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Use of a decision aid for prenatal testing of fetal abnormalities to improve women's informed decision making: a cluster randomised controlled trial [ISRCTN22532458]

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Objective To evaluate the effectiveness of a decision aid for prenatal testing of fetal abnormalities compared with a pamphlet in supporting women's decision making.

Design A cluster randomised controlled trial.

Setting Primary health care.

Population Women in early pregnancy consulting a GP.

Methods GPs were randomised to provide women with either a decision aid or a pamphlet. The decision aid was a 24-page booklet designed using the Ottowa Decision Framework. The pamphlet was an existing resource available in the trial setting.

Main outcome measures Validated scales were used to measure the primary outcomes, informed choice and decisional conflict, and the secondary outcomes, anxiety, depression, attitudes to the pregnancy/fetus and acceptability of the resource. Outcomes were measured at 14 weeks of gestation from questionnaires that women completed and returned by post.

Findings Women in the intervention group were more likely to make an informed decision 76% (126/165) than those in the control group 65% (107/165) (adjusted OR 2.08; 95% CI 1.14–3.81). A greater proportion of women in the intervention group 88% (147/167) had a 'good' level of knowledge than those in the control group 72% (123/171) (adjusted OR 3.43; 95% CI 1.79–6.58). Mean (SD) decisional conflict scores were low in both groups, decision aid 1.71 (0.49), pamphlet 1.65 (0.55) (adjusted mean difference 0.10; 95% CI –0.02 to 0.22). There was no strong evidence of differences between the trial arms in the measures of psychological or acceptability outcomes.

Conclusion A tailored prenatal testing decision aid plays an important role in improving women's knowledge of first and second trimester screening tests and assisting them to make decisions about screening and diagnostic tests that are consistent with their values.

Keywords Decision aid, decisional conflict, informed choice, prenatal testing.

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Introduction

It is widely accepted that all women in early pregnancy should be offered information on the screening tests available for fetal abnormalities.[1–3] Despite robust evidence evaluating the most effective screening options,[4,5] women continue to be offered a confusing range of choices to screen for fetal abnormalities.[6] Presented with a number of screening and diagnostic test options and with information that is complex, it is not surprising that studies have consistently demonstrated low levels of understanding by women.[7–9] Health professionals are an important source of information for women[10,11] although often, they too demonstrate a poor understanding of prenatal testing issues.[9,12,13]

It has been recommended that at a minimum, women need to understand the condition(s) for which testing is being offered, the characteristics of the test and the implications of testing.[14] Reassuringly, evidence does not support that an

increase in knowledge affects a woman's anxiety.[15] Informed choices have been conceptualised as decisions based adequate knowledge as well as being consistent with the individual's values[16] and facilitating an informed choice may therefore require more than the provision of evidence-based information alone.

Women and their partners need to deicide whether or not the information from prenatal testing, both screening and diagnostic testing, will be useful to them and if useful which test to have. These decisions are complex, value laden and preference sensitive.

Decision aids are interventions designed to assist individuals to make specific and deliberate choices on the relative risks, benefits and consequences of available options.[17] Evaluated in many health-related areas, decision aids contain information on the condition/treatment, probabilities of outcome based on the individual's *a priori* risk, an explicit values clarification exercise and guidance in decision making.[18] In prenatal testing, decision aids have been developed for women at increased risk of fetal abnormality on the basis of their age[19] and screening test result.[20] Decision aids supplement counselling provided by health professionals and formats used in prenatal testing include the use of decision analysis strategies,[20] audiotapes and booklet[19] and computerised touch screen information.[21] The role of decision aids for women of all ages considering prenatal tests (screening and diagnostic) has not been established. Given the complexity of prenatal testing decisions, it is vitally important that decision aids developed to support decision making in this sensitive area are carefully evaluated.

We investigated whether a decision aid for prenatal testing of fetal abnormalities, when compared with a standard pamphlet, improved women's informed choice and decreased their decisional conflict.

