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Stress management through cognitive reconstruction and positive thinking in women with recurrent failed In Vitro Fertilization: a randomized controlled trial

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Abstract

Background Individuals undergoing fertility treatments often experience heightened stress levels compared to the general population. With the increasing number of women facing recurrent failed in vitro fertilization (IVF) cycles, this research aimed to assess the effectiveness of positive thinking counseling and cognitive reconstruction in reducing perceived stress among infertile women.

Methods A randomized controlled clinical trial was conducted with 57 women who had undergone unsuccessful IVF cycles at the Fatemiyeh Infertility Center in Hamadan, Western Iran. Using block randomization, participants were randomly assigned to the control group (29 participants) and the intervention group (28 participants). The intervention group received individual face-to-face positive thinking counseling and cognitive reconstruction in eight sessions, each lasting 45 to 60 min. Stress levels were measured using the Cohen Perceived Stress Scale at the beginning of the study and on the embryo transfer day for both groups. Data were analyzed using Stata-13, with a significance level of $p < 0.05$.

Results Both groups' mean perceived stress scores showed no statistically significant differences before the intervention ($p = 0.168$). However, after the intervention, the mean perceived stress scores in the intervention group were significantly lower than those in the control group ($p < 0.001$).

Conclusions It appears that the use of these counseling approaches leads to a reduction in perceived stress among infertile women.

Trial registration Registration Number: IRCT20120215009014N474, registered on May 15, 2023.

Keywords Stress management, Positive thinking, Cognitive reconstruction, Perceived stress, In vitro fertilization (IVF)

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Introduction

Infertility is characterized as the failure to conceive even after engaging in regular unprotected sexual intercourse for a minimum of 12 months [1]. Globally, approximately 15% of couples experience infertility [2]. The prevalence of infertility varies between 3.5 and 30% in different countries [3]. In Iran, the prevalence of infertility is estimated to be between 10.3 and 24.9% [4]. This variability is likely due to differences in the studied population, definitions of infertility, and estimation methods [3].

Assisted reproductive technologies play a crucial role in treating infertility, and one of the most prevalent methods is In vitro fertilization (IVF) [5]. IVF boasts an average success rate of around 30% per cycle [6]. Despite extensive research in fertility and assisted reproductive techniques, over half of the embryos transferred during IVF and intracytoplasmic sperm injection (ICSI) cycles still do not successfully implant [7]. Recurrent IVF failure occurs when embryos, despite being of excellent quality, fail to implant after multiple attempts [8]. It is worth noting that there is currently no universally accepted guideline to determine the limit for unsuccessful cycles or the maximum number of embryos to be transferred [9]. Therefore, further investigation is crucial, particularly in cases where multiple unsuccessful cycles occur despite the transfer of apparently viable embryos [10].

IVF is a high-stress treatment for patients involving daily injections, serial transvaginal ultrasounds, fluid analysis, and other invasive procedures [11]. A study conducted by Aimagambetova et al. (2020) aimed to investigate the impact of stress, depression, and anxiety on IVF outcomes in 304 infertile women in Kazakhstan. The results indicated that the levels of stress, anxiety, and depression in women undergoing IVF were higher than in the general population [12]. Psychological pressures and negative behavioral states can pose a threat to the outcomes of IVF treatment. Stress is the most common reason for patients to discontinue infertility treatments [13], and it also contributes to the occurrence of defective cycles, leading to a weakened ability for couples to achieve fertility more than ever before [11].

Recently, there has been increased attention to the role of psychological factors in infertility [14]. Although psychological factors are not the primary cause of infertility, research suggests they may play a role [15]. Zhou et al. (2019) conducted a study to explore the connection between stress levels and pregnancy outcomes in infertile couples utilizing assisted reproductive technologies. It was found that elevated levels of alpha-amylase enzyme in saliva, recognized as a biomarker of high stress, increased the risk of pregnancy failure in infertile couples undergoing IVF [16].

