

Randomized Trial of a Decision Aid for Individuals Considering Genetic Testing for Hereditary Nonpolyposis Colorectal Cancer Risk

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BACKGROUND. Despite the potential benefits of genetic testing for hereditary nonpolyposis colorectal cancer (HNPCC) risk, individuals can find the genetic testing decision-making process complicated and challenging. The goal of the current study was to measure the effectiveness of a tailored decision aid designed specifically to assist individuals to make informed decisions regarding genetic testing for HNPCC risk.

METHODS. In all, 153 individuals were randomized to receive the decision aid or a control pamphlet at the end of their first genetic counseling consultation. Of these, 109 (71.2%) completed the first questionnaire 1 week after consultation, whereas 95 (62.1%) completed the 6-month follow-up questionnaire.

RESULTS. Although the decision aid had no significant effect on postdecisional regret or actual genetic testing decision, the trial results demonstrated that participants who received the decision aid had significantly lower levels of decisional conflict (ie, uncertainty) regarding genetic testing (chi-square(1) = 8.97; $P = .003$) and were more likely to be classified as having made an informed choice concerning genetic testing (chi-square(1) = 4.37; $P = .037$) than participants who received a control pamphlet. Also, men who received the decision aid had significantly higher knowledge levels regarding genetic testing compared with men who received the control pamphlet, whereas no such differences were found for women (chi-square(2) = 6.76; $P = .034$).

CONCLUSIONS. A decision aid for individuals considering genetic testing for HNPCC is an effective intervention to reduce uncertainty and assist individuals to make an informed choice regarding genetic testing for HNPCC after genetic counseling. *Cancer* 2008;113:956-65. © 2008 American Cancer Society.

KEYWORDS: hereditary nonpolyposis colorectal cancer, genetic testing, decision aid, patient education.

Up to 7% of colorectal cancers involve a family history consistent with hereditary nonpolyposis colorectal cancer (HNPCC).¹ HNPCC is an autosomal dominant disorder that involves the occurrence of colorectal cancer (CRC) and related cancers in multiple members of 2 or more generations of a family, as well as the presen-

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tation of CRC at an early age.² Inherited mutations in at least 4 mismatch repair genes (hMSH2, hMSH6, hMLH1, and PMS2) that confer a predisposition to HNPCC have been identified. The estimated risk of CRC by age 70 years conferred by HNPCC-related mutations is up to 80% in males and 30% to 80% in females.³ Female carriers of HNPCC-related mutations also have an estimated lifetime risk of ovarian and endometrial cancer of up to 10% and 40%, respectively.¹

Genetic testing in individuals with a strong family history of HNPCC-related cancers can establish whether an individual carries a mutation in 1 of the HNPCC-related mismatch repair genes. There are generally 3 stages involved in genetic testing for HNPCC. First, if available, the tumor of an affected family member can be screened for the presence of indicators that increase the chance of the tumors being related to HNPCC. Second, if the tumor test indicates the possible presence of HNPCC, blood is collected from an affected individual for a 'mutation search,' whereby the HNPCC-related genes are examined for pathogenic mutations. Finally, if a causative mutation is identified in an affected family member, then other adult at-risk family members who are unaffected by cancer can be offered a 'predictive' genetic test to determine whether or not they carry the family-specific mutation.

Given the increasing utilization of genetic testing, evidence suggests that high-quality patient education materials are needed to assist individuals to understand the benefits, risks, and limitations of genetic testing for HNPCC-related mutations. Kinney et al,⁴ for example, found that individuals with CRC and their first-degree relatives lacked knowledge concerning cancer genetics and expressed a desire for information describing the benefits, costs, and limitations of genetic testing for CRC susceptibility.

