A Randomized Controlled Trial of a Decision Aid for Women at Increased Risk of Ovarian Cancer

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Purpose**. To carry out a randomized controlled trial of a decision aid for women at increased risk of developing ovarian cancer to facilitate decision making regarding risk management options. **Methods**. This randomized trial, conducted through 6 familial cancer centers, compared the efficacy of tailored decision aid to that of a general educational pamphlet in preparing women for decision making. **Participants**. 131 women with a family history of breast and/or ovarian cancer or of hereditary nonpolyposis colorectal cancer. **Outcome measures**. Decisional conflict, knowledge about ovarian cancer risk management options, and psychological adjustment were reassessed at 3 time points. **Results**. Compared to those who received the pamphlet (control), women who received the decision aid (intervention) were significantly more likely to report a high degree of acceptability of the educational material at both follow-up assessment time points. Findings indicate neither group experienced significant increases in psychological distress at either follow-up assessment time points relative to baseline. Two weeks postintervention, the intervention group demonstrated a significant decrease in decisional conflict compared to the control group (*$t = 2.4$, $P < 0.025$*) and a trend for a greater increase in knowledge about risk management options (*$t = 2.1$, $P = 0.037$*). No significant differences were found 6 months postintervention. **Conclusion**. This form of educational material is successful in increasing knowledge about risk management options and in reducing decisional conflict in the shorter term. The decision aid is an effective and acceptable strategy for patient education to facilitate an inclusive and informed decision-making process about managing ovarian cancer risk. **Key words:** risk management; hereditary ovarian cancer; decision aid; randomized controlled trial. **(Med Decis Making 2006;26:360–372)

Women with a family history of breast/ovarian cancer syndrome or hereditary nonpolyposis colorectal cancer (HNPCC) are at increased risk of developing ovarian cancer, the most lethal form of gynecological malignancy.[1,2] These women have difficult decisions to make regarding management of that increased risk. Many health guidelines suggest surveillance methods such as annual screening in the form of transvaginal ultrasounds and/or CA-125 blood tests, or prevention methods such as taking oral contraceptive pills (OCP), or undergoing prophylactic oophorectomy as ways to reduce one's risk of developing ovarian cancer for certain high-risk women.[3-7] However, all these risk-reduction strategies have advantages and disadvantages,[8] and decisions regarding choice between these options may also be influenced by idiosyncratic values. When patients and physicians are faced with treatment decisions for which personal values and quality of life issues play a large role, patient participation is thought to be preferable.[9] For preventive treatment options particularly, shared decision-making is generally recommended because of the complicated balancing and compromising between the benefits and risks involved.[10] Given the paucity of firm evidence regarding the management options for individuals

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from high-risk families, there is an increasing need for the development and evaluation of educational materials that provide women with information and support during their decision-making process.

Decision aids are a practical strategy for patient education and have been developed as adjuncts to practitioners' counseling to facilitate patients' understanding of the advantages and disadvantages of treatment options, consideration of the personal importance they attach to the benefits and risks of each alternative, and to encourage active participation with their practitioners in deciding about options.[11,12] They have been developed to facilitate treatment decisions that share many of the features of the decisions that women at increased risk of ovarian cancer have to make. Therefore, this population of women may benefit from a decision aid to support them during their decision-making process. Studies indicate that decision aids are an effective strategy for patient education, are acceptable to both patients and clinicians, and help reduce decisional conflict.[11,13,14] A decision aid that covers much of the general information about surveillance and prophylactic strategies and associated risks and benefits may allow familial cancer clinic staff to concentrate on the provision of individualized advice and recommendations. A decision aid developed for women at increased risk for ovarian cancer may also be used to facilitate discussion between partners and family members, thereby allowing women to feel more supported during their decision-making process. In addition, it may lead to a better understanding of management issues, educated involvement in decision making, and increased consumer satisfaction.

METHODS

This study compared the efficacy of a tailored decision aid to that of a general educational pamphlet in preparing women at increased risk for ovarian cancer for decision making about screening and prophylactic options, and the following a priori hypotheses were tested. Compared to women in the control group (who receive the educational pamphlet), those in the intervention group (who receive the decision aid) will have the following:

1. Higher satisfaction with the educational materials in helping to reach a decision
2. Greater increases in knowledge of ovarian cancer risk management options
3. Greater decreases in psychological distress and decisional conflict

Intervention Material

The development process of the educational material designed specifically for this study has been explained in detail elsewhere.[15] In essence, the decision aid package consisted of a booklet and a separate values clarification exercise. The booklet contained information on the risk factors for ovarian cancer, the impact of family history on risk, issues of genetic testing, 4 options for managing increased risk (watchful waiting, screening, OCP, prophylactic oophorectomy), and the benefits and risks associated with each option. The values clarification exercise took the information presented in the booklet one step further by asking women to rate the importance of each risk and benefit as "leaning" toward each of the 4 management options, and it is included to facilitate a decision in line with personal values (see Figure 1). The decision aid was prepared in accordance with the National Health and Medical Research Council of Australia guidelines *How to Present Evidence for Consumers*.[16] Development was theoretically guided by the frameworks developed by O'Connor and others.[13,17-21]