Methods

Setting

This randomised controlled trial, called ADEPT (A Decision aid for Prenatal Testing of fetal abnormalities), was conducted in Victoria, one of the south-eastern states of Australia, where approximately 62 000 women give birth each year.[22] Women booked to give birth at publicly funded Victorian maternity services have access to a second-trimester maternal serum screening test for trisomy 21 (Down syndrome), trisomy 18 and neural tube defects, free of charge. If aged 37 years or older by their expected due date, women in the public system may elect to have a funded diagnostic test (chorionic villus sampling or amniocentesis) at a tertiary hospital. Other screening tests including nuchal translucency, combined first-trimester screening and second-trimester fetal anomaly ultrasounds are available to all women on a fee for service basis. Women with private health insurance may also choose to have a second-trimester screening test at their expense. Regardless of age, a woman may elect to have a diagnostic test at her own expense. Throughout Victoria, there is wide variation in the type and amount of information women receive on testing.

As GPs are often the first health professional a woman consults in early pregnancy, the trial was conducted in the primary healthcare setting. Providing information to women at an early gestation afforded them the time to consider first- and second-trimester screening and diagnostic options. A cluster randomised trial was deemed more appropriate than individual randomisation because a significant level of contamination was anticipated[23,24] in this setting through women in the control groups, accessing the decision aid in various social and/or maternity care environments.

Participants

Geographically diverse areas were selected for recruitment campaigns, to ensure GPs from both metropolitan and regional areas were represented. Letters seeking expressions of interest in the trial were sent to individual GPs, and contact details were accessed using online telephone listings, in-house databases of GPs interested in testing and professional organisations. The trial was advertised in the medical media and through professional General Practice organisations.

GPs who estimated that they consulted with at least 30 women in early pregnancy, within a 12-month period, were eligible to participate. Participation was restricted to one GP per practice. Women attending a participating GP were eligible to participate, provided they were aged 18 years or older and were equal to, or less than 12 weeks of gestation. Women were excluded if they were non-English speaking, unable to give written informed consent, experiencing vaginal bleeding, having a multiple pregnancy, required genetic counselling due to a recurrent risk for fetal abnormality or who had already undertaken testing in the current pregnancy.

Procedures

The intervention, a decision aid, was developed based on the Ottawa Decision Framework[25] and was informed by focus groups conducted with GPs and women and input from key informants. It was refined following piloting in a tertiary maternity setting. The decision aid is a 24-page booklet containing a worksheet and provides information on why testing is offered, the conditions tested, the different types of tests and the benefits, risks and limitations of the tests and the possible consequences following testing. Women could access all the information or use the summary tables or the contents page to select areas of interest. Particular attention was devoted to promoting the understanding of screening test results, and an individual age-related risk report was provided. Strong graphical design included the use of diagrams, images, charts and dot points.

Strategies in the decision aid to assist decision making include hypothetical scenarios of women's deliberations. Four scenarios were developed in response to analysis of the women's focus groups where women wanted to learn from other women's stories. A values clarification exercise was developed as a worksheet, and the scenarios were also used as examples within the worksheet.

Due to the significant variation in information that GPs provide to women on prenatal testing, a standard pamphlet was used in the control group rather than usual care. The pamphlet used was produced by Genetic Health Services Victoria and is freely available to women in Victoria. It is in the form of a fold out A3 paper size and contains information on maternal age-related risk, the difference between screening and diagnostic tests, what the tests consist of, the gestation they are available and what conditions they detect. The information is presented in detail and summarised. No decision support is provided, however, a resource list is included.

The unit of randomisation was the individual GP. The names of GPs who expressed interest in participating in the study were coded and randomly sorted. GPs were contacted in order. The first 60 GPs who confirmed interest, were eligible and agreed to be randomised, were selected. This process minimised the potential for selection bias.[24] GPs were randomised to provide women with the decision aid (intervention) or the pamphlet (control), stratifying by practice location (metropolitan/nonmetropolitan).

