



The Effect of Training Pregnant Women and Their Husband's on the Anxiety in Pregnant Women with Previous Adverse Pregnancy Outcomes: A Controlled Randomized Clinical Trial

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Abstract Pregnant women with previous adverse pregnancy outcomes have a higher level of anxiety, which creates several problems for the mother and the fetus/infant. Decreasing the anxiety in these pregnant women is therefore of great importance. The present study was conducted to evaluate the effect of training on the anxiety in women with previous adverse pregnancy outcomes. This randomized, controlled, clinical trial was conducted on 132 pregnant women with previous adverse pregnancy outcomes. The women were randomly assigned to training ($n = 66$) and control ($n = 66$) group. In the training group, women and their husbands received training sessions once a week, an instructional booklet and counseling on phone in the intervals between the sessions. The control group received routine treatment. Spielberger anxiety questionnaires were completed by the pregnant women before and 1 month after the intervention. Compared to the control group, significant reductions were observed in the state anxiety (adjusted mean difference -19.6 , 95% CI -21.9 to -17.3 , $P > 0.001$) and trait anxiety (adjusted mean difference: -20.1 , 95% CI -22.2 to -17.9 , $P > 0.001$) in the training group. Training pregnant women and their husbands with previous adverse pregnancy outcomes helps. This training should be added to the prenatal health care system.

Keywords Anxiety · Training · Pregnancy · Previous adverse pregnancy outcomes

Introduction

Pregnancy is associated with a massive change in women's life that causes more psychological and physical changes than at any other time and exposes women to tremendous anxiety and stress [1]. Anxiety is an unpleasant emotional state of sadness, excitement, stress and panic [2]. Its prevalence is about 18% during pregnancy [3].

Women with anxiety are at increased risk for some pregnancy complications. Among the reported associations are miscarriage and prenatal death, preterm delivery, low birth weight, intrauterine growth retardation, poor psychomotor development of the newborn and postpartum depression [4]. Many prospective studies have shown that, if a mother is anxious or stressed while pregnant, this increased for her child having a wide range of adverse outcomes, including emotional problems, symptoms of attention deficit hyperactivity disorder, or cognitive development [5, 6]. Additionally, the occurrence of anxiety and sub threshold anxiety symptoms can be detrimental for the relation between mother and her infant. There is a high correlation between anxiety before and after giving birth [7].

Factors associated with antenatal anxiety involved marital status, positive history of mental illness, gestational age (< 20 weeks), unplanned pregnancy and depressive comorbidity. Gestational age was a significant factor for antenatal anxiety; odds for antenatal anxiety was 4.85 times greater in pregnant women with gestational age of less than 20 weeks compared to those more than 20 weeks. Anxiety levels seemed to be higher during pregnancy when

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compared to the postpartum period [8]. Anxious mothers were less sensitive, less responsive and showed less competence in parenting [9].

Men who support their spouse during her pregnancy and prenatal care tend to experience lower levels of stress and anxiety and show more readiness for becoming a father [10]. Moreover, the spouses of multiparous women show less support for their wife during pregnancy compared to the spouses of primiparous women, and pregnancy outcomes are directly associated with the spouse's level of support and collaboration in these women [11].

Pregnancy may cause maternal fear due to physical problems during pregnancy and mothers become concerned about the possible damage to their fetus or newborn. This type of anxiety is more observed in women who have experienced adverse outcome in previous pregnancy [12]. Anxiety may give rise to feeling of inadequacy in mothers during their current pregnancy [5]. Holding training workshops helps improve the parents' awareness and promote their supportive behaviors [13]. Prenatal training involves the conveyance of information to the parents on topics including childbirth, psychological changes during pregnancy, natural physiological changes during pregnancy and the parents' readiness for parental role attainment [11].

