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Impact of an information booklet on satisfaction and decision-making about *BRCA* genetic testing

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ABSTRACT

The aim of this study was to assess the impact of a standardized patient information booklet on decisions women make about genetic testing. This French national multi-centre survey included all women with cancer to whom genetic testing for *BRCA1/2* mutation had been proposed. The control group was surveyed before the booklet became available ($n = 263$), and the experimental group, after being given it personally ($n = 297$). After multivariate adjustment, the booklet had a positive impact on satisfaction with the information provided (Odds ratio (OR) = 2.9; 99% confidence interval (CI) = 1.7–5.0; $P = 0.001$), decreased the decisional conflicts due to lack of information (OR = 1.9; 99% CI = 1.1–3.3; $P = 0.002$), and had a marginal impact on knowledge (R^2-gain = 3%; $P = 0.001$). The women in the experimental group decided more frequently to undergo testing (99% vs. 95%; $P = 0.009$). In addition to a consultation providing more tailored information, a standardized written document improved the decision-making process involved in giving informed consent to genetic testing.

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1. Introduction

Since the first breast/ovarian cancer susceptibility genes were identified,[1] the majority of patients and providers appear to be in favour of genetic testing with counselling on its implications.[2,3] The information provided at cancer genetic counselling sessions is complex[4,5] and despite the time it takes to give counselling, helping patients to reach a fully informed decision about taking a genetic test is important.[6]

Good information booklets are usually welcomed by patients and have had a general positive impact and sometimes even on doctor–patient relationships, anxiety and compliance with treatment.[7] Several booklets and complementary information tools have been developed to provide information on breast/ovarian cancer susceptibility genes and their impact on individual health.[8–13] The different information tools vary in their objectives as well as its target population. In the United States, where genetic testing is directly available to the general population, information tools have been given out to dissuade people from asking for genetic tests when there are no medical indications.[8,9] Information tools have also been distributed to prepare patients for genetic counselling[8,10] or to inform people who have undergone tests about chemoprevention options available.[11]

There has been a move in France to standardize the complementary information delivered to patients throughout the country. This has led the French Cancer Genetic Network (GGC), which depends on the National Federation of French Cancer Centres (FNCLCC), to draw up a common Patient Information Booklet (Appendix 1 http://www.fnclcc.fr/fr/sor/pdf/patient/ssp_familial_integral.pdf) that has been critically appraised using the DISCERN tool.[14] The aim of this study was to measure the impact of the standardized patient information booklet described above on women's decision-making about genetic testing for breast cancer susceptibility. The quality of the decision-making process was measured using the following indicators: satisfaction with the information provided, decisional conflict about genetic testing, knowledge, and the decision to be tested or not.

2. Patients and methods

2.1. Study population

This study was carried out at 11 centres located all over France. Sixteen cancer geneticists, all of whom were medical doctors belonging to the cancer genetic network, participated in the study. The study was carried out on consecutive series of adult women who were being treated for cancer; were attending cancer genetic clinics; and were the first members of their family where *BRCA1/2* analysis had been proposed (this service was free-of-charge). Even if self-referral was possible in France, women attend cancer genetics services after being referred by a specialist, and less frequently by a General Practitioner.[15,16]

2.2. Study design and process

This intervention study compared two independent groups of patients collected at the same centres by the same experienced doctors (>4 years of practice) at two consecutive time periods. The control group was assessed prospectively before the Patient Information Booklet was available (26/06/2001–10/09/2002), and the experimental group was assessed after it was distributed (11/09/2002–22/07/2003). The counselling sessions started with an evaluation of familial risk, before genetic testing was suggested.[15] For the purpose of this study, the booklet was handed out directly by the practitioner during or at the end of consultation to the women in the experimental group. Other information documents, mainly ad hoc information sheets, were also permitted to be distributed by practitioners prior to obtaining patients' informed consent to having blood samples taken for genetic testing. The cancer geneticists also gave the patients in both groups a fourteen-page questionnaire, along with a letter informing them about the study and a stamped, addressed envelope. The questionnaires were to be completed at home within one month of the consultation and mailed back to the research team, who had no previous contact with the patient. If the completed questionnaire had not been returned one month after the consultation, the practitioner sent another questionnaire, and again one month later, if necessary. The cancer geneticist completed a one-page inclusion sheet on each woman included in the study and faxed it to the research team. The study was approved by the French National Committee on Informatics and Freedom (Comité National Informatique et Libertés).