It's essential to highlight that relying solely on physical treatments may not be enough for infertility, and

addressing the psychological needs of couples is a crucial aspect of successful infertility treatment [17]. Numerous studies have demonstrated that psychological interventions for women undergoing infertility treatments can effectively reduce mental health disorder [18, 19] and reducing depression and anxiety of the patient [20, 21]. Stress management becomes a focal point in counseling interventions [17], aiming to boost individuals' coping mechanisms and develop suitable strategies [22]. A valuable skill in reducing stress among those facing infertility is positive thinking. This skill involves teaching individuals to adopt a different perspective on events, recognizing positive and negative aspects, and assigning value to these experiences [23]. Positive thinking generates a cycle of positive feedback in one's life [24]. In a quasi-experimental study, a shift in mindset and the emergence of positive emotions resulting from positive thinking interventions contributed to improvements in infertility-related stress and psychological well-being among women undergoing infertility [25]. In addition to positive thinking skills, a cognitive reconstruction approach may improve stress management and control. This approach posits that irrational thoughts give rise to irrational behaviors, which can be rectified by modifying foundational thoughts [26].

A limited number of studies have investigated the effects of positive thinking on infertility. Women who experience multiple failures in IVF cycles have received less attention. There is a recognized need for specific psychological interventions for all infertile women due to the negative effects of unsuccessful IVF cycles on their psychological well-being and the potential impact of their stress on IVF outcomes. Therefore, the current research aimed to assess the effectiveness of positive thinking counseling and cognitive reconstruction in reducing perceived stress resulting from recurrent IVF failures in infertile women.

Method

Design and participants

The present study was a randomized controlled clinical trial with a pretest-posttest design, including a control group. The research on female candidates for IVF was conducted at Fatemiyeh Hospital, affiliated with Hamedan University of Medical Sciences in western Iran, from May to December 2023. After obtaining approval from the ethics committee and permission from the heads of the center, the research objectives and methodology were explained. Subsequently, participants interested in participating in the study and meeting the inclusion criteria completed an informed consent form.

Inclusion criteria

Attaining a minimum score of 21/8 on the Cohen Perceived Stress Questionnaire (a cutoff point of 21/8 or higher indicates high perceived stress) [27], residency in the city of Hamadan, Iranian nationality, ability to read and write, primary infertility confirmed by a physician, proficiency in speaking Persian, Having a minimum of 2 unsuccessful IVF attempts, age range of 25–40 years, Body Mass Index (BMI) between 18 and 25, no diagnosed mental illnesses based on self-report and medical records, absence of medical conditions such as hereditary thrombophilia, diabetes, hypertension, thyroid diseases, liver diseases, heart conditions, etc., according to medical records and individual statements, no history of endometriosis and intra-abdominal adhesions, no recent adverse events within the past month, no history of hospitalization in psychiatric hospitals, no substance addiction, absence of neurological diseases or other progressive conditions, non-use of neurologic and psychiatric medications, stable life with a spouse, no stepchild, not under the care of a psychologist or psychiatrist during the study or at least one month before the study initiation, no severe family conflicts in the week leading up to the study commencement.

Exclusion criteria

The lack of response of the ovaries to ovulation stimulation drugs, failure to complete the IVF treatment cycle for any reason, the occurrence of adverse events such as the death of loved ones and stressful incidents during the study, absence of attending more than two counseling sessions in the experimental group, natural pregnancy without fertility assistance methods during the treatment stages, and the onset of physical or mental illness during the study.

The sample size for each group of 30 people was calculated using Rabeipour et al.'s study [17]. Stata-13 software and the Sampsi module were utilized for the calculation; considering a 30% attrition rate, The sample size for each group was determined to be 30 individuals.

$sd2 = 28.11$, $sd1 = 34.76$ $gm2 = 168.65$, $m1 = 137.86$, $power = 0.90$, $\alpha = 0.05$.

Initially, 94 individuals with a negative pregnancy test and eligible for IVF were recalled. After excluding those who did not meet the study criteria, 28 individuals in the intervention group and 29 in the control group were followed up and analyzed (Fig. 1).

Sampling and randomization

Initially, the researcher obtained a list of women eligible for repeated IVF from the infertility center of Fatemiyeh Hospital in Hamadan. Subsequently, they contacted these women, provided information about the research objectives and procedures, and evaluated them based on the

