

The Impact of Acceptance and Commitment Therapy on Perceived Stress in Women with Primary Infertility Undergoing in Vitro Fertilization: A Randomized Clinical Trial

Toktam Taheri (MSc)¹, Nahid Jahani Shoorab (PhD)^{2,3*}, Maliheh Afiat (MD)⁴, Jaleh Feyzi (PhD)⁵, Jamshid Jamali (PhD)⁶

¹ MSc Student in Midwifery, Student Research Committee, Mashhad University of Medical Sciences, Mashhad, Iran

² Assistant Professor, Nursing and Midwifery Care Research Center, Mashhad University of Medical Sciences, Mashhad, Iran

³ Department of Midwifery, School of Nursing and Midwifery, Mashhad University of Medical Sciences, Mashhad, Iran

⁴ Associate Professor, Department of Obstetrics and Gynecology, School of Medicine, Mashhad University of Medical Sciences, Mashhad, Iran

⁵ Associate Professor, Psychiatric and Behavioral Sciences Research Center, Mashhad University of Medical Sciences, Mashhad, Iran

⁶ Assistant Professor, Social Determinants of Health Research Center, Mashhad University of Medical Sciences, Mashhad, Iran

ARTICLE INFO	ABSTRACT
<p>Article type: Original article</p>	<p>Background & aim: In vitro fertilization (IVF) is a significant stressor for individuals facing infertility, potentially affecting treatment success. This randomized clinical trial investigates the effects of counseling utilizing Acceptance and Commitment Therapy (ACT) on perceived stress in women undergoing IVF for primary infertility.</p>
<p>Article History: Received: 25-Dec-2022 Accepted: 18-Jun-2023</p>	<p>Methods: This clinical study, Sixty-three Iranian women with primary infertility undergoing IVF treatment were selected from Milad Infertility Center in Mashhad, Iran between 2021 and 2022. Participant firstly recruited through convenience sampling and then randomly assigned to either intervention or control group. The intervention group received 6 sessions of individual ACT, each lasting 45-60 minutes, with sessions held every six days. Both groups received standard medical care. The Newton's Infertility Stress Questionnaire was administered before treatment, two weeks post-counseling (on egg collection day), and two weeks after embryo transfer (on pregnancy test day). Data were analyzed using SPSS software, including independent t-tests, Mann-Whitney, and repeated analysis of variance.</p>
<p>Key words: Infertility Counseling Acceptance and Commitment Therapy Perceived Stress Primary Infertility IVF Randomized Clinical</p>	<p>Results: Prior to intervention, the two groups were comparable in demographic characteristics and infertility stress. The intervention group experienced a statistically significant decrease in perceived stress on both egg collection and pregnancy test days, while the control group exhibited an increase ($p=0.001$). The perceived stress score two weeks after embryo transfer in the intervention group shows a decrease compared to before the intervention (-15.5 ± 24.0) while it was lower in the control group (and 7.4 ± 24.3) ($P=0\leq 0.05$).</p> <p>Conclusion: This study recommends individual ACT as an effective intervention for reducing perceived stress in women facing primary infertility during IVF treatment.</p>

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Introduction

For all infertile couples worldwide, infertility is one of the most bitter and stressful

experiences and a potentially threatening factor in life (1). According to the World Health

* Corresponding author; Nahid Jahani Shoorab, Assistant Professor, Nursing and Midwifery Care Research Center, Mashhad University of Medical Sciences, Mashhad, Iran. Tel: 00989153165194; Email: jahanishn@mums.ac.ir



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Organization (WHO), infertility is a disease affecting the reproductive system. It is defined as the inability to conceive after 12 months of regular unprotected intercourse. The average prevalence of infertility is estimated between 10-15 % worldwide (2). According to official statistics, approximately 60 to 80 million couples have infertility worldwide. According to WHO standards, the prevalence of infertility in Iran (2019) ranges between 9.2 and 12.8 percent for primary infertility and approximately 4.9 percent for secondary infertility.

