tivity[15] supports this. To what extent vitamin E and possibly other antioxidants participate in the regulation of energy metabolism in muscle cells is an important basic research question.

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A randomised trial of three methods of giving information about prenatal testing

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Abstract

***Objective*—To test the effect of extra non-directive information about prenatal testing, given individually or in a class.**

***Setting*—Antenatal clinics in a district general hospital and a university hospital.**

***Design*—Randomised controlled trial; participants allocated to control group or offer of extra information individually or in class.**

***Subjects*—1691 women booking antenatal care before 15 weeks' gestation.**

***Interventions*—All participants received the usual information about prenatal tests from hospital staff. Individual participants were offered a separate session with a research midwife in which prenatal screening was described in detail. Class participants were offered the same extra information in an early prenatal class.**

***Main outcome measures*—Attendance at extra information sessions; uptake rates of prenatal tests; levels of anxiety, understanding, and satisfaction with decisions.**

***Results*—Attendance at classes was lower than at individual sessions (adjusted odds ratio 0·45; 95% confidence interval 0·35 to 0·58). Ultrasonography was almost universally accepted (99%) and was not affected by either intervention. Uptake of cystic fibrosis testing, high in controls (79%), was lowered in the individual group (0·44; 0·20 to 0·97) and classes (0·39; 0·18 to 0·86). Uptake of screening for Down's syndrome, already low (34%) in controls, was not further depressed by extra information in classes (0·99; 0·70 to 1·39) and was slightly higher in the individual group (1·45; 1·04 to 2·02). Women offered extra information had improved understanding and were more satisfied with information received; satisfaction with decisions about prenatal testing was unchanged. The offer of individual information reduced anxiety later in pregnancy.**

***Conclusions*—Ultrasonography is valued for non-medical reasons and chosen even by fully informed people who eschew prenatal diagnosis. The offer of extra information has no overall adverse effects on anxiety and reduces uptake of blood tests when background uptake rate is high (but not when it is already low). High uptake of prenatal blood tests suggests compliant behaviour and need for more information.**

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Introduction

Parents need information to make choices about prenatal screening tests in pregnancy,[1] but it is not clear how this should be delivered and how much information is optimal.[2-7] Antenatal clinic staff often give little information about prenatal screening,[8]

although parents generally report wanting more.[9] Women may be reluctant to ask questions[10] and may accept any offered test by default—so called compliant behaviour.[11]

Research in information provision in early pregnancy is therefore a priority to identify the least costly option that maximally empowers women to make autonomous decisions without increasing anxiety.[2,12,13] There have been trials of psychological interventions in later pregnancy,[14] but the only randomised trial of written information and early prenatal classes was small and whole sample effects were not reported.[15] No unbiased information is available on the effect of altering the amount of information at the time of a screening offer.

We compared women given extra information with controls receiving only the information normally given in a routine antenatal clinic and tested the effects of giving the extra information in a class. Classes have not been used on any large scale for giving information on prenatal diagnosis, although the group dynamics may help decision making. Our primary hypothesis was that providing extra information would make women more anxious but would empower them to decline both ultrasonography and blood tests. We further hypothesised, without specifying the direction, that offering information in classes would cause different levels of anxiety than offering it individually. Classes might be perceived as threatening, but seeing others facing the same decisions might be reassuring.

Methods

SETTING

Women attending the antenatal clinics of Bradford Royal Infirmary from November 1991 to April 1993 and Leeds General Infirmary from April 1992 to June 1994 before 15 weeks' gestation were invited to participate by a research midwife. The trial was explained and consent obtained before they met any hospital clinical staff. Simple randomisation into three equal groups was achieved by opening the next in a series of numbered sealed opaque envelopes.

GROUPS

Control information—These participants were offered only the routine information given by the midwife or doctor booking them for delivery. Some 80 doctors and midwives were involved during the trial. An information sheet about prenatal screening was given to all women.

Individual information—This group was offered extra prenatal testing information, before 16 weeks' gestation, at an extra hospital visit scheduled specifically for this purpose. The following subjects were covered: population risks of Down's syndrome and spina bifida, age specific risks of Down's, risk revision for Down's by serum screening, and the procedure related risks of diagnostic amniocentesis. Subjects were told that detailed ultrasound examination at 18 weeks is a test for fetal abnormality (especially neural tube defects) and that they were free to decline it. The possibilities of false positive and negative screening results were discussed. Screening for haemoglobinopathy was discussed with patients from the relevant ethnic groups, and carrier testing for cystic fibrosis was discussed when available (see below). Risks were expressed graphically and set in the context of an estimated 2% background risk of significant mental or physical handicap at birth. All information was backed up by patient information leaflets in the appropriate language.

