



Effects of ultrasound on anxiety and psychosocial adaptation to pregnancy

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Abstract

Ultrasound is a common medical care procedure during pregnancy which has psychological implications. Research has found that it reduces the mother's level of anxiety, but there is not enough literature on the effects of the ultrasound in relation to the trimester it is done (first, second, and third) and the effects on the psychosocial adaptation to pregnancy. The purpose of this study was to investigate the effects of the ultrasound in the first, second, and third trimester on anxiety and variables related to psychosocial adaptation to pregnancy. A pre-post intervention design was used. Participants were 111 pregnant women attending a prenatal diagnosis ultrasound scan procedure, State-Trait Anxiety Inventory (STAI), and Prenatal Self-Evaluation Questionnaire (PSEQ) were used to measure anxiety and psychosocial adaptation to pregnancy, respectively. Previous history was obtained through an interview. Results indicated that anxiety diminished after the ultrasound regardless of the trimester in which the ultrasound took place. However, first trimester ultrasound showed an additional benefit favoring the mother's psychosocial adaptation to pregnancy, identification with the motherhood role, and the quality of the relationship with the partner. These findings suggest that in addition to the medical value of the ultrasound, it also has an important psychological value that has to be considered in order to guarantee an integral care of the pregnant women, especially in the first trimester.

Keywords Ultrasound · Anxiety · Psychosocial adaptation · Pregnancy · Motherhood

Introduction

During pregnancy and the transition to motherhood, women face significant challenges due to physical, social, and psychological changes. Mixed feelings emerge and women experience excitement about welcoming the baby, but they also feel worry and fear. Women have to adapt to this transition and make psychological adjustments, particularly in relation to their representation of the maternal self (Stern 1995) and the relationship to the fetus (Eichhorn 2012; Righetti et al. 2005).

Anxiety is a prevalent mental health problem during pregnancy observed in 6.6 to 15% of pregnant women (Rubertsson et al. 2014; Staneva et al. 2015) and is associated with many adverse outcomes for the mother and the baby such as

postpartum depression, premature birth, and low birth weight (Bayrampour et al. 2016). Some authors suggest that pregnancy-related anxiety is a specific type of anxiety (Bayrampour et al. 2016; Brunton et al. 2015; Huizink et al. 2017). Based on their review of the concept, Bayrampour et al. (2016) defined pregnancy-related anxiety as nervousness and fear related to the health of the baby; the health and appearance of the mother; experience with the health care system; and social and financial issues in the context of pregnancy, childbirth, and parenting that are accompanied by excessive worry and somatic symptoms.

Previous studies have found that women with a history of anxiety and depression are more prone to developing pregnancy-related anxiety (Rubertsson et al. 2014). Also, couples with fertility problems who have required assisted reproductive techniques (unlike those who conceived spontaneously) experience more anxiety related to pregnancy given the difficulties in conceiving and obstetric risks that they must cope with (Gameiro et al. 2010). Moreover, previous abortions can generate greater probability to present depression and excessive anxiety compared to pregnant women without such a history (Chojenta et al. 2014).

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Psychosocial adaptation to pregnancy has been defined by Lederman and Weis (2009) as a compound of dimensions or developmental challenges in pregnant women which serve as a guide for understanding and assessing pregnant women's adaptation to pregnancy and expectant motherhood. These dimensions include acceptance of pregnancy, identification with the motherhood role, relationship with the mother, relationship with the husband or partner, preparation for labor, fear of pain, helplessness, loss of control in labor, and fear of loss of self-esteem in labor. According to Alvarado-Esquivel et al. (2015), 5% of pregnant women have adjustment disorders. These authors state that women's specific adjustment to motherhood disorders during pregnancy is associated with a lack of social support and even more so with an unsatisfactory marital relationship which increases women's insecurities in the context of this important transition (Alvarado-Esquivel et al. 2015). There are also other factors such as age, occupation, socioeconomic status, and education that can be predictors of the maternal adjustment and attitudes during pregnancy (Figueiredo et al. 2014). The difficulties in adjustment to motherhood have implications related to the quality of a woman's developing relationship with her unborn baby, since mothers who do not develop the maternal identity during pregnancy are less likely to develop positive feelings about the fetus and less likely to feel comfortable with her pregnancy and committed to the fetus (Hart and McMahon 2006). Moreover, a negative relationship has been observed between anxiety and adaptation to pregnancy, so that a high level of anxiety in the mother is associated with less optimal psychological adaptation to pregnancy (Hart and McMahon 2006).

