Effect of Cognitive Behavioral Therapy-Based Counseling on Perceived Stress in Pregnant Women with History of Primary Infertility: A Controlled Randomized Clinical Trial

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Abstract

Background

Given the prevalence of infertility and consequences of stress, anxiety, and depression during pregnancy and after childbirth, this study aimed to determine the effect of cognitive behavioral therapy (CBT)-based counseling on perceived stress (primary outcome), anxiety, depression, and quality of life (QoL) of pregnant women with a history of primary infertility (secondary outcome).

Method:

This controlled randomized clinical trial was conducted on 56 pregnant women with a history of primary infertility referred to Infertility Clinic of Al-Zahra Teaching Hospital of Tabriz. The participants were divided into the intervention (n = 28) and control (n = 28) groups using block randomization. The intervention group received group CBT-based counseling after the 14th week of the pregnancy: six in-person sessions and two telephone sessions once per week. The control group received routine care. The Perceived Stress Scale (PSS), Edinburgh Postnatal Depression Scale (EPDS), Van den Bergh's Pregnancy-Related Anxiety Questionnaire (PRAQ), and Quality of Life in Pregnancy (Gravidarum) (QOL-GRAV) were completed through interviews before and four weeks after the intervention by the researcher.

Results

There was not any between-group difference in socio-demographic characteristics, except the gestational age and husband educational level ($p > 0.05$). Both of these variables were adjusted in ANCOVA. After the intervention, the mean scores of perceived stress (mean difference: -7.3; confidence interval: 95%, from − 0.9 to -5.6; $p < 0.001$) and anxiety (mean difference:-14.7; confidence interval: 95%. from − 20.6 to − 8.8; $p < 0.001$) were significantly lower in the intervention group. The mean depression score in the intervention group was lower than the control; however, this between-group difference was not significant (mean difference: -1.95; confidence interval: 95% from − 3.9 to 0.2; $p = 0.052$). The mean score of quality of life in pregnancy was significantly higher in the intervention group than the control (mean difference: -5.4; confidence interval: 95% from 3.4 to 7.4; $p < 0.001$).

Conclusion

CBT counseling can affect the perceived stress, anxiety, and quality of life of pregnant women with a history of primary infertility. As a result, this counseling approach is recommended along with other counseling approaches to improve the mental health of pregnant women with a history of infertility.

Trial Registration

IRCT Registration Number: IRCT20111219008459N12, registered on 10/11/ 2018 (https://irct.ir/user/trial/34677)

Background

Infertility is defined as the inability to become pregnant after one year of unprotected coitus (1). According to studies, approximately 72.4 million couples suffer from infertility (2). In a review study, the prevalence of infertility was reported 17.3% in Iran (3). The number of infertility treatments is growing and these treatments are stressful for infertile women (4). The associated psychological pressures and negative behavioral states can threaten the IVF/ICSI outcomes (5).

Stress is defined as an organism's total response to environmental demands or pressures which is perceived as a threat to their abilities and resources and endangers their health (6). Stress during pregnancy is related to neonatal delayed motor development, and cognitive and behavioral disorders (7). Moreover, it can cause such complications as pregnancy poisoning and spontaneous abortion (8, 9). Pregnancy-induced anxiety is a strong factor in the prediction of negative outcomes, such as poor fetal development, preterm delivery, low birth weight, and impaired psychomotor development (10, 11). Depression is the most common mental disorder during pregnancy (12) Untreated maternal depression during pregnancy causes growth disorder, low birth weight, preterm delivery, attention deficit hyperactivity disorder, and fetal arrhythmia (13). Investigations on the quality of life of couples undergoing IVF treatment showed that it was lower in women than in men (14).

Different studies have recommended several psychological interventions, including CBT (18, 19) etc. to improve depression and anxiety. CBT helps patients to understand their distorted thinking patterns and ineffective behaviors. The basis of CBT is to change the cognitive process. According to this theory, the experience of behavior alone is not sufficient; rather it is an individual’s interpretation of that experience that causes a psychological disorder. Such methods, known as CBT, are used to moderate misunderstanding and misinterpretation of important circumstances of life (20).