The GPs were each assigned study ID numbers and randomised using computer-generated random numbers by an independent statistician. As the statistician was unaware of the identities and characteristics of the GPs, allocation concealment was achieved. Women were recruited by GPs after they had been randomised. An audit of all women attending each ADEPT GP during the recruitment period was conducted. Due to the nature of the intervention, it was not possible to blind women, GPs or researchers.

All GPs were visited by researchers who collected baseline demographic and practice details, explained the process of enrolling women to the study, provided resources and obtained the GPs written consent to participate in the trial. In addition to providing their usual prenatal consultation, GPs were asked to inform all eligible women of the study until ten women had been recruited. For women interested in participating, GPs were asked to obtain the women's written consent to participate and to provide them with an information pack containing the allocated resource and a questionnaire with a reply paid envelope. A copy of the consent form and the women's contact details and estimated due date was sent to the research team to manage the reminder system for the return of the questionnaire. The woman was asked to complete the questionnaire when she had made a decision about prenatal testing or, if she had not made a decision in the first trimester of pregnancy, to return the questionnaire by 14 weeks of gestation. A computerised reminder system consisting of a letter at 16 weeks and a phone call at 18 weeks was used when questionnaires were not returned. GPs recruited women to the trial between August 2004 and September 2005.

Outcomes

There were two primary outcomes: informed choice and decisional conflict. A dichotomous measure of informed choice was derived from responses to the Multidimensional Measure of Informed Choice (MMIC).[14] Decisional conflict was quantified using the Decisional Conflict Scale (DCS).[26]

Using MMIC, an informed choice is one based on relevant knowledge, is consistent with a person's values and is behaviourally implemented. The measure was developed and validated for use in prenatal testing (alpha 0.68 and 0.78).[27] Three dimensions are incorporated in this measure: knowledge, attitude and uptake. A record of test uptake is included in the measure. Subjects are classified as having made an informed choice if they (a) score higher than the midpoint of the knowledge scale (>4), higher than the midpoint of the attitude scale (>16) and have the test or (b) score higher than the midpoint of the knowledge scale (>4), equal to or less than the midpoint of the attitudes scale (equal or <16) and do not have the test.[28]

Levels of decisional conflict were quantified using the DCS.[26] The DCS contains 16 items divided into three subscales: uncertainty about selection of alternatives, specific factors contributing to uncertainty and perceived effectiveness of decision making. Participants were directed to consider responses in terms of their decision about prenatal testing for fetal abnormalities and respond using a 5-point Likert scale (1 = strongly agree to, 5 = strongly disagree) (alpha 0.78 to 0.92)[26] (Appendix S2).

Mean scores across the items were calculated for each subscale and for the total scale. Higher scores indicate higher decisional conflict. People who delay choices have average scores greater than 2.5, while those who make choices have average scores equal to 2 or less.[26]

Secondary outcomes include psychosocial measures of anxiety, depression, attitudes to the fetus/pregnancy and the acceptability of the allocated resource to women and GPs. Anxiety was measured using the short version of the Speilberger State-Trait Anxiety Inventory (State) (alpha 0.82).[29] Attitudes to the pregnancy/fetus were measured using the scale by Reading *et al.*[30] (1984) (alpha 0.93 and 0.90). Depression was measured using the Edinburgh Postnatal Depression Scale,[31] which has been validated to use in pregnancy. Women were classified as probably clinically depressed using a cutoff score of ≥13 providing a sensitivity of 100% and specificity between 87 and 95.7%.[32]

Acceptability of the decision aid and pamphlet was quantified by recording whether women used the resource, the time taken and how helpful the allocated resource was (1 = very helpful to, 5 = very unhelpful) in increasing women's

understanding of the options, clarifying the benefits, the risks and decision making and reaching a decision that was right for them. In addition, GPs in the intervention arm were asked how often they would use the decision aid if it was found to be beneficial to women's decision making using a 3-point scale (1 = not at all, 2 = some of the time, 3 = all the time).