2.3. Medical, socio-demographic, and psychological characteristics

The data required to be able to check the inclusion criteria (personal history of cancer and *BRCA1/2* analysis proposed for the first time) and other characteristics (centre consulted; time elapsed since diagnosis; number of familial cases and the age at which the earliest case of cancer occurred in the family; and the duration of the consultation) were completed by the clinician at inclusion. Socio-demographics, including gender, age, marital status, education, occupation, and number of children still alive, were completed by the patients. Psychological characteristics included depressive symptoms (CES-D scale[17]) and coping style (Monitoring-Blunting scale).[18]

2.4. Satisfaction with the information provided

Satisfaction with the information provided at the cancer consultation was measured in terms of an overall score (Cronbach's $\alpha = 0.88$) calculated from a previously developed 17-item scale, which was tested on more than 100 patients.[19] This scale focused on the patients' satisfaction with various aspects of the cancer genetic consultation. All the answers were 4-point Likert scales (completely, partly, not really, and not at all).

2.5. Satisfaction with doctor–patient relationships

Satisfaction with doctor–patient relationship was measured via three questions, focusing to see if a good relationship was developed with the doctor (absolutely, partly, not really, and not at all); the usefulness of the counselling process (abso-

lutely, yes, not really, and not); and fulfilment of expectations (absolutely good, partly, not really, not at all, and I had no particular expectations). The doctor also had to answer two questions, about the perceived quality of the relationship with the patient and if patients' expectations were satisfied (both 4-point items: absolutely, partly, not really, and not at all).

2.6. Decisional conflict

Conflict about the decision to undergo *BRCA1/2* genetic testing or not was measured according to O'Connor's 16-item (all 5-point Likert scale) decisional conflict scale (DCS[20]) validated in French. This scale gives a total mean score (range = 1–5; Cronbach's $\alpha = 0.91$) and sub-scores (same range) for the 5 subscales: uncertainty, uninformed, unclear values, unsupported, and ineffective choice. Scores of 2 or less reflect the absence of decisional conflict.

2.7. Knowledge

Twelve items (Appendix 2) were designed to measure the patients' knowledge about various aspects of the consultation, such as the risks involved in genetic testing and their management. An overall score was calculated by counting the responses taken to be correct.

2.8. The decision to be tested or not

This decision was measured using a 4-point Likert scale (certainly, maybe, not really, and not at all) and was completed by asking the patient whether or not she had already a blood sample taken at the time of the survey.

2.9. Sources of information

The use of information complementary to the consultation was assessed via five questions. The receipt of the patient information booklet or "in-house" documents, the actual reading of these documents, the ease of reading and usefulness of these documents, and finally the fact of having consulted other sources of information.

2.10. Statistical methods

Data analysis were carried out in seven steps (SPSS 11.5 software).

Firstly, comparisons were made between the practitioners' inclusion sheet variables for respondents and non-respondents. Secondly, to check the similarity of the patients included in the experimental and control groups, the inclusion sheet variables and the socio-demographic and psychological data obtained on each group were compared. Thirdly, doctor–patient relationships and the sources of information used by the patients were compared in both groups. Even if the booklet was not received or read by some patients in the experimental group, they remained in that group on an "intention to treat" basis.

Fourthly, to assess the impact of the intervention, comparisons were made between the outcomes: satisfaction with the information provided, DCS, knowledge, and the decision to be tested or not. To harmonize the knowledge and satisfaction with the information provided scores, these were standardized taking a mean value and a standard deviation of 100 and 10, respectively.[21] Fifthly, to find out what effects the intervention may have had, the "dose–response" relationship was determined. It consisted in the statistical comparison of patients who had read completely, partly or not the patient information booklet given in the experimental group. Sixthly, to check the existence of spontaneous time trends for the main outcomes, we studied their distribution for every 3-month time period. Lastly, multivariate analyses were conducted, using multiple linear regression or logistic regression procedures, depending on the pattern of distribution of the outcome. In the case of satisfaction with the information provided and DCS, these scores were dichotomised using median values in the case of the experimental group ($n = 105$) for satisfaction, and the threshold of 2 for DCS. Adjustments were made systematically for centre of inclusion and depressive symptoms. Possible confounding factors were included in the models if the significance level was $P < 0.05$ (*F*-test or likelihood ratio test). The possibility of interactions occurring between groups and cofactors was tested. Usual two-sided tests were used to compare continuous data (Student's *t*-test, analysis of variance) and qualitative data (χ^2). As multiple outcomes were assessed, in all the tests, *P*-values of less than 0.01 were taken to be statistically significant. Mean values are presented with their 99% confidence intervals.