Information in classes—Subjects assigned to this group were invited for a similar session in classes of four to 12, again separate from any antenatal clinic visit. The same subjects were covered and again reinforced by written information.

We trained five part time research midwives and an Urdu speaking doctor to give the extra information individually and in classes, in a non-directive way.

AVAILABILITY OF PRENATAL TESTS

Detailed ultrasound examination of anatomy at 18 to 20 weeks' gestation was available to all women. Serum screening for Down's syndrome was only available to women aged 30 or over when the trial started in November 1991 but was extended to all participants from 1 June 1992. Cystic fibrosis carrier testing became available from 1 July 1993 in Leeds as part of a demonstration project. Haemoglobinopathy screening was available to women from at risk ethnic groups. Test uptake rates are expressed as a proportion of those eligible.

Outside the trial, ultrasonography, haemoglobinopathy, and screening for cystic fibrosis were equally available to participants and non-participants. However, non-participants were offered screening for Down's syndrome in Leeds only if they were aged over 29 and in Bradford if they were over 34.

PSYCHOLOGICAL QUESTIONNAIRES

Apart from a two month period in Leeds, all participants received the following questionnaires for self completion during the pregnancy and puerperium: the state-trait anxiety inventory,[16] the hospital anxiety and depression scale,[17] a modified questionnaire about self reported knowledge and understanding,[18] and an anxiety measure specific to pregnancy and fetal abnormality which we designed, in which the question stems sought to measure degree of concern about the baby's general health, physical disability, and mental handicap; possible responses ranged from 1 "not worried at all" to 6 "extremely worried."

The state-trait anxiety inventory (possible scores 20-80) and hospital anxiety and depression scale (possible scores 0-21) are reported and analysed as summary scores. The responses to the other questionnaires were converted into summary scores for "worries about the baby" (possible scores 3-18), self report of "relevant information received" (possible 7-28), self report of "understanding of relevant information" (possible 7-28), "satisfaction with information" (possible 4-16), and finally satisfaction with the decisions made (possible 1-4). For the hospital anxiety and depression scale, the modified questionnaire, and "worries about the baby" questionnaires high scores are bad; for the other elements of the pregnancy specific questionnaire they are good. The questions about amount and understanding of information were administered only at 16-18 weeks and the satisfaction questions only at 30 and 46 weeks.

The questionnaires were administered by post at 16-18 weeks, 20 weeks, and 30 weeks and at six weeks after delivery. The first set of questionnaires was completed after any abnormal blood test result was available but before receipt of the result of any invasive diagnostic test; thus this set measured any transitory anxiety at this time. The questionnaires at 20 weeks were completed soon after all results were available and therefore reflected worries that had not been dissipated by testing. The third set, at 30 weeks, was designed to show any differences at a time when increasing anxiety as delivery approached might be expected, and the final set was designed to measure differences persisting after delivery. Women who failed to return the final set received a reminder after four weeks.

POWER AND ANALYSIS

We initially aimed for 1000 subjects per group, which would have had 80% power to show a doubling

of a baseline 3% amniocentesis rate. Our achieved sample, of 564 per group, has over 90% power to show a 3% difference in the proportion of women declining ultrasonography given a baseline 1% refusal rate, and the same power to show a 10% difference in uptake of serum screening from the baseline 34% (α=0·05). This power is ample to show very small differences on anxiety scores between groups.

Statistical analysis was by SPSS; all analyses were by intention to treat. The effect of the offer of extra information on test uptake rates is reported as odds ratios and 95% confidence intervals. Logistic regression methods were used to assess differences in attendance for testing and uptake for cystic fibrosis and serum screening for Down's syndrome, adjusted for important predictors (city of residence; maternal age; gestational age; parity; previous miscarriage, termination, stillbirth or infant death; maternal and paternal socioeconomic class; telephone ownership; race). Unless otherwise stated, scores for questionnaire responses are reported as means and 95% confidence intervals for each group. The significance of any difference between groups was tested by analysis of variance by using Tukey's method to control for multiple comparisons.