Mothers with previous adverse pregnancy outcomes are prone to higher levels of stress and anxiety. These women often express a need for receiving support from their spouse as their main source of support during pregnancy. Considering the possible positive effects of decrease anxiety during pregnancy and given the lack of studies on how to decreasing anxiety in pregnant women with previous adverse pregnancy outcomes as per the researcher's review of literature, and since all the studies on this topic have focused on primiparous women –which is important because men tend to cooperate less and give less support to their spouse in later pregnancies compared to the first one-, and with regard to the impact of ethnic and cultural differences on these processes, the present study was conducted to examine the effect of training on anxiety in pregnant women with previous adverse pregnancy outcomes and their spouses at healthcare centers in Sarab county in Iran.

Methods

Study Type and Participants

The present controlled, randomized, clinical trial was conducted on 132 pregnant women with previous adverse pregnancy outcomes presenting to healthcare centers of Sarab county in Iran.

The criteria for entering the study consisted of age 18–35, singleton pregnancy, gestational age 24–28 weeks, a history of previous adverse pregnancy outcomes such as miscarriage, preterm birth, stillbirth, the death of the infant, an Edinburgh Postnatal Depression Scale score below 12 [14] and full physical and psychological health. The exclusion criteria consisted of the pregnancy having been unwanted, change in the place of residence, known psychological disorders, fetal abnormalities during the current pregnancy and attending childbirth classes.

Sample size was calculated through G-power software as 57, according to the study by Sanaati et al. [15] and considering $m_1 = 37.9$, $sd_1 = sd_2 = 11.1$, and the assumption of 20% reduction in the anxiety scores following the interventions $m_2 = 30.32$, power = 95%, the final sample size was increased to 66 per group.

Sampling

Sampling took place from February to June 2016 and began after obtaining permission from the Ethics Committee of Tabriz University of Medical Sciences (Code of Ethics: 5/4/12348) and after registering the study at the IRCT (ID: 20160104302730N). Seven healthcare centers in Sarab county were selected for sampling and the sample size for each center was determined based on the total sample size of 66 per group. The researcher then got access to the records of admitted pregnant women by visiting the centers and using their continuous pregnancy care registries and called any eligible candidates on the phone and provided them with some general information on the research and invited them to take part in a briefing session with their spouse. During the briefing session, the researcher introduced herself, explained the objectives and methods of the research and obtained participants' informed written consent forms and briefed them on how to fill out the questionnaire and then distributed the Edinburgh Postnatal Depression Scale (DPDS) among them.

Mothers who did not suffer from depression according to their DPDS score were instructed to fill out the other questionnaires, including a research-made demographic and midwifery information form, Spielberger anxiety questionnaires. Four weeks after the end of the classes, both groups filled out the questionnaires once again.

Randomization

The participants were divided into an intervention and a control group using block randomization in blocks of four and six with the allocation ratio of 1:1. Blocking was performed by a non-affiliated person. For allocation concealment, the type of intervention (training or control) was written on paper and put inside numbered opaque envelopes.

Envelopes were opened in order of participants' entry, and the participants' group was determined.

Intervention

The pregnant women in the training group received four weekly group-training sessions of 60–0 min. The first two trained the women and improved their knowledge on ways of promoting their mental health and the next two sessions trained them on psychological issues and how to promote their mental health. At the end of the second session, an instructive booklet was handed to the pregnant women in the training group. The other two sessions were separately held for their spouses and discussed mothers' physical and psychological changes during pregnancy compliance with these changes. The pregnant women in the control group received routine treatments. In the intervals between the sessions, the researcher gave weekly 10-min counseling by phone to the women in order to remind them of the main issues taught during the sessions. Four weeks after the intervention was completed, a session was held for all the pregnant women to fill out the Spielberger anxiety questionnaire once again.

Data Collection Tools

A personal-demographic questionnaire, Spielberger anxiety questionnaire were used in this study to collect the data. The personal-demographic questionnaire consisted of items on the mother's and her spouse's age, their education, their occupation, the mother's place of residence, the family's level of income, marital satisfaction and family support during pregnancy.

