Controlling the anxiety in Iranian pregnant women at risk of preterm labor by undergoing the counseling group intervention

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Abstract

Objective: The effect of a new, structured group training program on the anxiety reduction in Iranian pregnant women at risk of preterm labor (PTL) was assessed. **Design:** A randomized controlled clinical trial. **Setting:** The prenatal care center in the Gynecology Clinic of University Hospital. **Population:** 72 Iranian pregnant women at risk of PTL with a gestational age of 24–28 weeks. **Methods:** Several trained research nurses presented group educational counseling sessions for 6 weeks based on the integration of psychological instructions and interactive lectures for the intervened group ($n = 36$). Pregnant women in the control group ($n = 36$) only received routine pregnancy care. **Main Outcome Measures:** The completion of pregnancy-related anxiety questionnaire (PRAQ) for Iranian pregnant women at risk of PTL in the intervention (before and after 6-week counseling, and 1-month post-counseling) and control (before, and on the 6th and 10th week after the study) groups. **Results:** There was a significant difference in the mean anxiety score between the intervention (3.45 ± 0.75) and control (3.01 ± 0.34) groups before the group educational counseling sessions. After this intervention, a significant reduction in the mean anxiety scores of intervened pregnant women (2.48 ± 0.32) compared to the control (2.68 ± 0.81) was found. This decrease in mean anxiety score after the 1-month post-counseling was more pronounced than the 6th week after the study onset ($P < 0.001$). Low anxiety scores in the intervention group over time were also maintained. **Conclusions**: Implementing the group educational counseling sessions is recommended as a complementary, effective, and noninvasive intervention to efficiently control the anxiety in pregnant women at risk of PTL.

Keywords: Anxiety, group educational program, high-risk pregnancy, preterm delivery

Introduction

Preterm labor (PTL) is one of the main reasons for perinatal morbidity and mortality. PTL is defined as birth before the 37th week of pregnancy which is associated with the beginning of regular uterine contractions related to the progressive cervical change.[1] Although about 15 million people are annually born as preterm infants according to the World Health Organization (WHO) data, there will be tremendous growth in this adverse pregnancy outcome.[2] The incidence rate of PTL in the United States has been recently increased from 9 to 12.7%.[3] This rate in Canada,[4] Switzerland,[1] and Denmark[5] is reported to be 7.3, 7.7, and 6.4%, respectively. In general, the average PTL rate among 184 countries in the world ranged from 5 to 18% of newborns.[2] However, the prevalence rate of PTL in different

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cities of Iran was variable and ranged from 5.6% in Qom and 39.4% in Kerman.[6] On the other hand, PTL is the most crucial reason for mothers to be hospitalized during pregnancy, causing many economic problems for the family and society. The financial burden of premature babies born in Canada for the first 10 years of life owing to the national health care services is reported to be approximately $5 million.[7]

Even though the underlying cause of premature birth is unknown, some factors affecting the PTL incidence have yet reported. This risk factor for the birth of a small-for-gestational-age infant can be a result of medical risk conditions such as infections, malformations, premature rupture of membranes, intrauterine growth restriction, preeclampsia, gestational diabetes, and abnormal synthesis of maternal corticotropin-releasing hormone.[1,7-10] As well, some studies showed that maternal psychological distresses, particularly anxiety, play a significant role in adverse obstetric outcomes like PTL.[11-13] Anxiety has both short-term and long-term effects on maternal, pregnancy, and fetal outcomes.[13] The most common complications of pregnancy anxiety disorders are PTL, low birth weight, unintended pregnancy outcomes, severe nausea and vomiting in early pregnancy, fatigue, reduced breastfeeding, low Appearance, Pulse, Grimace, Activity, and Respiration (Apgar) score at 1st and 5th min, and postpartum anxiety.[14] There is some evidence that anxiety can lead to inappropriate maternal responses to the fetus during pregnancy and decrease the ability to play a motherly role.[15] Moreover, long-term effects of maternal anxiety in children include behavioral and emotional disorders, attention deficit hyperactivity disorder, cognitive problems, mood disorders, and low learning scores at 2 years of age. Accordingly, it is essential to find some efficient therapeutic plans to reduce maternal anxiety during pregnancy.[16]

Studies have shown that the application of some accessible interventions such as yoga, relaxation exercises, music therapy, active visualization techniques, support, empathy, training, and distraction techniques in a hospital setting can reduce the anxiety of pregnant women at risk of PTL.[17-19] Meanwhile, prenatal education plays an essential role in the prevention of psychological disorders and anxiety as well as in promoting physical and mental health. Nowadays, there are a high number of educational methods with different effects on the control of patients' anxiety. The training programs currently offered to pregnant women in the health system mainly are face to face, along with presenting educational pamphlets. However, the group educational counseling not only requires less time but also transfers a large amount of information to pregnant women at risk of PTL because of the regular scheduling program.[20] In group training, pregnant women with a more comfortable feeling than ever before communicated and discussed to each other about the different topics well. In this circumstance, the learning power and the learners' self-confidence sense are increased remarkably. Hence, anxiety and loneliness are reduced and provided opportunities to share ideas and to receive support collaboratively.[21]

Therefore, this study aimed to evaluate the effect of group educational counseling sessions based on the purposeful presentation of psychological instructions and interactive lectures during pregnancy on the reduction of mean anxiety scores and its other dimensions in Iranian pregnant women at risk of PTL.