Pregnant women are surrounded by medical care aimed at making their pregnancy develop in the best possible conditions.

Ultrasound is a procedure that helps specialists track the progress of the pregnancy and make intrauterine diagnoses of various conditions the fetus may present. The World Health Organization recommends performing an ultrasound for fetal assessment during pregnancy before 24 weeks (Belizán and Cafferata 2011) and the protocols of the Spanish Society of Obstetrics and Gynecology currently recommend three special ultrasounds for this purpose during each trimester of pregnancy (ProSEGO 2010). The purpose of the first trimester ultrasound is to measure fetal length, calculate gestational age, and confirm the vitality of the fetus by visualizing the heartbeat. In this ultrasound, it is also possible to detect the risk of fetal chromosomal abnormalities (trisomy 21, 18, and 13) given the extent of the nuchal translucency. In the second trimester ultrasound, the fetus is fully developed so it is possible to study the anatomy and integrity of its internal and external structures. Finally, in the third trimester ultrasound, the fetus is measured again and an anatomical review of

internal organs is performed. In this ultrasound, it is also possible to detect whether there is intrauterine growth retardation and to make a diagnosis of late-onset malformations.

The ultrasound examination has a very important psychological implication for the woman and her partner. For the mother, ultrasound is an opportunity to visualize and mentally represent her baby in a more concrete way, which increases her awareness of the baby, deepens the connection to the baby, and confirms a new role in her life (Molander et al. 2010; Nykänen et al. 2017). Similarly, the ultrasound examination provides the partner the opportunity to observe the baby on screen, which enhances his or her feelings of involvement with the baby, and provides the opportunity to make the pregnancy a shared event (Molander et al. 2010). Moreover, the importance of ultrasound in enhancing maternal-fetal attachment has been underlined in several studies (Carolan and Hodnett 2009; Laxton-Kane and Slade 2002; Righetti et al. 2005; Van den Bergh and Simons 2009). On the other hand, several studies have addressed the effects of ultrasound on anxiety, concluding that it has a calming effect and reduces anxiety in pregnant women (Da Silva et al. 2012; Kowalcek et al. 2003). As far as we know, there are no studies concerning the association between ultrasound and psychosocial adaptation to pregnancy according to the dimensions established by Lederman and Weis (2009).

The aim of this study is twofold: to evaluate the effect of ultrasound examination on anxiety and psychosocial adaptation to pregnancy and to analyze if these effects are modified by the moment in which the ultrasound is performed (first, second, and third trimester of pregnancy). In line with previous research, we hypothesize that visualizing the baby on the screen decreases state anxiety and promotes psychosocial adaptation.

Method

Participants and procedure

The present study was conducted with pregnant women who visited the Prenatal Diagnosis Unit of the Prenatal Diagnosis Unit of the NISA VITHAS 9 de Octubre in Valencia, (Spain) to have an ultrasound scan as a part of routine care. After receiving the information about the study, informed consent forms were signed. Assessment instruments were completed before the ultrasound to obtain pre-intervention test scores, and post-intervention measures were taken immediately following the ultrasound procedure. Data were collected between May 2016 and June 2016. A total of 111 pregnant women participated in the study. Three groups were formed according to the pregnancy trimester in which the ultrasound was performed (first, second, and third), with an equal number of women in each group ($n = 37$).

Measures

Interview

A semi-structured interview with the pregnant women was performed to collect information about history of parity, assisted reproductive techniques, previous miscarriages, and history of mental illness (anxiety, depression, or other mental illness) considering the relationship established in previous studies between these variables and anxiety during pregnancy.

Anxiety (state anxiety)

This measure was collected using the State-Trait Anxiety Inventory (STAI; Spielberger et al. 1983; Adaptation to Spanish and validation by Buela-Casal et al. 2014). This inventory assesses both state (transitory) and trait (relatively stable) anxiety, including 20 items for each. For this study, we assessed only state anxiety, which is characterized by consciously perceived subjective feelings that are linked to a precise and identifiable event. The inventory asks participants to indicate on a scale from 0 to 3 (0 = not at all to 3 = very much) how she feels in that precise moment. Total scores range from 20 to 60. This inventory has a good internal consistency, with Cronbach's alpha coefficient (α) equal to 0.9. For the present study, the Cronbach's alpha coefficient (α) is 0.76.