Sample size

The sample size was based on using a two-sided test at a 5% level of significance and 80% power to detect a difference of 18% in informed choice (68% in decision aid arm versus 50% in pamphlet arm). This difference was based on a study assessing women's knowledge of prenatal tests to detect Down syndrome[8] and is considered to be of public health significance. The sample size was adjusted for correlation between responses of women seeing the same GP[33] assuming an intracluster (intra-GP) correlation coefficient (ICC) of 0.05 on the basis of an unpublished study by one of the authors (J.G.) of 50 pregnant women consecutively sampled from 30 GP practices in Victoria. The total number of clusters was set at 50, and using the formula presented by Campbell[34] (2000), a required sample size of 162 women per trial arm was calculated. GPs were oversampled to allow for attrition.

Statistical analysis

Analyses were conducted using the intention-to-treat principle. The relative odds of dichotomous outcomes were estimated by fitting marginal logistic regression models using Generalised Estimating Equations (GEEs), with information sandwich estimates of standard error,[35] to allow for clustering of responses within GPs. For the GEE analyses, an exchangeable correlation structure was specified. When the estimated ICC of the outcome for a given analysis was negative, the results from ordinary logistic regression were used thereby assuming the ICC to be zero on the grounds that true negative values are unlikely in this context. Mean differences between the trial arms for quantitative outcomes were estimated using random effects linear regression models (maximum likelihood estimates)[36] again to allow for clustering. Bias-corrected accelerated bootstrap confidence intervals[37] were obtained to validate the model-based confidence intervals for skewed continuous outcomes. Bootstrap datasets were created using stratified resampling of clusters within each trial arm. As the bootstrap confidence intervals were similar to the model-based ones, the latter are presented.

Mean differences and odds ratios that were unadjusted and adjusted for confounders were estimated. The potential confounding factors were practice location, gender of GP,[38] years of general practice[39] and maternal age,[40,41] woman's highest education level,[41] woman's religion,[40] whether or not the woman had experienced a previous termination of pregnancy[42–44] or previously undertaken screening tests.[45,46] All analyses were implemented using Stata 9.2.[47]

Ethics approval

Project approval to conduct the study was obtained from the Royal Australian College of GPs (NREEC 03-16).

Trial registration

The ADEPT trial was registered in the UK with Current Controlled Trials [ISRCTN22532458] and with the Australian Clinical Trials Registry (No: 012606000234516).

Role of the funding source

The sponsor of the study had no role in study design, data collection, data analysis, data interpretation or writing of the report. The first named author had full access to all the data and full responsibility for the decision to submit for publication.

Results

Expressions of interest in participating in the trial were received from 69 GPs. Of the 60 GPs randomly selected to participate, the 5 who did not recruit any women were withdrawn from the study. Altogether, 55 GPs (clusters) were included in the analyses, and the median number of women's questionnaires analysed per GP was 7.0 in the intervention group and 6.5 in the control group.

Of the 467 women enrolled in the study, 338 returned questionnaires that were included in the analysis. It was discovered that one respondent was not eligible and was subsequently excluded from analysis (Figure 1).

The baseline characteristics at the cluster and individual level are shown in Tables 1 and 2.

A greater proportion of women in the intervention arm than in the control arm made an informed choice 76% (126/165) versus 65% (107/165) (adjusted OR 2.08; 95% CI 1.14–3.81) (Table 3). Eighty-eight percent (147/167) of women in the decision aid group had a 'good' level of knowledge compared with 72% (123/171) in the pamphlet group (adjusted OR 3.43; 95% CI 1.79–6.58). There was no difference in the proportion of women in the intervention arm having a positive attitude to having screening compared with those in the control arm (adjusted OR 1.35; 95% CI 0.68–2.69). The proportion of women intending to have a screening test for Down syndrome was high in both the intervention 87% (146/167) and control arms 85% (144/170) (adjusted OR 1.29; 95% CI 0.53–3.19).