Methods

Study design, subjects, and inclusion/exclusion criteria

A randomized controlled clinical trial was performed with 72 pregnant women living in Tehran, referred to the Gynecology Clinics of Akbarabadi Hospitals (Tehran, Iran) for receiving prenatal care between January and April 2019. The simple random sampling method was chosen to recruit and allocate the participants into two groups of intervention (*n* = 36) and control (*n* = 36). Sample size with 62 participants (31 in each group) was obtained to be adequate for assessing a clinically significant difference of 0.2 between groups in decreasing the average anxiety score in pregnant women assuming a standard deviation of 10 using a two-tailed t-test of difference between means with 80% power, effect size of 45%, and a 5% level of significance. However, the sample size to compensate for the subject drop-out based on the loss rate of 10% was increased to 72 subjects (36 in each group) [Figure 1].

The criteria for entering the study were Iranian nationality, living in Tehran city, the minimum literacy (reading and writing) skills to understand and answer questions, willingness to participate in the research plan, pregnancy for a healthy single baby, a gestational age between 24 and 28 weeks assessed by the last menstrual period and ultrasound examinations, obtaining the score 10 or more according to the risk-scoring system for prediction of PTL,[21] no history of specific mental illness, and anxiety scores between 17 and 119 based on the pregnancy-related anxiety questionnaire (PRAQ).[22] On the other hand, the exclusion criteria in this study included failure to attend two sessions of group educational counseling sessions, adverse events, and major stresses during the intervention (such as losing relatives and close friends) and migration of pregnant women [Figure 1].

In this study, a group meeting was taken place for pregnant women and their spouses to explain the research design and objectives. The written informed consent was obtained from all the subjects and their spouses. The pregnant women's involvement was wholly voluntary, and they could quickly leave the study whenever they would not like to continue their cooperation. All information was confidential and employed exclusively for scientific aims. This study was also approved by the "the Human Ethics Committee of the Iran University of Medical Sciences" in December 2018 (IR.IUMS.REC.1397.522).

Training intervention program

Subjects in the intervention group in addition to the routine pregnancy care programs received group educational counseling
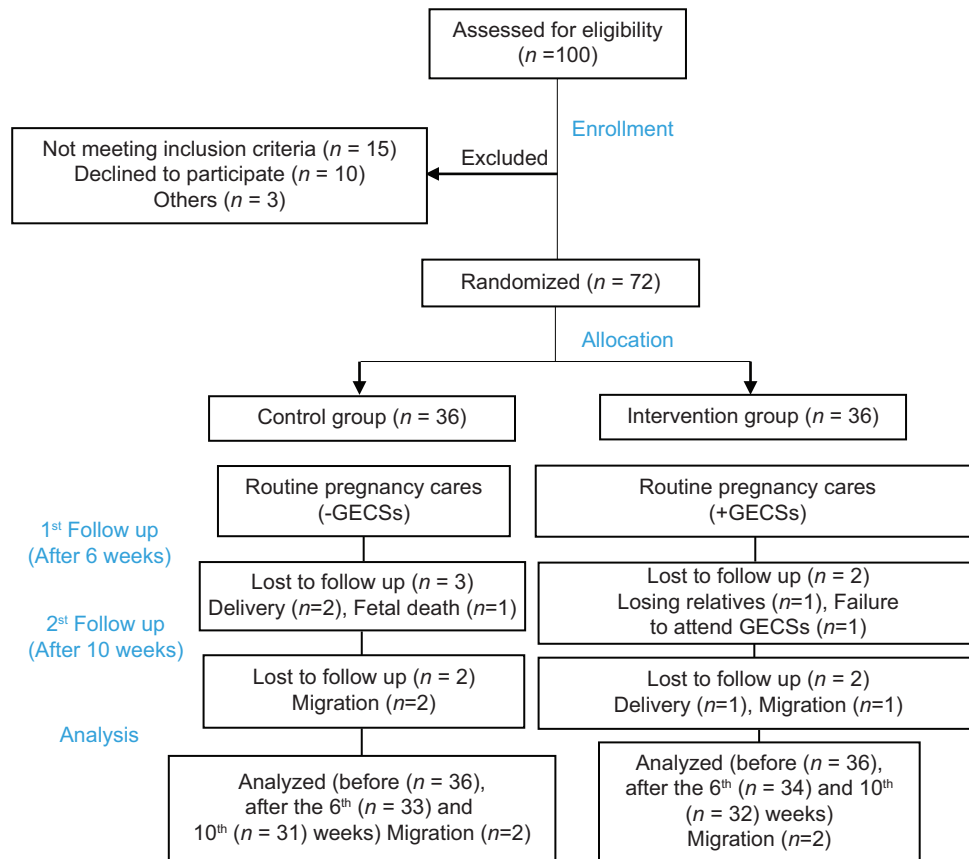
Figure 1: CONSORT 2010 flow diagram of participants in the present study (GECSs: group educational counseling sessions)