The benefits of genetic testing include the potential for carriers of an HNPCC-related mutation to reduce their risk of developing cancer through screening and preventative measures. CRC screening has proven highly efficacious.⁵ Consequently, mutation carriers are recommended annual or biannual colonoscopies from age 20 to 25 years, or from 10 years before the earliest occurrence of CRC in the family.^{1,2} Prophylactic colectomy has also been discussed as a potential management strategy for carriers, although this strategy is more controversial.³ Unfortunately, although receiving a positive genetic test result increases participation in colonoscopy, greater than half of mutation carriers describe colonoscopies as painful or unpleasant.⁶ Thus, an additional benefit of genetic testing is that individuals

proven to be noncarriers do not need to undergo the invasive and expensive increased surveillance offered to carriers.⁶ The majority of studies on the psychological impact of genetic testing for HNPCC demonstrate that genetic testing leads to a decrease in CRC distress, anxiety, and depression in the long term, even if it indicates carrier status.⁷

Despite the benefits described above, several features of HNPCC complicate decision-making regarding genetic testing. First, whereas CRC screening efficacy has been proven, the effectiveness of screening and risk reduction strategies for other HNPCC-related cancers is currently unknown. Strategies to reduce ovarian cancer risk for female mutation carriers include the oral contraceptive pill and internal ultrasound of the ovaries, with or without a CA 125 blood test.¹ Unfortunately, these strategies have not proven efficacious in reducing mortality in this group of women.⁸ Consequently, bilateral prophylactic salpingo-oophorectomy (removal of the ovaries and fallopian tubes) is also considered a potential risk management strategy for carriers.⁹ Likewise, evidence for the efficacy of endometrial ultrasound in reducing endometrial cancer risk is lacking, meaning that prophylactic hysterectomy is also considered a valid risk management strategy for mutation carriers.^{9,10} Although these measures may be effective in reducing risk, both strategies are invasive, may have adverse psychosocial impacts, and pose a particular dilemma for women who may not have completed their families.¹¹ Second, individuals considering genetic testing for HNPCC risk also need to consider the impact of testing on their family, their need to communicate results within the family, and the potential for family conflict caused by this process.¹² As well, an individual's genetic testing decision-making may be affected by concerns regarding the impact of a positive result on the individual's, and their offspring's, life insurance options.⁴ Some individuals may also feel concerned regarding other forms of discrimination, although it should be noted that very little coordinated empirical research is currently available that documents the extent of genetic discrimination.¹³

Decision Aid for Individuals Considering Genetic Testing for HNPCC Risk

Given the complexity of the potential benefits and limitations of genetic testing for HNPCC risk, a decision aid (DA) for individuals considering genetic testing for HNPCC was developed. Decision aids are aimed at facilitating decision-making and improving patients' understanding of the potential benefits and risks of their different options, as well as assisting

patients to consider the personal importance they place on each of these options.¹⁴ A recent Cochrane Review showed that, although hundreds of DAs have been developed for health-related decisions, none are currently available worldwide for individuals considering genetic testing for HNPCC.¹⁴ The development and evaluation of the DA was theoretically guided by the frameworks developed by O'Connor and colleagues.¹⁵

The 40-page DA provides balanced information concerning 3 options: not undergoing testing, undergoing testing, or deciding to consider the issue at a later date. Topics addressed include background information regarding HNPCC and genetic testing, possible test results, and the potential impact of testing on the individual and their family. The DA explains the evidence available on HNPCC-related cancer risks, the differences between mutation search and predictive testing, and the potential benefits, risks, and limitations of testing. The DA concludes with 2 patient stories and a blank personal worksheet (values clarification exercise) is provided for individuals to list and rate the importance of the pros and cons of genetic testing in their situation. A more detailed description of the DA is provided in Wakefield et al.¹⁶

The goal of the current study was to evaluate a DA for individuals considering genetic testing for HNPCC risk in a randomized controlled trial. It was hypothesized that compared with individuals receiving the standard best practice (a general educational pamphlet), those who received the DA would have: 1) decreased decisional conflict regarding genetic testing (primary outcome); 2) increased knowledge concerning genetic testing for HNPCC risk; and 3) an increased rate of informed choice.

MATERIALS AND METHODS

Participants

Participants included men and women (both affected and unaffected by cancer) who approached 1 of 6 Australian familial cancer clinics participating in this study. Individuals are referred to these clinics by general practitioners, oncologists, and surgeons who become aware of, or concerned about, a patient's family history of cancer.

To be eligible to participate in the study individuals were: 1) eligible for genetic testing in Australia, that is, individuals with a family history consistent with HNPCC who have an affected, living relative willing to provide a blood sample¹⁷; 2) able to provide informed consent; 3) able to read English; and 4) aged ≥ 18 years.

