobile application

the end of the session, mindfulness breathing and body awareness exercises were conducted, teaching the women how to meditate similarly to the audio recordings.

Training for the experimental group was conducted online via Zoom with slide presentations. Five separate training sessions were held with groups of four to five women, each session lasting two hours. Participant privacy and anonymity were maintained during Zoom meetings. The consent form indicated that video recordings would be taken. Additionally, prior to the Zoom meetings, participants were informed that they were not required to share their screens and could use pseudonyms to maintain their privacy.

The training content included:

- Introduction and getting acquainted.
- Providing information about the trial.
- Providing information about the infertility process and the psychosocial conditions experienced.
- Providing information about mindfulness (cognitive awareness).
- Presenting examples of scientific studies in the literature.
- Information on how to use the mobile application.
- Guiding a mindfulness breathing and body (uterus) awareness meditation.

For patients in the experimental group, an online cognitive awareness session was conducted to teach mindfulness practice. Afterward, the mobile application was installed on their phones, and individual support was provided for using the application and practicing mindfulness. Patients were encouraged to practice mindfulness twice daily, ideally in the morning and evening, using audio recordings from the mobile application.

Participants who completed the training were asked to listen to mindfulness audio recordings at least twice a day or more as needed. Individual meetings were conducted every 2 to 4 weeks with each participant to discuss their treatment process. Close contact was maintained with women approaching embryo transfer to conduct post-tests. Post-tests, including the Mindful Attention Awareness Scale (MAAS), Depression, Anxiety, and Stress Scale (DASS-21), Infertility Self-Efficacy Scale - Short Form, and Infertility Adjustment Scale, were administered two days before the pregnancy test day.

In the control group

After filling out the Personal Information Form, routine training was provided by the primary researcher. During the training, women were informed about the IVF treatment process, stages of infertility, and physical and mental changes experienced during infertility treatment. On the same day, pre-tests, including the Mindful Attention

Awareness Scale (MAAS), Depression, Anxiety, and Stress Scale (DASS-21), Infertility Self-Efficacy Scale - Short Form, and Infertility Adjustment Scale, were administered. Post-tests for the control group included the same scales as mentioned.

The entry times of each patient in the experimental and control groups varied, as did the duration of their treatments. Women were ideally included in the study from the first day their IVF treatment began; however, the treatment duration could vary for each woman, averaging between 4 and 5 weeks. Therefore, there was no standard pre-test and post-test application day; the tests were conducted individually at the start of the treatment and after the transfer. Pre-tests were conducted on the day the patient was met, followed by individual information and training sessions.

Results

A comparison of the socio-demographic characteristics of the participants showed that the experimental and control groups were homogeneously distributed. There was no significant difference in infertility-related characteristics between the experimental and control groups ($p > 0.05$) (Table 2).

Comparison of participants' scores on the mindful attention awareness scale scores

There was no statistically significant difference between participants' scores on the Mindful Attention Awareness Scale at pre-test ($U = 120,000$, $p = 0.398$). In the post-test, it was found that there was a statistically significant difference between the MAAS scores of experimental and control groups ($U = 0.000$, $p < 0.001$). Accordingly, it was concluded that the experimental group had higher score on the MAAS at the post-test compared to the control group, indicating greater mindful attention and awareness (Table 3).

These results highlight a significant effect of the intervention in the experimental group, while the changes in the control group were not statistically significant.

According to the analysis results, there was no statistically significant difference between the pre-test and post-test scores on the MAAS for participants in the control group (41.76 ± 7.22 vs. 42.65 ± 6.12 , $Z = -1.376$, $p = 0.169$, $d = 0.13$). However, for participants in the experimental group, there was a statistically significant difference between the pre-test and post-test MAAS scores (40.06 ± 8.63 vs. 66.88 ± 4.59 , $Z = -3.626$, $p < 0.001$, $d = 0.98$).