sessions designed by trained midwives. These pregnant women at risk of PTL were educated in groups of 4–6 people in 60 min sessions during six consecutive pregnancy weeks. The group educational counseling session was provided once a week in terms of interactive lectures, instructional videos, and exercise worksheets for stress management at home, and mental notes to refer to in stressful and anxious situations. All group educational counseling sessions to improve safety and adherence to the training program were accompanied by music and conducted in a spacious, air-conditioned room (temperature of $20 \pm 2°C$ and relative humidity of $50 \pm 5\%$) with ideal lighting. The educational content of the group educational counseling sessions was as follows: (i) 1st session—introduction to PTL as educational videos: The risk occurrence, symptoms, complications, available treatments, mental health, mother-infant relationship, maternal familiarity with neonatal intensive care unit, and preterm neonatal care were presented, (ii) 2nd session—introduction to the familiarity with anxiety and ways to deal with it: The step aimed to identify the thoughts of pregnant women at risk of PTL about the origins and symptoms of anxiety in everyday life. As well, the impact of anxiety on health, interpersonal relationships, health and performance, and accessible ways to deal with anxiety were discussed, (iii) 3rd session—subjective methods of coping with anxiety: attendees were encouraged to evaluate their daily thinking about anxiety. They challenged ways of perceiving and interpreting life events and examined patterns of irrational thinking, controlling anxious thoughts, and self-talk in times of anxiety, (iv)

4th session—physical solutions in facing anxiety: The effect of eating, drinking, and sleeping patterns, physical de-stressing skills, and hormones on the anxiety coping was discussed. A particular emphasis was also paid on getting enough food, sleeping to keep the immune system healthy, and raising energy levels, (v) 5th session—strengthening interpersonal and social relations skills: it was explained that although pregnant women at risk of PTL may feel that having relationships with others is a stressful and challenging task, these approaches are likely to be the most important support source in the fight against anxiety. Participants were also encouraged to discuss complicated relationships and how they cause anxiety, (vi) 6th session—improving mothers' self-esteem and respect: it was trained that how participants can value and respect themselves. Effective coping strategies were also put in place to keep anxiety away. The PRAQ by intervened pregnant women at risk of PTL was completed before 1st session, after the 6th session, and 1-month post-counseling (follow-up). On the other hand, pregnant women at risk of PTL allocated in the control group only received the routine pregnancy care programs. This group also answered queries present in the PRAQ before and after the 6th and 10th weeks of the study.

Data collection tools

Preterm labor risk assessment

Assessment Preterm Labor (APTL) risk-scoring system was used to screen pregnant women with the defined inclusion

criteria, according to the described method by Holbrook *et al.*[22] This questionnaire-based tool was contained major (14 items), minor (14 items), and background (12 items) risk factors. Major risk factors included multifetal gestation, history of PTL, preterm uterine contraction and pain in previous pregnancies, and cervical cone biopsy, surgical operations during pregnancy, injury, or trauma to the mother, abnormalities of the uterus or cervix, hydramnios, preeclampsia or gestational hypertension, premature contractions (>1.0 cm dilation or >70% effacement), and history of abortion, stillbirth, neonatal death and of each at least two cases. Minor risk factors were drug addiction, hyperthyroidism, essential hypertension, lung, cardiac and lung diseases, febrile diseases during pregnancy, urinary tract infection, smoking status (cigarettes [>10 per day] and water-pipe [2 times per day]), pregnancy lost (>2 in the 1st trimester, and at least 1 in the 2nd trimester), history of bleeding (in the 2nd trimester), and history of at least one stillbirth case. Background risk factors also were including maternal age (18 <or >35 years), height (<150 cm), weight (<48 kg at the pregnancy onset), and hemoglobin (<11 g/dL), weight (≥2.0 kg at the 18th week) loss and (<5.0 kg at the 32nd week) gain, pregnancy interval (≤1 year), weak socioeconomic status, severe physicoemotional stress, pregnancy status (1st or 5th and more), and pregnancy lost history (one case in the 1st trimester). Each major, minor, and background risk factor observed in the individual was scored 10.0, 5.0, and 2.5, respectively. The score of 10.0 was determined to be the cut-point for PTL risk assessment. Accordingly, each pregnant woman with a score lower and more than 10.0 was classified into low-risk and high-risk PTL groups, respectively.

Maternal sociodemographic and obstetric questionnaire

A self-developed questionnaire including socio-demographic (e.g., age, education level, and occupational and economic status), and midwifery (e.g., number of pregnancies and deliveries, history of miscarriage and stillbirth, pregnancy type (wanted, unwanted, and unprogrammed), delivery mode (vaginal and cesarean), and history of PTL risk characteristics for the subjects allocated in intervention and control groups was designed.