LoGiudice et al. (2018) performed a systematic review to investigate the effect of complementary therapies on psychological factors in women undergoing IVF and observed their effectiveness in reducing anxiety, depression, and stress, and improving quality of life during pregnancy (21). Klerk et al. (2005) investigated the effectiveness of psychological counseling on women going through IVF and found no significant between-group difference (22). Hämmerli et al. (2009) failed to show the effectiveness of psychological interventions in improving mental health (depression and anxiety) (23). Taking into account the anxiety and stress in pregnant women with a history of infertility (24), their adverse effects (25, 7), the lack of controlled randomized clinical trials, and contradiction in the literature results, the present study developed following hypothesis: CBT counseling reduces perceived stress, anxiety, and depression of pregnant women with a history of primary infertility and improves their quality of life.

Method

Research Design and Participants

This controlled randomized clinical trial was conducted on 56 pregnant women aged between 20 and 40 years old with a history of primary infertility referred to Infertility Clinic of Al-Zahra in Tabriz, Iran. Sampling was conducted from November 2018 to June 2019. Inclusion criteria were age range between 20 and 40 years, history of primary infertility, at least secondary school educational level, and gestational age between 14 to 20 weeks. Exclusion criteria were fetal abnormality, self-reported history of mental illnesses, chronic physical diseases and experience of unfortunate events in the past three months (e.g. relative loss).

Sample size estimation in G-Power was 24 per group based on the study by Hassan-Zadeh Lifshagerd (26), considering m1 = 35.2 (mean score of perceived stress), and presumed stress score reduction by 15% after the intervention (m2 = 29.92; sd1 = sd2 = 4.87; two-sided α = 0.05; power = 95%). The final sample size was 28 considering the probable sample loss.

Sampling and Randomization

Sampling was initiated after obtaining an ethics code from the Ethics Committee of Tabriz University of Medical Sciences (IR.TBZMED.REC.1397.625) and registering the study on the Iranian Registry of Clinical Trials (IRCT20111219008459N12) website. The researcher attended the Al-Zahra Teaching Hospital of Tabriz and extracted the list of women impregnated by assisted reproduction technologies (ART). Then, they were called and provided with a brief description of research objectives and methodology. Eligibility of the samples was assessed and eligible women who were willing to participate in the study were invited. In an in-person meeting, research objectives and methodology were completely explained. Women impregnated with ART, were interviewed and their Perceived Stress Scale (PSS) was completed by the author. The participants scored higher than the cut-off point of 21.8 (high level of stress) were included and their informed written consent was obtained. Then, the Postnatal Depression Scale (PDS), Pregnancy-Related Anxiety Questionnaire (PRAQ), and Quality of Life in Pregnancy (QOL-GRAV) were completed by the researcher through interviews.

The participants were divided into the intervention and control groups using block randomization with blocks of 4 and 6, based on the age range (20–30 and 30–40 years). For allocation concealment, the type of intervention was written on a piece of paper by a person not involved in sampling and data analysis. Papers were then enclosed in specific envelopes numbered sequentially. Each participant received an envelope on arrival.

Intervention

The intervention group, comprised of 5–7 participants, received six 60- to 90-minute in-person CBT sessions in a quiet and friendly room in the Infertility Clinic of Al-Zahra Teaching Hospital and two telephone sessions once a week by the researcher. In addition, the counseling was provided in participants' native language. A brief explanation of the content of the sessions is as follows (27).