For the three knowledge items in the informed choice scale requiring a numeric response, the odds of women responding correctly were at least twice as large in the intervention group compared with the control group. The numeric items included questions on the percentage of women screened who get a low-risk result (adjusted OR 2.58; 95% CI 1.53–4.33) and increased risk from screening tests (adjusted OR 3.10; 95% CI 1.74–5.54) and the percentage of affected

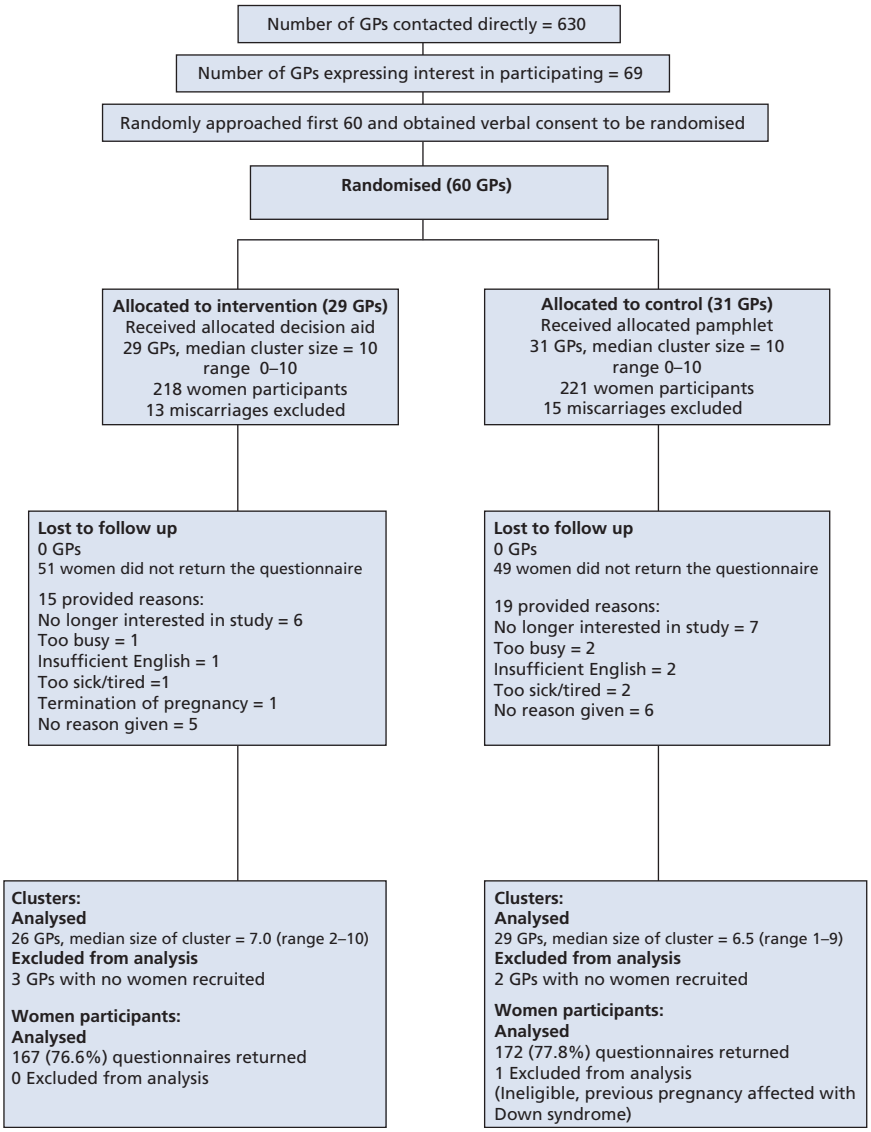

Figure 1. Diagram showing the flow of clusters and participants through the trial.

pregnancies with an increased risk result (adjusted OR 2.90; 95% CI 1.74–4.86).

