Original Article

Effect of Shared Decision-making on Anxiety of Women Recommended for Prenatal Screening Tests in Southeast of Iran

Zahra Moudi; Ph.D.[1], Raheleh Jam; M.Sc.[1], Hossein Ansari; Ph.D.[2], Mostafa Montazer Zohour; Ph.D.[3]

1 Department of Midwifery, Pregnancy Health Research Center, Zahedan University of Medical Sciences, Zahedan, Iran
2 Department of Epidemiology & Biostatistics, Zahedan University of Medical Sciences, Zahedan, Iran
3 Department of Medical Genetics, Zahedan University of Medical Sciences, Zahedan, Iran

Received May 2020; Revised and accepted September 2020

Abstract

Objective: To study the effect of shared decision-making (SDM) on the anxiety of women who were recommended for prenatal screening tests.

Materials and methods: This quasi-experimental study was conducted on a total of 200 pregnant women who referred to the health centers of Zahedan, Iran, for prenatal care within April 7 to September 7, 2019. The control group received routine care, and the intervention group attended a session based on SDM. The demographic characteristics form and Spielberger Six-item State-Trait Anxiety Inventory were filled out before and immediately after the counseling, as well as before receiving the results of maternal serum biochemical markers.

Results: No statistically significant effect of SDM on anxiety was reported between the control and intervention groups immediately after the counseling session (P=0.46). However, the obtained data showed that the mean value of anxiety scores (16.52±3.06) was higher among the women in the intervention group than that reported for the control group (13.80±3.55) on the day before receiving the results of the blood tests (P<0.001). Nevertheless, logistic regression analysis showed only women with a university level of education were likely to have higher anxiety scores than women with lower educational levels (AOR=10.60; 95% CI: 2.07-54.24; P=0.005).

Conclusion: Offering prenatal screening can cause a slight increase in the level of anxiety among women with a university level of education. Therefore, it is required to implement supportive strategies to help high-risk pregnant women in coping with anxiety.

Keywords: Anxiety; Shared Decision Making; Prenatal Diagnosis

Introduction

Recently, prenatal screening tests (PST) are medically accepted and offered to all pregnant women (1, 2) to estimate the genetic risk of having an unborn baby with a particular aneuploidy (e.g., trisomies 13, 18, or 21) (3, 4). Since 2011 in Iran, PST are included in prenatal care (5). The women who are diagnosed with a medium to higher risk of fetal aneuploidy are also offered additional diagnostic procedures for the confirmation of a particular aneuploidy (4, 6, 7). Subsequently, the subjects who are diagnosed with an affected fetus are allowed to carry out an abortion (in Iran, abortion is not permitted by law) (8).

It is asserted that offering PST to women may lead to concerns about fetal health and is associated with adverse psychological outcomes (e.g., anxiety) (2, 9, 10). It is explained that the screening

Correspondence:
Dr. Zahra Moudi
Email: moudi@zaums.ac.ir

procedures and women's perception of positive results regarding the tests can cause anxiety (9, 11, 12). Based on a review of the literature, it was shown that the anxiety of women can cause negative perinatal outcomes (13).

The likelihood of positive results for screening tests will bring difficult and complex decisions on choosing abortion or continuing the pregnancy and taking the risk of an affected neonate. Both of the aforementioned options can cause anxiety in women (14-17). In such a situation, the shared decision-making (SDM) counseling method with its collaborative and deliberative nature help women to make an informed decision about PST through effective decisional supports (e.g., the provision of accurate information on short- and long-term outcomes of each option (18-21).

However, it is reported that the SDM counseling method can decrease anxiety with regard to PST (22). Some studies also claimed that SDM can provoke anxiety in the short term (23). In addition, the results of studies revealed that the outcomes of SDM are context-dependent (e.g., depending on the characteristic of clients, culture, and infrastructure) (24, 25).

To the best of our knowledge, a limited number of studies have been carried out on the effect of SDM on women's anxiety over PST in low- and middle-income countries. Therefore, the current study was conducted to examine the effect of SDM on the anxiety of women who were recommended to undergo PST in a deprived area in the southeast of Iran.