Pregnancy-related anxiety questionnaire

The short-form PRAQ with 17 items (PRAQ-17) designed by Van den Bergh[23] was used to evaluate the prenatal anxiety of Iranian pregnant women at risk of PTL. This questionnaire has five subscales including (i) self-centered fear or fear of the changes in mother's personal life (F_{C-MPL}; three items, 3–21 scores), (ii) fear of bearing a physically or mentally handicapped child F_{B-PMHC}; four items, 4–28 scores), (iii) fear of childbirth (F_{CB}; three items, 3–21 scores), (iv) fear of mood changes and its consequences on the child (F_{MC-CC}; three items, 3–21 scores), and (v) fear of changes and disillusion in the marital relationship (F_{CD-MR}; four items, 4–28 scores). Therefore, each question is graded between 1.0 and 7.0, while the total score range of pregnancy anxiety was between 17 and 119.[24]

Huizink *et al.*,[25] to evaluate psychometric properties in nulliparous pregnant women with a normal risk status, found that there was an acceptable association between the results obtained from the PRAQ and the State-Trait Anxiety Inventory covering general anxiety and depression. They showed that the Cronbach's alpha of 0.76 for all the subscales throughout pregnancy.[25] The PRAQ was used with a highly significant validity in Iranian pregnant women. Babanazari and Kafi[26] earlier confirmed the face validity of the Van den Bergh's PRAQ by five psychologists and reported the Cronbach's alpha of 0.81. Askarizadeh *et al.*[27] also demonstrated the simultaneous validity of the Iranian version of the PRAQ and Beck Anxiety Inventory questionnaire. Based on the Cronbach's alpha, the PRAQ reliability was assessed to be 0.78, whereas this coefficient for the five subscales ranged from 0.69 to 0.76.[27] In this study, the Cronbach's alpha for PRAQ-17 was estimated to be 0.87 with a value of 0.76–0.89 for the different subscales.

Data analysis

All continuous data are presented as mean ± SD, while categorical variables are expressed as frequency and percentage. The comparison of continuous and categorical variables between the two groups was conducted using the independent-samples t-tests and Chi-square or Fisher's exact tests, respectively. The normality of data was assessed by the Kolmogorov-Smirnov test statistic. The results were examined using the analysis of variance (ANOVA) procedure with the *post hoc* Bonferroni's correction using SPSS 16.0 software (SPSS Inc., Chicago, IL, USA). The significance level was set at $P < 0.05$.

Results

Table 1 shows the sociodemographic and obstetric information of Iranian pregnant women at risk of PTL in control and intervention groups. The results showed that there was no significant difference ($P > 0.05$) in these primary data between the two groups [Table 1]. The mean age of participants in intervention and control groups was 28.06 ± 4.33 and 26.22 ± 4.43 years, respectively. The age groups of 31–35 years and 20–25 years were dominant (36.1%) in the intervention and control groups, respectively. Most pregnant women at risk of PTL in both control (58.3%) and intervention (50.0%) groups had a high school diploma. A sufficient economic status was assessed for most participants allocated in the intervention (83.3%) and control (91.7%) groups. Also, most of them were a housewife in the intervention (83.3%) and control (88.9%) groups.

The mean pregnancy age of pregnant women at risk of PTL in groups of control and intervention was 26.13 ± 1.45 and 26.02 ± 1.42 years, respectively. The gestational age of most subjects in intervention and control groups was 27th week (22.2%) and 28th week (25.0%), respectively [Table 1]. The percentage of stillbirth or abortion and PTL among pregnant women allocated in the control group was 27.8 and 22.2%, respectively, whereas the corresponding values for pregnant women present in the intervention group were 22.2 and 36.1%, respectively [Table 1]. Most of the pregnancies among pregnant women in the intervention (80.6%) and control (77.8%) groups were wanted. Moreover, 41.7% and 38.9% of pregnant women in intervention

Characteristics	Studies IPW groups[a]		Significance level
	Control (n=36)	Intervention (n=36)	
Pregnant women age (year)			t=1.77, P=0.08
<20	11.1 (n=4)	0.0 (n=0)	
20-25	36.1 (n=13)	33.3 (n=12)	
26-30	33.3 (n=12)	30.6 (n=11)	
31-35	19.5 (n=7)	36.1 (n=13)	
Pregnant women's education status			χ^2=1.87, P=0.39
Under diploma	33.3 (n=12)	30.6 (n=11)	
Diploma	58.3 (n=21)	50.0 (n=18)	
University education	8.4 (n=3)	19.4 (n=7)	
Economic status			Fisher's exact test (P=0.71)
Less-than-enough	2.8 (n=1)	2.8 (n=1)	
Enough	91.7 (n=33)	83.3 (n=30)	
More-than-enough	5.5 (n=2)	13.9 (n=5)	
Pregnant women's occupation			χ^2=0.46, P=0.49
Housewife	88.9 (n=32)	83.3 (n=30)	
Employee	11.1 (n=4)	16.7 (n=6)	
Pregnancy age (week)			t = -0.32, P=0.74
24th	17.6 (n=6)	19.4 (n=7)	
25th	22.2 (n=8)	19.4 (n=7)	
26th	16.7 (n=6)	19.4 (n=7)	
27th	19.4 (n=7)	22.2 (n=8)	
28th	25.0 (n=9)	19.4 (n=7)	
Pregnancy history (number)			χ^2=0.24, P=0.88
1	44.4 (n=16)	38.9 (n=14)	
2	38.9 (n=14)	41.7 (n=15)	
3 ≤	16.7 (n=6)	19.4 (n=7)	
Pregnancy type			Fisher's exact test (P=0.99)
Wanted	77.8 (n=28)	80.6 (n=29)	
Unwanted	13.9 (n=5)	11.1 (n=4)	
Unprogrammed	8.3 (n=3)	8.3 (n=3)	
Abortion or stillbirth history			χ^2=0.29, P=0.58
Yes	27.8 (n=10)	22.2 (n=8)	
No	72.2 (n=26)	77.8 (n=28)	
PTL history			χ^2=1.68, P=0.19
Yes	22.2 (n=8)	36.1 (n=13)	
No	77.8 (n=28)	63.9 (n=23)	
Delivery history			χ^2=0.24, P=0.88
Vaginal	38.9 (n=14)	41.7 (n=15)	
Cesarean	16.7 (n=6)	19.4 (n=7)	
No delivery	44.4 (n=16)	38.9 (n=14)	

[a]The number of participants in each intervention and control group was 36.PTL=preterm labor, IPW=inverse probability weighting

and control groups, respectively, experienced vaginal delivery in previous pregnancies.

