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ORIGINAL ARTICLE

Does fetal screening affect women's worries about the health of their baby?

A randomized controlled trial of ultrasound screening for Down's syndrome versus routine ultrasound screening

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Background. Screening for fetal abnormality may increase women's anxiety as attention is directed at the possibility of something being wrong with the baby. The aim of this study was to evaluate the effect of ultrasound screening for Down's syndrome on women's anxiety in mid-pregnancy and 2 months after delivery.
Method. Two thousand and twenty-six women were randomly allocated to an ultrasound examination at 12–14 gestational weeks (gws) including risk assessment for Down's syndrome or to a routine scan at 15–20 gws. Questionnaires including the State-Trait Anxiety Inventory (STAI), the Cambridge Worry Scale (CWS), and the Edinburgh Postnatal Depression Scale (EPDS) were filled in at baseline in early pregnancy, at 24 gws and 2 months after delivery.
Results. No statistically significant differences were found between the trial groups regarding women's worries about the health of the baby, general anxiety and depressive symptoms during pregnancy or 2 months after delivery. Women's worries about something being wrong with the baby in the early ultrasound group and routine group, respectively, decreased from baseline (39.1% versus 36.0%) to mid-pregnancy (29.2% versus 27.8%), and finally to 2 months after delivery (5.2% versus 6.6%).
Conclusion. Fetal screening for Down's syndrome by an early ultrasound scan did not cause more anxiety or concerns about the health of the baby in mid-pregnancy or 2 months after birth than in women who had a routine scan.

Key words: anxiety; fetal ultrasound screening; nuchal translucency thickness, pregnancy; worry

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When routine ultrasound screening during pregnancy was introduced in Sweden its aim was to estimate gestational age, detect multiple pregnancy, and localize the placenta. As equipment and skills have developed, screening for fetal malformations became part of the procedure. Recent studies have reported an association between increased fetal nuchal translucency in the first trimester and Down's syndrome (1–3), and these findings have in Sweden raised the question whether a routine examination at 12–14 gestational weeks (gws) including risk assessment for Down's syndrome should replace the routine scan at 15–20 gws. In order to provide evidence to guide such a decision a large multi-center trial was conducted between March 1999 and November 2002. A smaller sample was drawn from this trial in order to study the effect of fetal screening for Down's syndrome on women's anxiety during pregnancy and after the birth, with a specific

focus on women's worries about the health of the baby.

Pregnancy itself, regardless of ultrasound examinations, is in many women associated with psychological stress and anxiety (4,5). These problems are most apparent during the first trimester, while they seem to decrease in mid-pregnancy and increase again during the last trimester (6–8). Studies on women's worries during pregnancy have shown that the baby's health was the most important concern (5,8,9). Considering this state of increased vulnerability during pregnancy, it is reasonable to assume that an intervention aiming at looking for fetal abnormalities may affect women's anxiety.

Recent reviews of ultrasound screening during pregnancy concluded that ultrasound scans are very attractive to women and families (10,11). However, early studies reported that some women feared that ultrasound might harm the fetus, but such concerns have not been addressed in later research (11). Little is known about the appropriate time for conducting the scan with regard to women's anxiety. An Australian trial found lower anxiety in women who had an early scan at their first antenatal visit, but anxiety was only measured at that visit and no information on long-term effects was collected (12). Some studies have reported a reduction in anxiety after a scan (13–15), but increased anxiety just before the scan, suggesting that the examination as such may increase women's worries (11).

In general, studies of women's anxiety and emotional well-being have focused more on women who are faced with an adverse finding or other worrying test results, such as false positive or false negative tests, rather than on the large majority of women who have a normal outcome. Therefore, the aim of this study was to evaluate the effects of fetal ultrasound screening for Down's syndrome in a low-risk population on women's anxiety, specifically on women's worries about something being wrong with the baby, in mid-pregnancy and 2 months after delivery.