- First session: Inducting, determining the number and duration of each session, sequence of sessions and group regulations, identifying problem, introducing CBT, introducing cognitive-behavioral pattern, describing the problem based on the given pattern and receiving feedback.
- Second session: Conducting mood assessment, describing problem based on the given pattern, impacts of lack of control on stress process, introducing progressive muscle relaxation and practicing it, and allocating homework assignments.
- Third session: reviewing progressive muscle relaxation, asking participants to pose problems, introducing imagination and practicing it, and allocating homework assignments.
- Fourth session: reviewing imagination practices, introducing hot thought concept, and allocating homework assignments, receiving feedback.
- Fifth session: conducting discussion about treatment process and its completion, introducing cognitive distortions, introducing the concept of hot thought challenge, and determining homework assignments and receiving feedback.
- Sixth session: introducing challenge with thoughts, introducing the concept of hot thought challenge, allocating homework assignments, receiving feedback.
- Seventh session: completing seven columns of the thought record sheet during the session (situation, automatic thoughts, emotions and moods, confirmatory evidence, rejective evidence, alternative thought, and re-assessment), and allocating homework assignments, receiving feedback.
- Eighth session: reviewing the treatment process (reviewing and recording different CBT techniques), taking recurrence prevention process, introducing self-management sessions and its scheduling, and allocating homework assignments

The control group only received routine pregnancy care. Four weeks after the intervention, the posttest PSS, EPDS, PRAQ, and QOL-GRAV were completed by the author for both groups via a telephone call.

Data Collection Tools

Data were collected using the socio-demographic and midwifery scale, Cohen's perceived stress scale, PRAQ, EPDS, QOL-GRAV.

The socio-demographic and midwifery questionnaire was prepared by the authors and its validity was confirmed by 10 faculty members of Tabriz University of Medical Sciences.

Cohen’s perceived stress scale

The degree of stress was measured using PSS-14. The scale is scored based on a 5-point Likert scale; the lowest and highest scores are 0 and 56, respectively. The cut-off point was 21.8 and a higher score indicated a higher degree of stress. The internal consistency and reliability coefficients were obtained through Cronbach’s alpha in a range of 0.84–0.86 in two groups of students and a group of tobacco users in a smoking cessation program (28). Ghorbani et al. reported Cronbach’s alpha of 0.81 for an

Iranian population (29). The reliability of the Farsi version was calculated by Bastani et al., using the internal consistency method and the Cronbach's alpha of 0.74 was obtained (30).

Van Den Burgh's Pregnancy-Related Anxiety Questionnaire

The shortened version of the PRAQ (PRAQ-17) contains 17 items and the score of each item ranges between 1 and 7. Therefore, the total PRAQ score is between 17 and119 (31). The higher total PRAQ score indicates a higher level of anxiety (30).

The Edinburgh Postnatal Depression Scale

This scale is used to measure the level of depression during pregnancy and postpartum. Items are scored from 0 to 3 based on the severity of symptoms. An individual's score is the total sum of all 10 items, which varies between 0 and 30. Mothers scored higher than the threshold level (12) had different levels of depression (32). In the present study, such mothers were referred to a psychologist.

Quality of Life in Pregnancy (Gravidarum) (QOL-GRAV) Questionnaire

This questionnaire was developed by Vachkova et al. (2013) using the WHO Quality of Life-BREF (WHOQOL-BREF). It is composed of 9 items to measure individuals' experience of the quality of life during pregnancy. The QOL-GRAV's score varies between 9 and 63. Higher scores indicate a higher quality of life. Mirghafoorvand et al. indicating acceptable validity and reliability of the questionnaire (33).

In the present study, the reliability of the questionnaire was determined through test-retest on 20 women in a two-week interval and the Cronbach's alpha and intraclass correlation coefficient (ICC) was determined. The ICC for PSS, PRAQ, EPDS, and QOL-GRAV was 0.91, 0.88, 0.83, and 0.93, respectively. The Cronbach's alpha for these questionnaires was reported as 0.87, 0.78, 0.72, and 0.91, respectively.