A general educational pamphlet was designed as a control and is a précis of the information contained in

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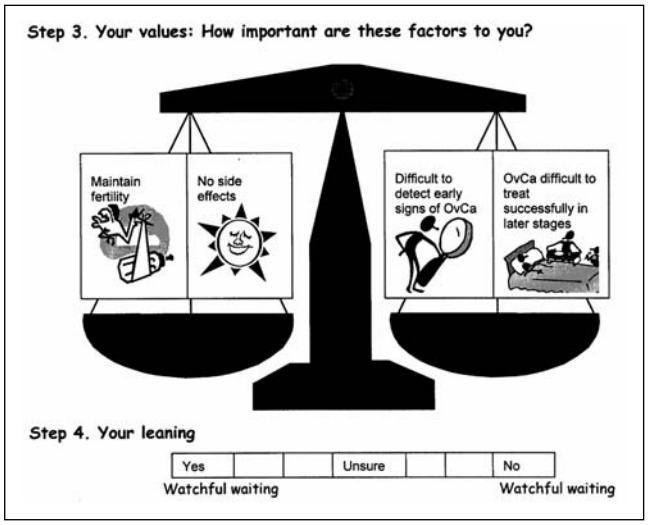

Figure 1 Example of a values clarification exercise in the decision aid. Women shade in a large portion of the box if the factor is very important to them and only a small portion if the factor is less important. OvCa = ovarian cancer.

the decision aid but does not include the strategies commonly used in decision aids, such as a values clarification exercise.

Participants

Eligibility criteria and recruitment procedures are outlined in detail elsewhere.[22] Briefly, the research sample included women from high-risk families who approached 1 of 6 participating familial cancer clinics in New South Wales and Victoria, Australia. These clinics provide risk assessment, advice about risk management options, and genetic testing where appropriate, according to national guidelines.[4] After face-to-face genetic counseling, women were invited to participate if they were at potentially high ovarian cancer risk and had discussed ovarian cancer screening and/or prevention at the familial cancer clinic.[22] Women also had to be aged 30 years or older and proficient in English, as assessment involved completing self-report questionnaires. Proven noncarriers of ovarian-cancer-related gene mutations (i.e., predictive genetic testing had identified the individual did not carry the *BRCA1/2* or HNPCC gene mutation) or those who had already undergone a bilateral oophorectomy were ineligible for participation, as were those who had previously been diagnosed with ovarian cancer. However, women affected with breast cancer or any other cancer associated with hereditary breast/ovarian cancer or HNPCC were not excluded from the sample.

Data were collected at 3 time points. Specifically, participants were asked to complete and return a baseline questionnaire approximately 2 weeks after attending the familial cancer clinic. When these questionnaires were returned, participants were randomized to receive either the decision aid or the pamphlet and sent the relevant educational material. The participants were blinded to the intervention type in that they were told that the purpose of the study was to compare 2 different types of educational material but were not told how the 2 types differed or which type they would receive. Follow-up questionnaires were mailed 2 weeks and 6 months postintervention.

MEASURES

Baseline Measures Only

Family history data and measures of objective risk of ovarian cancer were collected from familial cancer clinic staff following face-to-face counseling at the clinic, and data on sociodemographic characteristics were collected from participants.

Outcome Measures Administered at the 2nd and 3rd Time Points

Acceptability of the Educational Material

Acceptability of the pamphlet and decision aid was assessed by asking women to rate the overall comprehensibility of the educational material on a visual analogue scale, anchored by *poor* (0) and *excellent* (100).[19]

Use of the 2 Components of the Decision Aid Package

This item measured the extent to which the information booklet and/or the values clarification exercises were used. Participants were asked whether they used the information booklet of the decision aid package "thoroughly," "briefly," or "only the parts that were relevant to me" and whether they used the values clarification exercises "thoroughly," "briefly," or "only the parts that were relevant to me." This measure was included only in the questionnaires sent to the intervention group.

Perceived Helpfulness of Educational Material

Five items were also used to assess perceived helpfulness in 1) increasing understanding of ovarian cancer risk management options, 2) clarifying the risks and 3) benefits of each option, 4) helping participants to

reach a decision about ovarian cancer risk management, and 5) clarifying the decision-making process, using structured response categories ranging from *extremely helpful* to *very unhelpful*.[19] During analysis, this variable was recoded into a binary variable to reflect whether participants found the educational material *extremely helpful* or *very helpful* as opposed to *satisfactory* or *unhelpful*.