Psychosocial adaptation to pregnancy

This variable was measured using the Prenatal Self-Evaluation Questionnaire, (PSEQ; Lederman 1996; Adaptation to Spanish and validation by Armengol et al. 2007). This questionnaire assesses aspects related to psychosocial adaptation to the pregnancy. The Spanish adaptation includes six factors: acceptance of pregnancy, identification with the motherhood role, relationship with the mother, relationship with the partner, preparation for labor, and concern for well-being of the self and the baby. It has 42 items answered on a 4-point Likert scale from 1 to 4. The higher the subscale score on the PSEQ, the more positive a mother's evaluation of that dimension. The Spanish adaptation by Armengol et al. (2007) showed a good internal consistency for the total ($\alpha = 0.856$) as well as for the subscales ($\alpha = 0.763$ to 0.854), except for the acceptance of pregnancy subscale, which has a lower internal consistency ($\alpha = 0.561$). In the present study, the alpha value obtained was satisfactory ($\alpha = 0.963$), as well as the alpha values obtained for the subscales (acceptance of pregnancy $\alpha = 0.855$; identification with the motherhood role $\alpha = 0.923$; relationship with the mother $\alpha = 0.960$; relationship with the partner $\alpha = 0.980$; preparation for labor $\alpha = 0.930$; concern for well-being of the self and the baby $\alpha = 0.933$).

Analysis

Preliminary analyses were performed to compare pre-intervention means of anxiety and psychosocial adaptation to pregnancy in women regarding their previous history including parity, assisted reproductive treatments, miscarriages, and mental illness. Statistically significant differences between means of some of these variables would justify including them as covariates in posterior analysis to control for their effects. Split plot ANOVAs were carried out for the dependent variables anxiety and psychosocial adaptation to pregnancy. The within subject variables were the pre-intervention and post-intervention measures of anxiety and psychosocial adaptation to pregnancy, and the between subjects variable was the trimester in which the ultrasound examination was performed (first, second, and third trimester). A statistically significant interaction effect between both variables would indicate that the change in anxiety and psychosocial adaptation to pregnancy from pre-intervention to post-intervention differs as a result of the trimester in which the ultrasound was performed. A simple effects analysis was conducted following significant interactions to explore their exact nature. Analyses were performed using the SPSS software package (version 23.0) and the significance level established was $p < 0.05$.

Results

Regarding socio-demographic characteristics of the sample (see Table 1), the age range of the participants was between 26 and 43 and the mean age was 34.57 years old ($SD = 3.787$). 80.6% of the participants had university degrees, 91.4% reported having a job, 97.3% had a partner/husband, 55% were first-time mothers, 14.4% had assisted reproductive treatment, 28.8 had previous miscarriages, and 7.2% reported a history of mental illness while 92.8% reported no previous mental illness. All the ultrasound scans in the sample reported normal results. To evaluate possible differences in socio-demographic and medical variables among the women in the first, second, and third trimesters, chi-square or ANOVA tests were performed; all the results were found to be statistically non-significant (see Table 1).

Preliminary analyses were performed to test the equivalence of pre-intervention measures of anxiety and psychosocial adaptation to pregnancy according to the mother's history. The results of the *t* tests revealed that significant differences in pre-intervention measures for anxiety and psychosocial adaptation to pregnancy were found only in the group of pregnant women who had previous miscarriages ($p < 0.05$); women who had previous miscarriages showed higher levels of anxiety and worse psychosocial adaptation to pregnancy than those without this background (see Table 2). Considering this result, the

Table 1 Socio-demographic and medical characteristics of the sample

Age (M, SD)—min/max	34.57 (3.787)—26/43
Education (%)	
High school	14.6
Graduate degree	80.6
Post-graduate degree	4.9
Employment (%)	
Employed	91.4
Unemployed	8.6
Marital status (%)	
With partner	97.3
Single parent	2.7
Parity (%)	
Nulliparous	55.0
Parous	45.0
Assisted reproductive treatment (%)	
Yes	14.4
No	85.6
Previous miscarriages (%)	
Yes	28.8
No	71.2
History of mental illness (%)	
No	92.8
Anxiety	3.6
Depression	1.8
Other	1.8

variable of previous miscarriages was taken as a covariate variable in the following ANOVAs to control for its effects.