Statistical Analysis

After collecting data from all participants, they were analyzed in SPSS-21. The normality of the quantitative data was determined using the Kolmogorov-Smirnov Test and all variables were normal. The chi-square test, Trend chi-square test, Fisher's exact test, and independent t-test were used to assess the consistency of socio-demographic data. The independent t-test was used to compare the two groups before intervention in terms of perceived stress, anxiety, depression, and quality of life. After the completion of the intervention, this comparison was conducted using the ANCOVA while controlling the baseline values.

Results

At the beginning of the study, 150 women with positive pregnancy test results were contacted. Finally, 94 women were excluded based on eligibility criteria. The research instruments were completed for the remaining women (n = 56) and they were equally randomized into counseling and control groups. Due to

premature birth, two participants in the counseling group and three participants in the control group were excluded. As a result, the post-intervention follow-up analysis was conducted with 26 participants in the counseling group and 25 participants in the control group (Fig. 1).

The comparison of socio-demographic characteristics of participants in study groups was shown in Table 1. There was no significant between-group difference in socio-demographic data, except gestational age and husband educational attainment (Table 1). However, both variables were moderated using the ANCOVA ($p > 0.05$).

Table 1
Socio-demographic characteristics of participants in study groups

Characteristic	Counseling (n = 28) number (%)	Control (n = 28) number (%)	P-value
Age (years) *	31.8 (5.85)	31.1 (5.3)	0.668†
Husband's age(years) *	37.1 (7.2)	36.1 (5.0)	0.551†
Duration of infertility(years) *	8.1 (5.2)	7.5 (4.5)	0.663†
Gestational age (years) *	15.9 (2.4)	17.1 (2.6)	0.046†
Causes of Infertility			0.515††
For men	21 (75.0)	23 (82.1)	
Feminine	7 (25.0)	5 (17.9)	
Level of education			0.240‡
Secondary school	3 (10.7)	9(32.1)	
High school	4 (14.3)	2(7.1)	
Diploma	11 (39.3)	8(28.6)	
University	10 (35.7)	9(32.1)	
Job			0.143§
Housewife	21(75.0)	26(92.9)	
Employed	7(25.0)	2(7.1)	
Husband's education			0.034‡
Illiterate	0(0)	2(7.1)	
Elementary	0(0)	4(14.3)	

Mean (SD) *

§ Fisher's exact test

Independent t-test †

†† Chi-square test

‡ Trend Chi-square test

Characteristic	Counseling (n = 28) number (%)	Control (n = 28) number (%)	P-value
Secondary school	3(10.7)	5(17.9)	
High school	4(14.3)	2(7.1)	
Diploma	10(35.7)	6(21.4)	
Academic	11(39.3)	9(32.1)	
Husband's occupation			0.265§
Jobless	1(3.6)	0(0)	
Employee	12(42.9)	7(25.0)	
Worker	5(17.9)	8(28.6)	
Shopkeeper	7(25.0)	12(42.9)	
Other	3(10.7)	1(3.6)	
Monthly income level			0.752‡
Adequate	6(21.4)	7(25.0)	
Inadequate	7(25.0)	2(7.1)	
Relatively adequate	15(53.6)	19(67.9)	
House status			0.310§
Personal	16(57.1)	19(67.9)	
Rental	6(21.4)	2(7.1)	
Woman's parents' house	1(3.6)	0(0)	
Husband's parents' house	5(17.9)	7(25.0)	
Life satisfaction			0.440‡

Mean (SD) *

§ Fisher’s exact test

Independent t-test †

†† Chi-square test

‡ Trend Chi-square test

Characteristic	Counseling (n = 28) number (%)	Control (n = 28) number (%)	P-value
Completely	25(89.3)	23(82.1)	
Relatively	2(7.1)	3(10.7)	
Unsatisfied	1(3.6)	2(7.1)	
Having a history of domestic violence	0(0)	0(0)	
Frequency of treatment failure			0.823‡
Zero	5(17.9)	4(14.3)	
One	7(25.0)	6(21.4)	
Twice and more	18(64.2)	16(67.)	
Mean (SD) *			
§ Fisher's exact test			
Independent t-test †			
†† Chi-square test			
‡ Trend Chi-square test			

The independent t-test showed no significant between-group differences of the total perceived stress score before intervention (p = 0.561). Based on the ANCOVA and adjusted baseline values, the mean ± standard deviation of the total perceived stress score was significantly lower in the counseling group than that of control group after intervention (mean difference = -7.3; confidence interval of 95%: from − 0.9 to -5.6; p < 0.001)(Table 2).