The phenomenon of fertility in humans has social and psychological components in addition to physiological ones (4). Every couple desire to have children for cultural, social, familial, and inherent reasons. Family and social pressures for the survival of the family name impose a very high negative psychological burden on the infertile couple. Environmental and familial pressures caused by infertility disrupt patients' regular lives and compel them to struggle with their sickness daily. On the other hand, the extended duration and high cost of infertility therapy endanger the lives of these individuals' physical and emotional health (5, 6). These mental strains and concerns created by infertility can affect a couple's physiological function and, ultimately, their fertility. Mental stresses and stress cause mental disorders to emerge and intensify in infertile couples during this process, making infertility treatment more difficult by escalating mental and psychological symptoms. This two-way process of infertility treatment is occasionally connected with treatment termination (7-8). A descriptive study conducted in Ethiopia in 2021 found that the prevalence of infertility stress was very high, at around 92.7% (9). Infertility is considered a severe psychological trauma that, in addition to reducing women's sense of self-worth and self-esteem, causes tension in interpersonal, social, and marital relationships. According to studies, psychological interventions for infertile women increase their mental health and possibly fertility rate (6). Infertility stress is caused by the interaction of physical circumstances that predispose to infertility and medical interventions, as well as the reactions of others and individual psychological features, and can last for years (10-11).

In vitro fertilization (IVF) is one of the assisted reproductive technologies used to treat infertile couples who have tubal obstruction, infertility due to severe male reasons, or failure of initial therapy. In this approach, sperm and egg were mixed and fertilized in a laboratory setting. In this manner, sperm and egg are placed adjacent to each other in the culture media, where the sperm enters the egg and fertilizes it. The created embryos are then transferred into the woman's uterus (2). In a 2019 study in Brazil, IVF was employed in 70.6% of ART cases (12). A report of 52 infertility treatment centers in Iran (2016) included 35,000 cases of IVF with intracytoplasmic sperm injection (ICSI) (13). Despite its popularity, this therapeutic procedure is highly stressful for patients. It necessitates daily injections of disposable ampoules, serial vaginal ultrasonography, sperm analysis, and other invasive procedures. Although couples try to adjust to the therapy approaches, those who lack the essential adaptability will suffer twice (14). Therefore, in addition to medical treatments for infertility, attending to the psychological needs of infertile couples is an essential part of the success of infertility treatment (15). IVF is typically considered the last therapeutic option for infertile couples, and failure will almost certainly result in childlessness (16). Financial concerns exacerbate the stress of infertility. Failure of these therapies, concerns about the deterioration of marital foundations, decline in marital satisfaction, and the possibility of divorce are all identified as causes of mental health disorders in these couples (17).

Countless medical and infertility organizations strongly advise counseling for infertile people (1). Counseling based on acceptance and commitment therapy, which appears to be more beneficial than other counseling approaches due to its acceptance and flexibility (4,17), is one of the most extensively used treatment methods, with much research confirming its benefit on lowering depression, anxiety, and perceived stress. Acceptance and Commitment Therapy (ACT) is a new type of behavioral therapy that uses methods of mindfulness, acceptance, and cognitive skills to increase psychological adaptations and prevent behavioral changes following the values chosen, intending to create psychological flexibility (18),

which takes its name from two key messages: accepting what is out of control and committing to action that improves one's living circumstances (19). A study was conducted (2015) to determine the effects of counseling based on acceptance and commitment on anxiety and depression in pregnant women undergoing ectopic fertilization. The implementation of acceptance and commitment therapy on 35 women in Mashhad over eight 90-minute sessions was able to reduce depression and anxiety in the post-test phase as well as the one-month follow-up period after the intervention (4). In another study, however, psychological counseling for depression and anxiety in infertile women receiving IVF treatment in the Netherlands was not beneficial over three 60-minute sessions on 44 infertile couples (15).

Because women undergoing IVF treatment have high anxiety and stress (19), and counseling in infertility is strongly emphasized, the present study was designed to investigate the effect of acceptance and commitment therapy on perceived stress in infertile women undergoing IVF treatment.

Materials and Methods

This study is a two-group randomized clinical trial, which has been registered in IRCT under code of IRCT20210510051249N1. Based on the average comparison formula and the study of Strabadi et al. (1399) (16) and considering the error of 5% and the test power of 80%, the minimum sample size in each group was determined to be 31 individuals, which was determined to be 70 people with a 10% decline. To generate a random allocation sequence, subjects were assigned to one of two intervention and control groups using the Random Allocation Software. There were two blocks in the present study, AB and BA. A block was selected at random. If the first block, AB, was chosen, the first individual was assigned to group A, the second to group B, and so on, until all samples were assigned.