Outcome Measures Administered at All Time Points

Knowledge of Ovarian Cancer Risk Management Options

These 10 true-false items were developed from previous studies[22,23] and assess knowledge about screening and prophylactic measures for women at risk for ovarian cancer. One score was allocated for each correct answer, and scores added to derive a total score (range 0 to 10).

Intrusion Subscale of the Impact of Event Scale

The original Impact of Event Scale (IES) is a 15-item measure of intrusion and avoidance responses in relation to a specific stressor and has demonstrated psychometric qualities.[24] The 7-item Intrusion Subscale of the IES measures the frequency and severity of intrusive thoughts only. Previous studies have found that this subscale has good internal consistency (Cronbach's alpha = 0.88).[25,26] The Intrusion Subscale of the IES has also been shown to be associated with intention to undergo prophylactic oophorectomy and mastectomy[25,27] and to predict uptake of genetic testing.[28] In this study, the particular stressor was concern about being at risk of developing ovarian cancer. Participants were asked to rate symptoms of anxiety (for example, "I had strong waves of feelings about being at risk of ovarian cancer") on a scale ranging from *not at all* to *often*. Scores range from 0 to 35.

The Short-Form State-Trait Anxiety Scale

The 6-item State-Anxiety Scale assesses the presence or absence of temporary anxiety and has been adapted from the original Spielberger State-Trait Anxiety Inventory (STAI).[29] This shortened 6-item version of the STAI has been widely used in psychological research and practice and has demonstrated psychometric properties.[30] The STAI-State asks respondents to indicate how they feel "right now, at this moment" and to rate particular symptoms (for example, "I feel strained") on a scale ranging from *not at all* to *very much so*. Prorated scores range from 20 to 80.

Hospital Anxiety and Depression Scale

The Hospital Anxiety and Depression Scale (HADS) is a widely used measure of emotional disturbance and has 2 subscales measuring anxiety (HADS-A) and depression (HADS-D). Each item has response options ranging from 0 (*not at all*) to 3 (*very much*). This measure has been used extensively in cancer studies and has demonstrated reliability, sensitivity, and specificity.[31-34]

Decisional Conflict or Uncertainty Scale

This scale measures the degree to which an individual is uncertain or in conflict with the decision he or she has to make.[35] The scale includes 3 subscales eliciting 1) the participant's uncertainty about choosing among alternatives; 2) modifiable factors contributing to uncertainty, such as being uninformed and unclear about values and feeling unsupported in decision making; and 3) perceptions of effectiveness of decision making. Each item is paired with a 5-point Likert-type response scale, with scores that range from 1 (*strongly agree*) to 5 (*strongly disagree*). The scale is reliable,[36,37] can discriminate between those who make or who delay decisions, is responsive to change,[19,38] and discriminates significantly between different decision-supporting interventions.[19,39] The scale has high test-retest reliability (coefficient = 0.81), and internal consistency coefficients for the scale range from 0.78 to 0.92.[36]

For the purposes of this study, items were added to elicit patients' perceptions that they were informed about the risks and benefits of each of the 4 identified risk management options for ovarian cancer; that is, the risks and benefits of watchful waiting, screening, the OCP, and prophylactic oophorectomy. Modification of the original scales did not affect overall internal consistency (Cronbach's alpha = 0.84), or internal consistency for each of the subscales (Cronbach's alpha ranging from 0.75 to 0.87).

Outcome Measures Administered at the 3rd Time Point Only

Actual Decision

Participants were asked to indicate whether they made a decision regarding their risk management options, what decision that was, and whether they had followed through with that decision.