Materials and methods

This study was part of a multi-center randomized controlled trial, here defined as the medical study, in which 40 000 pregnant women were randomly allocated to either an ultrasound examination at 12–14 gws including screening for Down's syndrome or to a routine ultrasound screening at 15–20 gws. The principal outcome of the medical evaluation was the number of fetuses and born babies diagnosed with Down's syndrome. Data from the medical study are currently being analyzed. The principal outcome of the present study was women's worries about the fetus, and a subsample of 2026 women was drawn from the medical study.

The two interventions compared

Women in the intervention group (EUG = early ultrasound group) were offered an ultrasound scan at 12–14 gws, including risk assessment for Down's syndrome by measurement of fetal nuchal translucency thickness. A risk score was calculated using a software combining the measure of nuchal translucency, gestational age and maternal age (1). If the risk was 1/250 or higher, corresponding to the risk of a pregnant woman aged 35 years of carrying a fetus with Down's syndrome at 12 gws or above, the woman was offered a diagnostic amniocentesis. In case of a positive test result, i.e. the fetus had Down's syndrome, the woman was informed about the possibility of a termination. In case of a negative test result she was offered a follow-up scan at 18–20 gws. Besides screening for Downs' syndrome, the early ultrasound scan aimed at estimating gestational age and to screen for other structural malformations and multiple pregnancy.

Women in the routine ultrasound group (RUG) served as controls and were offered an ultrasound scan at 15–20 gws including screening for fetal malformations and multiple pregnancy, assessment of gestational age and localization of the placenta. Women who were 35 years or older were offered an amniocentesis for detection of Down's syndrome.

Sample size

The power calculation was based on figures from an English survey showing that 22% of the women were worried about the fetus in mid-pregnancy and 23% in late pregnancy (8). Women's worries about the 'possibility of something being wrong with the baby' were measured by the Cambridge Worry Scale including 16 items of common concerns during pregnancy. In order to detect a clinically significant increase by 25% of women who were worried about the health of the fetus from the expected 23% in the routine ultrasound group to 29% in the early ultrasound group [80% power, 95% confidence interval (CI)], 840 women were required in each group. To detect a reduction of the same size, from 23% to 17%, 700 women would be required in each group. After taking non-responders into account, the final sample was estimated at 2000 women with 1000 in each group.

Recruitment

Women who booked in at 22 antenatal clinics in the Stockholm region and who consented to participate in the medical study were also invited to take part in the present study. The antenatal clinics were selected in order to represent a population of mixed socio-economic background. In total 8717 women, of whom approximately 80% participated in the medical study, were booked in at the included clinics during the recruitment period from March 2000 to April 2001. The midwives gave verbal and written information to women who participated in the medical study, and during the given time frame they were also instructed to inform the women about this study. Non-Swedish speaking women were excluded because of difficulties filling in questionnaires. The number of women who were not approached or who declined to participate in this study were not recorded, due to the large number of midwives involved and their heavy workload. In total, 2026 women consented to participate in this study. When a woman had consented to participate in the medical study, her demographic and obstetric data were faxed to the ultrasound clinic where randomization took place using a computerized internet-based randomization program. The randomization was performed

in blocks to ensure that the same number of participants would be allocated to the study groups within each block.

Data collection

After women had consented to participate in the present study they received the first questionnaire from the midwife at the antenatal clinic. Women were encouraged to fill it in at the clinic or, if this was not possible, at home, and mail it back as soon as possible. A second questionnaire was sent to the women in gestational week 24. This point of time was chosen to ensure that all the women, regardless of group allocation, had undergone their scans, and amniocenteses in some cases. Additionally, mid-pregnancy is regarded as a period during pregnancy when emotional as well as physical well-being is peaking. Measuring women's worries at this point of time would also allow comparisons with data from the British study on which the power calculation was based. The third and last questionnaire was posted 2 months after delivery. Two reminder letters were sent to non-responders.