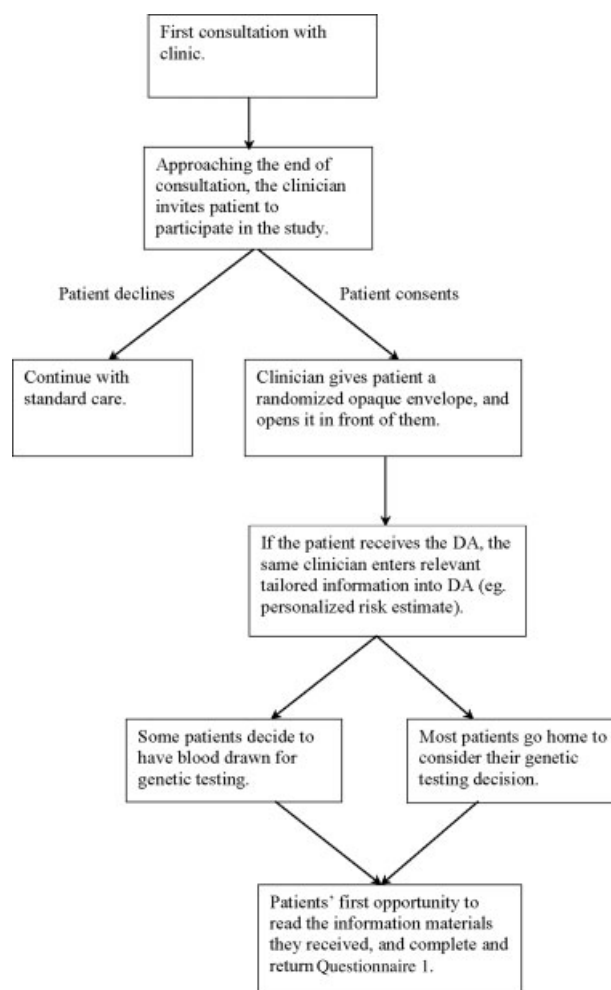


FIGURE 1. Flowchart detailing recruitment process. DA indicates decision aid.

Procedures

The human research ethics committee responsible for each clinic approved the study and informed consent was obtained from all participants. The efficacy of the DA was compared with that of an educational pamphlet currently used in most clinics in Australia.¹⁸ The 4-page pamphlet is comparable to the DA in describing HNPCC, its pattern of inheritance, and the benefits and risks of genetic tests. However, it does not include characteristic DA features, such as balanced information describing different decision options, patient stories, and a values clarification exercise.

Figure 1 presents a flowchart of the recruitment process. Consent to participate was sought by clinic staff toward the end of each eligible patient's initial consultation. Those who agreed were given a prerandomized envelope containing the DA or the control pamphlet, a consent form, the first questionnaire,

and a reply-paid envelope. They were asked to complete and return the questionnaire within 7 days after counseling.

Participants were randomized according to family-wise randomization. That is, all patients who were the first of their family to attend the clinic were randomly allocated to the control or DA condition. Subsequent members of the same family were then assigned to the same condition as their other family members to prevent potential contamination across groups. Six months after consultation, a second questionnaire was mailed to assess any longer-term effect of the DA.

Measures

Staff at familial cancer clinics provided the following data.

Type of genetic test

Clinicians indicated whether the participant was considering either tumor-testing or mutation search (considered by individuals with a previous diagnosis of HNPCC-related cancer) or predictive testing (considered by individuals unaffected with cancer). For predictive testing the clinician indicated whether a family-specific mutation had already been identified, and if not, whether a mutation search had commenced in the family.

Disease status

Participants were classified as affected or unaffected by an HNPCC-related cancer, and if unaffected, their mutation carrier risk was given.

Blood drawn

Staff noted whether or not blood was drawn on the day of the first consultation. This was an important variable, as it determined whether the participant was able to read the DA or control pamphlet before having blood drawn for testing. In most Australian clinics it is standard practice to allow a 'cooling off' period after the consultation before drawing blood. In some clinics, however, and in other individual cases, blood may be drawn immediately after the first consultation following patient requests.