Comparison of the participants' infertility self-efficacy scale scores

There was no statistically significant difference between infertility self-efficacy scale scores of participants in

Table 2 Demographic characteristics of participants

Variable		Experimental Group		Control Group		Total		X ²	p
		n=17	%	n=17	%	N=34	%		
Age	30 and below	5	29,4	4	23,5	9	26,5	0,563 ^f	0,825
	31-35 years	5	29,4	4	23,5	9	26,5		
	36 and above	7	41,2	9	52,9	16	47,1		
Current Work Status	Yes	12	70,6	11	64,7	23	67,6	0,134	1,000
	No	5	29,4	6	35,3	11	32,4		
Economic Status	Better than expenses	6	35,3	4	23,5	10	29,4	1,360 ^f	0,554
	Equal to expenses	10	58,8	10	58,8	20	58,8		
	Less than expenses	1	5,9	3	17,6	4	11,8		
Family Type	Nuclear family	13	76,5	15	88,2	28	82,4	1,893 ^f	0,537
	Extended family	2	11,8	2	11,8	4	11,8		
	Other	2	11,8	0	0,0	2	5,9		
Education Level	Primary School	0	0,0	2	11,8	2	5,9	2,075 ^f	0,601
	High School	2	11,8	1	5,9	3	8,8		
	University and above	15	88,2	14	82,4	29	85,3		
Marital Education Level	Primary School	0	0,0	1	5,9	1	2,9	1,538 ^f	0,838
	High School	1	5,9	1	5,9	2	5,9		
	University and above	3	17,6	4	23,5	7	20,6		
Marital Duration	Primary School	13	76,5	11	64,7	24	70,6	1,074	0,300
	5 years and below	11	64,7	8	47,1	19	55,9		
	More than 5 years	6	35,3	9	52,9	15	44,1	1,417 ^f	1,000
Who Covers Treatment Costs	Self	10	58,8	11	64,7	21	61,8		
	Social Security	2	11,8	1	5,9	3	8,8		
	Partially self, partially social	4	23,5	3	17,6	7	20,6		
	Family and relatives support	1	5,9	2	11,8	3	8,8		

X²: Ki-square analyse, ^fFisher Exact Ki square analyse**Table 3** Comparison of the MAAS scale pretest-posttest scores of the experimental-control groups

Groups	Experimental Group (Mean ± SD)	Control Group (Mean ± SD)	U Statistic	p-value	Cohen's d
Pre-Test	40.06 ± 8.63	41.76 ± 7.22	120.000	0.398	-0.21
Post-Test	66.88 ± 4.59	42.65 ± 6.12	0.000	0.000*	0.71
Min-Max	30.00-55.00	30.00-59.00			
Median (Q1-Q3)	37.00 (32.50-47.00)	42.00 (35.50-44.50)			
p-value	0,000*	0,169			
Cohen's d	0.98	0.13			

U: Mann Whitney U test statistic *p<0,05

Cohen's d: Effect size measure for the post-test scores

the experimental and control groups in the pre-test ($U = 125,500$, $p = 0.503$). In the post-test, there was a statistically significant difference between infertility self-efficacy scale scores of the experimental and control groups ($U = 0.000$, $p < 0.001$). Accordingly, the experimental group had higher scores on the infertility self-efficacy scale than the control group, indicating greater self-efficacy in dealing with infertility (Table 4).

These results highlight a significant effect of the intervention in the experimental group, while the changes in the control group were not statistically significant.

The analysis revealed a statistically significant difference in the ISES scores for the experimental group

($Z = -3.628$, $p < 0.001$), indicating that the post-test scores were higher than the pre-test scores (26.88 ± 2.32 vs. 15.29 ± 2.78 , $p < 0.001$, $d = 0.71$). In contrast, there was no statistically significant difference in the ISES scores for the control group between pre-test and post-test (15.35 ± 3.44 vs. 15.35 ± 3.44 , $Z = -0.926$, $p = 0.355$, $d = 0.37$).