The Kolmogorov-Smirnov test was used to assess the data normality of pregnancy anxiety and its five dimensions (F_{C-MPL}, F_{B-PMHC}, F_{CB}, F_{MC-CC}, and F_{CD-MR}) defined in the PRAQ-17. Results shown in Table 2 demonstrated that the anxiety-related data were normal in both groups at three evaluation times (before and after the 6th and 10th weeks of the study). Thus, the parametric tests were thus used to analyze normally distributed data.

The mean anxiety scores and values of its PRAQ-dimensions at triple times for pregnant women at risk of PTL in the intervention and control groups were summarized in Table 3. The lowest anxiety amounts in the intervened individuals at all the evaluation times were related to the F_{C-MPL} criterion, while the F_{CB} index caused the highest anxiety level among this group. There was no significant difference in F_{MC-CC} and F_{C-MPL} scores between before and after implementing the group educational counseling sessions. There was a highly significant difference ($P < 0.001$) in F_{B-PMHC}, F_{CB}, and F_{CD-MR} scores of the intervention group over time. The Bonferroni's correction results showed that this variance between before and the 6th and 10th weeks after the intervention. Accordingly, the F_{B-PMHC}, F_{CB}, and F_{CD-MR} scores on the 6th and 10th week were meaningfully reduced compared to those of before the intervention, while

Table 2: The normality of pregnancy anxiety and PRAQ-dimensions in pregnant women at risk of preterm labor in the two groups

Pregnancy anxiety and its PRAQ-dimensions[a]	Before		After (the 6th week)		After (the 10th week)	
	Control	Intervention	Control	Intervention	Control	Intervention
F_{C-MPL}	0.20	0.10	0.14	0.15	0.20	0.17
F_{B-PMHC}	0.069	0.07	0.20	0.16	0.18	0.22
F_{CB}	0.19	0.052	0.061	0.19	0.20	0.20
F_{MC-CC}	0.058	0.06	0.16	0.28	0.22	0.21
F_{CD-MR}	0.13	0.10	0.18	0.26	0.20	0.23
Anxiety	0.20	0.22	0.20	0.20	0.20	0.15

[a]F_{C-MPL}=fear of changes in mother's personal life, F_{B-PMHC}=fear of bearing a physically or mentally handicapped child, F_{CB}=fear of childbirth, F_{MC-CC}=fear of mood changes and its consequences on the child, and F_{CD-MR}=fear of changes and disillusion in the marital relationship, PRAQ=pregnancy-related anxiety questionnaire

Table 3: A comparative study on pregnancy anxiety and PRAQ-dimensions of pregnant women at risk of preterm labor in the two groups at different analysis times

Pregnancy anxiety and PRAQ-dimensions (Intervention group)[a]	PRAQ analysis time			ANOVA results
	Before	After (the 6th week)	After (the 10th week)	
F_{C-MPL}	2.20±0.84	2.12±0.62	2.18±0.81	F=0.24, *P*=0.88
F_{B-PMHC}	4.56±0.85	2.70±1.02	2.91±1.17	F=94.88, *P*<0.001
F_{CB}	4.66±0.75	2.90±1.16	3.22±1.22	F=74.93, *P*<0.001
F_{MC-CC}	2.38±1.21	2.28±1.03	2.46±1.04	F=1.27, *P*=0.28
F_{CD-MR}	3.44±1.00	2.41±1.01	2.65±0.98	F=75.40, *P*<0.001
Pregnancy anxiety (control group)[a]	3.45±0.75	2.48±0.74	2.68±0.81	F=71.15, *P*<0.001
F_{C-MPL}	1.92±0.68	2.54±0.70	2.87±0.74	F=13.16, *P*<0.001
F_{B-PMHC}	4.41±0.83	5.04±0.82	5.34±0.83	F=5.89, *P*=0.005
F_{CB}	4.23±1.05	4.84±0.99	5.22±0.96	F=4.99, *P*=0.01
F_{MC-CC}	2.21±0.59	2.41±0.62	2.66±0.52	F=4.16, *P*=0.021
F_{CD-MR}	2.31±0.77	2.64±0.81	2.83±0.73	F=31.00, *P*=0.102
Pregnancy anxiety	3.01±0.34	3.50±0.32	3.78±0.31	F=29.99, *P*<0.001

[a]F_{C-MPL}=fear of changes in mother's personal life, F_{B-PMHC}=fear of bearing a physically or mentally handicapped child, F_{CB}=fear of childbirth, F_{MC-CC}=fear of mood changes and its consequences on the child, and F_{CD-MR}=fear of changes and disillusion in the marital relationship

no significant differences in F_{B-PMHC} ($P = 0.60$), F_{CB} ($P = 0.20$), and F_{CD-MR} ($P = 0.11$) scores between the 6th and 10th weeks were observed. A significant difference in the mean anxiety score of the intervention group was found over time [Table 3, Figure 2]. The Bonferroni's correction analysis also proved that the mean anxiety score on the 6th and 10th weeks was significantly lower than that of before the group educational counseling sessions, whereas there was no significant difference in the mean anxiety score between the 6th and 10th weeks after the intervention ($P = 0.068$).