The initial questionnaire for participants elicited:

1. *Demographic characteristics.* Including age, educational level, previous medical or health training and marital status.
2. *Reading the materials.* Participants were asked how thoroughly they read the information materials they received (response options included: "from cover to cover," "thoroughly," "briefly," "just the relevant parts," and "not at all").

3. *Decisional conflict.* The Decisional Conflict Scale (DCS) was used to assess uncertainty regarding choosing among alternatives.¹⁹ It has 4 subscales that assess modifiable factors contributing to decisional conflict, including feeling informed, being clear with regard to values, feeling supported in decision-making, and feeling certain about the decision.²⁰
4. *Knowledge of genetic testing.* Eight true-false items were purposively designed for this study and assessed knowledge regarding the genetic testing process, and the benefits, risks, and limitations of genetic testing.
5. *Multidimensional Measure of Informed Choice (MMIC).* This scale classifies respondents as having made an informed or uninformed choice. An informed choice is one based on relevant knowledge, consistent with the decision maker's values and behaviorally implemented.²¹
6. *Family involvement.* Two items assessed the extent to which other family members read the information materials (response options ranged "from cover to cover" to "briefly" for each family member named) and the extent to which other family members were involved in their decision-making process (response options ranged from "extremely involved" to "a little involved" for each family member named).
7. *Impact of Event Scale (IES).* The 15-item IES was used to measure the frequency and severity of intrusive and avoidant thoughts about being at risk of developing HNPCC-related cancers.²²
8. *Hospital Anxiety and Depression Scale (HADS).* The HADS is a 14-item self-report scale that requires respondents to choose between 4 responses that most closely describe how they have been feeling in the past week.²³
9. *Genetic testing decision.* One item asked participants about their decision regarding genetic testing. To reduce the demand for potentially sensitive information, participants were not asked about their test results.

The second questionnaire collected data on measures 2 to 9 described above, as well as the:

10. *Decision Regret Scale (DRS).* The 5-item DRS assesses level of healthcare decision regret, and has good internal consistency and validity.²⁴

Data Analysis

An 'intention to treat' analysis on the effects of the randomized trial of DA provision was conducted. Data were analyzed using SPSS 14.0²⁵ and STATA 9.2²⁶ software. Because DCS and regret scores were