Of the 147 women who had a 'good' level of knowledge in the intervention group, 19 (13%) displayed screening behaviour that was inconsistent with their values compared with 10 of the 123 women (8%) in the control group. This included eight women (5%) in the intervention group having a positive attitude to prenatal testing for fetal abnormalities but not having a test compared with four women (3%) in the control group. In addition, 11 (8%) women in the intervention group had testing, despite having a negative attitude, compared with 6 (5%) women in the same category of the control group.

The level of decisional conflict was low in both the intervention and control groups, and there was no strong evidence of differences between the groups in either the total mean scores (Table 3) or the subscales of decisional conflict with the exception of 'unclear values' (adjusted mean difference 0.17; 95% CI 0.02–0.31). This amounted to women in the intervention group being less aware of the importance of the personal risks and benefits of their decision about testing and less clear in identifying which (risks/benefits) were most important.

There was no strong evidence of differences in the secondary outcomes of depression, anxiety or attitudes to the pregnancy/fetus (Table 4).

The odds of women assessing the resource as 'very helpful' in increasing understanding of prenatal testing options in the intervention arm were larger than those in the control arm (adjusted OR 1.67; 95% CI 1.11–2.53). The proportion of women who reported taking 20 minutes or less to use the

Table 1. Baseline information for each trial arm at the GP (cluster) level

Variables	Decision aid (*n* = 26)	Pamphlet (*n* = 29)
Age, median (IQR)	49.5 (40–54)	43 (39–48)
Gender, *n* (%)		
Male	11 (42)	8 (28)
Female	15 (58)	21 (72)
Years in general practice (years), *n* (%)		
<5	3 (12)	1 (4)
6–10	3 (12)	9 (35)
11–19	6 (24)	12 (46)
20+	13 (52)	4 (15)
Sessions per week, *n* (%)		
<6	4 (16)	6 (22)
6–10	18 (72)	19 (70)
>10	3 (12)	2 (7)
Size of practice, *n* (%)		
Solo	2 (8)	2 (7)
2–4	7 (27)	7 (25)
5–10	13 (50)	15 (54)
11+	4 (15)	4 (14)
Graduated in Australia, *n* (%)		
Yes	22 (85)	23 (79)
Postgraduate Obstetric training, *n* (%)		
Yes	19 (73)	15 (52)
Professional/personal contact with disability, *n* (%)		
Yes	21 (81)	20 (69)
Average time spent on prenatal testing in a consultation (minutes), *n* (%)		
<5	5 (19)	3 (11)
5–9	9 (35)	10 (37)
10–20	10 (38)	9 (33)
>20	1 (4)	3 (11)
Could not be coded	1 (4)	2 (7)

IQR, interquartile range.

Table 2. Selected characteristics of each trial arm at the woman (individual) level

	Decision aid (*n* = 167)	Pamphlet (*n* = 171)
Socio-demographic variables		
Age, median (IQR)	30 (27–34)	31 (28–35)
Born in Australia, *n* (%)	144 (86.2)	150 (88.2)
Private health insurance, *n* (%)	73 (43.7)	79 (46.5)
Living with partner, *n* (%)	157 (96.5)	164 (94.0)
Religion, *n* (%)		
None	61 (37.2)	55 (32.3)
Catholic	46 (28.1)	63 (37.0)
Anglican	24 (14.6)	23 (13.5)
Other	31 (20.1)	32 (17.1)
Education, *n* (%)		
<Year 12	28 (16.8)	20 (11.8)
Completed year 12	33 (19.8)	25 (14.9)
Trade/college	50 (29.9)	41 (24.4)
Tertiary	56 (33.6)	82 (48.8)
Main source of income, *n* (%)		
Wages/salary	150 (89.8)	152 (90.5)
Pension	10 (6.0)	10 (6.0)
Other	7 (4.2)	6 (3.5)
Obstetric variables		
Gravidity, *n* (%)		
Primigravida	64 (38.3)	61 (35.7)
Previous pregnancy outcomes*		
Previously experienced a miscarriage, *n* (%)	37 (36)	33 (30)
Previously experienced a stillbirth, *n* (%)	2 (2)	1 (1)
Previously experienced a termination of pregnancy, *n* (%)	15 (15)	27 (25)
Previous prenatal testing		
Previous screening testing for DS, *n* (%)	82 (80)	78 (71)
Previous diagnostic testing for DS, *n* (%)	4 (4)	7 (6)