This randomized controlled trial, eligible women who visited Milad center were recruited from Oct 2021 to May 2022 and allocated to two groups. Iranian women aged 20 to 40 residing in Mashhad with limited literacy, suffering from primary infertility, no children or adopted children, and no history of mental (no history of

hospitalization or use of psychoactive medicines) or medical illness (diabetes, thyroid, hyperfunction or hypofunction of kidneys and adrenals, or pituitary disease), undertaking IVF treatment for the first time, not smoking or drinking alcohol, owning a smartphone with an Android operating system, and not suffering from severe stress-anxiety-depression (based on DASS-21) were the criteria for entering the study. Failure to attend more than one counseling session, as well as the occurrence of unfortunate or stressful circumstances in the previous three years (death of a spouse or first-degree relatives), served as an exclusion criterion.

In the first stage, infertile women who came to plan their IVF treatment on the first day of treatment to perform a basic ultrasound (day 2-3 of the menstrual cycle) and were eligible for the study were identified, and after stating the objectives of the study and explaining the confidentiality of the research information their consent was obtained. They entered the study following agreeing to participate and completing the written consent form. The data collection tools included the research unit selection checklist, a questionnaire of demographic characteristics and infertility information, Newton's infertility stress questionnaire, the DASS-21 stress-anxiety-depression questionnaire, and Kasadi's social support questionnaire, which was modified and completed by the subjects at the beginning of the study. Newton's Infertility Stress Questionnaire (1999) consists of 46 items divided into five subtests: social concerns (questions 1-10), sexual concerns (questions 11-18), communication concerns (questions 19-28), childless lifestyle (29-36), and the need to be a parent (37-46). The range of scores is between 46 and 276. A higher stress level yields a higher score (1). This questionnaire was performed two weeks after the intervention, during the egg retrieval, and two weeks following the embryo transfer concurrently with the pregnancy test.

The Kasadi social support questionnaire comprise seven questions with the answers affirmative (2), not sure (1), and no (0). The scoring is based on a Likert scale ranging from zero (no social support) to two (2) with support. Scores ranging from 10 to 14 indicate high levels

of social support (20). The DASS-21 stress-anxiety-depression questionnaire has three subscales of depression, anxiety, and stress, as well as 21 questions, seven statements for each of the above subscales. It is scored on a Likert scale from not at all (zero) to very high (3), with a minimum score of zero and a maximum score of 63. A score of less than 21 in depression, 15 in anxiety, and 26 in stress indicate that depression, anxiety, and stress are less severe (21).

Newton's Infertility Stress Questionnaire, DASS-21 Stress-Anxiety-Depression Questionnaire, and Cassadi's Social Support Questionnaire are valid instruments, and their

validity and reliability have been confirmed in Iran through content validity in the studies of Latifnejad (1), Talai (20), and Kakmam (21), respectively. The content validity of these tools and the questionnaire on demographic characteristics and infertility information was confirmed in this study. The reliability of Newton's infertile stress questionnaire was confirmed with a Cronbach's alpha of 0.91, the DASS-21 stress-anxiety-depression questionnaire with a Cronbach's alpha of 0.93, and Cassadi's social support questionnaire with a Cronbach's alpha of 0.93. Sessions' content is presented in Table 1).

Table 1. Content of counseling sessions in acceptance and commitment therapy for women undergoing IVF

Session	Session description
First	Acquaintance with the consultant and references, statement of the rules, familiarity with the concepts of acceptance and commitment counseling, a discussion about experiences and their evaluation, efficiency as a measurement criterion, employment of the farm technique and toolbox to produce creative frustration, assisting clients in recognizing ineffective control strategies and realizing their futility, practicing brief mindfulness, and assigning homework.
Second	A brief description of the anatomy and physiology of reproduction, the definition of infertility and IVF methods of treatment, and an explanation of infertility stress, acceptance of painful events without conflict using the Golzar technique and bus passengers, and homework assignments.
Third	Review of previous exercises, alternatives to avoidance and control, the definition of fusion and faulting, the exercise of leaves in the river, and the exercise of the mind.
Fourth	Connecting with the present moment, explaining the awareness of different sensory perceptions, and separating the senses that are part of the mental content by using the practice of conscious eating and specifying the homework.
Fifth	Teaching the concept of self as a context and making contact with yourself using the metaphor of the sky and weather, specifying homework.
Sixth	Introducing the concept of value, creating motivation to change and empowering clients for a better life, discovering the practical values of life using a compass and magic wand training, teaching commitment to action, identifying behavioral plans per values, and making a commitment to act on them, and practicing brief awareness and summarizing.