3. Results

3.1. Characteristics of the study population

Among the 644 women included, 560 (87%) mailed back their questionnaire ($n = 263$ in the control group and $n = 297$ in the experimental group) (Fig. 1). There were no significant differences between the medical characteristics or the age of respondents versus non-respondents. No statistical differences were observed between the socio-demographic and medical characteristics of the patients in the two groups (Table 1). The coping styles (monitoring-blunting score) were similar in both groups (Control group: 2.2 (1.8–2.5); Experimental group: 2.1 (1.7–2.4); $P = 0.554$). The CES-D score showed that there were fewer depressive symptoms in the control group (29.5%; Control group: 34.4%; Experimental group $P = 0.022$).

3.2. Comparability between groups

There were no significant differences as regards the patients' level of satisfaction with the doctor–patient relationship, as perceived by either the women themselves or the practitioners (Table 2). The patients' tendency to consult complementary information sources about genetic testing was also similar in both groups. In the control group, "in-house" documents were received by 65.3% of the patients. Only two women in the second group declared that they did not receive the Patient Information Booklet. The patients who had received it read the whole booklet less often than the "in-house" documents (78.8%; vs. 93.3%; $P < 0.001$), but stated more frequently that they found it very useful (56.3%; vs. 43.7%; $P = 0.024$).

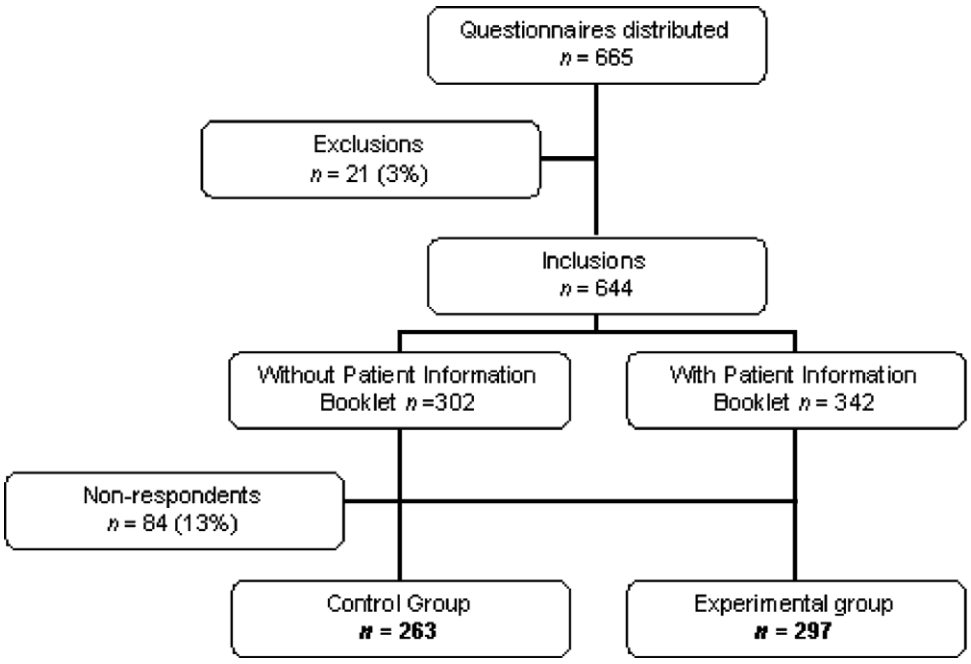

Fig. 1 – Participant flow.