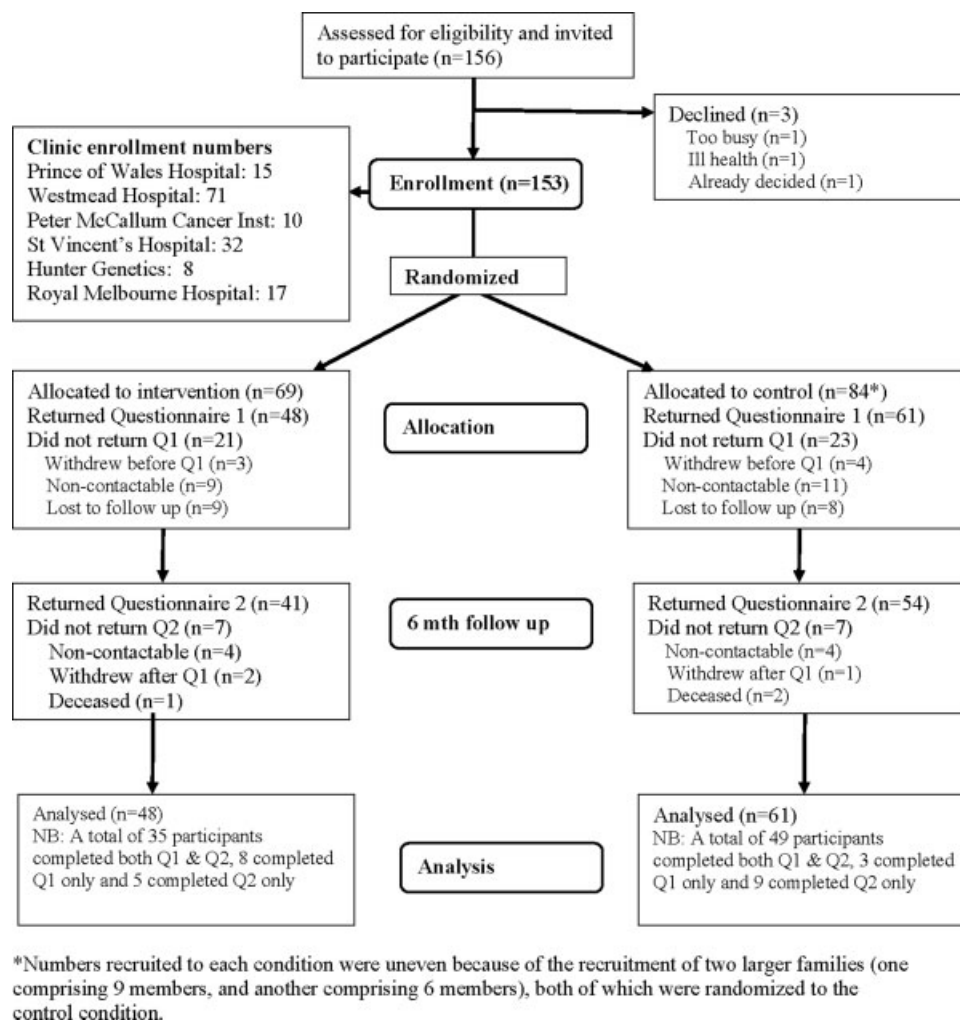


FIGURE 2. Participant flow. Q1 indicates Questionnaire 1; Q2, Questionnaire 2.

highly skewed, these variables were recoded into binary dichotomous variables. Similarly, knowledge was recoded into a categorical variable with 3 levels (low, medium, and high knowledge).

To take account of the family-wise randomization, observations from the same family were treated as clusters using the method described by Williams.²⁷ This approach improves the accuracy of the analysis by taking into account the finding that observations from the same cluster (or family) are likely to be more correlated than data collected from independent observations (or individuals). A Bonferroni adjustment for multiple tests was not used, as we wanted to control for Type 1 error at a 0.05 level of significance for each dependent variable separately. All tests conducted were 2-tailed. Extensive data analysis revealed no significant differences between scores for participants considering tumor-testing, mutation search, or predictive testing on any of the

dependent variables. In addition, analysis of all 2-way interactions revealed that the DA did not have a significantly different effect on the 3 groups of participants for any dependent variable, so the groups were combined for analysis.

The analyses used binary logistic regression for dichotomous dependent variables and multinomial logistic regression for knowledge (a test of proportional odds showed that ordinal regression was not appropriate because the effect of the independent variable was not uniform over the 3 levels of the dependent variable). Results are reported as Wald tests of parameters, which allow significance testing using the chi-square statistic. All regression models were run separately for each dependent variable, and always included time as a covariate and the clinic the participant attended as a fixed factor in the models. This strategy allowed us to incorporate the available data from both timepoints in the same analysis,

TABLE 1
Demographic Characteristics (N=109)

		DA Group (n=48) No. (%)	Control Group (n=61) No. (%)
Gender		19 males (39.6) 29 females (60.4)	27 males (44.3) 34 females (55.7)
Mean age, y		49.9 (range, 24-78)	50.9 (range, 18-74)
Type of genetic test	Tumor marker testing	9 (18.8)	7 (11.5)
	Mutation search	15 (31.3)	20 (32.8)
	Predictive testing: mutation identified	18 (37.5)	29 (47.5)
	Other predictive testing*	6 (12.5)	5 (8.2)
Disease status	Affected by cancer	24 (50.0)	27 (44.3)
	Unaffected by cancer	24 (50.0)	34 (55.7)
Education level	High school only	17 (35.4)	27 (44.3)
	Certificate/diploma	14 (29.2)	20 (32.8)
	Undergraduate degree	12 (25.0)	7 (11.5)
	Postgraduate degree	5 (10.4)	7 (11.5)
Any medical/health training?	No	40 (83.8)	52 (85.2)
	Yes	8 (16.7)	9 (14.8)
Marital status	Never married	5 (10.4)	6 (9.8)
	Married/de facto	38 (79.2)	48 (78.7)
	Widowed	1 (2.1)	3 (4.9)
	Separated/divorced	4 (8.3)	4 (6.6)
Biologic children	No children	11 (22.9)	11 (18.0)
	Yes	37 (77.1)	50 (82.0)

DA indicates decision aid.