Materials and methods

Study design*:* This quasi-experimental study was carried out on a total of 200 pregnant women with a gestational age < 13 weeks who referred to the health centers of Zahedan, Iran, for prenatal care within April 7 to September 7, 2019. The present study was approved by the Ethics Committee of Zahedan University of Medical Sciences, Zahedan, Iran (March 22, 2019; IR.ZAUMS.REC.1397.490).

Participants and data collection procedures: The inclusion criteria were the age range of ≥ 18 years, singleton pregnancy, no previous history of a disabled child or pregnancy with fetal malformation, no history of mental illness/psychiatric antecedents or illicit drug use, pregnancy not following infertility, as well as ability to speak and understand Farsi. The main exclusion criteria were abortion, previous selection for amniocentesis/chorionic villus sampling (e.g., carrier of beta-thalassemia major), and diagnosis of skeletal malformation in ultrasound.

Multistage sampling was used to choose the subjects for the present study. Firstly, the city was divided into three strata based on the socioeconomic variation. Secondly, bearing in mind the total number of health centers and pregnant women with the gestational age < 13 weeks in each stratum, 24 health centers (in the northern [n=9], central [n=6], and southern [n=9] areas of the city) were selected using simple random sampling. Finally, at each health center, all the eligible women with pregnancy less than 13 weeks were invited to participate in the study. In each health center, the block randomization method was utilized to assign women into intervention and control groups (Figure 1).

The inquiry and observation of the researchers showed that the women in the control group did not receive any (genetic) counseling on PST. There was a one-way flow of information that is if you wish to undergo a screening test to assess your fetal health, ask an obstetrician for PST. Although the request for PST is common among obstetricians, women usually do not receive counseling on the requested tests. The participants in the control group received routine care, and then, the Spielberger Six-item State-Trait Anxiety Inventory (STAI-6) was completed for them (before and after receiving routine care, as well as before receiving the results of maternal serum biochemical markers, with less than 14 weeks of pregnancy).

The women were called to be explained about the objectives of the study. If they announced their consent to participate in the study, they were invited to attend a 90-minute long counseling session. In addition, the three-talk model of SDM was used in this study (20, 21). The SDM counseling session occurred before 13 weeks of gestational age. The counseling session was held with the presence of the women (and sometimes one of their relatives) and a counselor in a separate room instead of the maternal and child health service room.

The counselor was a postgraduate counseling student trained on SDM. The initial sessions (n=5) were held in the presence of a PhD candidate of reproductive health who had the experience of SDM. Moreover, the remaining 35 sessions were also audiotaped, transcribed, and checked for the essential and ideal elements of SDM and general qualities of consultation (26). At the end of the session, the pamphlets containing the content of the session were given to the participants. The demographic characteristics form and STAI-6 questionnaire were completed for the study subjects (Figure 1).