DS, Down syndrome; IQR, interquartile range.
*Using number of multigravid women as denominator (*n* = 103 decision aid, *n* = 110 pamphlet).

allocated resource was 65% (84/162) in the intervention arm compared with 84% (140/167) in the control arm. There were no significant differences in the other measures of acceptability to women (data not shown).

Forty-four of 55 GPs (20 intervention, 24 control) completed a feedback survey. Ninety-five percent (19/20) of GPs in the intervention arm indicated that they would use a decision aid 'all the time' if the decision aid was found to be effective in improving women's informed decision making.

Discussion

In the complex area of genetic prenatal testing, our findings indicate that this decision aid, delivered by GPs in early pregnancy, is more effective than a pamphlet in improving women's informed choice (76 versus 65%). The success of the decision aid in improving women's knowledge, particularly their understanding of numeric risk, reinforces the need to present this information in a variety of ways using graphical depictions, positive and negative framing of risk and concise wording.

In our study, the intervention group was more informed about testing and had slightly more positive attitudes to having the tests (MMIC). However, they were less aware of whether the personal risks or benefits of testing were more important (DCS subscale) compared with the control group. No association between knowledge and attitudes has been established in validation studies of MMIC.[28]

The provision of hypothetical scenarios served to highlight specific decisions that confront women and provide examples

Table 3. Results of primary outcomes

	Decision aid (n = 167)	Pamphlet (n = 171)	Adjusted	
			Comparative statistic*	95% CI
MMIC outcomes, *n* (%)				
Informed choice	126 (76)	107 (65)	2.08	1.14–3.81
Knowledge				
Good	147 (88)	123 (72)	3.43	1.79–6.58
Attitudes				
Positive	138 (86)	132 (81)	1.35	0.68–2.69
Uptake of test				
Yes	146 (87)	144 (85)	1.29	0.53–3.19
Decisional conflict mean score (SD)				
Total score	1.71 (0.49)	1.65 (0.55)	0.10	−0.02 to 0.22
Uncertainty	1.96 (0.79)	1.97 (0.86)	0.05	−0.14 to 0.24
Uninformed	1.61 (0.58)	1.51 (0.59)	0.10	−0.05 to 0.25
Unclear values	1.76 (0.61)	1.62 (0.63)	0.17	0.02–0.31
Unsupported	1.61 (0.55)	1.58 (0.63)	0.06	−0.07 to 0.20
Ineffective choice	1.65 (0.55)	1.60 (0.57)	0.10	−0.04 to 0.23

Sample size for decision aid arm ranges from 148 to 166 for the adjusted analyses.
Sample size for pamphlet arm ranges from 155 to 160 for the adjusted analyses.
*Comparative statistic: OR for categorical variables (MMIC outcomes) and mean differences for continuous variables (Decisional conflict outcomes).

of how decisions can be processed. The stories reinforced information and demonstrated behaviour that was consistent with values.

In our study, the high uptake rates in both arms of the trial may reflect a heightened awareness of testing by both women and GPs as a by product of participating in a trial or a limitation of the MMIC to provide insights into the influences of testing uptake that may act to override an individual's attitudes to having the test.

The dichotomisation of knowledge as 'good/poor', attitudes as 'positive/negative' and informed choice as 'yes/no' has been criticised as artificial, and this limitation is acknowledged by the authors.[48] Notwithstanding these issues, the MMIC provided this study with a validated and reliable measure for informed choice.