* This group was comprised of unaffected individuals considering predictive testing in families where a family-specific mutation had not yet been identified.

as well as account for any potential differences between clinics.

With a sample size of 109, the study had 73% power at a .05 significance level to detect differences in decisional conflict scores (the primary outcome) between intervention groups of a magnitude of 0.5 of a standard deviation, which is a medium effect size.²⁸ This effect size is considered clinically significant and has been reported in other randomized controlled trials of decision aids.¹⁴

RESULTS

Response Rates and Sample

Figure 2 presents the composition of the participants. Briefly, 156 individuals were invited to participate in the study, of whom 153 (98.1%) agreed. Of these, 109 returned Questionnaire 1 (71.2%) and 95 returned Questionnaire 2 (62.1%). Table 1 presents participants' demographic characteristics. There were no significant group or clinic differences in demographic characteristics, nor in any of the clinician-reported data, indicating that randomization was successful in spreading potential confounding variables equally between the groups and across clinics. With regard to participation bias, a comparison of those participants who returned both questionnaires compared with those who returned none or only 1 questionnaire revealed no sig-

nificant between-groups differences in: sex (chi-square(1) = 2.11; $P = .147$); disease status (chi-square(1) = 2.43; $P = .119$); the type of test being considered (chi-square(3) = 6.74; $P = .081$); and whether blood was drawn at the first consultation (chi-square(1) = 1.32; $P = .251$).

Clinician Report

Type of genetic test

Thirty-two percent of participants were considering mutation search, and 15.0% were considering tumor-testing; all of these participants were affected with cancer. Approximately 53% of participants were considering predictive genetic testing; these participants were unaffected. Of those considering predictive testing, 81.0% were considering predictive testing after a mutation had been identified in their family, and 19.0% were comprised of other types of predictive testing situations, such as individuals considering future predictive testing in families where a mutation had not yet been identified. There were no significant differences between participants considering different types of predictive testing on any of the dependent variables.

Participant disease status

Of the 51 participants (46.8%) who had a previous diagnosis of cancer, 40 (78.4%) were affected with

TABLE 2
Dependent Variable Mean Scores and Proportions

		No.	DA Group (SD)	Control Group (SD)
Knowledge of genetic testing	Time 1	109	6.70 (1.20)*	6.08 (1.59)*
	Time 2	93	6.50 (1.49)*	6.13 (1.27)*
Decisional Conflict Scale	Time 1	105	1.53 (0.08) [†]	1.73 (0.34) [†]
	Time 2	95	1.69 (0.45) [†]	1.74 (0.52) [†]
DCS: Informed subscale	Time 1	105	1.57 (0.25)*	1.83 (0.51)*
	Time 2	95	1.77 (0.61)*	1.85 (0.77)*
DCS: Clear values subscale	Time 1	107	1.59 (0.26)*	1.86 (0.58)*
	Time 2	95	1.74 (0.72)*	1.89 (0.77)*
DCS: Supported subscale	Time 1	105	1.52 (0.10)	1.66 (0.36)
	Time 2	95	1.59 (0.33)	1.62 (0.45)
DCS: Certainty subscale	Time 1	100	1.50 (0.0)	1.60 (0.41)
	Time 2	95	1.66 (0.62)	1.63 (0.43)
Decisional Regret Scale [‡]	Time 2	88	7.86 (11.39)	5.73 (9.73)
Proportional Data for Dichotomous Variables (%)				
Multidimensional Measure of Informed Choice	Time 1	106	34.0% "informed"*	23.7% "informed"*
	Time 2	91	43.6% "informed"*	23.1% "informed"*
Did any family member read the information materials?	Time 1	109	43.8% "yes"	52.5% "yes"
	Time 2	95	70.7% "yes"	74.1% "yes"
Did any family member contribute to decision-making	Time 1	107	46.8% "yes"	38.3% "yes"
	Time 2	94	45.0% "yes"	51.9% "yes"
Genetic testing uptake [‡]	Time 1	98	92.5% "yes"	94.8% "yes"
	Time 2	95	95.4% "yes"	97.6% "yes"

DA indicates decision aid; SD, standard deviation; DCS, Decisional Conflict Scale; MMIC, Multidimensional Measure of Informed Choice.