Following the approval of the Mashhad University of Medical Sciences Ethics Committee and the receipt of the clinical trial code, the researcher began sampling at the Milad Infertility Center in Mashhad. In the first stage, infertile women who came to plan their IVF

treatment on the first day of treatment to perform a basic ultrasound (day 2-3 of the menstrual cycle) and were eligible for the study

were identified, and after stating the objectives of the study and explaining the confidentiality of the research information their consent was obtained. They entered the study following agreeing to participate and completing the written consent form. Clients in both groups received the same treatment program. The control group received the center's usual services in the standard long protocol (prescription of contraception pills and folic acid in the first visit of the first cycle and, beginning on day 21, prescription of Super fact

50 Iranian- 25 units of Super fact and azithromycin on the second day of the second cycle - follicubgraphy six days later in the third visit) and ultrasound every two to three days to reach the dominant follicle, cut the super fact,

and inject 2 HCG hormones, and 34-36 hours later, they obtained egg aspiration under the direction of vaginal ultrasound (under anesthesia) without consultation.

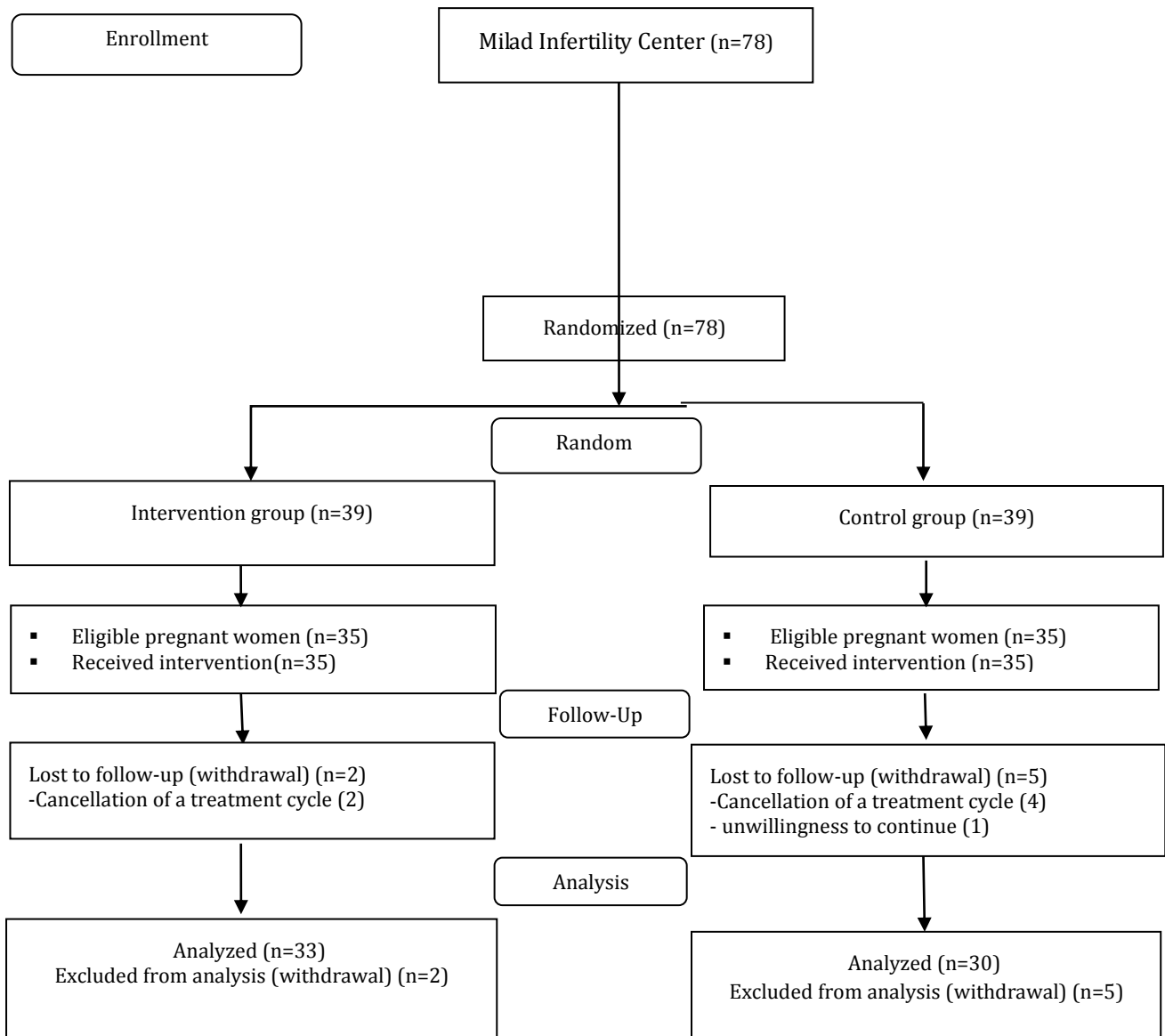


Figure 1. Flowchart of the study

In addition to the treatment protocol, the intervention group received six individual counseling sessions of 45-60 minutes through Skyroom at six-day intervals during the

treatment period. Counseling was provided in the form of questions and answers. The first session occurred on the second or third day of the first cycle (after the basic ultrasound), and the

remaining sessions were on days 8-14-20-26 of the same cycle, with the last session taking place on the second or third day of the next cycle. The researcher was present on the day of egg collection (two weeks after the last counseling session), and all subjects completed Newton's infertile stress questionnaire.

Newton's infertile stress questionnaire was completed for the final time 15 days after the embryo transfer and pregnancy test stage (the counseling).

Results

Seventy-eight participants were enrolled, in the study (34 in each group). Four participants in the intervention group were excluded from the