The scores of pregnancy anxiety and PRAQ-dimensions for pregnant women at risk of PTL in the control group during the evaluation time are given in Table 3. The F_{C-MPL} had the lowest effect on pregnancy anxiety in the control group before and after 6 weeks since the beginning of the study. On the 10th week, F_{MC-CC} had the smallest impact on the pregnancy anxiety of this group. The highest anxiety level in the control group at all times was related to the F_{B-PMHC}. There was no significant difference in F_{CD-MR} among the three times. However, a substantial increase in the scores of other dimensions causing the pregnancy anxiety was obtained [Table 3]. A similar tendency was also found for the mean anxiety scores so that there was a significant difference in pregnancy anxiety between the 6th and 10th weeks [Table 3, Figure 2].
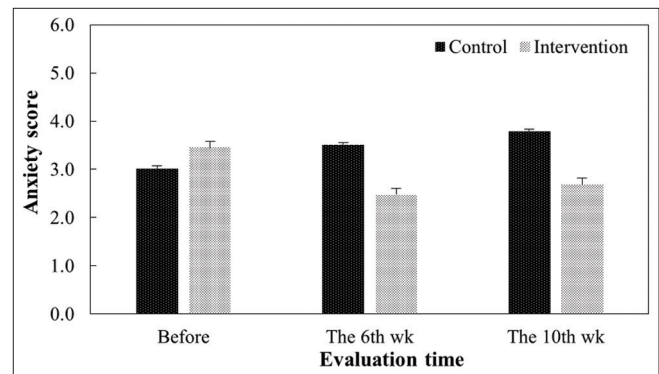

Figure 2: The total anxiety score of pregnant women at risk of preterm labor in the two groups at different evaluation times. Symbols: ** and *** are significant (*P*-value) at ≤ 0.01 and ≤ 0.001, respectively

Table 4 compares the effect of evaluation times and pregnant women at risk of PTL groups on the scores of pregnancy anxiety and PRAQ-dimensions. The evaluation time significantly affected all the assessed anxiety parameters, while the clinical groups did not influence the F_{MC-CC} and F_{CD-MR} scores. Before the study, subjects in the intervention group had a higher mean anxiety score than the ones in the control group. Nonetheless, the implementation of group educational counseling sessions could significantly reduce the mean anxiety score [Figure 2]. Figure 3a depicts significant differences in F_{CB} ($P = 0.048$) and
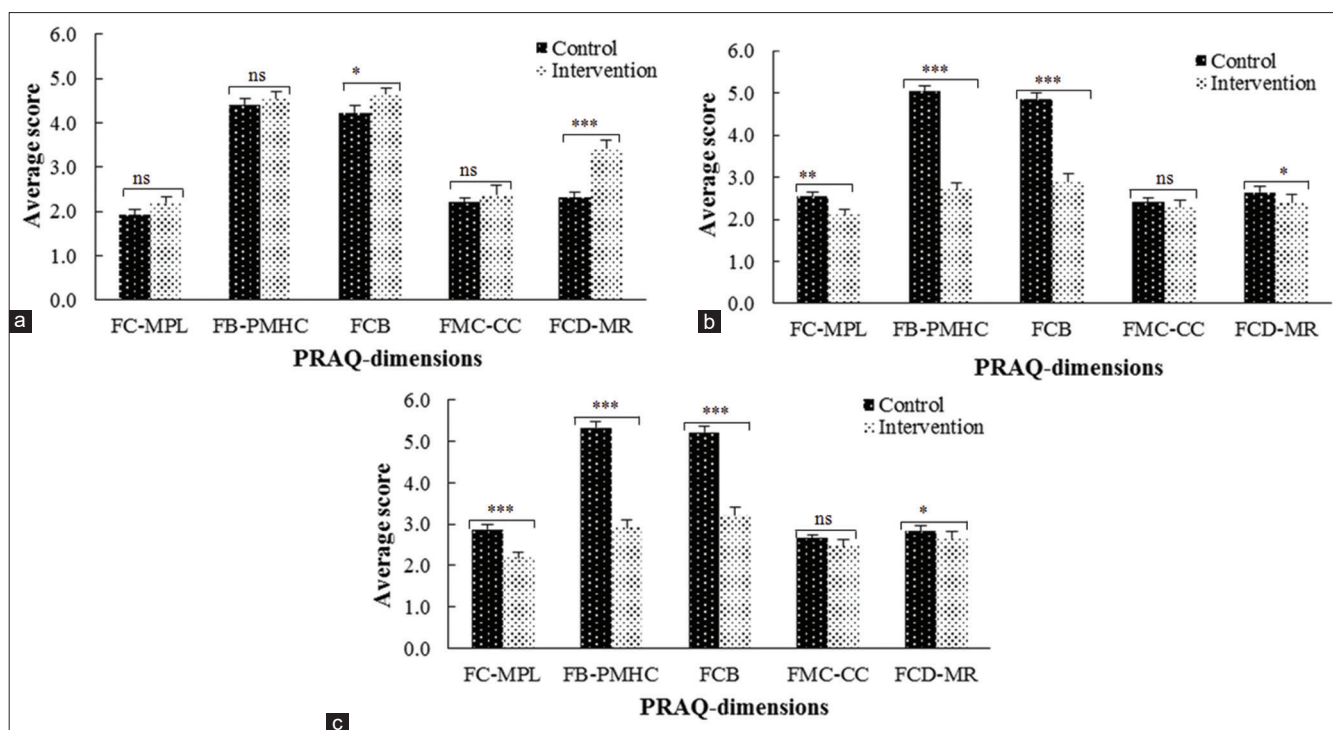
Figure 3: A comparative study on scores of pregnancy-related anxiety questionnaire-dimensions between control and intervention groups of pregnant women at risk of preterm labor at different analysis times (before (a), and after the 6th (b) and 10th (c) weeks of study). F_{C-MPL}: Fear of changes in mother's personal life, F_{B-PMHC}: fear of bearing a physically or mentally handicapped child, F_{CB}: fear of childbirth, F_{MC-CC}: fear of mood changes and its consequences on the child, and F_{CD-MR}: fear of changes and disillusion in the marital relationship. Symbols: ns, *, **, and *** are nonsignificant, and significant (*P*-value) at < 0.05, ≤ 0.01, and ≤ 0.001, respectively