Results

RECRUITMENT AND ATTENDANCE

A total of 2004 women were invited in Leeds and 1362 in Bradford (total 3368); 994 and 697 respectively (total 1691) consented to participate. Those who declined to participate included a slightly higher proportion of women from ethnic groups (21% *v* 15% among participants). The reasons for declining to participate were recorded for a cohort of 58 women, of whom two disliked classes, 23 were too busy, nine wanted no more information, and 24 gave no reason. Table I shows characteristics of the groups and attendance rates.

Attendance at the extra sessions was low (52% overall) and was lower at classes than at individual appointments (adjusted odds ratio 0.45; 95% confidence interval 0.35 to 0.58). Attendance was higher with increasing maternal age and for those eligible for serum screening for Down's syndrome, with telephones, and without children.

TEST UPTAKE

Table II shows the uptake rates for each test. Uptake of the ultrasound examination at 18 weeks was almost universal in all three groups.

Uptake of screening for Down's syndrome was slightly increased when extra information was offered individually (1·45; 1·04 to 2·02) but the offer of a class had no effect (0·99; 0·70 to 1·39). Uptake was lower in Bradford and among women without telephones, members of ethnic minorities, and mothers who had had a pregnancy loss; uptake declined in association with decreasing maternal age and decreasing social class of father. It was much lower if testing would not have been offered outside the trial (table II).

Results for cystic fibrosis testing were based on fewer participants (n=220) as this screening was available only at the Leeds centre. Women offered extra information, whether singly or in classes, had similar rates, which were considerably lower than controls (individual 0·44, 0·20 to 0·97; classes 0·39, 0·18 to 0·86). Uptake was lower with decreasing social class of father, but unexpectedly seemed to be higher with advancing gestation.

PSYCHOLOGICAL OUTCOMES

Table III shows that there were no significant differences in the mean anxiety scores on the hospital anxiety and depression scale and state-trait anxiety inventory at 16 weeks, but by 20 weeks those offered individual information were significantly less anxious than controls on the hospital anxiety and depression scale (P=0·02). The difference on the state-trait anxiety inventory was in the same direction but did not reach statistical significance (P=0·06). At 30 weeks the group given individual information was still less anxious on both scales (hospital anxiety and depression scale P=0·049, state-trait anxiety inventory P=0·044) but at six weeks after delivery the difference was significant only on the state-trait anxiety inventory (P=0·018).

The full analysis of the remainder of the psychological questionnaires will be reported separately. In brief, women who were offered individual information were less worried about the baby at 20 weeks than those offered classes. Women in both intervention groups felt that they had received more relevant information and understood it better. They were also more satisfied with the information they had received, although this did not translate into feeling more sure that they had made the right decisions about prenatal testing.

TABLE I—*Comparability of groups of women given information about prenatal testing. Values are numbers (percentages) unless otherwise indicated*

	Control (n=567)	Individual information (n=561)	Information in classes (n=563)
Mean (SD) age (years)	28 (5·4)	28 (5·3)	28 (5·3)
Mean (SD) gestational age at entry (weeks)	12 (1·9)	12 (1·8)	12 (2·0)
Parous	285/558 (51)	267/557 (48)	260/559 (47)
Non-white	75/564 (13)	88/559 (16)	80/562 (14
Non-manual social class:			
Mother	289/538 (54)	318/541 (59)	308/541 (57)
Father	240/504 (48)	256/503 (51)	245/504 (49)
From clinics in Bradford	232/567 (41)	230/561 (41)	235/563 (42)
Attendance at extra information sessions:			
Withdrew (miscarriage or changed mind)	41/567 (7·2)	38/561 (6·8)	49/563 (8·7)
Pregnant and in trial at time of appointment	526	523	514
Attended appointment	N/A	319 (61)	218 (42)

TABLE II—*Uptake of prenatal testing. Values are numbers tested/numbers eligible (percentages)*

Screening	Control	Individual information	Information in classes
Down's syndrome:			
Whole trial	146/431 (34)	164/441 (37)	135/427 (32)
Screening would have been offered outside trial:			
Yes	99/148 (67)	108/162 (67)	97/159 (61)
No	47/283 (17)	56/279 (20)	38/268 (14)
Ultrasonography	519/526 (99)	514/523 (98)	507/514 (99)
Cystic fibrosis	61/77 (79)	48/74 (65)	43/69 (62)
Amniocentesis	19/526 (3)	18/523 (3)	10/514 (2)

TABLE III—*Mean (95% confidence interval) for hospital anxiety and depression scale and state-trait anxiety inventory and anxiety scores after information given on prenatal testing. Minimum No in each group=295*