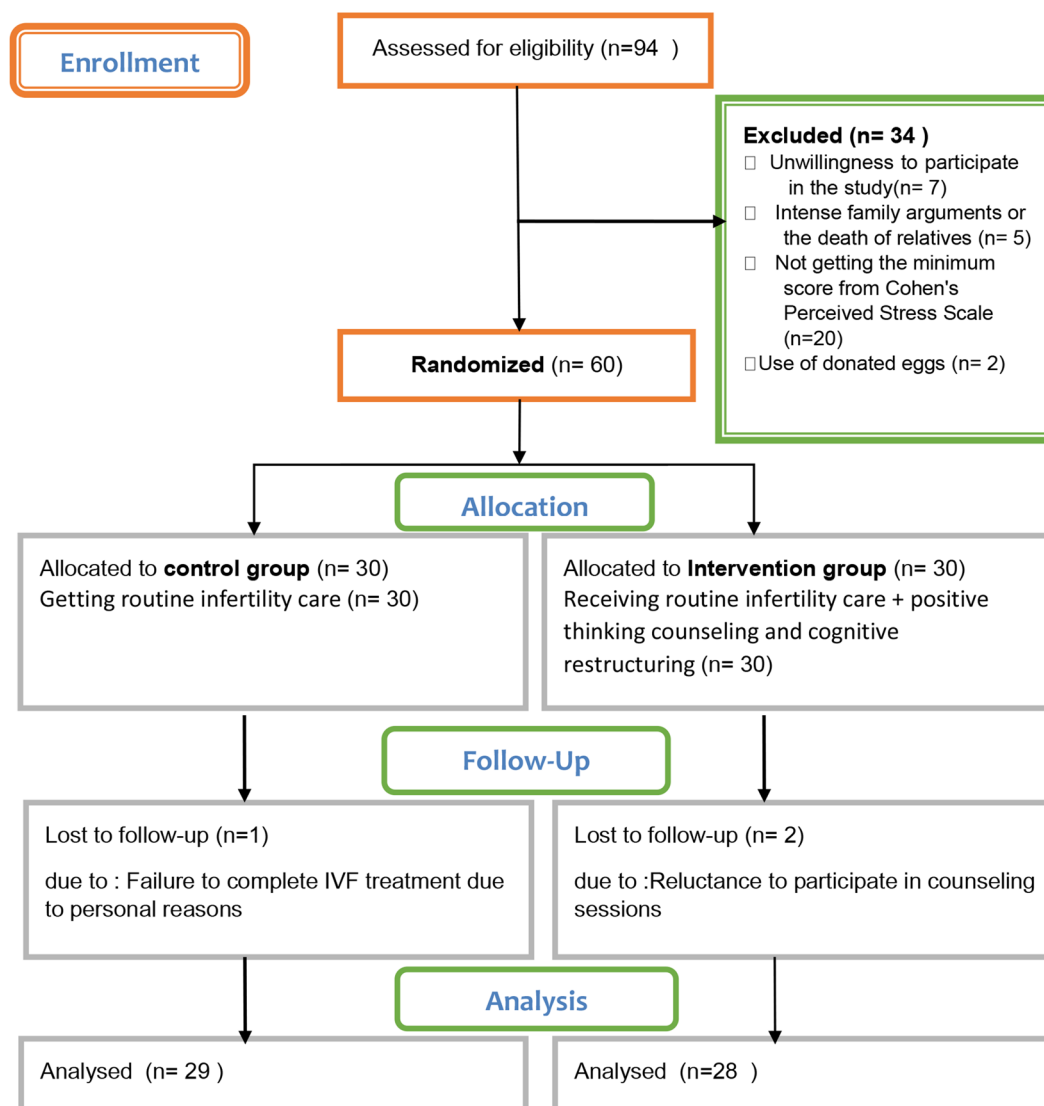
entry criteria. To encourage eligible women to participate in the study, the importance of psychological therapy and its role in improving assisted fertility treatment outcomes was explained, and they were invited to attend the hospital if they were interested in participating.

During an in-person meeting, the women were provided with a comprehensive explanation of the research objectives and methodologies. Those who expressed their willingness to participate in the study were asked to fill out the Cohen Perceived Stress Scale self-report questionnaire. Only individuals who scored 21/8 or higher, expressed their commitment to attend all counseling sessions, and provided informed written consent were included in the study. Afterward, participants were asked to complete demographic and midwifery information forms. Once individuals were confirmed for the IVF treatment plan, the research samples entered the study. The randomization process was carried out by an independent third party, who had no involvement in the research protocol. Participants were randomly assigned to two groups (intervention and control) in a 1:1 allocation ratio. The allocation sequence was determined using the random block method. This involved using web-based¹ software and AABB blocks of 4 to determine the sequence. The type of intervention was then placed in opaque sealed envelopes and numbered based on the determined sequence.