The first questionnaire included questions about the women's socio-demographic background, such as age, marital status, native language, education and parity; and obstetric background, such as previous miscarriage, abortion, stillbirth and infertility. All three questionnaires included the same instruments for measuring anxiety and depressive symptoms.

Women's worries, including the principal outcome 'worry about something being wrong with the baby', were measured by a Swedish version of the Cambridge Worry Scale (SCWS), which measures common concerns during pregnancy (16). This scale is a translated and tested version of the English scale, with the addition of three items related to worries about the maternity services. Some of the items were not relevant after birth, and therefore were excluded in the postnatal questionnaire. Responses were on Likert-like scales ranging from 0 (no worry) to 5 (major worry).

Women's general anxieties were studied by the State-Trait Anxiety Inventory (STAI), including two scales measuring trait anxiety, i.e. how the subject generally feels, and state anxiety, i.e. how the subject presently feels. Each scale includes 20 statements, and responses may range from 20 (minimum anxiety) to 80 (maximum anxiety) (17). STAI is one of the most widely used scales for the evaluation of anxiety and is well validated.

The Edinburgh Postnatal Depression Scale (EPDS) is a 10-item, self-report scale assessing common symptoms of depression, such as dysphoric mood, anxiety, feelings of guilt and of not coping well (18). Each item is assessed on a four-point scale (from 0 to 3), and the total scores may range from 0 to 30. The scale has been validated for antenatal use in the United Kingdom (19), but in Sweden only for postnatal use (20).

Analyses

In analyzes comparing the outcomes of the EUG and RUG, the six-point SCWS was dichotomized and women scoring 4 or 5 were defined as worried, similarly to the English study (8). Analyzes based on the whole distributions were also conducted using Student's *t*-test and the Mann–Whitney *U*-test but these findings did not add additional information and are not presented in this paper. A cut-off at 11/12 was used in the analysis of the EPDS both during pregnancy and postpartum in order to allow comparison between the two occasions. All statistical tests were two-sided, and statistical significance defined as $p < 0.05$ or less. Categorical data were analyzed using the χ^2 test, odds ratio and associated 95% confidence interval, and continuous data using Student's *t*-test for normally distributed variables and the Mann–Whitney *U*-test when distributions were skewed. All statistical analyzes were conducted using SPSS 11.0 (Statistical Package for Social Science, Inc., Chicago, Illinois, USA).

Ethical considerations

The Regional Research and Ethical Committee at Karolinska Institutet approved the study (Dnr. 99-394).

Results

Of the 2026 women who consented to participate in the trial, which was 23% of all women booked for antenatal care at the participating clinics during the study period, 1030 were randomized to the EUG and 996 to the RUG (Fig. 1). All women filled in the first questionnaire, 1688 before and 338 after being randomized. The latter group was equally distributed between the trial groups with 165 in the EUG and 173 in the RUG. The average time when filling in the first questionnaire was at 10.2 and 10.3 gws in the EUG and RUG, respectively, the second questionnaire at 24.9 gws in both groups, and the third questionnaire at 9.8 and 9.5 weeks after delivery ($p = 0.02$). The comparison of the trial groups and analyzes in mid-pregnancy and 2 months after delivery were based on the responders to all three questionnaires, which were 854 (82.7%) in the EUG and 837 (84.1%) in the RUG.