Comparison of the participants' infertility adjustment scale scores

At pre-test, no statistically significant difference was found between the scores of the participants in the experimental and control groups on the Infertility Adjustment

Table 4 Comparison of the infertility self-efficacy scale pretest-posttest scores of the experimental and control groups

Groups	Experimental Group (Mean ± SD)	Control Group (Mean ± SD)	U Statistic	p-value	Cohen's d
Pre-Test	15.29 ± 2.78	15.35 ± 3.44	125.500	0.503	-0.02
Post-Test	26.88 ± 2.32	15.71 ± 2.17	0.000	0.000*	0.54
Min-Max	22:00- 30:00	13:00-21:00			
Median (Q1-Q3)	28.00 (26.00-28.50)	15.00 (14.50-16.50)			
p-value	0,000*	0,355			
Cohen's d	0.71	0.37			

U: Mann Whitney U test statistic * $p < 0,05$

Cohen's d: Effect size measure for the post-test scores

Table 5 Comparison of the infertility adjustment scale pretest-posttest scores of the experimental and control groups

Groups	Experimental Group (Mean ± SD)	Control Group (Mean ± SD)	U Statistic	p-value	Cohen's d
Pre-Test	25.94 ± 3.44	26.53 ± 4.14	106.500	0.184	-0.14
Post-Test	15.53 ± 3.43	29.59 ± 5.65	3.000	0.000*	-2.35
Min-Max	15.00-31.00	14.00-39.00			
Median (Q1-Q3)	27.00 (24.50-28.00)	28.00 (25.00-29.00)			
p-value	0,000*	0,006*			
Cohen's d	-2.74	-0.63			

U: Mann Whitney U test statistic * $p < 0,05$

Cohen's d: Effect size measure for the post-test scores

Scale ($U = 106.500$, $p = 0.184$). In the post-test, a statistically significant difference was found between the scores of the participants in the experimental and control groups on the Infertility Adjustment Scale ($U = 3,000$, $p < 0.001$). The experimental group had lower scores on the Infertility Adjustment Scale compared to the control group, indicating better adjustment to infertility (Table 5).

Within-group analysis

Experimental Group: A large effect size was found between pre-test and post-test scores ($p = 0.000$; $d = -2.74$), reflecting a substantial improvement.

Control Group: A medium effect size was found between pre-test and post-test scores ($p = 0.125$; $d = -0.63$), but it was not statistically significant.

These results highlight a significant effect of the intervention in the experimental group, while the changes in the control group were not statistically significant.

Group-wise comparisons of pre-test and post-test scores on the IAS showed a statistically significant difference in the IAS scores for the experimental group ($Z = -3.625$, $p < 0.001$), indicating that the post-test scores were lower than the pre-test scores (15.53 ± 3.43 vs. 25.94 ± 3.44 , $p < 0.001$, $d = -2.74$). Conversely, a statistically significant difference was also found in the IAS scores for the control group ($Z = -2.739$, $p = 0.006$), with the post-test scores being higher than the pre-test scores (29.59 ± 5.65 vs. 26.53 ± 4.14 , $p = 0.006$, $d = -0.63$).

Comparison of participants' scores on the depression anxiety stress scale (DASS 21)

There was no statistically significant difference between the pre-test scores of participants in the experimental and control groups on the DASS 21 scale ($U = 141,000$, $p = 0.904$) (Table 6). However, it was found that there was a statistically significant difference between the participants' post-test scores ($U = 56.500$, $p = 0.002$). The experimental group scored lower on the DASS 21 scale than the control group, indicating lower levels of depression, anxiety, and stress (Table 6).

Participants in the experimental group showed a significant decrease in scores from pre-test to post-test (27.59 ± 9.00 vs. 16.65 ± 5.00 , $p < 0.003$, $d = 1.07$). Conversely, no significant change was found in the DASS 21 scores for the control group, with the pre-test scores being slightly higher than the post-test scores (27.00 ± 9.61 vs. 26.82 ± 9.46 , $p = 0.604$, $d = 0.57$).

These results highlight a significant and large effect of the intervention on the experimental group, leading to substantial improvements, while the changes observed in the control group were not statistically significant.

Sub-dimensions of the DASS 21 scale

Depression

The experimental group had lower post test scores in the depression sub-dimension of the DASS scale ($U = 59.500$, $p = 0.003$) compared to the control group, indicating lower levels of depression. There was a statistically significant decrease in post-test scores compared to pre-test scores in the experimental group (4.35 ± 2.23 vs.