study due to the termination of the treatment cycle, and one person was dropped due to unwillingness to continue the research. Two persons in the control group were excluded from the study due to treatment cycle cancellation. Finally, after the study, data analysis was performed on the information acquired from 63 individuals (Figure 1). The results revealed that the two groups were homogeneous in terms of quantitative variables such as woman's age, husband's age, duration of infertility, duration of marriage, duration of infertility treatment, number of IUIs, social support, anxiety, depression, and stress, cause of infertility, and duration of infertility diagnosis. Table 2 includes some specifications.

Table 2. Mean and standard deviation of some demographic characteristics and infertility-related data of intervention and control groups

Variable	Group		Test result
	Intervention (n=30)	Control(n=33)	
	Standard deviation ± mean (Third quartile, first quartile) middle	Standard deviation ± mean (Third quartile, first quartile) middle	
Female age (years)	30.1 ± 4.5 30.5(28.0, 32.0)	30.1 ±5.4 31.0(26.0, 35.0)	*t= -0.3 P= 0.798
Social support	4.2±5.0 2.0 (1.0,2.0)	3.8 ± 4.4 2.0(1.0,4.5)	**Z=-0.1 P=0.955
Duration of marriage (months)	8.81± 41.3 71.0 (48.0 ,102.0)	82.7 ±42.2 84.0 (48.0 ,102.0)	**Z=-0.1 P=0.956
Duration of infertility diagnosis (months)	63.8 ±37.6 57.0 (36.0,84.0)	68.0 ±40.2 60.0 (36.0,84.0)	**Z=-0.4 P= 0.678
Duration of infertility treatment (months)	63.8±37.6 57.0 (36.0,84.0)	68.0 ±40.2 60.0 (36.0,84.0)	**Z=-0.4 P= 0.678
Number of IUIs performed so far	1.1±1.7 1.0(0.0,1.0)	1.0 ± 1.0 1.0(0.0,2.0)	**Z=-0.2 P=0.845

* Independent T-test, ** Mann-Whitney test

The independent t-test results revealed no significant difference in the mean total infertility stress levels before the intervention between the two intervention groups, 167.9± 21.3 and 162.7±16.7 (P=0.276). However, according to the independent t-test's results, two weeks after the intervention ended, the average total score of infertility stress in the intervention group was

151.7±29.8, a substantial increase compared to the control group (P=0.017). Furthermore, two weeks after embryo transfer, the mean overall

infertility stress score of the women in the intervention group was 152.5±29.6 and 170.0±29.7 in the control group.