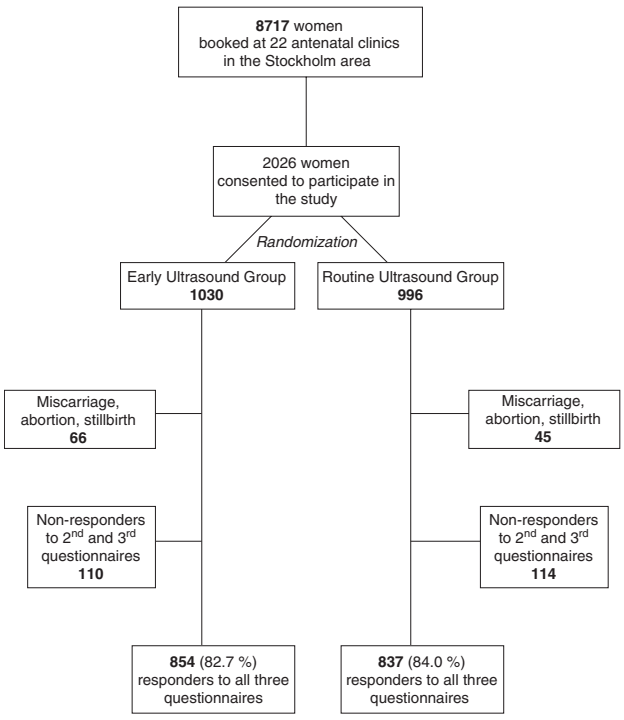

Fig. 1. Flow chart.

Comparability of groups

Table I presents the socio-demographic and obstetric background of all women randomized including the responders to all the three questionnaires. No statistically significant differences were observed between the EUG and the RUG, and the non-responders to the questionnaires did not seem to skew the distribution of women to the final study groups. Emotional well-being at baseline in early pregnancy was also similar. Women in the EUG had a tendency to be more worried about something being wrong with the fetus than women in the RUG (39.1% versus 36.0%) but this difference was not statistically significant. The only item of the SCWS that differed statistically between the groups was worry about housing, with women in the RUG being more worried at baseline (OR 0.6; 95% CI 0.4–0.9). No statistically significant differences between the study groups were observed in state and trait anxiety and depressive symptoms.

Anxiety in mid-pregnancy and 2 months after delivery

Table II shows that when asked in mid-pregnancy 29.2% of the women in the EUG and 27.8% in the RUG were worried about something being wrong with the baby. This difference, as well as other differences between the EUG and the RUG on the SCWS, except worry about the relationship with the partner, was not statistically significant. Women's general anxiety, measured by STAI, and depressive symptoms, measured by the EPDS, did not differ statistically between the trial groups. Two months after delivery, no statistical differences were observed between the trial groups. The level of major worry about something being wrong with the baby had decreased to 5.2% and 6.6% in the respective trial group.

Figure 2 illustrates the levels of major worry about the baby's health. In both trial groups there is a statistically significant decrease from early to mid-pregnancy ($p < 0.001$), and from mid-pregnancy to two months after delivery ($p < 0.001$).

Discussion

This study showed that fetal screening for Down's syndrome by means of an ultrasound scan in early pregnancy did not affect women's worries about the health of the fetus in mid-pregnancy or 2 months after delivery. Neither

Table I. Socio-demographic and obstetric background (%)

	Women randomized		Responders to all three questionnaires	
	EUG 1030	RUG 996	EUG 854	RUG 837
Age (years)				
15–24	10.4	8.3	9.8	8.5
25–34	72.5	73.7	73.3	74.7
35–44	17.1	18.0	16.7	16.9
Marital status				
Married or cohabiting	96.1	95.6	96.8	96.5
Single/divorced	0.9	0.9	2.8	3.5
Other	0.3	0.3	0.4	0
Native language				
Swedish	92.8	92.2	93.9	92.8
Other than Swedish	7.2	7.8	6.1	7.2
Education				
College or university	51.5	50.8	52.7	51.3
High school	40.4	40.8	39.9	41.5
Elementary	5.0	4.0	4.4	2.8
Other	6.1	4.3	3.1	4.4
Parity				
Nullipara	53.8	52.1	54.7	53.9
One child	32.6	34.8	31.9	33.4
Two or three children	13.0	12.6	12.8	12.3
Four to six children	0.6	0.5	0.7	0.4
Obstetric history				
Miscarriage	18.8	15.5	17.8	15.5
Abortion	27.7	28.5	27.8	27.6
Stillbirth	0.9	0.8	0.5	0.8
Infertility (> 1 year)	6.9	5.4	6.8	5.1