Table 4: The effect of evaluation time and study group on pregnancy anxiety and its PRAQ-dimensions in pregnant women at risk of preterm labor

Pregnancy anxiety and PRAQ-dimensions[a]	Evaluation time[b]	Group (control-intervention)[c]
F_{C-MPL}	<0.0001	0.0061
F_{B-PMHC}	<0.001	<0.001
F_{CB}	0.001	<0.0001
F_{MC-CC}	0.01	0.80ns
F_{CD-MR}	0.001	0.26ns
Pregnancy anxiety	<0.001	<0.0001

[a]F_{C-MPL}=fear of changes in mother's personal life, F_{B-PMHC}=fear of bearing a physically or mentally handicapped child, F_{CB}=fear of childbirth, F_{MC-CC}=fear of mood changes and its consequences on the child, and F_{CD-MR}=fear of changes and disillusion in the marital relationship. [b]Before (a), and after the 6th (b) and 10th (c) weeks of study. [c]ns: nonsignificant

F_{CD-MR} (*P* < 0.001) scores between the two groups. But there was no significant difference in other PRAQ-dimensions. On the 6th week after the research, a significant difference in scores of all the anxiety dimensions except F_{MC-CC} was recorded [Figure 3b]. Moreover, the significant and higher values of all the PRAQ-dimensions in the intervention group was detected in the comparison to the control group on the 10th week after group educational counseling sessions [Figure 3c].

Discussion

Although there is no positive relationship between the maternal and fetal nervous systems, a direct relationship between maternal mood before birth and fetal behavior can be found. Exposure to the long-term effects of prenatal anxiety causes different mechanisms at different stages of fetal growth and development. With increased anxiety, cortisol hormone appears to cross the placenta and affect the fetus, disrupting ongoing processes, affecting the limbic and prefrontal cortex, and releasing chemicals such as acetylcholine and adrenaline in the mother's body. These chemicals pass through the placenta into the fetus and have a detrimental effect on proper fetal growth.[28] Therefore, there is a necessity to reduce pregnancy anxiety to promote healthy growth and development of newborns.

The success in implementing this prenatal care in reducing anxiety requires the collaboration and coordination of pregnant women and primary care providers such as family physicians, midwives, and nurse practitioners. In this study, the two groups statistically were homogeneous in terms of demographic characteristics and all dimensions of pregnancy anxiety. However, the mean anxiety score in the intervention and control groups was different significantly. Implementing the group educational counseling sessions under the planned practice of primary care is an effective way to reduce this risk factor among Iranian pregnant women at risk of PTL. Düzgün and Ege[18] found that the application of relaxation exercises by 60 hospitalized primiparous pregnant women at risk of PTL could significantly lessen the pregnancy anxiety level after 2- and 4-month follow-ups. The relaxation exercises were trained through the educational booklet and CD,

and face-to-face and question-and-answer communications, which were in agreement with the research methodology applied in our study. Nevertheless, the selected subjects (primiparous and hospitalized) and the intervention duration differed from the present study. But the samples in our study were randomly divided into two groups. This study was similar to ours in terms of the type of therapeutic intervention and the psychological variable. Kao and Chen[19] also evaluated the effect of two weeks of support interventions on 240 Taiwanese hospitalized pregnant women at risk of PTL in the 1st week of admission. They showed that instructing the participants to perform techniques involving psychophysiological relaxation in the hospital and the following practicing at home could significantly contribute to decreasing feelings of anxiety and depression. However, one of the disadvantages of this study was the selection of an excessive sample size that can highly attenuate the quality and conditions of educational intervention as well as the low number of training sessions.