Table 2
Comparison of mean perceived stress score of anxiety, depression and quality of life in the Study Groups

Variable	Counseling group (n = 28) mean (SD)	Control group (n = 28) mean(SD)	Mean difference (95% confidence interval)	P-value
Perceived stress score (score: 0 to 56)				
Before intervention	46.5 (2.6)	46.8 (2.4)	-0.4 (-1.7 to 0.95)	▯561/0
4 weeks after intervention	38.9 (3.9)	46.6 (2.2)	-7.3 (-9.0 to -5.6)	†001/0 >
Anxiety Score: (Score: 17 to 119)				
Before intervention	63.2 (11.9)	65.6 (13.8)	-2.4 (-9.3 to 4.5)	▯484/0
4 weeks after intervention	48.0 (9.6)	63.9 (12.4)	-14.7 (-20.6 to -8.8)	†001/0 >
Depression Score (score: 0 to 30)				
Before intervention	16.2 (4.7)	17.0 (4.2)	− .82 (-3.2 to 1.6)	▯495/0
4 weeks after intervention	13.1 (3.2)	15.3 (5.3)	-1.95 (-3.9 to 0.2)	†052/0
Quality of Life Score (score: 9 to 63)				
Before intervention	25.7 (3.1)	25.5 (4.4)	0.21 (-1.8 to 2.2)	▯833/0
4 weeks after intervention	31.5 (3.1)	25.8 (3.2)	5.4 (3.4 to 7.4)	†001/0 >
▯ Independent t-test				
† ANCOVA with baseline score control and gestational age and spouse education variables				
Before intervention, the number of patients in the counseling group was 28 and in the control group was 28, and after the intervention in the counseling group was 26 and in the control group was 25.				

The independent t-test showed no significant between-group differences of total anxiety score before intervention ($p = 0.484$), whereas based on the ANCOVA and adjusted baseline values, the mean ± standard deviation of total anxiety score was significantly lower in the counseling group than that of control group after intervention (mean difference = -14.7; confidence interval of 95%: from − 20.6 to -8.8; $p < 0.001$) (Table 2).

The independent t-test showed no significant between-group differences of total depression score before intervention ($p = 0.495$). After intervention, based on the ANCOVA and adjusted baseline values, the mean ± standard deviation of depression was lower in the counseling group than that of control group; however, this between-group difference was not significant (mean difference=-1.95; confidence interval of 95%: from 3.9 to -0.2; $p = 0.052$) (Table 2).

The independent t-test showed no significant between-group differences of total quality of life score before intervention ($p = 0.833$). After intervention based on the ANCOVA and adjusted baseline values, the mean ± standard deviation of the total quality of life score was significantly lower in the counseling group than that of control group (mean difference = 5.4; confidence interval of 95%: from 3.4 to 7.4; $p < 0.001$) (Table 2).

Discussion

Results from this study showed that the mean perceived stress and anxiety scores were significantly lower in the counseling group than the control four weeks after intervention. The mean depression score was lower in the control group four weeks after intervention with adjusted baseline values; however, this between-group difference was not significant. Moreover, the mean quality of life score was significantly higher in the counseling group than the control.