Table II. Worries and emotional well-being in mid-pregnancy and 2 months after delivery (% unless stated otherwise)

	Gestational week 24			Two months postpartum		
	EUG 854	RUG 837	OR(95%CI) RUG[1]	EUG 854	RUG 837	OR(95%CI) RUG[1]
SCWS (major worry: 4+5)						
Your housing	7.6	8.4	0.9 (0.6–1.3)	6.0	6.6	0.9 (0.6–1.4)
Money problems	8.2	8.7	0.9 (0.7–1.3)	7.6	9.0	0.8 (0.6–1.2)
Problems with the law	1.3	0.7	1.8 (0.7–4.9)	1.8	1.1	1.6 (0.7–3.8)
Your relationship with your partner	4.1	2.0	2.1 (1.1–3.7)	3.8	3.2	1.2 (0.7–2.0)
Your relationship with family and friends	2.5	1.9	1.3 (0.7–2.5)	1.8	2.5	0.7(0.4–1.4)
Your own health	3.8	5.6	0.6 (0.4–1.0)	3.4	3.2	1.1 (0.6–1.8)
The health of someone close to you	10.4	9.3	1.1 (0.8–1.6)	11.3	13.2	0.8 (0.6–1.1)
Employment problems	8.9	7.5	1.2 (0.8–1.7)	5.8	5.0	1.2 (0.8–1.8)
The possibility of something being wrong with the baby	29.2	27.8	1.1 (0.9–1.3)	5.2	6.6	0.8 (0.5–1.2)
Going to hospital	6.1	6.6	0.9 (0.6–1.4)	2.2	2.2	1.0 (0.5–2.0)
Baby going to hospital				7.7	8.6	0.9 (0.6–1.2)
Internal examination	3.0	3.4	0.9 (0.5–1.5)			
Giving birth	26.0	27.4	0.9 (0.7–1.2)			
Coping with the new baby	5.7	4.6	1.3 (0.8–2.0)	1.3	2.4	0.5 (0.3–1.1)
Giving up work	3.0	3.6	0.8 (0.5–1.4)	2.1	1.8	1.2 (0.6–2.4)
Whether your partner will be with you for the birth	2.0	1.2	1.7 (0.8–3.7)			
The possibility of miscarriage	14.5	12.2	1.2 (0.9–1.6)			
The organization of intra-partum care (e.g. number of delivery beds, staffing)	37.4	37.3	1.0 (0.8–1.2)			
Safety of medical care during labor	20.7	22.3	0.9 (0.7–1.1)			
Treatment by staff during labor	20.2	22.7	0.9 (0.7–1.1)			
Anxiety (STAI)	$n=$ 827/815	$n=$ 814/800		$n=$ 826/834	$n=$ 811/823	
Trait anxiety, mean (SD)	34.0 (8.6)	34.0 (8.5)		32.0 (8.8)	32.1 (8.4)	
State anxiety, mean (SD)	32.8 (8.7)	32.9 (8.8)		30.2 (8.4)	31.0 (8.2)	$p=0.051$
Depressive symptoms (EPDS)	$n=849$	$n=826$		$n=845$	$n=831$	
Scores 12–30	11.8	13.3	0.9 (0.6–1.2)	8.2	9.0	0.9 (0.6–1.3)

did it affect general anxiety nor the risk of depression. The only statistically significant difference, that is more worry about the relationship with the partner in the EUG, may have occurred by chance, considering the large number of items studied. This conclusion about no effect, based on the comparison between an ultrasound scan with the explicit aim of screening for Down's syndrome and a routine scan with less focus on fetal screening, was reassuring. We cannot, however, exclude that participation in this study, regardless of group allocation, increased women's worries. The British study on which data for the power calculation was based (8) reported lower levels of anxiety (22% of the women felt a major worry about something being wrong with the baby in mid-pregnancy) compared with the figures of the present study (29% in the EUG and 28% in the RUG in mid-pregnancy). These differences might be explained by the selection of British and Swedish women into the respective study. However, another study based on a survey of a national sample of Swedish women conducted about the same time period as the current study, and using the same worry scale (SCWS), found that only 25% of the women expressed a major worry about the health of the fetus when asked in gestational week 16 (21). The higher rates of anxiety observed in our study could be explained by the information about the aim of the study, to which all women were exposed when invited to participate in trial. This information