Intervention

The intervention group received individual face-to-face counseling sessions on positive thinking and cognitive reconstruction at the infertility section of Fatemiyeh Hospital. The counseling sessions were conducted over eight sessions, lasting 45 to 60 min, twice a week. Counseling was provided to the intervention group by a researcher trained in this field, with the content approved by a psychologist. The mothers' attendance times were coordinated in advance via phone calls. The sessions aimed to reduce stress by teaching positive thinking and cognitive reconstruction skills. At the end of each session, homework assignments were given, and the tasks and discussions from the previous session were reviewed at the beginning of each subsequent session. Throughout the treatment period (from the sessions to the embryo transfer), the researcher maintained telephone contact with the participants and encouraged them to reach out in case of any issues or questions. For ethical considerations, educational pamphlets were provided to the control group at the end of the study. It's important to note that both groups underwent routine and identical IVF treatment procedures. After implementing the educational sessions (in the intervention group), the perceived

¹<https://www.sealedenvelope.com/simple-randomiser/v1/lists>.

**Fig. 1** Flow diagram

stress test was administered to both groups on the day of embryo transfer (post-test design). The content and objectives of the counseling sessions were tailored to the specific needs of this group [28, 29](Table 1).

Instruments for data collection

The data collection tool included demographic and midwifery questionnaires and the perceived stress scale developed by Cohen.

The demographic questionnaire included age, height, weight, occupation, level of education, spouse's age, spouse's education and occupation, duration of marriage, duration of infertility and treatment, and number of failed laboratory insemination attempts. The content validity method was used to determine the validity of the demographic and midwifery information. The questionnaire was prepared after reviewing various articles

in the field of research and was validated and revised by the supervisors and consultants. It was then made available to ten Hamadan University of Medical Sciences faculty members. The final tool for data collection was used based on their corrective and suggestive opinions.

The Perceived Stress Scale (PSS) is a 14-item scale developed by Cohen et al. in 1983 to measure perceived stress in the past month [27]. This scale assesses an individual's perceived stress in life situations. The PSS is scored on a five-point Likert scale ranging from "None" (0) to "Very Much" (4). This scale's minimum and maximum scores are 0 and 56, respectively. A score higher than 21.8 indicates a significant level of perceived stress. Cohen et al. reported the test-retest reliability of the PSS as 0.85. They calculated the reliability of this scale using Cronbach's alpha method for each subscale and the total score, obtaining values between 0.84 and 0.86. To assess

Table 1 Content and objectives of counseling sessions

Sessions	Objectives	The content of each session	
		Cognitive restructuring	Thinking positive
First session	Preparation	Introducing and providing explanations about the goals and holding meetings, understanding infertility and explaining its female and male types, diagnostic and treatment methods, discussing IVF, success rate and reasons for failure, explaining the nature of stress, its effects, causes and methods. How to deal with it	
Second session	Increasing knowledge and awareness	Acquaintance with positive and negative emotions, identification of automatic, illogical thoughts, expressing points by the subject about the stress she experiences.	Discussing the types of female infertility, the negative effects of smoking, drugs, environmental pollution, mental disorders, and the positive effect of healthy eating, exercise, and meditation on reproductive health.
Third session	Identification of personal capabilities	Identifying situations and people that cause stress, paying attention to thoughts and beliefs before stress or factors that affect the quality of the subject's life, paying attention to automatic thoughts before emotions, paying attention to physical and emotional symptoms after beliefs, paying attention to behaviors after thoughts	Discussing the impact of positive and negative thoughts on fertility - Note three positive events in life
Fourth Session	Knowledge of the effect of exercise, music, meditation, etc. on physical and mental health	Teaching behavioral methods such as talking and negotiating about stress, calming down, postponing the reaction, focusing on breathing, which will cause relaxation during stress.	Mental health and talk about positive abilities and the ways in which a person can express his abilities. The effect of exercise, music, meditation, etc. on physical and mental health.
Fifth Session	Creating positive emotions and mentioning blessings - identifying destructive thoughts	Pay more attention to negative thoughts before stress. Identifying and changing destructive behaviors	Discussion about the effect of positive emotions on the quality of married life and sexual performance of couples
Sixth session	Enjoying the present and the good things in life and the joy of becoming a mother and having a warm and friendly family	Evaluation of cognitive errors and ineffective thoughts, Discuss their benefits and losses	Discussions about the experience of enjoying the present, the joy of having children - note three positive characteristics of successful families
Seventh session	Teaching life style and skills and improving relationships with others	Teaching communication skills, communication barriers and various communication styles and conflict resolution methods	Discussing the supportive actions of parents in the family to increase the quality of married life
Eighth session	Increasing positive emotions and reviewing previous meetings	Examining the subject's progress in reaching the goals, teaching how to generalize what has been learned to real life, identifying supportive people in their lives.	Talk about positive thinking and choose a favorite exercise from the exercises presented in the previous sessions and discuss in that context