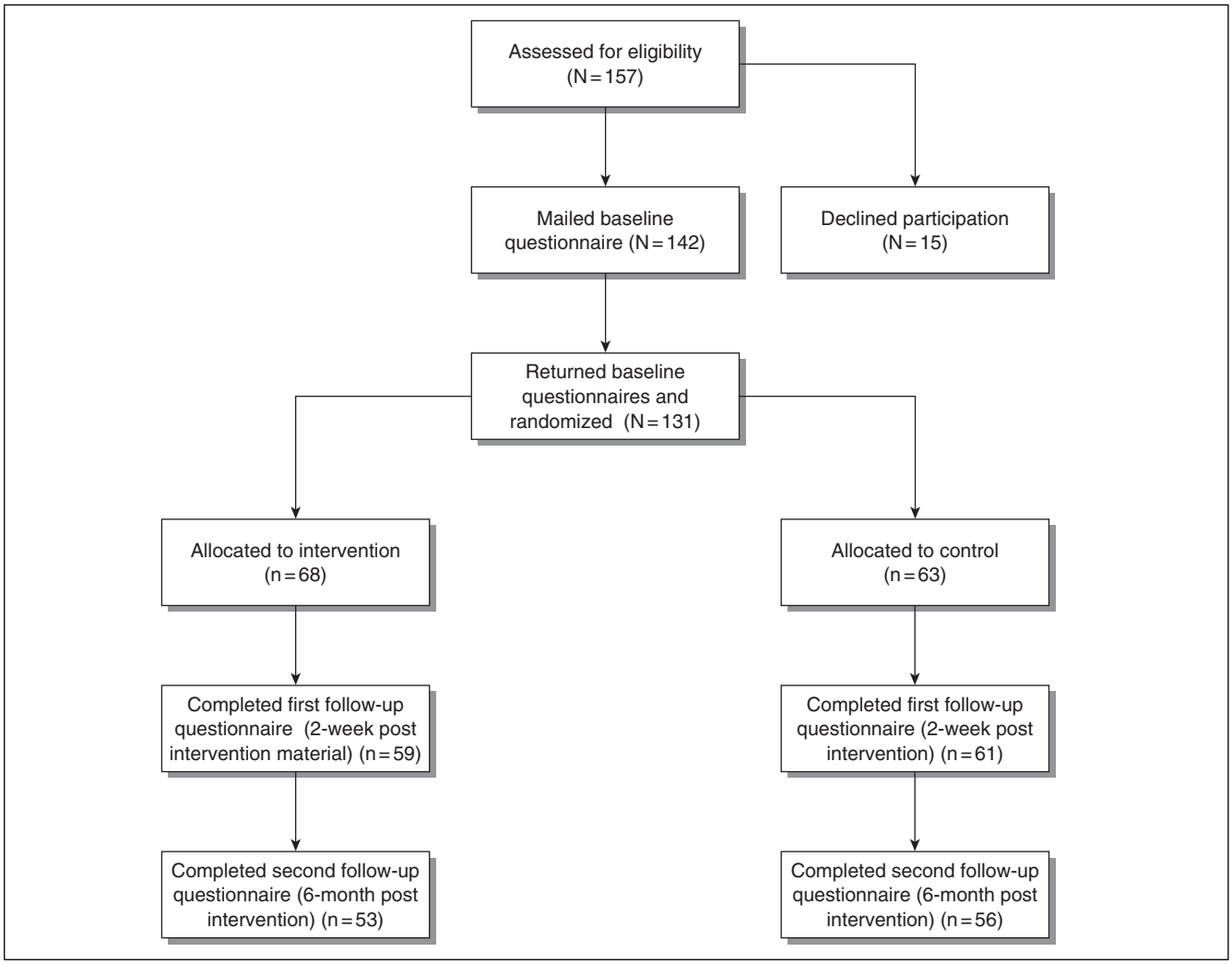

Figure 2 Flow diagram of the number of participants at each stage of the randomized controlled trial.

Influence on Decision

This item measured the extent to which women reported that their decision had been influenced by their gynecologist, geneticist, general practitioner, and/or information received as part of this study.

STATISTICAL ANALYSIS

Data were analyzed using SPSS 11.5 (Statistical Program for the Social Sciences) for univariate analyses and MlwiN version 1.02 for multilevel regressions.[40] Descriptive statistics were used to describe the sample in terms of sociodemographic, clinical, and psychological characteristics. Possible baseline differences between the intervention and control group were explored by comparing means of all sociodemographic, psychological, and decision-related variables. As this was a randomized controlled trial, these confounding variables were equally distributed in the intervention and control groups and, therefore, adjustment for confounders was unnecessary. This was followed by an "intention to treat" analysis on the effects of the randomized trial of decision aid provision. Chi-square analyses (for categorical variables) and independent *t* tests (for continuous variables) were employed to test for differences between groups.

A repeated measures linear regression was also conducted to explore the differences in psychological outcomes between groups. This analysis was undertaken

Table 1 Comparison of Sociodemographic, Family History, and Disease Status Variables between Intervention and Control Groups

Variable	Intervention (Decision Aid) (n = 68)	Control Pamphlet) (n = 63)	P
Age	Mean = 45.8	Mean = 46.3	0.76
Education, %			
No postschool	28.80	29.0	0.80
Postschool	71.20	71.00	
Completed family	93.70	86.9	0.20
Marital status, %			
Married	88.10	87.1	0.86
Not married	12.10	12.70	
Family history, %			
No ovarian cancer in family history	25.80	28.6	0.94
Ovarian cancer in family history	74.20	71.40	
Total no. of relatives diagnosed with ovarian cancer, %			
1 or less	70.30	62.3	0.44
2 or more	29.70	37.70	
Disease status, %			
Affected	51.50	52.4	0.91
Unaffected	48.50	47.60	

using multilevel modeling, which is appropriate when there are differing numbers of observations per patient. Such models consider repeated observations (level 1) to be "nested" within patients (level 2).[40]

A Bonferroni adjustment for multiple tests was made to adjust for the fact that 2 tests were performed for different time points for each outcome measure; hence P was set at 0.025. Effect sizes for differences between groups in outcome measures were also calculated for each time point.