In a review and meta-analytical study, Hopkinson et al. (2018) showed that CBT significantly reduced depression ($p < 0.001$) and stress ($p < 0.001$) among caregivers of patients with dementia; whereas, their anxiety level did not reduce ($p = 0.47$) (34). Their findings were consistent with our findings in terms of the effect of counseling on stress. The present study was similar to the above study in terms of holding in-person and telephone CBT sessions; whereas, they differed in the target population(that comprised of people aged 57–73 years old), and there was no limitation regarding the number and duration of intervention sessions.

In a review study, Ying et al. (2016) investigated the effect of psychological interventions on mental health, pregnancy rate, and marital function of infertile couples undergoing IVF. In 20 trials under investigation, 14 interventions, such as CBT, mindfulness, counseling, coping with stress, and positive reassessment used at different IVF stages were studied. The authors concluded that none of these interventions were effective in soothing stress and depression of patients undergoing IVF (35). Results from the above study were inconsistent with the present study, which could be attributed to the following reasons. The present study investigated the use of CBT on pregnant women with successful IVF; whereas, Ying et al. implemented interventions during the course of treatment. Moreover, none of the reviews investigated the psychological outcomes of intervention in the two-week wait period, despite the fact that this period is one of the most difficult times in the life of infertile couples.

Given that stress perception and responding to it are affected by previous experiences, the present situation and learned behaviors(36), it could be concluded that the CBT counseling in which new thinking and behavior techniques are taught to replace negative thoughts of patients about self, world, and

future(37, 38), are helpful in identifying stressful situations and using coping strategies. The correction of cognitive assessments, improvement of coping skills, and combination of practices to integrate learned techniques with real-life situations can reduce the level of stress (26).

Hamzeh Poor (2013) showed that anxiety in infertile women was significantly lower in the CBT group than the control (39). Findings of the present study were consistent with those of the above study. However, Hamzeh Poor investigated the participants from the initial treatment to the IUI stage, i.e. before getting positive pregnancy result. In a quasi-experimental study, Salehi (2016) compared the effectiveness of group CBT and interactive lecturing in reducing anxiety in pregnancy. Results showed a significant reduction in the state and trait anxiety in CBT and IL groups after four weeks ($p < 0.001$). In addition, group CBT was more effective than interactive lectures in reducing participants anxiety; however, this between-group difference was not significant ($p > 0.05$) (40). Results from the above study were consistent with the findings of the present study; however, there was a difference between two studies in the number of counseling sessions and participants.

Iman-Parast et al. (2013) showed that CBT can significantly reduce anxiety in nulliparous women (41). Chatwin et al, (2016) investigated the effectiveness of CBT and EFT in reducing depression and anxiety in adults and showed that both methods significantly reduced depression symptoms in adults with major depression. However, the post-intervention anxiety score was not significantly diffident from the pretest score ($p = 0.104$). Moreover, anxiety score in the CBT group was significantly lower than that of EFT group ($p = 0.032$) (42). In a study on patients with major depression disorder, Rosso et al. (2017) showed that depression symptoms were significantly lower in the Internet-based CBT group than the control group ($d=-0.80$)(43). In a controlled randomized clinical trial, Fann et al. (2015) investigated the effect of in-person and telephone CBT on reducing major depression in patients with traumatic brain damage. Results showed no significant difference between the CBT and control groups ($p = 0.37$) (44). This inconsistency may be due to the difference in the target population and intervention type.

According to the cognitive-behavioral theory, anxiety disorders are caused by mistaken beliefs, which affect the interpretation of events and induce a disproportionate emotional response (45). As a result, holding counseling sessions for muscle relaxation, and identification of challenging thoughts and beliefs can replace the wrong attitudes of pregnant women with rational ones, indicating the effectiveness of CBT in anxiety management (33, 46). Studies have shown that infertility treatment failure may cause permanent emotional burden in 20% of infertile women (47, 48). To explain the results, in many participants, negative experiences, such as infertility treatment costs, continuous worries about treatment outcomes, fatigue from frequent visits to medical centers, curiosity of relatives, fear of family breakdown, and fear of losing husband interest before and during mental and social stress assessment resulted in a sense of helplessness, conflict, frustration, sharp decline in self-esteem and self-confidence, and isolation (49). These severe mental stressors play a significant role in depression. As a result, our intervention may be insufficient for addressing many of the participants' psychosocial needs.