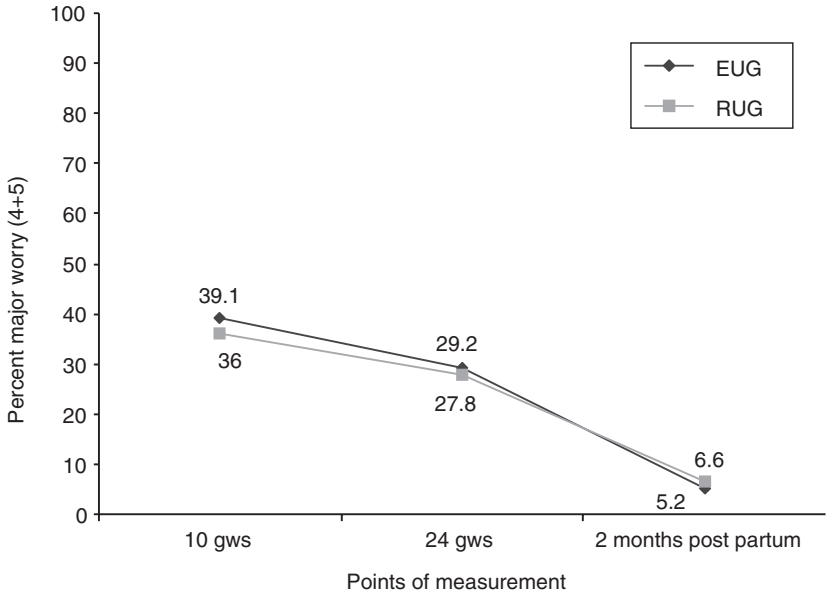

Fig. 2. Worry about the fetus'/baby's health in women randomized to fetal screening by an early ultrasound versus routine ultrasound screening.

had a strong focus on fetal abnormality and may have made all the women more aware of the possibility that something may go wrong. This interpretation is supported by several experimental studies, which have found that routine ultrasound screening may increase women's anxiety prior to the scan, but in these studies anxiety was reduced after the scan when no fetal problems were identified (13–15). The filling in of the questionnaire in gestational week 24 could also have contributed to women's worries about the health of the fetus, also in the control group.

On the other hand, we cannot exclude that women who consented to participate in the trial were more anxious than those who did not. Reasons for participation were not recorded, and one could have been a need for attention and reassurance. Even if participation in the study as such may have raised women's anxiety, this effect did not seem to remain after birth, as a rather low proportion of the women were worried about the baby's health 2 months after birth.

The selection of participants to this study took place in two steps: first approximately 80% of all women approached consented to participate in the medical study and then 29% of these women consented to take part in the present study. Possible reasons for not participating could be that the midwife did not inform the woman about this study, the woman was not interested because of lack of time, difficulties filling in questionnaires or other reasons, or an early miscarriage before returning the questionnaire.

Introduction of fetal screening for Down's syndrome as a routine procedure in early pregnancy needs to include comprehensive information, which inevitably must focus on the possibility that the fetus may suffer from a chromosomal abnormality. This information may have the same effect as participation in the current trial, and the possibility that women may become more anxious, and that this anxiety may persist during pregnancy, needs to be considered when assessing the pros and cons with the new method.

In conclusion, this study showed that fetal screening for Down's syndrome using an early ultrasound scan did not cause more anxiety or concerns about the health of the fetus in mid-pregnancy or 2 months after birth than in women who had a routine scan. Whether women's anxiety will decrease or not if the method becomes a routine part of antenatal care is a question for future research.

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