RESULTS

Figure 2 provides an overview of the participation rate at each assessment point. A total of 157 women were eligible for the study and invited to participate. Ten women immediately declined to participate, and a further 5 declined participation when telephoned by the research staff. An additional 11 women failed to return the baseline questionnaire, yielding a response rate of 83%. Of the 131 who returned the baseline questionnaire, 109 also returned the 6-month follow-up questionnaire, giving an overall response rate of 69.4%.

Table 1 shows sociodemographic characteristics and family history variables separately for each group. There were no important differences between the groups in terms of sociodemographic and family history characteristics, disease status, and baseline decision-related and psychological variables, indicating that randomization was successful in spreading potential confounding variables equally between the 2 groups.

Analysis of Participation Bias

Women who completed both the baseline and the 6-month follow-up questionnaires (n = 109) were compared to those who did not (n = 22). The groups did not differ in respect to demographics, psychological measures, or in baseline preferences for information. Therefore, no evidence of participation bias follow-up was detected.

Acceptability of Educational Material

A high degree of acceptability of the educational material was reported by both the intervention group (mean rank = 68.7) and the control group (mean rank = 51.6) 2 weeks after receipt of materials. However, women randomized to receive the intervention were significantly more likely to report a high degree of acceptability (Z = –2.7, P = 0.006). Six months postintervention, this finding remained significant (Z = –2.5, P = 0.010).

With respect to amount of information, a trend was observed for women in the control group to indicate that the amount they received was insufficient compared to the intervention group at 2 weeks (32.8% v. 17.2%, χ^2 = 4.6, P = 0.051); this difference

Table 2 Mean Knowledge, Psychological, and Decisional Conflict Outcome Scores by Group (Raw scores) at All 3 Assessment Times

	Baseline		2 Weeks Postintervention		6 Months Postintervention	
Measure	***n***	**Mean (*SD*)**	***n***	**Mean (*SD*)**	***n***	**Mean (*SD*)**
Knowledge score						
Decision aid	68	6.4 (2.3)	59	9.2 (1.0)	40	8.0 (1.6)
Pamphlet	63	6.3 (2.1)	61	8.5 (1.9)	47	7.5 (1.8)
IES (Intrusive)						
Decision aid	68	6.2 (6.9)	59	6.2 (6.3)	52	5.0 (7.3)
Pamphlet	63	5.6 (6.6)	61	5.8 (7.0)	56	5.6 (7.4)
STAI-short						
Decision aid	65	39.9 (14.7)	58	38.2 (13.4)	53	35.7 (9.0)
Pamphlet	61	39.1 (15.1)	60	38.0 (15.2)	55	36.2 (13.6)
HADS (total score)						
Decision aid	68	11.5 (5.4)	58	10.9 (5.6)	50	10.1 (4.7)
Pamphlet	63	11.3 (6.1)	61	10.7 (6.4)	56	10.8 (6.4)
DCS (total score)						
Decision aid	68	2.7 (0.6)	58	2.07 (0.5)	51	1.9 (0.5)
Pamphlet	62	2.6 (0.6)	61	2.21 (0.5)	55	2.1 (0.5)

Note: IES = Impact of Event Scale; STAI = State-Trait Anxiety Inventory; HADS = Hospital Anxiety and Depression Scale; DCS = Decisional Conflict Scale.

became statistically significant 6 months postintervention (33.3% v. 11.3%, $\chi^2 = 7.4$, $P = 0.006$).

Use of the 2 Components of the Decision Aid Package

Data were analyzed to ascertain whether each part of the decision aid (the information booklet and the values clarification exercise) was used thoroughly, briefly, or partly by the intervention group. Results indicate that the majority of those who received the decision aid used both parts thoroughly. Eighty-eight percent reported that they read the booklet thoroughly, 8.6% read just the parts that were relevant to them, and the remaining 3.4% used the booklet briefly. For the values clarification exercise, 57.6% indicated that they used it thoroughly, 22.0% used it briefly, and 20.4% used just the parts that were relevant to them.

Perceived Helpfulness of Educational Material

Two-week postintervention results indicated no significant differences between groups with regard to perceived helpfulness of educational material. Those who received the decision aid were no more likely to report that they found it helpful in increasing understanding about the options ($\chi^2 = 0.52$, $P = 0.46$), in clarifying the risks ($\chi^2 = 2.42$, $P = 0.12$) or benefits ($\chi^2 = 2.42$, $P = 0.12$) of each option, or in helping reach a decision ($\chi^2 = 2.00$, $P = 0.15$) than women who received the pamphlet. However, a trend was observed for a difference between groups in reported helpfulness of the educational material in clarifying the decision-making process 2 weeks postintervention. Women randomized to receive the decision aid reported a greater degree of perceived helpfulness in clarifying the decision-making process than did women who received the pamphlet ($\chi^2 = 4.3$, $P = 0.037$).