In this study, cognitive-behavior counseling improved the quality of life of pregnant women with a history of primary infertility. In the review of literature, the author found no relevant study on pregnant women. In a controlled randomized clinical trial, Cooney et al. (2018) investigated the effect of CBT on weight and quality of life of women with polycystic ovary syndrome (PCOS). Results showed that weekly CBT + LS (lifestyle) for eight weeks was more effective than LS alone in reducing weight and improving the quality of life in women with PCOS (50). In a quasi-experimental study, 'Isa-Zadegan et al. (2013) showed that CBT in patients with hypertension can significantly increase the mean quality of life score in the counseling and control groups ($p < 0.01$) (51). In a clinical trial, Jalilian et al. (2018) showed that the CBT can affect and enhance the psychological and physical components of the quality of life in women with PCOS ($p < 0.05$)(52). Results from the above study were consistent with the present study; however, there were between-study differences in the target population, CBT type, and the number of follow-up sessions.

The financial burden from infertility treatment, lengthy treatment period, irrational thoughts about having a child, psychological pressures from relatives, and low educational level are among factors having adverse effects on the quality of life of infertile women (53). Women impregnated after these difficult stages experience a very stressful and challenging pregnancy (54). The researchers believe that although infertility, as a source of psychological pressure, can endanger mental health of infertile people, its effect depends on the psychological assessment and coping skills of those people. Therefore, teaching these skills to control emotions plays a significant role in reducing psychological pressures caused by infertility-induced stress (55). It could be concluded that CBT can cause some changes in the psychological dimensions of pregnant women. When these women use CBT skills in stressful situations, they feel capable of making decisions, controlling their life events, and taking effective measures to achieve desirable results. They internally feel satisfaction which, in turn, increases happiness, mental well-being, and self-efficiency, as the quality of life factors. (51).

Limitations And Strengths

In the present study, all responses of participants were assumed to be correct as their validation was beyond the researchers' ability. Moreover, all participants were literate, which could affect generalizability of the results. Among the strengths of this study are observing all principles of clinical trials, including allocation randomization and allocation concealment, completion of the questionnaire by the researcher, and reduction of plausible incomplete, null, and wrong responses. To make a better communication with the participants, their native language was used during the counseling sessions.

Conclusion

According to the results, CBT-based counseling is effective in reducing perceived stress and anxiety, and improving quality of life. Given the needs of pregnant women with a history of primary infertility for both psychical and psychological supports to improve pregnancy outcomes, mental health, and quality of life, healthcare providers can provide them with this counseling technique, along with routine pregnancy care.

Abbreviations

CBT: Cognitive Behavioral Therapy; QoL: Quality of Life; PSS: Perceived Stress Scale; EPDS: Edinburgh Postnatal Depression Scale; PRAQ: Pregnancy-Related Anxiety Questionnaire; QoL-GRAV: Quality of Life in Pregnancy (Gravidarum).

Declarations

Ethics approval and consent to participate

This study was conducted in accordance with the Helsinki Declaration and relevant guidelines All participants were informed about the study and written informed consent was obtained from them. The Ethics Committee of Tabriz University of Medical Sciences confirmed the study (ethical code: IR.TBZMED.REC.1397.625).

Consent for publication

Not applicable.

Availability of data and materials

Data and materials of this study are available from the corresponding author upon reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

FG implemented the study and was responsible for data collection and wrote the first draft of the manuscript. SHH and MM contributed in the study design and data analysis, assisted in the preparation of the final version of the manuscript, KHE designed the counseling protocol. All the authors read and approved the final version of the manuscript.