the criterion validity of the scale, they calculated the correlation coefficient with cognitive measures, obtaining values between 0.52 and 0.76 [30]. Our study assessed the scale's reliability by asking 30 infertile women to complete the scale before the study. The reliability was assessed using Cronbach's alpha, which yielded a value of 0.89.

Data analysis

The data were analyzed using Stata-13 software. Descriptive statistics, including central tendency and dispersion measures, were employed to describe quantitative variables. Qualitative variable descriptions were performed using frequencies, percentages, tables, and charts. The normality of the distribution of quantitative data was assessed using the Kolmogorov-Smirnov test. The comparison of two groups concerning demographic and midwifery variables was conducted using independent t-tests or Mann-Whitney tests for quantitative data and chi-square tests for qualitative data. The average scores of perceived stress between the two groups were compared using the ANOVA/ANCOVA test, with a significance level of less than 0.05 in all statistical tests.

Ethical considerations

This study was registered under IRCT20120215009014N474 at the Clinical Trial Center of Iran and obtained ethical approval with the code IR.UMSHA.REC.1402.103 from the Ethics Committee. A written informed consent form was obtained from all participants before entering the study.

Findings

The distribution of research variables was assessed for normality using the Kolmogorov-Smirnov test, which confirmed that they followed a normal distribution. Therefore, parametric tests were employed to evaluate the research hypotheses. The mean age of participants in the intervention group was 37.29 ± 2.47 years, while in the control group, it was 36.14 ± 3.50 years. However, this difference was not statistically significant ($p = 0.16$). The average duration of infertility for the intervention group was 10.21 ± 3.65 years, while the control group had an average duration of 9.48 ± 4.37 years. There was no statistically significant difference between the two groups ($p = 0.49$). Furthermore, 53.6% of women in the intervention group and 44.8% in the control group reported a history of 4 or more failed IVF attempts, which was not statistically significant ($p = 0.27$). As a result, both groups were homogeneous in terms of demographic characteristics (Table 2).

The initial perceived stress scores of the control and experimental groups did not show a significant difference before the intervention ($p = 0.16$). However, following the intervention, the average perceived stress scores

of the experimental group were significantly lower than those of the control group ($p < 0.001$). Specifically, in the experimental group, there was a significant decrease in the average perceived stress score after the intervention ($p < 0.001$). Conversely, the control group exhibited a significant increase in the average perceived stress scores after the intervention. ($p = 0.003$) (Table 3).

Due to the significant changes in perceived stress scores within the control group, ANOVA/ANCOVA was used to control for pre-test effects. The results indicated that the mean perceived stress scores in the experimental group were lower than those in the control group ($P < 0.001$) (Table 4).

Discussion

The present study has demonstrated the positive impact of psychosocial stress management interventions in women undergoing IVF treatment. The study results indicated that the average stress scores in the intervention group significantly decreased compared to the control group after the intervention. This suggests the effective and beneficial role of interventions in improving the mental health of women experiencing unsuccessful IVF cycles.

Ahmadian et al. (2022) [31], Rabeipour et al. (2016) [17], and Rahimi et al. (2021) [32] have confirmed the importance of counseling interventions in reducing psychological consequences of infertility and demonstrated that acceptance and commitment-based, participatory, and hope-oriented approaches play a significant role in reducing stress in infertile women. In acceptance and commitment therapy, the focus is not on altering thoughts but on enhancing the individual's emotional bond with their thoughts and feelings. The primary objective of this approach is to foster cognitive flexibility, which entails enabling individuals to select the most suitable action from various options instead of forcing them to act solely to avoid uncomfortable thoughts, emotions, memories, or disruptive tendencies [31].

Group counseling is a dynamic process that focuses on conscious behaviors and thoughts, encompassing therapeutic functions such as liberation, inclination towards reality, emotional discharge, mutual trust, care, understanding, acceptance, and support. The group setting allows participants to share in each other's abilities and utilize their skills [17].