Six-month postintervention results indicated significant differences between groups with regard to perceived helpfulness of educational material. Those who received the decision aid were significantly more likely to report a greater degree of perceived helpfulness in increasing understanding about risk management options ($\chi^2 = 5.4$, $P = 0.019$) and in clarifying the risks ($\chi^2 = 7.0$, $P = 0.008$) and benefits ($\chi^2 = 8.0$, $P = 0.005$) of each option, compared to those who received the pamphlet. There was also a trend for those in the intervention group to report a greater degree of perceived helpfulness in clarifying the decision-making process ($\chi^2 = 2.9$, $P = 0.087$) and in making a decision ($\chi^2 = 3.1$, $P = 0.074$) compared to those who received the pamphlet.

Psychological Measures

Table 2 provides a summary of the mean knowledge, intrusive thoughts about ovarian cancer, state anxiety, depression, and decisional conflict scores at

Table 3 Differences in Psychological Outcomes between Groups ($N = 131$)

Group-by-Time Effect[a]	Mean Difference[b]	*t* Value	*P* Value	Effect Size
Knowledge scores				
Group × Time effect (2 weeks postintervention)	0.71	2.16	0.037	0.45
Group × Time effect (6 months postintervention)	0.57	1.63	0.14	0.29
Intrusive thoughts about ovarian cancer				
Group × Time effect (2 weeks postintervention)	−0.20	0.18	0.85	0.06
Group × Time effect (6 months postintervention)	−1.10	0.86	0.39	0.08
State anxiety				
Group × Time effect (2 weeks postintervention)	−0.76	0.37	0.71	0.01
Group × Time effect (6 months postintervention)	−1.59	0.74	0.42	0.04
HADS (total score)				
Group × Time effect (2 weeks postintervention)	−0.13	0.20	0.83	0.03
Group × Time effect (6 months postintervention)	−0.63	0.90	0.36	0.12
DCS				
Group × Time effect (2 weeks postintervention)	−0.31	2.40	0.017*	0.28
Group × Time effect (6 months postintervention)	−0.13	0.99	0.32	0.40

Note: HADS = Hospital Anxiety and Depression Scale; DCS = Decisional Conflict Scale.
a. Reference group is control group (pamphlet).
b. Average difference from the referent group and the parameter under consideration.
*$P < 0.025$ (P value adjusted for multiple testing).

each of the assessment time points. As illustrated, at baseline there are no significant differences between groups with regard to the main outcome measures, although those randomized to receive the decision aid did report higher levels of ovarian cancer–related anxiety.

Knowledge of Cancer Risk Management Options

Table 3 shows the group-by-time effects of the final regression models for knowledge of ovarian cancer risk management options, intrusive thoughts about ovarian cancer, state anxiety, depression, and decisional conflict over the 3 time points.

A trend was observed for women who received the decision aid to report greater knowledge of ovarian cancer risk management options 2 weeks postintervention ($t = 2.2$, $P = 0.037$), compared to women who received the pamphlet. No differences were found 6 months postintervention ($t = 1.6$, $P = 0.14$). The effect size differences between groups were 0.45 and 0.29 two weeks and 6 months postintervention, respectively, indicating small to medium effect size differences in knowledge scores.

Differences in Psychological Outcomes between Groups

No significant differences between groups were observed for any of the psychological outcomes (intrusive thoughts about ovarian cancer, state anxiety, and depression) 2 weeks or 6 months postintervention.

Decisional Conflict

Women who received the decision aid had significantly lower decisional conflict scores 2 weeks postintervention ($t = 2.40$, $P = 0.017$). Although decisional conflict continued to decrease, no significant differences between groups were found 6 months postintervention ($t = 0.99$, $P = 0.32$); however, a small to medium effect size difference in decisional conflict scores was found between groups.