Regarding the relationship between the dependent variables in the study, it was observed that there was a statistically significant negative correlation between anxiety and the following psychosocial adaptation variables: overall adaptation to pregnancy ($r = -0.482$; $p < 0.01$), acceptance of pregnancy ($r = -0.382$; $p < 0.01$), preparation for labor ($r = -0.419$; $p < 0.01$), and concern for the well-being of the self and the baby ($r = -0.552$; $p < 0.01$).

Table 3 presents descriptive statistics and quantitative results of the ANOVAs. Figure 1 depicts the change between pre-intervention and post-intervention means by ultrasound trimester for each of the dependent variables. Regarding the dependent variable anxiety, the pre-intervention to post-intervention change was statistically significant ($F(1, 107) = 10.632$; $p < 0.01$), so that the overall anxiety mean reduced from 16.52 to 10.53. This effect was not modified by the trimester in which the ultrasound was performed. Regarding the global measure of psychosocial adaptation to pregnancy and its factors, the interaction effect between pre-intervention to post-intervention and trimester was statistically significant for the following variables: psychosocial adaptation to pregnancy ($F(2, 107) = 3.926$; $p = < 0.05$), identification with the motherhood role ($F(2, 107) = 3.92$; $p < 0.05$), and relationship with the partner ($F(2, 107) = 5.374$; $p < 0.01$), indicating that the change between pre-intervention and post-intervention measures differs as a function of the trimester in which the ultrasound was done.

For a more detailed analysis of these interaction effects, simple effects tests were performed (Table 4). The change between pre-intervention and post-intervention overall scores of psychosocial adaptation to pregnancy was statistically significant only when the ultrasound was performed in the first trimester (the mean increased from 136.62 to 139.7). The same result is observed for the subscales, so that the change from pre-intervention to post-intervention measures of identification with the motherhood role and relationship with the partner is statistically significant only in the first trimester (the increase is from 14.97 to 15.27 for identification with the motherhood role, and from 27.65 to 28.49 for relationship with the partner).

Neither the pre-intervention to post-intervention main effect nor the interaction effect was statistically significant for the rest of the variables: acceptance of pregnancy, relationship with the mother, preparation for labor, and concern for well-being of the self and the baby.

Table 2 Pre-intervention means and *t* tests results for difference of means as a result of patient history

		Anxiety				Psychosocial adaptation to pregnancy			
		Mean	<i>t</i>	<i>df</i>	<i>p</i>	Mean	<i>t</i>	<i>df</i>	<i>p</i>
Parity	Nulliparous	17.03	0.591	95.39	0.556	135.02	-1.770	107.29	0.080
	Parous	15.90				139.82			
Miscarriages	Yes	20.09	2.414	53.81	0.019	131.16	-2.723	51.21	0.009
	No	15.08				139.62			
Assisted reproductive techniques	Yes	16.56	0.015	18.27	0.988	137.00	-0.53	20.12	0.959
	No	16.52				137.21			
Mental illness	No	16.02	-0.827	3.08	0.467	137.72	1.331	3.31	0.267
	Anxiety	23.00				129.00			

Table 3 Descriptive statistics and split plot ANOVA results for the dependent variables in the study