Table 6 Comparison of the Depression-Anxiety-Stress scale (DASS 21) and sub-dimension pretest-posttest scores of the experimental-control groups

Groups	Experimental Group (Mean ± SD)	Control Group (Mean ± SD)	U Statistic	p-value	Cohen's d
DASS 21					
Pre-Test	27.59 ± 9.00	27.00 ± 9.61	141.000	0.904	-0.03
Post-Test	16.65 ± 5.00	26.82 ± 9.46	56.500	0.002*	-1.11
Min-Max	6-42	10-45			
Median (Q1-Q3)	17.00 (12.50-21.50)	28.00 (17.00-34.00)			
p-value	0,003*	0,604			
Cohen's d	1.07	0.57			
DASS 21 Anxiety					
Pre-Test	8.47 ± 3.00	9.06 ± 2.90	119.000	0.375	-0.14
Post-Test	4.88 ± 2.26	9.00 ± 2.89	39.500	0.000*	0.80
Min-Max	2-14	3-14			
Median (Q1-Q3)	5.00 (3.00-7.00)	10.00 (7.00-11.00)			
p-value	0,004*	0,813			
Cohen's d	1.06	0.55			
DASS 21 Depression					
Pre-Test	7.12 ± 4.04	7.88 ± 4.20	126.000	0.519	-0.10
Post-Test	4.35 ± 2.23	7.82 ± 3.80	59.500	0.003*	0.51
Min-Max	0-14	1-17			
Median (Q1-Q3)	4.00 (2.50-7.00)	8.00 (5.50-9.50)			
p-value	0,029*	0,647			
Cohen's d	0.85	0.55			
DASS 21 Stress					
Pre-Test	12.00 ± 4.83	10.06 ± 4.07	105.500	0.176	-0.15
Post-Test	7.41 ± 2.53	10.00 ± 4.36	89.500	0.057	0.38
Min-Max	5-19	3-17			
Median (Q1-Q3)	8.00 (5.50-9.00)	12.00 (5.00-13.00)			
p-value	0,000*	0,792			
Cohen's d	0.65	0.46			

U: Mann Whitney U test statistic * $p < 0,05$

Cohen's d: Effect size measure for the post-test scores

7.12 ± 4.04, $p = 0.029$, $d = 0.85$). There were no statistically significant changes in post-test scores compared to pre-test scores in the control group (7.82 ± 3.80 vs. 7.88 ± 4.20, $p = 0.647$, $d = 0.55$).

Anxiety

The anxiety post test scores of the experimental group were lower than that of the control group ($U = 39.500$, $p < 0.001$), indicating lower levels of anxiety. There was a statistically significant decrease in post-test scores of the experimental group compared to pre-test scores (4.88 ± 2.26 vs. 8.47 ± 3.00, $p = 0.004$, $d = 1.06$). There was no statistically significant change in post-test scores compared to pre-test scores in the control group (9.00 ± 2.89 vs. 9.06 ± 2.90, $p = 0.813$, $d = 0.55$).

Stress

There was no statistically significant difference between the participants' post- test scores on the stress sub-dimension of the DASS scale ($U = 89.500$, $p = 0.057$),

suggesting similar levels of stress between the two groups, There was a statistically significant decrease in post-test scores compared to pre-test scores in the experimental group (7.41 ± 2.53 vs. 12.00 ± 4.83, $p < 0.001$, $d = 0.65$). There was no statistically significant change in post-test scores compared to pre-test scores (10.00 ± 4.36 vs. 10.06 ± 4.07, $p = 0.792$, $d = 0.46$).

Discussion

The most important and even unique element of holistic care is nursing. By its very nature, nursing observes and assesses patients throughout their lives. Due to many factors, such as the patient's social environment and adaptation to the disease, nursing requires being with the patient in every area and moment of care. In addition to the inherent aspects of nursing, the nurse-patient relationship plays a crucial role in the effectiveness of interventions like mindfulness. The quality of this relationship can significantly influence patient outcomes by

fostering a supportive environment that enhances trust and openness.

In recent years, Western medicine has begun to investigate the effects of meditation-like practices on medical treatments [59]. The benefits of using many practices such as mind-body exercises, relaxation techniques and yoga in the field of health have been demonstrated in many studies [60–62].