* $P < .05$.[†] $P < .01$.[‡] Some participants did not complete the Regret Scale or uptake questions because they either remained undecided regarding genetic testing or were awaiting the results of a relative's genetic test and therefore were unable to undergo testing at this point.

bowel cancer, 4 (7.8%) with large polyps and 3 (5.9%) with endometrial cancer. The following cancers affected 1 individual each: ovarian, duodenal, ureter, and melanoma. Four of the individuals with bowel cancer also had a second cancer diagnosis (2 with pancreatic, 1 with uterine, and 1 with renal cancer). Of the 58 participants who were unaffected by cancer, 53 (91.4%) had a 50% mutation-carrier risk and 5 (8.6%) had a 25% mutation-carrier risk.

Blood drawn

Blood was drawn immediately after the consultation in 56.1% of the 82 participants able to have blood drawn at that time. There was no significant difference in this variable between those considering mutation search compared with predictive testing ($\chi^2(1) = 1.32$; $P = .250$).

Questionnaire 1

Reading the materials

Fifty-eight percent of the DA group and 59.0% of the control group reported having read the DA or the pamphlet 'from cover to cover' or 'quite thoroughly' before

completing Questionnaire 1. There were no sex differences in the how thoroughly participants reported reading the decision aid ($\chi^2(4) = 0.97$; $P = .808$) or control pamphlet ($\chi^2(4) = 2.02$; $P = .733$).

Decisional Conflict

Dependent variable mean scores and proportions are presented in Table 2. Participants who received the DA had significantly lower decisional conflict full-scale scores than participants who received the control pamphlet ($\chi^2(1) = 8.97$; $P = .003$). There were no significant interactions between sex and the effect of the DA for any of the decisional conflict scores.

Knowledge Scores

The main effects model showed that the DA significantly improved knowledge at both timepoints ($\chi^2(2) = 7.28$; $P = .026$). More specifically, however, there was a significant interaction between sex and knowledge scores, such that men who received the DA had significantly higher knowledge levels (mean knowledge category averaged across timepoints = 2.0) compared with men who received the

control pamphlet (mean = 1.50), whereas no such differences were found for women (mean intervention group = 1.85, vs 1.75 for control group) (chi-square(2) = 6.76; $P = .034$).

Informed Choice

Individuals who received the DA were significantly more likely to be classified as having made an "informed" choice than participants who received the control pamphlet (chi-square(1) = 4.37; $P = .037$). There was no significant interaction between sex and the effect of the DA on informed choice.

Family Involvement

The majority of participants reported sharing the information materials they received with other family members (Table 2). Logistic regression demonstrated that participants who received a DA were equally as likely to share the materials they received, compared with participants who received the control pamphlet (chi-square(1) = 0.36; $P = .549$). Similarly, there was no significant group difference in the level of perceived family involvement in decision-making (chi-square(1) = 0.09; $P = .769$). Participants named their spouse or partner most often as the family member who had read the information materials and had contributed to their decision-making process.

Psychologic Variables

The DA did not appear to affect participants' reported levels of psychological distress, with no significant group differences in intrusive and avoidant thoughts, anxiety, or depression.

Regret

There were no significant group differences in participants' reported regret about their genetic testing decision 6 months after their consultation (chi-square(1) = 0.32; $P = .571$). There was no significant interaction between sex and the effect of the DA on regret.

Genetic Testing Uptake

Receipt of the DA had no effect on genetic testing decision (chi-square(1) = 3.78; $P = .286$). Ninety-three of 99 (93.9%) participants eligible for genetic testing after their first consultation decided to undergo testing. There was no significant difference in this variable between those considering different types of genetic test (chi-square(1) = 5.50; $P = .139$). Of the 10 participants who were awaiting the results of a relative's genetic test, all were still waiting for the results 6 months postconsultation. The remaining

6 participants reported that they did not want to undergo genetic testing.

Effect of Having Blood Drawn Immediately After the Consultation

There were no significant interactions between choosing to have blood drawn on the day of the consultation and the effect of the DA on any of the dependent variables, suggesting that the DA was equally effective in those who chose to have blood drawn immediately after their consultation compared with those who did not.