	Ultrasound first trimester (n = 37)		Ultrasound second trimester (n = 37)		Ultrasound third trimester (n = 37)		Overall results (n = 111)		ANOVA			
	Pre-I mean (SD)	Post-I mean (SD)	Pre-I mean (SD)	Post-I mean (SD)	Pre-I mean (SD)	Post-I mean (SD)	Pre-I mean (SD)	Post-I mean (SD)	Interaction effect	Main effect Pre-I to post-I		
									F(2,107)	p	F(1, 107)	p
Anxiety (STAI)	18.43 (8.82)	10.57 (8.26)	15.95 (11.56)	10.14 (9.93)	15.19 (8.83)	10.89 (8.97)	16.52 (9.83)	10.53 (9.00)	1.91	0.154	10.63	0.001
Psychosocial adaptation to pregnancy (PSEQ)	136.62 (13.33)	139.7 (13.44)	138.35 (15.51)	138.38 (16.32)	136.57 (14.80)	136.54 (16.02)	137.18 (14.46)	138.21 (15.23)	3.93	0.023	1.80	0.182
Acceptance of pregnancy	17.54 (2.47)	17.78 (2.62)	17.89 (2.59)	17.59 (3.08)	17.65 (2.07)	17.43 (2.24)	17.69 (2.37)	17.6 (2.65)	0.96	0.387	0.07	0.795
Identification with the motherhood role	14.97 (1.77)	15.27 (1.59)	15.46 (1.22)	15.22 (1.53)	15.32 (1.63)	15.19 (2.13)	15.25 (1.56)	15.23 (1.76)	3.92	0.023	0.89	0.346
Relationship with the mother	31.19 (4.01)	31.03 (4.34)	32.54 (2.49)	32.08 (3.14)	29.38 (6.36)	29.65 (6.64)	31.04 (4.71)	30.92 (4.98)	1.57	0.213	0.81	0.369
Relationship with the partner	27.65 (3.66)	28.49 (3.31)	27.76 (7.42)	27.41 (7.69)	27.81 (6.15)	27.78 (6.10)	27.74 (5.90)	27.89 (5.94)	5.37	0.006	2.29	0.133
Preparation for labor	17.84 (4.27)	17.97 (4.90)	17.76 (4.10)	17.7 (4.15)	18.76 (2.89)	18.51 (3.05)	18.12 (3.80)	18.06 (4.08)	0.36	0.697	0.32	0.572
Concern for well-being of the self and baby in labor	24.51 (6.28)	25.97 (5.68)	23.68 (7.10)	25.11 (6.12)	24.57 (6.61)	24.89 (6.74)	24.25 (6.62)	25.32 (6.16)	1.54	0.220	1.23	0.271

Discussion

This study compares measures of anxiety and psychosocial adaptation to pregnancy before and after the ultrasound scan to determine the effects of this procedure considering the trimester in which the scan was performed. The main finding of the present study is that the ultrasound helps to reduce state anxiety in a similar way in the first, second, and third trimester. This result is consistent with previous studies on anxiety related to ultrasound examination (Da Silva et al. 2012; Kowalceck 2003). The ultrasound can be seen as a form of reassurance (Garcia et al. 2002) and as having a calming effect on the parents-to-be (Stephens et al. 2000).

Moreover, findings of this study suggest that first trimester ultrasound is particularly relevant from a psychological perspective as it contributes to positive adaptation to pregnancy and motherhood. It has been observed that the first trimester ultrasound improves identification with the motherhood role. Several authors suggest that the ultrasound examination represents an opportunity for the woman to recognize that the baby is there, anticipate his/her presence, and develop expectations about his/her psychological characteristics. The first trimester ultrasound is related to an improvement in the quality of the relationship with the partner. These findings correspond with previous studies that consider the ultrasound to be an opportunity for the partner to be involved, to see with his own eyes that the baby actually exists and to regard the pregnancy as a mutual project (Molander et al. 2010).

Ultrasound examination in the second and third trimester is important from a psychological point of view as it helps to reduce state-anxiety. However, it has no significant effect on the other psychosocial variables studied. It is possible that women have already begun to adapt and construct mental representations of themselves as mothers, so the effect of these ultrasounds on maternal psychosocial adaptation is not as significant as it is during the first trimester. The visual observation of the baby in the first trimester could be especially important due to the fact that it supplies the sensual limitation of the mother who cannot feel the baby moving at this time, so the ultrasound provides visual feedback to show the parents-to-be that the baby is there.

Considering the relationship between anxiety and psychosocial adaptation to pregnancy, the findings of the present study suggest that a pregnant woman with a higher level of anxiety also experiences less psychosocial adaptation. Women with higher anxiety also show less acceptance of pregnancy, less preparation for labor, and more fear and concern for the well-being of the self and the baby. These findings correspond with Hart and McMahon (2006), who relate anxiety with lower quality of maternal-fetal attachment, and greater negative attitudes toward motherhood. Similarly, Bayrampour et al.