	Control	Individual	Classes
HAD anxiety:			
16-18 Weeks	6·7 (6·4 to 7·0)	6·5 (6·1 to 6·8)	6·9 (6·5 to 7·3)
20 Weeks	6·8 (6·4 to 7·2)	6·1 (5·7 to 6·5)*	6·8 (6·3 to 7·3)
34 Weeks	7·3 (6·9 to 7·8)	6·6 (6·2 to 7·0)*	6·9 (6·4 to 7·4)
6 Weeks postpartum	6·5 (6·1 to 6·9)	6·1 (5·6 to 6·5)	6·5 (6·0 to 7·1)
STAI "state" anxiety:			
16-18 Weeks	37 (36 to 38)	36 (35 to 38)	38 (36 to 39)
20 Weeks	37 (36 to 38)	35 (34 to 37)	37 (36 to 39)
34 Weeks	39 (38 to 41)	37 (35 to 38)*	37 (36 to 39)
6 Weeks postpartum	35 (34 to 36)	34 (33 to 35)*	37 (35 to 38)

*P<0·05, Tukey test, individual *v* control.

Discussion

This is the largest trial to assess in unbiased fashion the effect of giving extra non-directive information about prenatal testing in pregnancy. Other trials of similar size of psychological interventions in preg-

nancy have been of antismoking advice[19] and psychological support later in pregnancy.[14] In one small trial, whole clinics were randomly allocated to a prenatal class to receive information leaflets or to a control group, but psychological outcomes were reported only for those women who had a positive result on a screening test.[15]

Other researchers have noted the apparent discrepancy in the uptake of ultrasonography and other prenatal diagnosis tests.[20] Presumably women choose ultrasonography also for other reasons.[21,22] Blood tests for congenital disease are not uniformly accepted, and uptake rates are sensitive to the amount and type of extra information offered, increasing slightly from a low baseline for Down's syndrome but falling sharply from a high baseline in the case of cystic fibrosis. Down's screening is a relatively well established test; most women will be aware of it before they become pregnant and may have preconceived attitudes towards it. In contrast, cystic fibrosis testing is new; this trial took place at the start of a demonstration project, so few women were aware of this test before they attended the antenatal clinic. Acceptance under these conditions may consist partly of compliant behaviour, and extra information may have empowered some women to decline testing.

The uptake rate of Down's testing overall was lower than in other demonstration projects[23] but similar to rates previously reported elsewhere in Leeds.[24] The difference is not due to failure to offer the test[25] but to the lower uptake among women to whom Down's screening would not have been offered outside the trial. Uptake among older women who would have been offered Down's screening anyway was the same in the trial as outside it. We suspect that many women chose screening if doing so was perceived to be "normal."

Although only half the women who were asked to take part in the study participated, the direction of the observed effects is unlikely to have been affected; however, generalisation to ethnic minorities, who were less likely to participate, must be done with caution. It is also unlikely that much extra information could be given routinely during the first antenatal clinic, as women already face information overload at this visit. Much routine care in later pregnancy is probably ineffective,[26] so resources could be shifted to the prescreening phase of pregnancy. We believe that the present trial reflects what would occur if this opportunity were taken to increase information giving about prenatal screening.

The relative unpopularity of classes, as measured by attendance, has also been observed for classes at later stages of pregnancy.[27] This makes them an inferior way of transmitting information in practice.

Over the later part of pregnancy, extra information provided individually does reduce anxiety slightly and this effect seems to persist into the puerperium. Since people's decisions change when they have more information, without adverse effect on anxiety, and since informed decisions require knowledge, we conclude that as much non-directive information as can be afforded should be offered before prenatal screening. The low uptake of classes makes information offered individually preferable where possible. Since there is probably little effect on overall satisfaction with decisions and because the rate of uptake of ultrasonography and of established blood tests with low uptake rates is little altered, the benefit of offering all women extra information from a specially trained counsellor is modest. When high uptake rates are associated with the introduction of a new test and women are vulnerable to compliant behaviour, however, the benefit could be greater; antenatal resources should be shifted towards giving more information at this time.

Key messages

- Whatever their views about prenatal diagnosis in general, women want ultrasound examination
- Enhanced provision of information is particularly important when a new screening test is introduced, since the risk of compliant behaviour is highest at this stage
- Giving prenatal diagnosis information in classes is not popular and attendance is low
- Offering healthy people more information does not increase anxiety overall

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