Table 1 – Socio-demographic and medical characteristics by intervention group

	Control group ($n = 263$)		Experimental group ($n = 297$)		P-value
	n	(%)	*n*	(%)	
Civil status					0.900
Married	182	(69.2)	202	(68.7)	
Other	81	(30.8)	92	(31.3)	
Living with a partner					0.827
Yes	198	(77.3)	225	(78.1)	
No	58	(22.7)	63	(21.9)	
Education					0.709
Lower or equal to high school	153	(58.2)	167	(56.6)	
Higher than high school	110	(41.8)	128	(43.4)	
Occupational activity					0.403
Yes	165	(63.5)	167	(60.0)	
No	95	(36.5)	118	(40.0)	
Probability of a BRCA1/2 mutation being identified					0.212
<25%	124	(47.1)	124	(41.9)	
⩾25%	139	(52.9)	172	(58.1)	
Cancer type					0.662
Breast	245	(93.2)	270	(90.9)	
Ovarian	14	(5.3)	18	(6.1)	
Breast + ovarian	3	(1.1)	7	(2.4)	
Other	1	(0.4)	2	(0.7)	
	Mean	SD	Mean	SD	
Age	49.1	(10.8)	50.3	(11.2)	0.204
Number of children still alive	2.0	(1.1)	2.1	(1.2)	0.407
Number of first degree relatives with cancer	1.6	(1.3)	1.6	(1.2)	0.633
Age of earliest case of familial cancer	40.9	(10.0)	40.5	(10.0)	0.428
Time elapsing since cancer diagnosis (months)	60.3	(76.1)	65.5	(79.9)	0.789
Duration of the consultation (min)	58.1	(20.6)	56.4	(17.4)	0.292

Table 2 – Counselling and information variables by intervention group

	Control group (n = 263)		Experimental group (n = 297)		P-value
	n	(%)	n	(%)	
Practitioners' perception					
Good relationship with patient					0.651
Absolutely	213	(81.0)	236	(79.5)	
Partly	50	(19.0)	61	(20.5)	
Patient's expectations satisfied					0.815
Absolutely	154	(58.6)	171	(57.6)	
Partly	109	(41.4)	126	(42.4)	
Patients' perception					
Good relationship with doctor					0.093
Absolutely	233	(89.3)	277	(93.3)	
Partly- No	28	(10.7)	20	(6.7)	
Expectations satisfied					0.610
Absolutely	147	(57.0)	175	(59.1)	
Partly	111	(43.0)	121	(40.9)	
Usefulness of counselling					0.386
Very useful	163	(62.7)	196	(66.2)	
Other	97	(37.3)	100	(33.8)	
Personal search for information about genetic tests					0.977
Yes	62	(24.1)	71	(24.2)	
No	195	(75.9)	222	(75.8)	
Information document (patient information booklet and/or other) received					<0.001
Yes	169	(65.3)	294	(99.3)	
No	90	(34.7)	2	(0.7)	

3.3. *Crude impact of patient information booklet*

3.3.1. *Satisfaction with the information provided*

The overall mean satisfaction with the information provided score was higher in the experimental group (102.3 (101.0–103.7) vs. 97.3 (95.6–99.0); $P < 0.001$).

3.3.2. *Decisional conflict scale*

The overall DCS did not differ between the two groups, but uninformed subscale score was significantly lower in the experimental group, as well as one other item in the scale (making an informed choice) (Table 3).

3.3.3. *Knowledge*

On the whole, the knowledge score was higher in the experimental group (101.7 (100.2–103.2.) vs. 98.0 (96.4–99.7); $P < 0.001$).

3.3.4. *The decision to be tested or not*

The overall majority of patients declared that they wanted to be tested, since only two of them (0.4%) declared that they really did not want to be tested. Patients in the experimental group were more often certain that they wanted to undergo the test (99.0% vs. 95.4%; $P = 0.009$). Patients who certainly wanted to be tested had a lower DCS score than the other patients (1.7 (1.6–1.7) vs. 2.3 (1.9–2.6); $P < 0.001$).

3.4. *Effects of reading the patient information booklet ("dose–response" relationship)*

Reading the booklet (no, partly, and entirely) had significant positive effects on the knowledge and satisfaction with the information provided scores in the experimental group. Reading significantly decreased conflicts about the decision to be tested, i.e., DCS and the DCS uninformed subscale, and had no significant effect on CES-D (Table 4).

3.5. *Time-trend for the main outcomes*

There was no spontaneous time-trend for the three main outcomes surveyed (Fig. 2). A clear cutoff was observed at introducing the intervention.

3.6. *Multivariate analyses*

The three models obtained here included different adjustment variables, but all showed that the booklet had a positive impact (Tables 5 and 6). No significant interactions between factors were observed. The models accounted for 27%, 18% and 15% of the variance in satisfaction with information provided, DCS uninformed subscale, and knowledge scores, respectively.

In the case of satisfaction with the information provided (Table 5), other positive factors were a really good relationship with the counsellor and total satisfaction of expectations. The size of the centre was negatively associated with the satisfaction level: patients attending larger centres were less satisfied than patients attending smaller ones.