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Figures

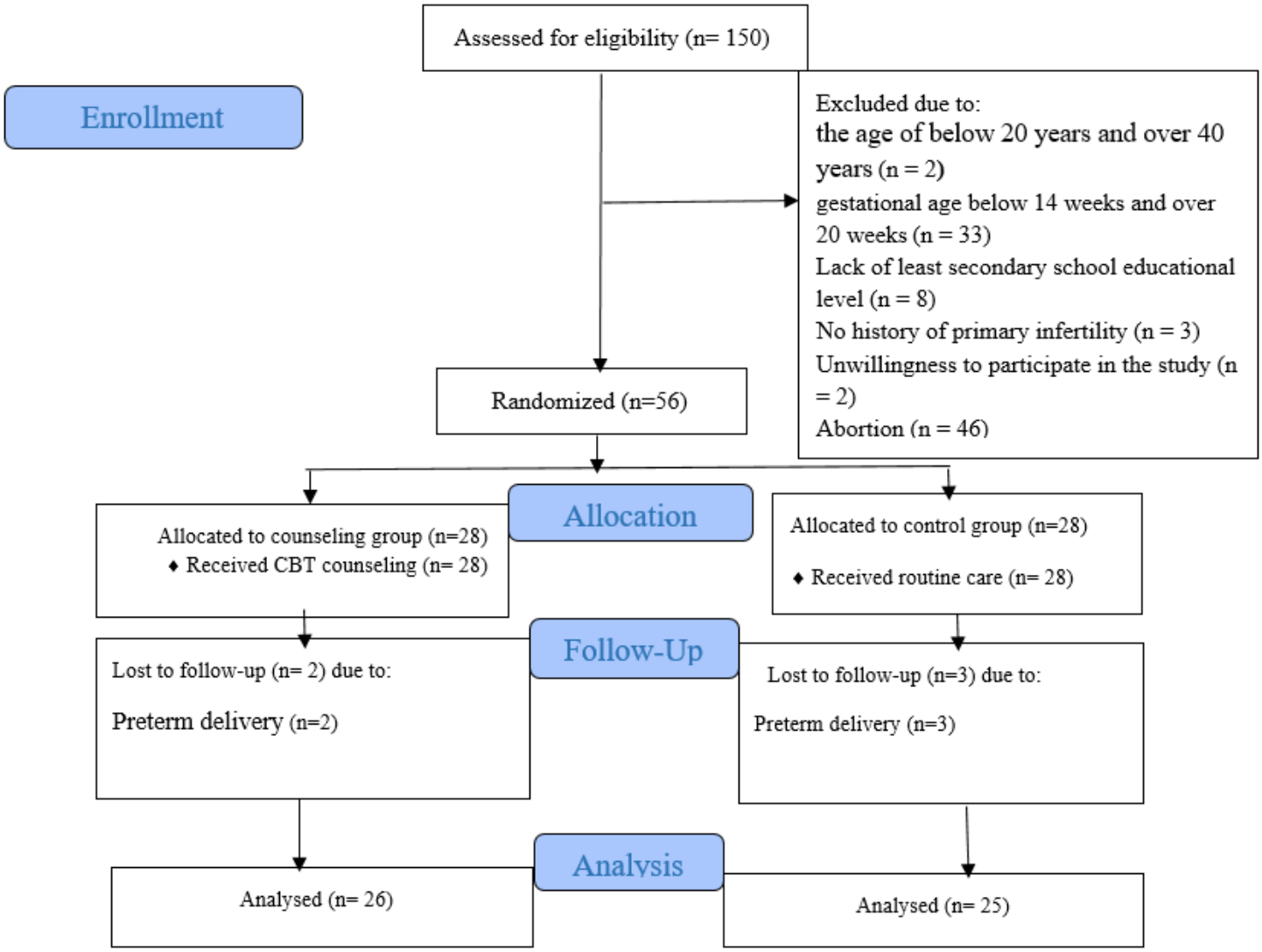

Figure 1

Flow chart of the study