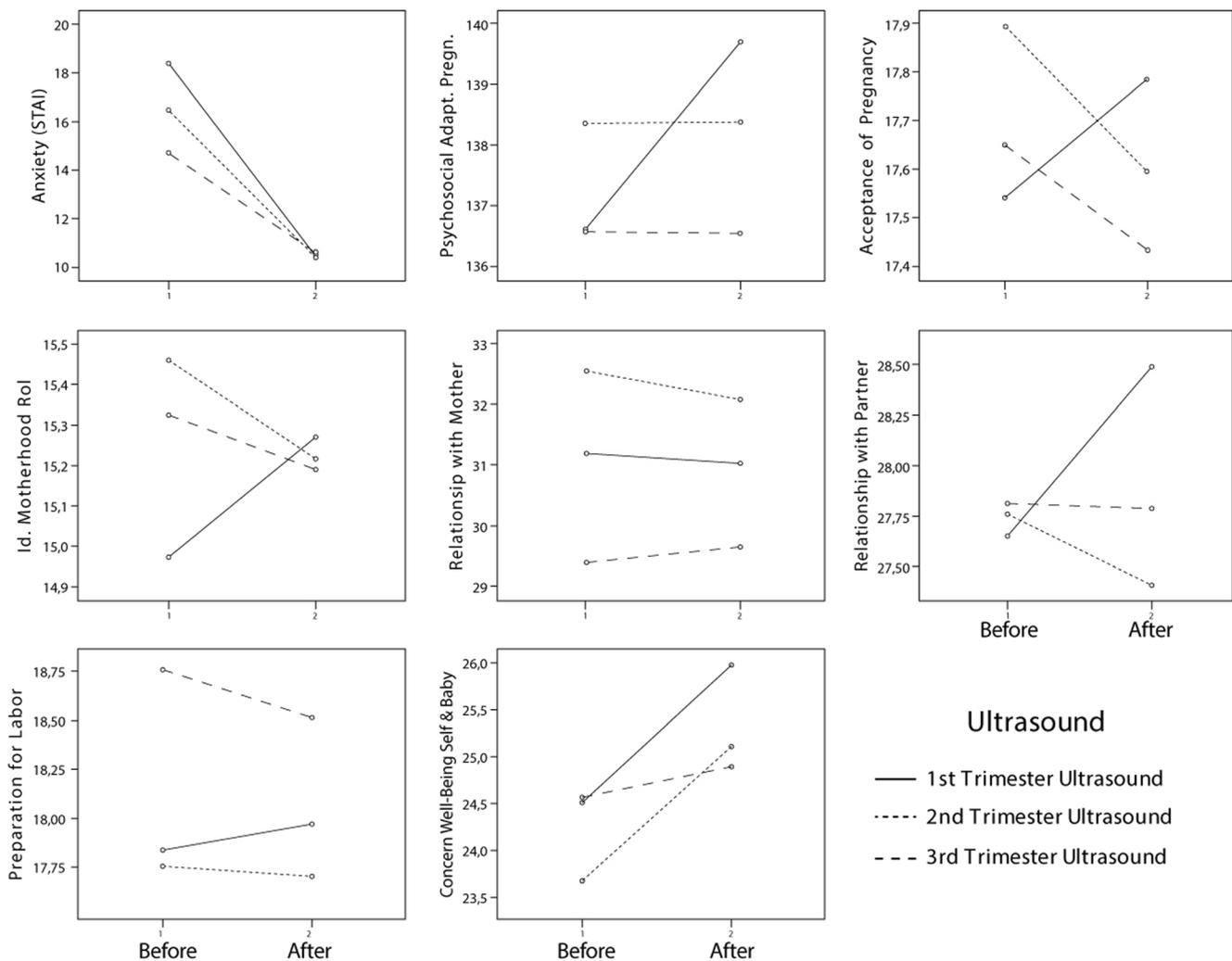


Figure 1 Graphs of mean scores pre-intervention (before) and post-intervention (after) for the dependent variables in the study

(2016) argue that women with anxiety exhibit excessive concern about many aspects of pregnancy, childbirth, and the postpartum period.