Mindfulness is a psychological coping strategy commonly used by infertility patients. Studies in the field of infertility show that mindfulness interventions are an effective way to improve women's psychological health (such as quality of life, stress, and marital harmony) in women [37–39]. The role of nursing in facilitating these interventions cannot be overstated. Nurses, through their continuous engagement and personalized care, can create a conducive environment for mindfulness practices. This supportive relationship can enhance patients' engagement with mindfulness techniques, leading to better psychological outcomes. The increased efficiency of self-consciousness through mindfulness can be attributed to its ability to enhance self-awareness and emotional regulation. Previous studies suggest that mindfulness promotes greater awareness of internal states, leading to improved psychological outcomes [63–65]. A randomized controlled trial, it was found that infertile women in the experimental group had increased self-compassion and mindfulness skills and higher pregnancy rates [22]. Building on these findings, our study supports the efficacy of mindfulness in enhancing self-compassion and mindfulness skills among infertile women. Mindfulness can also be chosen as an effective method to reduce stress, anxiety and depression in infertile women and to gain self-efficacy and adjustment to infertility.

Our study found that the mindfulness scores of the experimental group were significantly higher than those of the control group. This result aligns with similar studies, which also reported a significant increase in mindfulness scores among participants undergoing mindfulness interventions [22, 57].

In a study investigating the effect of mindfulness-based therapy on the psychological well-being of infertile women, the control and experimental groups were evaluated [38]. As a result of the study, it was found that there was a significant difference in the psychological well-being scores of the experimental group and sub-dimension mindfulness scores compared to the control group. This suggests that mindfulness interventions might enhance psychological resilience by improving self-regulation and emotional awareness. The support and encouragement provided by nurses during these interventions can further enhance their effectiveness. Nurses can help reinforce mindfulness practices by regularly checking in with patients, addressing concerns, and providing

motivation, which contributes to sustained engagement and better outcomes. In another study, a group of 25 women undergoing IVF treatment underwent the MBSR Fard et al. intervention, 12 weeks of mindfulness and relaxation meditation. At the end of the study, it was found through the interviews with the women that psychological improvements, such as general well-being and mindfulness, were achieved [66]. The consistent findings across different studies highlight that mindfulness practices not only improve general well-being but also contribute to specific psychological outcomes such as enhanced mindfulness and reduced symptoms of stress and anxiety.

According to the data of our study, it was observed that the self-efficacy perceptions of the experimental group increased and their adjustment to infertility improved. This aligns with theories suggesting that improved self-efficacy through mindfulness can facilitate better adjustment and coping with infertility [41, 67]. It is known that self-efficacy is generally low in women with infertility [67, 68]. Our findings contribute to the growing body of evidence suggesting that mindfulness therapy can enhance self-efficacy in infertile women. It can be argued that mindfulness practices not only cause an increase in mindfulness scores but also have a mediating effect on the improvement of other psychological symptoms.

In this study, the short form of the DASS-21 scale developed by Lovibond and Lovibond was used to measure the depression, anxiety, and stress levels of infertile women and their changes after embryo transfer. The results indicated that there was no significant difference between the pre-test scores of the experimental and control groups. However, significant decreases in depression and anxiety levels were observed in the post-test scores of the experimental group. These findings are consistent with studies in the literature. For example Zahra et al. (2019) found that relaxation and breathing exercises, as well as meditation, reduced anxiety levels [69]. Similarly, a study by Rahimi et al. (2018) found that resilience therapy and breathing exercises significantly reduced anxiety scores [70].

The effects of a mindfulness intervention developed by Galhardo et al. specifically for infertile women were followed for 7 years, and it was found that mindfulness skills and self-efficacy improved, and anxiety and depression symptoms decreased in women who received mindfulness [57]. This study observed similar increases in self-efficacy and mindfulness scores in the experimental group, with concurrent decreases in depression, anxiety, and stress levels. This aligns with previous findings that suggest long-term mindfulness interventions contribute to sustained improvements in psychological well-being.

In another study investigating the effect of a mindfulness stress reduction program on “depression, anxiety,

stress, and tolerance to uncertainty” in infertile women in Iran, participants in the MBSR group received 2 h of face-to-face mindfulness meditation once a week for 8 weeks. A significant difference was found between the post-test scores of the experimental and control groups in terms of depression, anxiety, and stress scores [71]. According to our results of the analysis, a statistically significant difference was found between the pre-test and post-test DASS scores of participants in the experimental group. Accordingly, our study observed a decrease in depression anxiety levels in the experimental group. These results are consistent with the literature, which shows that mindfulness-based practices are effective in reducing anxiety in infertility [22, 39, 45, 57, 72, 73].