Spielberger State-Trait Anxiety Inventory (STAI) includes 40 self-report questions. The state section of the questionnaire contains 20 items that are scored based on a Likert scale: (1) very low, (2) low, (3) high and (4) very high. State anxiety (AState) can be defined as fear, nervousness, discomfort and the arousal of the autonomic nervous system induced temporarily by situations perceived as dangerous (i.e. how a person is feeling at the time of a perceived threat). The trait section of the questionnaire is also scored based on the Likert scale: (1) almost never, (2) sometimes, (3) often, (4) and almost always. Trait anxiety (A-Trait) can be defined as a relatively enduring disposition to feel stress, worry and discomfort. The total score is between 20 and 80 for each of the state and trait sections [16]. This questionnaire was validated in Iran with a Cronbach's alpha of 0.91 [17].

The validity of the demographic questionnaire was verified by surveying ten professors at the Faculty of Nursing and Midwifery of Tabriz University of Medical Sciences. The reliability of the tool was confirmed using

the internal consistency method (Cronbach's alpha coefficient) and a test-retest within an interval of 2 weeks performed on 20 pregnant.

Data Analysis

The data collected were analyzed in SPSS-21. The K-S test was used to examine the normality of the quantitative data. The Chi-square test, the Chi-square test for trend, the independent *t* test and Fisher's exact test were used to examine the consistency of the personal-demographic characteristics. The independent *t*-test was used to compare the mean pre-intervention scores of anxiety the ANCOVA with adjusted base values was used to compare the mean post-intervention scores. All the analyses were performed based on the 'intention to treat' principle. The level of statistical significance was set at $P < 0.05$.

Result

The study was performed from February to June 2016 and 140 eligible women from seven urban healthcare centers were selected for entering the study. One of the pregnant women had an intrauterine fetal death and two had preterm births and were thus excluded from the study while five others withdrew due to their spouse's unwillingness. A total of 132 pregnant women ultimately entered the study and were randomly divided into training and a control group. The pregnant women in the training group attended the classes regularly with their spouses. Four weeks after the end of the intervention, the women were followed up with both in the training group ($n = 66$) and the control group ($n = 65$); one participant was excluded due to a change in her place of residence) and the questionnaires were filled out once again and the data were analyzed (Table 1).

The mean age (\pm standard deviation) of the women was 26.7 (\pm 5.6) years in the training group and 26.5 (\pm 5.4) in the control group. A total of 21.2% of the mothers in the training group and 9.1% of those in the control group had university education. The majority of the mothers in the training group (80.3%) and the control group (89.4%) were housewives. As for the level of income, 13.2% of the training group and 14.7% of the control group had inadequate incomes (inadequate income < 200 dollars). A total of 45% of the women in the training group and 41% of those in the control group were completely satisfied with their marital life. Satisfaction with the infant's gender was similar in both groups (54%). The two groups were also similar in terms of their demographic characteristics (Table 1).

Table 1 A comparison of the personal-demographic characteristics of the women with previous adverse pregnancy outcomes between the control group and the training group