DISCUSSION

Individuals who received a DA to assist their decision-making concerning genetic testing for HNPCC-risk had significantly lower decisional conflict scores and were more likely to be classified as having made an informed choice compared with those who received a general educational pamphlet. As well, men who received the DA had significantly higher knowledge levels than men who received the control pamphlet. Consistent with previous research, the DA did not appear to affect participants' psychological functioning nor their actual genetic testing decision.¹⁴ Our data suggest that the decision to have testing has apparently been made already in nearly all cases when people attend genetic counseling. Therefore, the decision aid might have a greater impact on genetic testing uptake and other patient outcomes in a setting where patients have not yet considered genetic counseling and testing, such as in patients newly diagnosed with colorectal cancer.

Congruent with the results of our previous randomized trial of a DA for women considering genetic testing for breast/ovarian cancer risk,²⁹ the family member most likely to be named as having read the information materials they received at the clinic and having contributed to the decision-making process was the participant's spouse or partner. These data support recent research emphasizing the importance of considering the spouse within the familial cancer setting, despite the fact that they are not blood relatives of the patient and therefore not at increased cancer risk themselves.³⁰

The possible sex differences in the effectiveness of the DA warrant further discussion. Traditionally, research has reported that men have a less positive attitude toward health-related issues in general and toward genetic counseling and testing for hereditary cancer syndromes specifically.^{31,32} It has been suggested that women may view themselves as more personally responsible for the healthcare of their

family members and/or the family transmission of hereditary cancer risk, and are therefore more motivated to participate in genetic counseling and testing.³³ Women have also been reported as preferring to be better informed and more active in medical decision-making in general than men.³⁴ A recent qualitative survey of popular cancer websites confirmed these portrayals, concluding that treatment decision-making was portrayed to women as a complex process with emotional, social, and medical implications, whereas treatment decision-making for men was portrayed as more isolated and less likely to involve family and friends. In addition, men's cancer websites rarely presented other patients' stories and encouraged men to make their decisions in an active, problem-focused way.³⁵

Based on these studies, it might have been expected that our long and relatively emotion-focused DA would be most effective for women. Our findings, however, contrast the suggestions above, as we report that men benefited strongly with respect to knowledge gains in response to the DA, in contrast to women who showed no such increases in knowledge, despite reporting that they read the DA equally as thoroughly as the men in the study. Interestingly, a similar finding was recently reported by Stromberg et al,³⁶ who showed that males participating in a computer-based education program on heart failure had greater knowledge improvements than females.

It is possible that men with a family history of HNPCC may have different information and decision-making needs than women from these families, and the developed decision aid addressed the men's needs most appropriately. It is also possible, however, that decision-making regarding genetic testing for HNPCC risk is more complicated for women, given that they are at increased risk of multiple cancers. The data surrounding endometrial and ovarian cancer risks and appropriate risk management strategies for these cancers are only raised briefly in the current DA. It is possible that women may have benefited from receiving a 'female' version of the DA that provided more extensive information concerning these issues. Either way, our findings reinforce the finding that making assumptions regarding sex differences in information and decision support needs can be unhelpful.

Limitations

It was not feasible to collect a baseline assessment of participants; however, given that the participants were randomized, any precounseling characteristics in patients that might have influenced outcomes

should have been evenly distributed across both groups. It was also not possible for clinicians to be blinded to the randomization status of the participants because some clinicians expressed a preference for being able to tailor the DA to the patient by entering personalized information (such as risk estimations based on family history) into the DA. However, we attempted to minimize the impact of this by instructing clinicians to open the recruitment package near the end of the consultation. Nonetheless, the potential for contamination as a result of lack of blinding should be acknowledged; in particular, clinic staff who perceived the DA to be superior to the control pamphlet might have orally supplemented the information to the control group. It was also possible that some participants completed their questionnaires before reading their information materials, despite clear requests not to do so. The data provided on reading the materials, however, showed that the large majority of participants reported that they did read the materials before completing the questionnaire. Finally, study participants tended to have a higher education level than the general population, with 59.6% having a postschool qualification, compared with 52.0% of the general population.³⁷ Although this phenomenon has been identified in previous studies in familial cancer, the discrepancy between the general and clinic population appears to be narrowing.

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