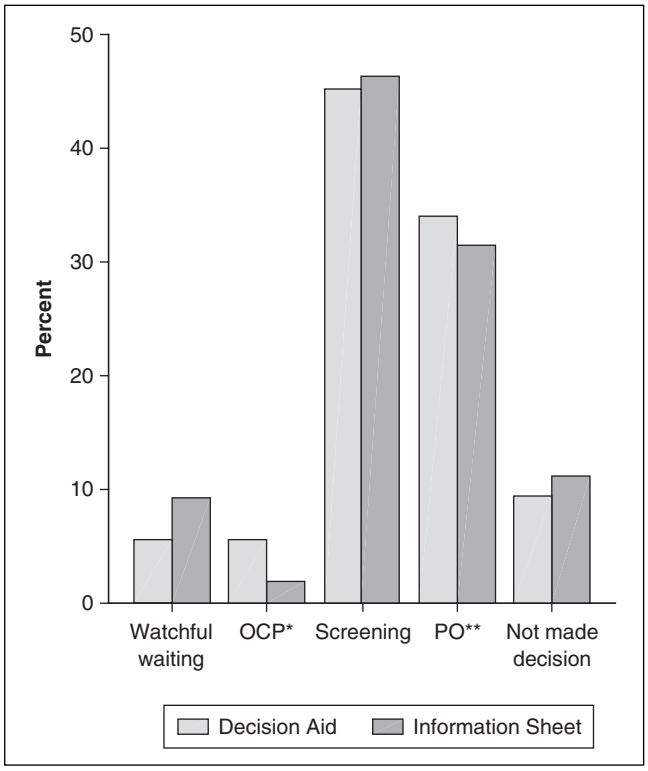

Figure 3 Differences between groups in decision 6 months postintervention.
*Oral contraceptive pill.
**Prophylactic oophorectomy.

Actual Decision

No significant differences were found between groups 6 months postintervention with regard to actual decision. The number of women who had opted for prophylactic surgery since receipt of the educational materials was split almost evenly, with 17 in the control group and 18 in the intervention group. The number of participants who indicated they still had not made a decision was also equally distributed across the 2 groups ($\chi^2 = 1.63$, $P = 0.8$). Figure 3 illustrates the risk management options selected by each group.

Influences on Decision

Participants were asked to what extent their decision had been influenced by their gynecologist, geneticist, general practitioner, and/or information received as part of this study. No differences between groups were found with regard to the extent to which the 1st 3 had influenced their decision.

Table 4 Differences between Groups in Perceived Degree of Influence of Different Health Professionals and Study Materials on Decision

Influence on Decision	A Little %	A Lot %	*P*
Gynecologist			
Decision aid	64.9	35.1	0.11
Control	50	50	
Geneticist			
Decision aid	27.1	72.9	0.21
Control	17.5	82.5	
General practitioner			
Decision aid	58.6	41.4	0.31
Control	67.9	32.1	
Study information			
Decision aid	19	81	0.004
Control	44.1	55.9	

However, a significant difference was found between groups in the extent to which information received as part of the study had been influential (see Table 4). Those who received the decision aid were significantly more likely to indicate that the information had influenced their decision quite a lot or very much, compared to those who received the pamphlet ($\chi^2 = 8.5$, $P = 0.004$).

DISCUSSION

This study assessed the effectiveness of a decision aid in preparing women at increased risk of ovarian cancer for decision making about their options regarding management of that risk. Findings indicate that the decision aid is more acceptable as educational material than an information pamphlet. Those who received the decision aid were significantly more likely to report a high degree of acceptability at both 2 weeks and 6 months postintervention, indicating an enduring effect. This lends support to the previous research that demonstrates patients want as much information as possible about "their" disease[41,42] and that the amount of information contained in the decision aid was appropriate for the majority of women.

As the decision aid package was in 2 parts it was also important to ascertain if the values clarification exercise (Part 2), an intrinsic aspect of a decision aid, was used or if participants just used the information booklet (Part 1) as reference material and did not access the values clarification exercise. The results from this current study demonstrated that the information booklet was used thoroughly by the majority of participants (88%), whereas nearly 60%

used the values clarification exercise thoroughly, indicating that this aspect of the decision aid is an accessible and a successful aspect of the decision aid, thus supporting previous research.[13,43,44]

The findings from this study illustrate the complex nature of decision making regarding risk management options. In the longer term, the decision aid was significantly more helpful than the pamphlet in increasing understanding of ovarian cancer risk management options, in clarifying the benefits and risks of each option, and in helping participants to reach a decision about ovarian cancer risk management options. The issues surrounding ovarian cancer risk management decisions are particularly complex, and the decision aid was designed to deconstruct the decision-making process and facilitate focusing on the key issues that needed consideration.[45] The participants had more time over the 6 months to reflect on their decision-making process, and it appears that it is here, in the longer term, that the decision aid revealed its superiority over the educational pamphlet.

These longer term findings are consistent with the high degree of acceptability of the decision aid as educational material and may be indicative of the cumulative effect of the informed decision-making process encouraged by the decision aid. If individuals are satisfied with their decision-making process, they may be more understanding of the fact that good decisions sometimes have bad outcomes and accept that the decision was the best that they could have made at that time.[46] This highlights the importance of identifying "good" decisions by the process by which they are made, rather than by the outcome.[47-50]

Knowledge of Ovarian Cancer Risk Management Options

The findings here also demonstrate that the decision aid may influence different aspects of decision making. At the 1st follow-up, a trend was found for women who received the decision aid to have greater knowledge of ovarian cancer risk management options compared to those who received the pamphlet. Although not statistically significant, we found a medium effect size difference, which we considered clinically significant. This lends partial support to our hypothesis and is in line with the Cochrane review of 23 randomized controlled trials of decision aids, which concluded that decision aids perform better than usual care or alternative interventions in improving knowledge.[13,14] Although not significant in the longer term, knowledge scores still remained high, and so it may be appropriate to encourage women to review the decision aid to refresh their knowledge of risk management options when reassessing their decision due to changing life circumstances.