Limitations and future investigations

One limitation of the present study is the cross-sectional design used to collect the data. A longitudinal design would have allowed the researchers to test for change in anxiety and psychosocial adaptation over time, as well as to test the possible effect of previous scans in the second and the third trimester. Practical aspects concerning the setting of the investigation didn't allow us to carry out a longitudinal study. However, we proved that there are no statistically significant differences in socio-demographic or medical variables among the women in the three trimesters. This equivalence in background variables increases the validity of the cross-sectional study. Another limitation of the cross-sectional design is that we do not have data about the women's anxiety levels one or two

weeks before the ultrasound. Of course, future studies should be done according to a longitudinal design to control for individual differences in mothers-to-be during pregnancy and to establish a baseline of anxiety to test the effect of the ultrasound in a more reliable way.

Regarding the characteristics of the sample, this study was conducted with pregnant women with low psychosocial risk. There is a high percentage of participants with an educational attainment of undergraduate study or higher, most of them are employed and have a stable family situation (see Table 1). In regard to recognizing the importance of the ultrasound experience on anxiety and psychosocial adaptation, it would be of great interest for future research to perform a study with pregnant women with high psychosocial risk. Moreover, the results of this study must be interpreted taking into account that all the ultrasound scans reported normal results. This could be due to the features of the participants (women without previous medical risk factors) and to the routine nature of the scan. Future studies with bigger and random samples would be desirable to grasp the variability in the population of pregnant

Table 4 Simple effects analysis

		Mean difference	<i>p</i>	95% confidence interval for mean difference	
				Lower bound	Upper bound
Psychosocial adaptation to pregnancy	First trimester ultrasound	-3.081	0.001	-4.855	-1.307
	Second trimester ultrasound	-0.027	0.976	-1.801	1.747
	Third trimester ultrasound	0.027	0.976	-1.747	1.801
Identification with the motherhood role	First trimester ultrasound	-.297	0.039	-0.579	-0.015
	Second trimester ultrasound	0.243	0.090	-0.039	0.525
	Third trimester ultrasound	0.135	0.344	-0.147	0.417
Relationship with the partner	First trimester ultrasound	-.838	0.002	-1.353	-0.322
	Second trimester ultrasound	0.351	0.180	-0.164	0.867
	Third trimester ultrasound	0.027	0.917	-0.489	0.543

women. A future study should also examine the effects of negative ultrasound scan results.

Furthermore, future research should focus on the psychological and relational aspects of routine prenatal care that go with the ultrasound examination process and favor emotional well-being and adaptation to motherhood, such as how the information is transmitted by health professionals. This is especially relevant when communicating information about potential fetal abnormalities.

Practical implications

Currently, in many countries, all women are expected to undergo the ultrasound procedure as part of the medical care they receive during pregnancy (Lalor and Devane 2007). Most women find the ultrasound worthwhile and elect to undergo it (Garcia et al. 2002); nevertheless, some authors consider it to be a medicalization of pregnancy that presents ethical dilemmas for the parents (Molander et al. 2010). In the context of this study, ultrasound reduces maternal state-anxiety and provides possibilities and opportunities, helping women reach different goals during their pregnancy such as allowing them to imagine meeting their child, forming a mental representation of themselves as a mother, and putting forth the pregnancy as a mutual project for the parents. Ultrasound examination in the first trimester not only helps to detect possible problems in fetal development and pregnancy but also generates an improvement in mental health, contributing to transition and adaptation to motherhood.

Research in this field allows proper detection of potential risks and conditions that may affect the mental health of pregnant women in key settings such as prenatal diagnostic procedures. We believe this creates an increased sensibility to the woman's psychological needs related to pregnancy, allowing medical professionals working with pregnant women to promote their adaptation and transition to motherhood.

Conclusion

Ultrasound examination has a calming effect as it helps to reduce the state of anxiety and uncertainty in the mother during the gestational period. In the first trimester, ultrasound examination has an additional psychological value because it is performed at a time when women are starting to construct their mental representations as mothers, making this particular ultrasound an event that promotes identification with the motherhood role and improves the quality of the relationship with her partner.

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Compliance with ethical standards

The study was approved by The Research Ethics Committee of the University of Valencia and The Regional Ethics Committee of Clinical Studies of Medicaments and Medical Devices of the Valencian Community (CAEC) and was performed in accordance with the ethical standards laid down in the operative version of the Declaration of Helsinki. Informed consent was obtained from all individual participants included in the study.

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

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