An independent t-test revealed that this difference was significant (P=0.022). Analysis of variance with repeated measurements indicated a significant difference between the stages in the intragroup comparison with the subject group (P=0.001). The post hoc Bonferroni test revealed a significant difference (P=0.004) between two weeks after and before the intervention, a substantial change (P=0.004) between two weeks after embryo transfer with before the

intervention, and further showed no statistically significant difference between two weeks after embryo transfer and two weeks following intervention (P=1.000). According to the post hoc Bonferroni test, there was a significant difference (P=0.004) between two weeks after and before the intervention, as well as between two weeks after embryo transfer and before the

intervention (P=0.004). However, no significant difference was found between two weeks after embryo transfer and two weeks following intervention (P=1.000). The analysis of the variance test with repeated measures revealed no significant difference between the stages in the control group (P=0.092) (Table 3).

Table 3. Mean and standard deviation of the total perceived stress scores at different stages in intervention and control groups

Total Infertility Stress Score	Group		Test result
	Intervention (N=30)	Control (N=33)	
	Mean± SD (Third quartile, first quartile) middle	Mean± SD (Third quartile, first quartile) middle	
Before the intervention	167.9±21.3 164.5 (153.5, 176.5)	162.7±16.7 162.0(148.0,174.5)	*t=1.1 P=0.276
Two weeks after the intervention	151.7 ±29.8 147.0 (130.0,165.0)	170.0 ±29.7 172.0(153.0,190.0)	*t=-2.4 P=0.017
Two weeks after embryo transfer	152.5±29.6 148.5(130.0,169.5)	170.0±29.7 172.0(153.0,190.0)	*t=-2.3 P=0.022
Changes in perceived stress two weeks after the intervention compared to the baseline	-16.3±25.1 -21.5(-32.0, -3.0)	7.4 ±24.3 13.0(-7.5,20.0)	*t=-3.6 P >0.0001
perceived Stress changes two weeks after embryo transfer compared to baseline	- 15.5 ±24.0 -20.5(-31.0, -4.5)	7.3 ± 24.3 13.0 (-7.5, 20.0)	*t=-3.4 P =0.0001
The result of the intragroup test	F=12.3 P=0.001 ANOVA with repeated measures	F=0.3 P=0.092 ANOVA with repeated measures	

* Independent T-test

Discussion

The present study aimed to determine the effect of acceptance and commitment therapy-based counseling on perceived stress in infertile women undergoing IVF treatment. According to the findings, counseling based on acceptance and commitment therapy reduces the perceived stress of infertility. In a study on the effect of group counseling on the perceived stress of women undergoing fertility treatment, the

performance of six counseling sessions with the implementation of relaxation techniques on 50 infertile women referring to the infertility treatment centers of Sari City, Iran was evaluated

as very positive in reducing the perceived stress of infertility (22). In terms of outcomes, the two studies are similar; however, in the Sari study, the perceived stress level of the test group two weeks after embryo transfer or when the pregnancy test was performed was significantly lower than in the current study. This difference may be attributed to various factors, including the difference in the participants' understanding of stress, their accuracy in registering the questionnaire, and perhaps the implementation and continuation of relaxation techniques until a positive pregnancy test is obtained. Although a study on the effect of collaborative infertility counseling on perceived stress and coping methods of infertile women undergoing IVF treatment was undertaken on 60

women in Mashhad, Iran (23), the changes in perceived stress reduction were less than in the current study and the implementation of five collaborative sessions with the presence of a specialist and a psychologist, as well as executing relaxation techniques over two cycles under the supervision of IVF, the reduction of changes in infertility general stress scores before the intervention (day 2-3 of the first cycle) and the time of embryo transfer in the second cycle were reported to be statistically different. Therefore, the average perceived stress changes in the intervention group were higher than the control group (2.5 ± 8.2 in the test group versus 0.9 ± 15.2 in the intervention group). This difference in effectiveness can be attributed to the style of counseling employed.