Psychological Outcomes

There are differing opinions in the literature with regard to provision of information and the effect it may have on anxiety. Some contend that providing patients with detailed information may raise anxiety.[51-53] Others argue that if patients believe they have not received enough information about treatment options, higher levels of anxiety and depression may be experienced posttreatment.[54-56] This study found no significant differences between groups in psychological outcomes at either follow-up. It is reassuring that the amount of information provided in the decision aid did not increase distress. Indeed, this finding is consistent with the aforementioned Cochrane review, which found no increase in anxiety with the use of decision aids[14] and lends support to the view that provision of adequate information does not appear to have adverse psychological effects.

To the authors' knowledge, this is the 1st study to measure the impact of a decision aid on cancer-related distress, which is a potentially more sensitive measure of emotional outcome than generalized anxiety. For example, receipt of a genetic testing result was found to impact cancer distress among carriers, whereas other psychological outcomes remained unchanged.[57-59] The results of this randomized controlled trial confirm that decision aids impact knowledge and decision-related outcomes, whereas emotional outcomes remain largely unaffected, confirming results from previous Cochrane reviews.[14]

Decisional Conflict

This study found that those who received the decision aid reported significantly lower decisional conflict compared to the control group at 2 weeks postintervention, thus supporting our hypothesis in part. This replicates findings of previous research on the effectiveness of decision aids in reducing decisional conflict.[11,13,18,60] Understanding about complex issues may provide a feeling of cognitive control, but many patients also desire emotional control over the decision they make, that is, to be "at peace" with the choice made and its consequences.[46] Our short-term results show that those who received the decision aid experienced a reduction in decisional conflict, indicating that they may have gained emotional control over their decision. Again, this effect was not

maintained in the longer term, which lends support to encouraging women to revisit the decision aid if reassessing their decision due to changing life circumstances.

Actual Decision

The decision aid did not appear to make a difference in whether participants reached a decision or not. Although our hypothesis was not supported, this finding is compatible with previous research[13] and with earlier findings from this study that a small number of women also remained undecided regardless of the degree of hypothetical risk they were at of developing ovarian cancer.[22] This suggests that for a small minority of women, risk management decisions remain difficult no matter what.

Influences on Decision

Those who received the decision aid were significantly more likely to indicate that the information they received as part of the study had influenced their decision compared to those who had received the pamphlet. This may be because the decision aid was seen as a comprehensive review, covering all the issues regarding ovarian cancer risk management. This finding indicates that the decision aid was highly influential in the decision-making process, and it emphasizes the value of using guidelines when developing decision aids to ensure a high standard.[21]

The limitations of this study should be mentioned. The study sample was more highly educated than the general population, which has implications for generalizing the findings to a wider population. Nevertheless, this is consistent with previous studies concerning women who access familial cancer services.[61,62] Women of a lower education level might have difficulty in understanding the inherently complicated information contained in the decision aid. However, the decision aid is designed not to be used in isolation but in addition to expert counseling by an appropriate clinician to facilitate the understanding of this complex issue.

CONCLUSION

To summarize, this study found that the decision aid worked on different aspect of the decision-making process at different times. Shorter term, it was superior in decreasing decisional conflict and increasing knowledge about options. Longer term, it was perceived as being significantly more helpful and acceptable as a form of educational material than the pamphlet.

To the best of the authors' knowledge, this is the first study that has tested a decision aid for ovarian cancer risk management strategies in a randomized controlled trial design involving women at increased risk for this disease. As with previous research on decision aids, the results of this present study indicate that this form of educational material is successful not only in increasing knowledge about risk management options but also in reducing decisional conflict and allowing women to feel supported during their decision-making process.

Future research on developing educational material may benefit from focusing on and refining the most effective components of decision aids. For example, a values clarification–type exercise appears not only to facilitate clarification of personal values but also to encourage retention of the information contained in the educational material. It may also be useful for future research to explore the acceptability of decision aids for diverse patient groups and the impact that decision aids have on patient-clinician communication and on adherence to the decision. To this end, a longer term follow-up period may be required for future studies. Providing good-quality patient educational material, designed to supplement genetic counseling, allows people to take information home and digest it at their own pace. It also encourages communication not only between the individual and the clinician but also between the individual and other family members. In the context of hereditary cancer, genetic vulnerability, and risk management decisions, this is essential.

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