In keeping with the high levels of intention to test, are the low levels of decisional conflict seen in both arms of the trial. This finding is consistent with results from a descriptive study, where women undertaking screening were less likely to deliberate about the decision than those who declined.[49]

Not surprisingly, we found women with lower levels of education (less than year 12) in both arms of the trial were less

Table 4. Results of secondary outcomes

	Decision aid (n = 167)	Pamphlet (n = 171)	Adjusted	
			Comparative statistic*	95% CI
STAI, mean score (SD)	37.20 (12.1)	37.36 (12.6)	−0.21	−0.46 to 0.05
EPDS, score ≥13 *n* (%)	19 (11.6)	19 (11.2)	1.12	0.53–2.35
Attitudes to pregnancy, mean score (SD)	5.03 (1.14)	5.05 (1.17)	−0.06	−0.35 to 0.24
Attitudes to fetus, mean score (SD)	4.92 (1.05)	5.05 (1.05)	−0.21	−0.46 to 0.05

EPDS, Edinburgh Postnatal Depression Scale; STAI, State-Trait Anxiety Inventory.
Sample size for decision aid arm ranges from 151 to 152 for the adjusted analyses.
Sample size for pamphlet arm ranges from 152 to 159 for the adjusted analyses.
*Comparative statistic: OR for categorical variable and mean differences for continuous variables.

likely to make an informed choice regarding prenatal testing than those with a minimum of year 12 education. In the intervention arm, 14% (18/126) of women with lower educational levels made an informed choice compared with 12% (13/107) in the control arm. Consideration is being given to trialing a simpler form of the decision aid to decrease the time taken to read it, broaden the access of the decision aid to women of lower educational levels and facilitate translation to other languages for women from culturally and linguistically diverse backgrounds who were not well represented in this study.

A limitation of the study is the potential for selection bias due to women being recruited by GPs after the GPs had been randomised. However, the baseline characteristics of women were not markedly dissimilar between the trial arms, and potential confounding factors were identified *a priori* and adjusted for during analysis.

It is acknowledged that social class was not controlled for; however, a number of attributes associated with socioeconomic status were collected, and of these, we stratified by location (practice) and adjusted for education level.

The restriction of the sample to women who could speak English and the low participation rate of less educated women are recognised as limitations to the generalisability of the study. An audit of the eligible population attending participating GPs found no difference between women who participated in the trial and those who did not with respect to age and parity. Not surprisingly, participants were more likely to be born in Australia.

Notwithstanding the significant findings of the trial, there are still gains to be made in improving the informed choice of women considering prenatal testing.

Conclusion

At a time when utilisation of these tests is increasing, the ability to double the odds of women making an informed choice using a tailored resource rather than a generic pamphlet presents an easy to implement intervention to assist the decision making of women of all ages considering screening or diagnostic testing. This decision aid has proven helpful in increasing women's knowledge, particularly in improving women's understanding of numerical risk expression.

Demand for the decision aid from public maternity services and the private sector is high. Currently, the 2006 revised edition is being rolled out as part of a funded statewide pregnancy care education programme and continuing funding options including provision on a cost recovery basis are being considered.

Contribution to authorship

J.H. conceived the project. C.N., J.G., R.B., S.L., B.M., S.M. and J.H. designed the intervention and participated in the project and advised on study design and implementation. O.C.U., C.N. and S.L. conducted the analysis and together with J.G., R.B. and J.H. interpreted the data. C.N. wrote the article and all authors participated in revisions of the article.

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Supplementary material

The following supplementary materials are available for this article:

Appendix S1. Multidimensional Measure of Informed Choice.
Appendix S2. Decisional Conflict Scale.

These materials are available as part of the online article from: http://www.blackwell-synergy.com/doi/abs/10.1111/j.1471-0528.2007.01576.x.

(This link will take you to the article abstract).

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