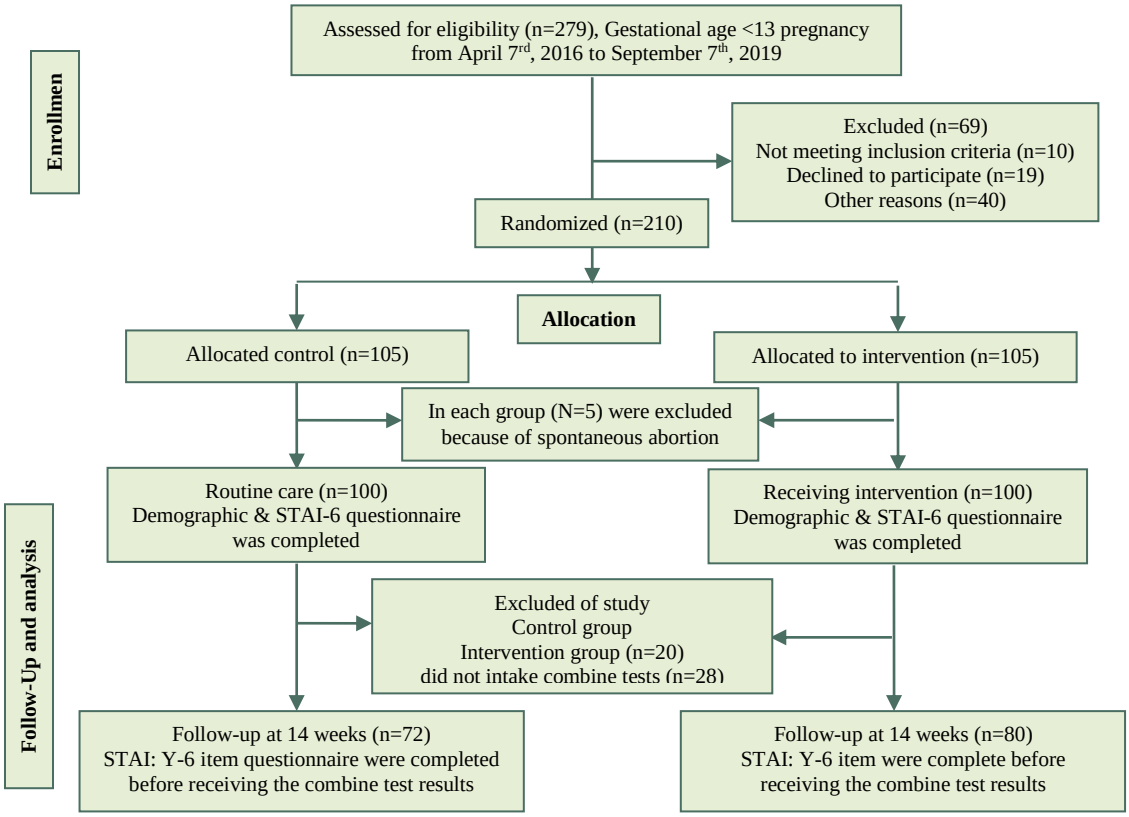

Figure1: Flow diagram of study participants

Data collection instruments: In the health system of Iran, all information on households and types of healthcare provided for patients/clients are entered into database software referred to as Ceib. This database was used to complete the demographic characteristics form. In addition, the anxiety of women was measured using the STAI-6 (27). The results of previous studies indicated that this scale is a valid alternative to the full version of the STAI (28). This scale contains 6 items for the measurement of anxiety using a 4-point Likert scale (i.e., 1: Almost never, 2: Sometimes, 3: Often, and 4: Almost always). The reversed score of positive items included items 1, 4, and 5. Then, all six scores are added together to calculate the total anxiety score, and the total score is within the range of 6-24. The continuous data were used for statistical analysis. As the score gets higher, the anxiety becomes greater (28).

The STAI-6 was completed to determine the level of women's anxiety before the intervention (i.e., before the SDM counseling or receiving routine care) and immediately after the counseling or receiving routine care. Moreover, the STAI-6 questionnaire was filled out to determine the level of women's anxiety before receiving the results of maternal serum biochemical markers (with less than 14 weeks of pregnancy). In the present study, a Cronbach's alpha coefficient of 0.81 confirmed the good internal consistency of this measure.

The SPSS software (version 21) was used to analyze the collected data. The two-tailed tests were utilized to interpret the statistical differences between the intervention and control groups. In this regard, p-value less than 0.05 was considered statistically significant. The Kolmogorov-Smirnov test was applied to measure the normality of continuous data. The Mann-Whitney U test was conducted in case the data were not normally distributed. The Chi-square and Fisher's exact tests were carried out to compare the categorical and binary data between the two groups.

Logistic regression with forward likelihood ratio was used to examine the association between the anxiety before receiving the results of maternal serum biochemical markers (i.e., the dependent variable) and independent/predictor variables (i.e., the insurance coverage, educational level, occupation of the women). To convert the continuous anxiety into a dichotomous variable, the total anxiety score was multiplied by 20/6 and the total score was within the range of 20-80. (29). The dependent variable was the anxiety score, which was considered categorical and dichotomous ($1 \leq 36$ and $2 > 36$) A normal score was approximately 36(29).

All the independent variables were categorical.