In a randomized controlled trial in which Bai et al. investigated the effects of a self-administered mindfulness intervention on psychological distress in women undergoing IVF or ICSI and found that the intervention was effective on depression and sleep quality [74]. Scales were administered on the day of regulation, 1 day before embryo transfer and 2 days before the pregnancy testing. The study was similar to our mindfulness practice study, and the patients were listened to 20-minute audio recordings. However, Bai’s study included mindfulness practice focused on breath and body awareness, whereas our study incorporated additional elements such as uterus awareness, needle therapy awareness, pre-oocyte pick-up awareness, and pre/post embryo transfer awareness.

The use of a mobile application for mindfulness in this intervention presents both benefits and risks. Key benefits include accessibility and convenience, allowing users to engage in mindfulness practices at their own pace and without the financial burden of in-person sessions. However, potential risks include technical issues and the lack of direct supervision from a trained professional, which could affect the effectiveness of the practice. Comparing our study with others, face-to-face and group therapy sessions offer immediate feedback and support, while the mobile application provides flexibility. Yet, the support from mobile applications may be limited, and some users might benefit more from face-to-face interactions.

Conclusion

According to our study, mindfulness-assisted psychosocial support with a mobile application was found to reduce problems such as depression and anxiety in infertile women and increase the level of mindfulness and infertility self-efficacy and compliance. As a result, it was observed that the mobile application developed for mindfulness contributed positively to the psychosocial status of infertile women during the treatment process.

Our findings align with existing literature, which indicates that mindfulness-based interventions improve the mindfulness levels and overall psychosocial status of infertile women. These interventions can be delivered in various formats, including face-to-face, group therapy, online, or via audio recordings. In our study, the mobile application was particularly advantageous due to its accessibility, cost-effectiveness, and the convenience of allowing users to engage in mindfulness practice tailored to their specific treatment needs.

Additionally, our study observed significant statistical changes in the dependent variables, including reductions in depression, and anxiety scores, as well as increases in mindfulness and self-efficacy scores among the experimental group. These results underscore the efficacy of mindfulness interventions in addressing psychological challenges associated with infertility and highlight the potential for mobile applications to support mental health in this context.

The findings of this study suggest that mindfulness interventions may play a significant role in infertility treatment. Future research should explore the integration of such interventions into standard care protocols and investigate their adaptability for various populations and stages of treatment.

Mindfulness programs could be made accessible to a broader audience through online platforms or group sessions. Training healthcare professionals, particularly nurses, in mindfulness techniques would support patients in utilizing these strategies effectively. This approach could provide a holistic sense of well-being in infertility treatment. Future studies could further examine the long-term effects of mindfulness interventions and their impact on overall well-being.

Strengths and limitations of the research

Strengths of the study

- The study was designed as a randomized controlled trial.
- It involves a mobile application developed specifically for nursing care and support.
- The “Mindfulness/Cognitive Awareness” content used in the developed mobile application is tailored specifically to infertile women and their treatment periods.
- It is the first domestic mobile application developed in the field of infertility.
- It is the first “Cognitive Awareness Mindfulness” program developed in our country for infertility.
- The study utilized visual, auditory, and written materials through the developed mobile application.

Limitations of the study

- The study did not include male participants in the sample group.
- Mindfulness/Cognitive Awareness practices were not conducted face-to-face; they were left to the initiative of the women using the mobile application.
- Generalizability is limited due to the number of participants in the study.

Abbreviations

IVF	In Vitro Fertilization
MAAS	Mindful Attention Awareness Scale
DASS 21	The Depression Anxiety Stress Scale
MBSR	Mindfulness-Based Stress Reduction

Supplementary Information

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Supplementary Material 1

Supplementary Material 2

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Author contributions

Ö.İ. collected and analyzed the data and wrote the article. The article was reviewed and conceptualized by Ö.İ. and İ.G.S. All authors approved the final manuscript.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Competing interests

The authors declare no competing interests.

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