Recently, some clinical studies have been conducted to reduce the pregnancy depression and anxiety of Iranian pregnant women.[29,31-33] Samani *et al*.[29] found that the use of cognitive-behavioral counseling could positively improve the mental health of premature infants' mothers in neonatal intensive care units. Thus, mothers by receiving the essential pregnancy-related awareness and implementing primary care practices show appropriate reactions under critical mental conditions. The high social interactions and relationships of pregnant women undergoing this counseling group intervention have a high potential in decreasing anxiety and stress and adverse pregnancy outcomes such as PTL.[30] Khanzadeh *et al*.[31] assessed the efficiency of 12 90-min sessions of cognitive-behavioral training on the pregnancy anxiety and delivery mode in 24 primiparous pregnant women. They realized that the prenatal cognitive-behavioral education was a powerful tool in decreasing the pregnancy anxiety of pregnant women and increasing their tendency from cesarean to vaginal delivery mode. Azogh *et al*.[32] in a quasi-experimental study investigated the role of psychoeducation on pregnancy anxiety reduction in 100 pregnant women with a stillbirth history. The analysis of Van den Bergh's PRAQ results after an 8-week follow-up proved that pregnancy anxiety was significantly lower in the intervention group after the psychological training than in the control group. Although none of these studies were conducted on the anxiety reduction in pregnant women at risk of PTL,[31,33] the results indicated the effect of educational intervention as an important indicator in reducing pregnancy anxiety. However, Moghadasi *et al*.[33] found that the participation of pregnant women at risk of PTL in two 60-min supportive counseling sessions could lead to a significant reduction in the State Trait Anxiety (STA) level. A slight increase in trait anxiety of the control of pregnant women at risk of PTL was recorded, while their situational anxiety decreased. This fact may be contributed to counseling with their trusted physician or midwife. This study had a discrepancy with our research framework in terms of hospitalized subjects in the prenatal care unit and the number and content of educational sessions.

Limitations

The anxiety assessment during pregnancy based on the questionnaire scale is difficult because some physical complaints can be related to both pregnancy and anxiety. The self-report nature of scores obtained in this study can also limit the generalizability and clinical uses of results. Gathering the information related to the anxiety control by Iranian pregnant women at risk of PTL allocated in the control group from other sources may interfere with the resulted findings. However, this limitation was controlled by shortening the study time to the extent possible. Moreover, it was not possible to prevent a selection bias in the choice of subjects because participation was voluntary and without any financial compensation. As mothers' income levels in studied families were different, it may potentially affect their anxiety level that was beyond the control of the researcher. There was a failure to cooperate with a number of selected individuals in the research. Nonetheless, attracting trust and establishing effective communication with pregnant women at risk of PTL could well prevent disturbing the sampling process. In future studies, a medium- and large-sized population of pregnant women at risk of PTL should also be considered to ensure the usefulness of newly developed group educational counseling sessions in reducing prenatal anxiety. Besides, the current study was conducted among pregnant women at risk of PTL in the capital of Iran and restricted to the 1st trimester of pregnancy. First, further studies should be done among Iranian pregnant women at risk of PTL with a broader territory. Second, the effectiveness of using the PRAQ should be assessed in the three trimesters because the anxiety incidence and the number and type of worries faced by pregnant women at risk of PTL are different throughout pregnancy.

Conclusions

1. The implementation of group educational counseling sessions based on the behavioral and cognitive psychology framework could significantly reduce the prenatal anxiety in pregnant women at risk of PTL immediately after the intervention and after 1-month-follow up.
2. The anxiety score in the intervened pregnant women was much less than that in control. Thus, group educational counseling sessions implemented in this study as a primary care practice could play a key role in alleviating the risk of PTL.
3. Compared to the PRAQ-17 subscales of F_{B-PMHC}, F_{CB}, and F_{CD-MR}, the intervention after the 6th and 10th weeks effectively reduced the fear scores of F_{B-PMHC}, F_{CB}, and F_{CD-MR}, leading to a significant reduction in the PTL risk of pregnant women.
4. Fear of changes in the mother's personal life (F_{C-MPI}) at all the evaluation times had the minimum effect on anxiety scores in the intervention group.
5. Reducing the fear of giving birth to a physically or mentally disabled child (F_{B-PMHC}) was the most significant effect of newly structured educational counseling sessions after the intervention and follow-up steps.

6. This specialized group training program as a complementary and non-invasive intervention is recommended for pregnant women who suffer from different anxiety disorders during pregnancy. Moreover, midwives and health care providers can adapt to this efficient intervention for use in a hospital setting.

7. Since group educational counseling sessions do not require special facilities and time consuming; therefore, due to the lack of human resources in hospitals, it can be an appropriate way to reduce maternal anxiety during pregnancy.

8. Decision-makers can consider the possibility that for primary care physicians

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient (s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Abbreviations

PTL: Preterm labor, PRAQ: Pregnancy-Related Anxiety Questionnaire, F_{C-MPL}: Fear of changes in mother's personal life, F_{B-PMHC}: fear of bearing a physically or mentally handicapped child, F_{CB}: Fear of childbirth, F_{MC-CC}: Fear of mood changes and its consequences on the child, and F_{CD-MR}: Fear of changes and disillusion in the marital relationship

Conflicts of interest

There are no conflicts of interest.

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