Results

The statistical analysis was carried out on the data obtained from 200 eligible women (n=100 for each group). There were no significant differences between the two groups in terms of religion. All the participants were Muslim (i.e., Shia and Sunni) (P=1). Table 1 tabulates the characteristics of the women in the two groups.

The obtained results showed that there was no statistically significant difference regarding the effect of SDM on anxiety between the control and intervention groups immediately after the counseling session (P=0.46). However, the collected data showed that the mean value of the anxiety scores (16.52 ± 3.06) was higher among women in the intervention group than that reported for the control group (13.80 ± 3.55) before receiving the results of maternal serum biochemical markers (P < 0.001) (Table 2).

The Hosmer-Lemeshow goodness of fit statistic test (X^2 < 0.001; df = 2; Sig=1) showed that the model fit the data well. The results of logistic regression indicated that the educational level of the women was a significant predictor of the anxiety score before receiving the results of the blood tests. According to the obtained data, it was demonstrated that the women with a university level of education were 10.60 times more likely to have higher anxiety scores than the subjects with lower educational levels (OR = 10.60; 95% CI: 2.07-54.24; P = 0.005).

Discussion

The findings of the present study revealed that participating in an SDM counseling session on PST slightly increased the level of anxiety (as measured by the STAI-6) immediately after offering PST; however, this result was not significantly different between the women who attended the SDM session and the controls. This finding can be explained by previous findings indicating that the women who participated in the counseling session perceived for the first time that their fetus could be affected by a congenital abnormality (30).

The results of previous studies showed that offering PST can increase the anxiety of women by drawing attention to the possibility that there is something wrong with the fetus (2). In addition, anxiety can increase with the concerns about what to do in case of an abnormal result (33), prediction of the possible needs for invasive procedures, and probability of value-sensitive decision-making (e.g., risk of baby loss). It is important to mention that based on the evidence, this greater distress in the short-term is not necessarily bad because it helps people actively processing their risk-reduction options (23).

Table 1: Comparison of main variables in women between two groups

Characteristics of women	Groups		p-value†
	Intervention (n=100)	Control (n=100)	
	n (%)††	n (%)††	
Educational level			
Illiterate and primary school	10	27	< 0.001
Secondary school	6	16	
Diploma	37	32	
University degree	47	25	
Occupation			
Housewife	74	92	0.003
Self-employed‡	11	3	
Organizational employee	15	5	
Insurance coverage			
Public (governmental) sector	73	90	0.008
Private health insurance	19	7	
No coverage	8	3	
	Mean (SD)	Mean (SD)	P-value*
Age (year)	29.62(6.12)	28.27(6.40)	0.1
Gravida	2.53(1.25)	2.00(1.60)	0.7
Number of abortions	0.38(0.72)	0.30(0.65)	0.3
Stillbirth	0.03(0.17)	0.02(0.20)	0.2

† Chi-square; †† Percentages were not computed because the number of participants were 100‡ With a fixed salary per month; * Mann-Whitney U test

Table 2: Comparison of anxiety scores between two groups

Anxiety	Groups		P-value (univariate)	P-value* (multivariate)
	Intervention (n=100)	Control (n=100)		
	Mean (SD)†	Mean (SD)		
Before counseling	12.93(3.28)	13.46(3.24)	0.19	-
After counseling	13.67(3.31)	13.39(3.39)	0.46	-
	n = 80	n = 72		
Before receiving results of blood test‡	16.52(3.06)	13.80(3.55)	<0.001	0.3

† Highest possible score: 24 * After adjustment for occupation, educational level, and insurance coverage ‡ Approximately14 weeks of pregnancy

This study presented valuable data on the effect of an SDM counseling plan on women's anxiety among the subjects who underwent first-trimester PST as a routine part of prenatal care. However, it is required to mention some considerations. Firstly, this study showed the anxiety scores of women who lived in a deprived socioeconomic context; therefore, the generalizability of the results needs to obtain data on different populations.

Secondly, the short-term effects of an SDM counseling session (immediately after the counseling session and before receiving the results of first-trimester PST) on the anxiety of pregnant women were measured in this study. The anxiety level requires to be measured over time among women who need to undergo second-trimester screening tests (with positive results for first-trimester screening tests) or with an affected fetus. In addition, it is important to know different types of coping strategies among laypeople.