The findings of the current study support the efficacy of acceptance and commitment therapy-based counseling in reducing perceived stress during ovulation and pregnancy testing in female participants. Another study investigated the effect of cognitive behavioral interventions during IVF treatments on women's perceived stress, plasma cortisol, and pregnancy rate in 50 Israeli women in two experimental and control groups. They announced six stress-reduction CBT sessions without mentioning the amount of stress in the test group, and they emphasized the relevance of the frequent practice of CBT techniques in reducing perceived stress (24). It should be noted that these researchers employed Cohen's (1983) 14-item Perceived Stress Questionnaire, which examines a person's stress over the previous month and is not a particular measure for infertile stress. Therefore, it was impossible to compare the level of perceived stress reduction in the two counseling procedures based on acceptance and commitment therapy and CBT. A two-group randomized clinical trial with the two stages of pre-test and post-test on 104 infertile women referred to Hamedan's Fatemiyeh Hospital indicated that implementing four sessions of cognitive-behavioral group counseling over four weeks significantly reduces women's stress. The researchers who employed Harry's (Harry's Stress Assessment questionnaires) stress questionnaire reported a significant reduction in perceived stress in the test group compared to the control group (25). The high level of

perceived stress reduction in this study may also be due to the difference in tools, the accuracy of the participants in registering the questionnaire, and possibly the type of counseling method, which necessitates a comparison of these two methods in the field of infertility stress with a specific tool. The ACT method is a counseling method that has been introduced as one of the most effective approaches to perceived stress reduction due to its induction of flexibility and acceptance, which is one of its principles (4). Therefore, more research is needed to determine its effectiveness in reducing infertility stress when compared to CBT. As a result, one of the next study's recommendations is to compare the effect of acceptance and commitment counseling against cognitive behavioral counseling on perceived stress in infertile women undergoing IVF treatment. Another study found that while the internet infertility stress intervention reduces overall stress symptoms in infertile women, there is no statistically significant change in reported infertility stress between the two groups (26). In the recent study, the perceived stress of infertility at the end of the study was lower in both groups than at the beginning, which contradicts the current findings. Considering the nature of the intervention in the described study, it appears that numerous intervening variables in this study were not adequately controlled and were beyond the control of the researchers and had an effect on the outcomes. Furthermore, the subjects are from the general population of infertile people, and variables such as the type of infertility, the duration of infertility, the current treatment approach, the number of cases of assisted reproductive methods, and numerous other instances were not controlled by the researcher.

One of the strengths of this study is a low-cost and effective midwife consultation performed on infertile women undergoing IVF therapy. Furthermore, the Milad Infertility Centre was chosen since patients from all districts of Mashhad attended it, making the results generalizable to the entire society. The personal characteristics and mental state of the participants who had an impact on the counseling sessions and the duration of the research, as well as the way the participants

responded, are among the limitations of the current study, which could not be fully controlled; however, the random assignment of participants to two groups eliminates this restriction to a significant extent. Blinding the subjects due to consultations with them and the ease of access to the Internet was not possible, and the researcher, in connection with acquiring information such as demographic information and information connected to infertility and the history of medical conditions, has made the accuracy of the subjects' assertions a criterion. The coincidence of the current research with the corona disease caused a limitation in holding face-to-face counseling sessions, which can be efficient in the effectiveness of counseling sessions.

Conclusion

According to the findings of this study, acceptance, and commitment therapy-based counseling reduces the perceived stress of infertility. This consultation can be utilized in infertility centers as a simple, inexpensive, and free-of-adverse-effects method to reduce the perceived stress of infertile women undergoing IVF treatment.

Declarations

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Conflicts of interest

Authors declared no conflicts of interest.

Ethical Considerations

After receiving approval from the Mashhad University of Medical Sciences Ethics Committee, the researcher initiated sampling at the Milad Infertility Center in Mashhad. The study was carried out with strict confidentiality, and written permission was secured from all participants prior to their participation.

Code of Ethics

The ethics committee of Mashhad University of Medical Sciences has approved this research with the code (IR.MUMS.NURSE.REC.1400.032.).

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Authors' contributions

NJ supervised the study. TT participated in data collection, data analysis, Zh F and MA assisted with data interpretation. JJ assisted with data analysis. All authors have read and approved the manuscript.

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