Hope-oriented group counseling has been introduced and suggested as an influential factor in stress management for women with unsuccessful IVF cycles. Hope is one of the crucial psychological support factors in complex crises, serving as an essential emotional coping mechanism, helping individuals more easily tolerate crises in their lives. Hope therapy highlights individuals' strengths rather than focusing on weaknesses [32]. The

Table 2 Sociodemographic characteristics of the research participants in the two study groups

Variable	Intervention group		Control group		t	P-value*
	Mean	sd	Mean	sd		
Age (Year)	37.29	2.47	36.14	3.50	-1.42	0.16
BMI	21.21	2.22	21.50	2.06	0.51	0.61
Spouse's age (Year)	41.93	3.49	40.52	4.50	-1.31	0.19
Duration of marriage (Year)	13.57	3.93	13.10	4.74	-0.40	0.68
Duration of infertility (Year)	10.21	3.65	9.48	4.37	-0.68	0.49
Duration of treatment (Year)	9.32	3.67	8.48	4.18	-0.80	0.42
Variable	Intervention group		Control group		t	P-value**
	N	%	N	%		
Education						
Primary	3	10.7	1	3.4	4.05	0.27
High school	13	46.4	8	27.6		
Diploma	7	25.0	12	41.4		
University	5	17.9	8	27.6		
Occupation						
House maker	26	92.9	26	89.7	---	1.00
Employee	2	7.1	3	10.3		
Spouse's education						
Primary	3	10.7	2	6.9	1.61	0.71
High school	5	17.9	7	24.1		
Diploma	15	53.6	12	41.4		
University	5	17.9	8	27.6		
Occupation Spouse's						
Employee	6	21.4	7	24.1	0.18	1.00
Self-employee	19	67.9	19	65.5		
Manual worker	3	10.7	3	10.3		
Number of failed IVF cycles						
Twice	3	10.7	8	27.6	2.62	0.27***
Thrice	10	35.7	8	27.6		
4 times and more	15	53.6	13	44.8		
Causes of infertility						
Female factor	10	35.7	12	41.4	1.73	0.42***
Male factor	9	32.1	5	17.2		
Both factors	9	32.1	12	41.4		
Family history of infertility						
Yes	5	17.9	6	20.7	0.073	0.78***
No	23	82.1	23	79.3		

* independent sample t test ** Fisher's Exact Test *** Chi-squared test

Table 3 Comparison of perceived stress scores before and after the intervention in the two study groups

Variable	Intervention group		Control group		t	p-value*
	Mean	sd	Mean	sd		
Pre - Intervention	45.07	4.50	43.34	4.80	-1.39	0.168
Post- Intervention	27.64	3.72	45.55	4.44	16.45	<0.001
t	15.93		-3.18			
p-value**	<0.001		0.003			

* independent sample t test

** Paired Samples t test

results of these studies are consistent with the current research.

In accordance with conducted studies, psychological pressures, and stress are considered risk factors for

reducing the success of IVF. Neglecting emotional disorders in infertile women can lead to a dysfunctional cycle, reducing the likelihood of fertility treatment success [11]. Since psychological counseling prevents psychological

Table 4 Comparison of perceived stress scores in the two study groups by controlling the pre-test effect

Variable	Adjusted mean	sd	F	p-value *
Intervention group	27.33	3.78	324.57	< 0.001
Control group	45.84	3.78		

* ANOVA /ANCOVA

damage by providing information, recommendations, and awareness to infertile women, it helps them recognize the problem, analyze and assess it, and make informed decisions and appropriate choices [22]. Therefore, this study aimed to investigate the impact of positive thinking skills and cognitive reconstruction on perceived stress in women experiencing repeated failure in IVF.

The current research findings align with the results of other studies regarding the effectiveness of cognitive reconstruction. In this regard, Hashemi et al. (2014) [33], Marashi et al. (2021) [19], Zahra OA et al. (2019) [34], Khodakarami et al. (2020) [22] and Karaca et al. (2019) [35]demonstrated that cognitive-behavioral programs reduce psychosocial problems associated with infertility experienced by women. In a meta-analysis examining cognitive behavioral therapy’s effects on depression and anxiety in infertile women, results indicated that it effectively improved patients’ mental health [20]. These interventions contribute to improving depression, anxiety, and the mental health of individuals. The findings from these studies suggest that this approach effectively increases individuals’ awareness of stress-triggering thoughts, enhances their ability to communicate their emotions and concerns, and externalizes incompatible reactions. Various studies have demonstrated the beneficial effects of positive thinking and cognitive rehabilitation skills on different aspects of quality of life [23]. Positive psychology aims to improve individuals’ abilities and positive qualities [36], which can safeguard mental well-being and result in positive outcomes across various domains of life [24]. Active psychologists in this field believe that the surest way to achieve well-being and happiness is to use techniques that cultivate positive emotions, behaviors, and thoughts, improving individuals’ performance and well-being [23].