Conclusion

The obtained results of the present study showed that SDM counseling can slightly increase anxiety among the women who were offered PST; however, this association depends on the educational level of the women. Therefore, to provide information about PST, healthcare providers should consider the implementation of (emotional) supportive strategies to help high-risk pregnant women in coping with anxiety (18).

Conflict of Interests

Authors have no conflict of interests.

Acknowledgments

The authors would like to thank all the women who participated in the present study. They would also like to appreciate the staff of the health centers in Zahedan for their support to carry out this study.

***Funding*:** The current study was supported by Zahedan University of Medical Sciences, Zahedan, Iran, with the grant number of 9224.

References

1. Chitayat D, Langlois S, Wilson RD. No.261-Prenatal screening for fetal aneuploidy in singleton pregnancies. J Obstet Gynaecol Can 2017; 39: e380-e94.
2. Kleinveld JH, Timmermans DR, de Smit DJ, Ader HJ, van der Wal G, ten Kate LP. Does prenatal screening influence anxiety levels of pregnant womens? a longitudinal randomised controlled trial. Prenat Diagn 2006; 26: 354-61.
3. Driscoll DA, Gross SJ. First trimester diagnosis and screening for fetal aneuploidy. Genet Med 2008; 10: 73-5.
4. Health Quality Ontario. Noninvasive Prenatal Testing for Trisomies 21,18, and 13, sex Chromosome Aneuploidies, and Microdeletions: A Health Technology Assessment. Ont Health Technol Assess Ser 2019; 19: 1-166.
5. Rabiee M, Jouhari Z, Pirasteh A. Knowledge of Prenatal screening, Down syndrome, Amniocentesis, and Related Factors Among Iranian Pregnant Women: A Cross-Sectional Study. International Journal of Community Based Nursing and Midwifery 2019; 7: 150-60.
6. Cocciolone R, Brameld K, O'Leary P, Haan E, Muller P, Shand K. Combining first and second trimester markers for Down syndrome screening: think twice. Aust N Z J Obstet Gynaecol 2008; 48: 492-500.
7. Sánchez-Durán MÁ, Bernabeu Garcia A, Calero I, Ramis Fossas J, IIIescas T, Aviles MT, et al. Clinical application of a contingent screening strategy for trisomies with cell-free DNA:a pilot study. In: BMC Pregnancy and Childbirth 2019; 19: 274.
8. Chandrasekharan S, Minear MA, Hung A, Allyse M. Noninvasive prenatal testing goes global. Sci Transl Med 2014; 6: 231fs15.
9. Lou S, Mikkelsen L, Hvidman L, Petersen OB, Nielsen CP. Does screening for Down's syndrome cause anxiety in pregnant women? A systematic review. Acta Obstet