Characteristic	Training (n = 66) P value	Control (n = 66) n (%) ^a	
n (%) ^a			
Age (year)	26.7 (5.6)	26.5 (5.4)	.182 ^c
Type of delivery			.822 ^b
Vaginal without tears or incision in the genital area	12 (66.7)	6 (33.3)	
Vaginal with an incision in the genital area	11 (22.9)	20 (40.8)	
Vaginal with tears	3 (6.3)	2 (4.1)	
Caesarian section	22 (45.8)	21 (42.9)	
Mother's occupation			.147 ^b
Housewife	53 (80.3)	59 (89.4)	
Employed	13 (19.7)	7 (10.6)	
Junior high school	24 (40.9)	27 (36.4)	.278 ^d
High school	9 (13.6)	12 (18.2)	
High school diploma	19 (28.8)	21 (31.8)	
Father's level of education			.278 ^d
Junior high school	24 (40.9)	27 (36.4)	
High school	9 (13.6)	12 (18.2)	
High school diploma	19 (28.8)	21 (31.8)	
University education	14 (21.2)	6 (9.1)	
Infant's gender			.430 ^b
Female	29 (42.6)	42 (61.8)	
Male	39 (57.4)	26 (38.2)	
Satisfaction with the infant's gender			.589 ^b
Yes	54 (81.8)	54 (81.8)	
No	12 (18.2)	12 (18.2)	
Satisfaction with marital life			.279 ^d
Completely	45 (68.2)	41 (62.1)	
To some degree	18 (27.3)	19 (28.8)	
Not at all	0 (0)	4 (6.1)	
I do not know	3 (4.5)	2 (3)	
Number of pregnancy			.208 ^b
Second	49 (55.1)	40 (44.9)	
Third	11 (37.9)	18 (62.1)	
Fourth and above	6 (9.1)	8 (12.1)	
Place of residence			.049 ^b
Homeowner	27 (52.9)	24 (47.1)	
Renting	21 (53.8)	18 (46.2)	
Staying with the parents of the spouse	13 (40)	8 (60)	
Spousal support	6 (46.2)	7 (53.8)	
Yes	0 (0)	9 (100)	
No	65 (49.6)	66 (100)	1.000 ^b
Support from woman's own family			.402 ^d
Yes	7 (53.8)	6 (46.2)	
No	32 (43.8)	41 (56.2)	
Support from the spouse's family	27 (58.7)	19 (41.3)	
Yes			.765 ^b
No	29 (43.9)	24 (36.4)	

^aFigures in frequency (percentage)^bThe Chi-square test^cThe independent *t* test^dThe linear-by-linear Chi-square test

Table 2 A comparison of the mean scores of anxiety in the pregnant women with previous adverse pregnancy outcomes between the control group and the training group

Variable	Training		Control		P value		MD (95% CI) ^b 1 month after the intervention
	n = 66 Pre-intervention mean (SD) ^a	n = 66 Post-intervention mean (SD) ^a	n = 66 Pre-intervention mean (SD) ^a	n = 65 Post-intervention mean (SD) ^a	Pre-intervention ^c	Post-intervention ^d	
State anxiety	46.9 (6.9)	31.7 (6.1)	47.5 (5.6)	51.5 (7.2)	.567	< .001	– 19.6 (– 21.9 to – 17.3)
Trait anxiety	46.5 (5.9)	30.2 (5.4)	47.3 (6.4)	40.2 (11.5)	.467	< .001	– 20.1 (– 22.2 to – 17.9)

^aMean (standard deviation)^bMean difference (95% CI)^cThe independent sample *t* test^dThe ANCOVA

The mean (\pm standard deviation) state anxiety score was 46.9 (6.9) in the training group and 47.5 (5.6) in the control group and before the intervention and 31.7 (6.1) in the training group and 51.5 (7.3) in the control group after the intervention. There were no significant differences between the two groups in terms of the mean score of state anxiety ($P = .567$). According to the ANCOVA with adjusted base values, a significant decrease was observed in the mean score of quality of life in the training group compared to the control group after the intervention (adjusted mean difference: – 19.6, 95% CI – 21.9 to – 17.3, $P > 0.001$; Table 2).

The mean (\pm standard deviation) trait anxiety score was 46.5 (5.9) in the training group and 47.3 (6.4) in the control group and before the intervention and 30.2 (5.4) in the training group and 40.2 (11.5) in the control group after the intervention. There were no significant differences between the two groups in terms of the mean score of trait anxiety ($P = .467$). According to the ANCOVA with adjusted base values, a significant decrease was observed in the mean score of quality of life in the training group compared to the control group after the intervention (adjusted mean difference: – 20.1, 95% CI – 17.9 to – 22.2, $P > 0.001$; Table 2).

Discussion

The positive impacts of training on anxiety have been reported in several articles [15, 18, 19]. In Iran, Sana'ati et al. examined the impacts of lifestyle training on anxiety in pregnant mothers and their husbands through training sessions, booklets and phone follow-ups. Training of lifestyle to pregnant mothers and their husbands decreased pregnant mothers' anxiety compared to the control group. Furthermore, this study showed that training pregnant

mothers and their husbands reduced anxiety more effectively in pregnant mothers than training pregnant mothers alone [15]. However, this study differs from the current study in terms of the study population, the number of educational sessions assigned for pregnant mothers, the time at which the intervention effects were appraised as well as the method.