The impact of positive thinking skills has been somewhat established in various research communities. In a clinical trial, the positive thinking approach was effective in reducing anxiety and depression and improving the quality of life in mothers of children with leukemia [37]. In another study, the effectiveness of positive thinking training in enhancing resilience and life satisfaction in the elderly was demonstrated. Having a positive mindset can enhance the overall quality of life, leading to greater life satisfaction [38]. Positive psychological training can significantly contribute to promoting positive and healthy thinking. By engaging in positive thinking training, individuals can amplify positive emotions, develop a deeper understanding of their abilities

and strengths, and acquire effective stress management skills [25].

Furthermore, the association between perceived stress and the success rate of IVF treatment was investigated. The current study demonstrated a correlation between the success rate of IVF and perceived stress levels on the Cohen scale, consistent with the findings of Koumparou [11]et al. (2021) (11). Another study revealed a significant decrease in anxiety levels among participants who underwent psychological intervention, specifically relaxation training and coping skills, and later experienced successful IVF [39].

In conclusion, it is crucial to acknowledge that although this study’s results align with previous research, additional research is required to comprehensively comprehend and analyze these findings. This is due to the limitations in the current study, as is common in other experimental research. The data collection method was self-reported, which may introduce biases associated with this data type. Furthermore, as this study specifically targeted infertile women, future studies are recommended to incorporate psychological interventions forcouples.In this study, the post-test was conducted on the day of embryo transfer. However, to determine whether the psychological interventions had an effect on perceived stress in the period following the embryo transfer, it would be beneficial to consider a longer follow-up period.

Conclusion

The present study showed that stress management interventions are effective when they include cognitive restructuring and positive thinking approaches, significantly reducing the average scores of perceived stress. Since infertile women require psychological support in addition to physical assistance to improve fertility outcomes and mental well-being, counselors and therapistsare recommended to utilize these therapeutic approaches in infertility centers and educational classes to address psychological issues in infertile women.Additionally, due to the scarcity of psychological research focusing on positive thinking in infertile women, this study aims to make a valuable contribution towards the advancement of holistic health and treatment programs. By promoting mental well-being and fostering healthy behaviors, the findings of this study have the potential to have a significant impact. Moreover, the authors suggest conducting further studies with larger sample sizes to obtain more accurate and precise results.

Abbreviations

IVF	In vitro fertilization
ICSI	Intracytoplasmic Sperm Injection
PSS	Perceived Stress Scale
BMI	Body mass index
CONSORT	Consolidated Standards of Reporting Trial

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12888-025-06533-9>.

Supplementary Material 1

Supplementary Material 2

Acknowledgements

This article is derived from the master's thesis in midwifery counseling approved by the Research Council of Hamadan University of Medical Sciences. The authors express their gratitude to the Research and Technology Deputy of Hamadan University of Medical Sciences, the esteemed staff of the infertility department at Fatemiyeh Educational Hospital in Hamadan, and all individuals who assisted in this study.

Author contributions

conceptualization: SZM and SA.; methodology, SZM, SA and FK.; software, FK.; investigation, SZM And SHP; data curation SA.; writing—original draft preparation, SZM, SA, MA, BK and FF.; writing-review and editing, SZM; supervision, SZM.; project administration, SA. All authors have read and agreed to the published version of the manuscript.

Funding

Financial support for this research was provided by Hamadan University of Medical Sciences (Grant No: 140203021510).

Data availability

Data is provided within the manuscript or supplementary information files.

Declarations

Ethics approval and consent to participate

This study was conducted in accordance with the Helsinki Declaration and relevant guidelines. All participants were given the necessary information about the study and their informed written consent was obtained. The Ethics Committee of Hamadan University of Medical Sciences confirmed the study (ethical code: IR.UMSHA.REC.1402.103).

Consent for publication

Not applicable.

Standards of reporting

CONSORT guidelines were followed.

Competing interests

The authors declare no competing interests.

Received: 22 February 2024 / Accepted: 23 January 2025

Published online: 12 February 2025

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