Gynecol Scand 2015; 94: 15-27.
10. Kaiser AS, Ferris LE, Pastuszak A, Llewellyn-Thomas H, Johnson JA, Conacher S, et al. The effects of prenatal group genetic counselling on knowledge, anxiety and decisional conflict: issues for nuchal transluency screening. J Obstet Gynaecol 2002; 22: 246–55.
11. Kowalcek I. Stress and anxiety associated with prenatal diagnosis. Best Pract Res Clin Obstet Gynaecol 2007; 21: 221-8.
12. Biesecker BB. The psychological well-being of pregnant women undergoing prenatal testing and screening: a narrative literature review. Hastings Center Report 2019; 49: s53-s60.
13. Grigoriadis S, Graves L, Peer M, Mamisashvili L, Tomlinson G, Vigod SN, et al. Maternal anxiety during pregnancy and the association with adverse perinatal outcomes: systematic review and meta-analysis. In: J Clin Psychiatry 2018; 79: 17r12011.
14. Kowalcek I, Huber G, Lammers C, Brunk J, Bieniakiewicz I, Gembruch U. Anxiety scores before and after prenatal testing for congenital anomalies. Arch Gynecol Obstet 2003; 267: 126-9.
15. Zindler L. Ethical decision making in first trimester pregnancy screening. J Perinat Neonatal Nurs 2005; 19: 122-31.
16. Pop-Tudose ME, Popescu-Spineni D, Armean P, Pop IV. Attitude, Knowledge, and informed choice towards prenatal screening for Down syndrome: a cross-sectional study. In: BMC Pregnancy Childbirth 2018; 18: 439.
17. Bakst S, Romano-Zelekha O, Ostrovsky J, Shohat T. Determinants associated with making prenatal screening decision in a national study. J Obstet Gynaecol 2019; 39: 41-8.
18. Portocarrero MEL, GGiguere AMC, Lepine J, Garvelink MM, Robitaille H, Delanoe A, et al. Use of a patient decision aid for prenatal screening for Down syndrome: what do pregnant women say? In: BMC Pregnancy Childbirth 2017; 17: 90.
19. Grad R, Legare F, Bell NR, Dickinson JA, Singh H, Moore AE, et al. Shared decision making in preventive health care: what it is; what it is not. Can Fam Physician 2017; 63: 682-4.
20. Elwyn G, Frosch D, Thomson R, Joseph-Williams N, Lloyad A, Kinnersley P, et al. Shared decision making: a model for clinical practice. J Gen Intern Med 2012; 27: 1361-7.
21. Elwyn G, Durand MA, Song J, Aarts J, Barr PJ, Berger Z, et al. A three-talk model for shared decision making:multistage consultation process. BMJ 2017; 359: j4891.
22. Vlemmix F, Warendorf JK, Rosman AN, Kok M, Mol BWJ, Morris JM, et al. Decisional aids to improve informed decision-making in pregnancy care: a systematic review. BJOG 2013; 120: 257-66.
23. Hooker GW, Leventhal KG, DeMarco T, Peshkin BN, Finch C, Wahl E, et al. Longitudinal changes in patient distress following interactive decision aid use among BRCA1/2 carriers: a randomized trial. Med Decis Making 2011; 31: 412-21.
24. Waldron T, Carr T, McMullen L, Westhorp G, Duncan V, Neufeld SM, et al. Development of a program theory for shared decision-making: a realistic synthesis. In: BMC Health Service Research 2020; 20: 59.
25. Evidence: helping people shared decision making. A review of evidence considering whether shared decision making is worthwhile. The Health Foundation 2012.
26. Makoul G, Clayman M. An integrative model of shared decision making in medical encounters. Patient Educ Couns 2006; 60: 301-12.
27. Marteau TM, Bekker H. The development of a six-item short-form of the state scale of the Spielberger State-Trait anxiety inventory (STAI). Br J Clin Psychol 1992; 31: 301-6.
28. Court H, Greenland K, Margrain TH. Measuring Patient anxiety in primary care: rasch analysis of the 6-item Spilberger state anxiety scale. Value Health 2010; 13: 813-9.
29. Marteau TM, Bekker H. The development of a sixScoring_6item_STAI_shortform_Bekker2015.
30. Hewison J, Cuckle H, Baillie C, Sehmi I, Lindow S, Jackson F, et al. Use of videotapes for viewing at home to inform choice in Down syndrome screening: a randomised controlled trial. Prenat Diagn 2001; 21: 146-9.
31. Say R, Robson S, Thomson R. Helping pregnant women make better decisions: a systematic review of the benefits of patient decision aids in obstetrics. BMJ Open 2011; 1: e000261.
32. van den Berg M, Timmermans DR, Ten Kate LP, van Vugt JM, van der Wal G. Are pregnant women making informed choices about prenatal screening? Genet Med 2005; 7: 332-8.
33. Lou S, Nielsen CP, Hvidman L, Petersen OB, Risør MB. Coping with worry while waiting for diagnostic results: a qualitative study of the experiences of pregnant couples following a high-risk prenatal screening result. BMC Pregnancy Childbirth 2016; 16: 321.

Citation: Moudi Z, Jam R, Ansari H, Montazer Zohour M. **Effect of Shared Decision-making on Anxiety of Women Recommended for Prenatal Screening Tests in Southeast of Iran**. J Fam Reprod Health 2020; 14(3): 192-7.