Toosi et al.'s studied the reduction in anxiety of primiparous women and the improvement of fetal-maternal attachment along with relaxation techniques in Iran in 2010. Relaxation techniques reduced pregnant mothers' anxiety in the training group compared to the control group. Anxiety increased in mothers in the control group [20]. This study differed from the current study in terms of the study population, time of intervention, type of intervention and method. In the present study, pregnant mothers' husbands were also trained. Baghdari et al. examined the impacts of training of adjustment with pregnancy on reducing pregnant mothers' anxiety with the history of intrauterine and neonatal death. Educational classes, booklets and DVDs were given to the pregnant mothers in the training group [21]. In the present study, training led to reduce anxiety in pregnant mothers in the training group compared to the control group. This study was different in terms of time of intervention, method, the study population and the fact that pregnant mothers' husbands did not receive training. Because of their increasing worries, high-risk mothers need more protection and participation by their husbands and families. Pregnant mothers' husbands' participation in the present study is a turning point that leads to a reduction in pregnant mothers' anxiety. In the Baghdari's study, DVDs were used as educational tools, though not all pregnant mothers can use them.

Shahnazi et al. [7] examined the effects of training on reducing pregnant mothers' anxiety in Iran based on the Health Belief Model, and reported that Health Belief

Model-based training decreased anxiety in pregnant mothers in the training group via changing their attitude and behavior compared to the control group. In 2014, Rahimi et al. conducted a study with the aim of measuring the effects of training of active relaxation on high-risk mothers' anxiety. In this study, pregnant mothers attended 4-week training sessions during 32–35 weeks of pregnancy as they received Jacobson's relaxation training, conducted exercises with light music, and received educational pamphlets.

The trainings reduced pregnant mothers' anxiety in the training group compared to the pregnant women in the control group. The Shahnazi and Rahimi's study differed from our study in terms of the time of intervention, method, non-participation of husbands in the training courses and time at which the intervention was appraised. In Rahimi's study, training was performed in the last weeks of pregnancy and high-risk pregnant mothers were found to need more peace, security and reduced anxiety during pregnancy. Training should begin earlier so that pregnant mothers can effectively apply them and thus improve their psychological status during and after pregnancy [22].

One of the strengths of the present study was that it is the first study conducted on the effect of training on the anxiety in pregnant women and their husband's with previous adverse pregnancy outcomes. The research was a randomized, controlled, clinical trial in design that observed all the principles of conducting clinical trials, including random allocation and allocation concealment; an eligible attrition was also another strength of the study. Moreover, training the spouses of pregnant women, especially in the context of the Iranian culture, and encouraging their collaboration comprised another advantage of this study. The emphasis on pregnant women with previous adverse pregnancy outcomes was also another advantage of this study since these women tend to experience more problems during their pregnancy and after delivery; the devised intervention program can thus be incorporated into prenatal care programs in healthcare centers across the country for achieving better outcomes.

The limitations of the study include the researcher's failure to examine fathers' anxiety during their wife's pregnancy and after childbirth, Further studies are thus recommended to be conducted on this topic. Moreover, the present study was conducted in Iran and its results may not be generalizable to other cultures. In addition, the pregnant women examined had presented to urban healthcare centers and since there are more limited facilities and lower levels of education and awareness in rural areas, future studies are recommended to examine pregnant women in both urban and rural areas.

Conclusion

This study demonstrated that teaching pregnant women with previous adverse pregnancy outcomes and their husbands with can decrease anxiety of pregnant women. This study offers a new approach to authorities for preparing a program for training pregnant women and their husbands, and incorporating these trainings into the instruction schedule of pregnant women may constitute a crucial step in the promotion of health in pregnant women and infants in the country. The supply and distribution of instructive booklet son anxiety can further help promote maternal and fetal health during pregnancy and after childbirth.

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Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

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