In the case of the DCS uninformed subscale (Table 5), a higher educational level, a really good relationship with the counsellor and complete satisfaction of expectations were positively linked to a lower level of decisional conflict, whereas depressive symptoms were associated with a higher level of decisional conflict.

Table 3 – Decisional conflict scores by intervention group

	Control group (n = 263)		Experimental group (n = 297)		
	Mean	(99%CI[a])	Mean	(99%CI)	P-value
Uncertainty (subscore ss1)	1.6	(1.5–1.7)	1.6	(1.5–1.7)	0.727
Easy choice	1.8	(1.6–1.9)	1.8	(1.7–1.9)	0.638
Sure what to do	1.4	(1.3–1.6)	1.4	(1.3–1.5)	0.271
Clear best choice	1.6	(1.5–1.7)	1.6	(1.5–1.7)	0.544
Uninformed (ss2)	2.0	(1.9–2.1)	1.8	(1.7–1.9)	0.002
Know alternatives	1.8	(1.7–1.9)	1.7	(1.6–1.8)	0.022
Know benefits	2.0	(1.9–2.1)	1.9	(1.7–2.0)	0.020
Know risks	2.2	(2.1–2.4)	2.0	(1.8–2.1)	<0.001
Unclear values (ss3)	1.8	(1.7–1.9)	1.7	(1.6–1.8)	0.168
Aware importance of benefits	1.5	(1.4–1.6)	1.5	(1.4–1.6)	0.736
Aware importance of risks	2.2	(2.0–2.3)	2.0	(1.9–2.1)	0.039
Sure which are more important	1.8	(1.6–1.9)	1.7	(1.6–1.8)	0.604
Unsupported (ss4)	1.8	(1.7–1.9)	1.7	(1.6–1.8)	0.039
Feel no pressure from others	1.3	(1.3–1.4)	1.3	(1.2–1.4)	0.511
Have enough support	2.1	(1.9–2.2)	1.9	(1.8–2.1)	0.136
Have enough advice	2.1	(2.0–2.3)	2.0	(1.8–2.1)	0.028
Ineffective choice (ss5)	1.5	(1.4–1.6)	1.5	(1.4–1.6)	0.477
Informed choice	1.8	(1.7–1.9)	1.6	(1.5–1.7)	0.009
Reflects values	1.5	(1.4–1.6)	1.5	(1.4–1.6)	0.441
Will stick with	1.4	(1.3–1.5)	1.4	(1.3–1.5)	0.756
Satisfied with	1.5	(1.4–1.6)	1.5	(1.4–1.6)	0.903
Total decisional conflict scale score	1.7	(1.7–1.8)	1.7	(1.6–1.7)	0.059

a CI, confidence interval.

Table 4 – Impact of reading patient information booklet on main outcomes in the experimental group ("dose–response" relationship, n = 292)

	Not read (n = 11)		Partly read (n = 51)		Entirely read (n = 230)		F	P-value
	Mean	(99%CI[a])	Mean	(99%CI)	Mean	(99%CI)		
Satisfaction with information provided	90.4	(83.6–97.1)	99.1	(95.9–102.3)	103.6	(102.1–105.1)	16.28	<0.001
Decisional conflict scale (DCS)	2.0	(1.6–2.3)	1.8	(1.7–2.0)	1.6	(1.5–1.7)	7.33	0.001
DCS uninformed subscore	2.3	(1.8–2.9)	2.1	(1.9–2.4)	1.7	(1.6–1.8)	10.24	<0.001
Knowledge	95.3	(87.9–102.7)	98.5	(95.0–101.9)	102.9	(101.3–104.5)	7.22	0.001
CES-D	17.5	(8.5–26.5)	19.5	(15.5–23.6)	16.7	(14.8–18.6)	1.42	0.244

a CI, confidence interval.

The proportion of the variance in knowledge accounted for by the booklet (Table 6) was quite small (δR^2 = 3%), and lower than the effect of educational level. Other factors significantly associated with knowledge were found to be the coping style ("monitorers" had higher scores), depressive symptoms and age ("depressed" and/or older patients had poorer knowledge).

4. Discussion

As far as we know, this is the first time an attempt has been made to assess the impact of a single standardized patient information booklet distributed throughout a whole country at cancer genetic consultations. The booklet led to an increase in satisfaction with the information provided, and to a decrease in the level of decisional conflict due to lack of information. The increase of knowledge was marginal and the booklet was found to strengthen patients' decision to undergo the tests.

In the present context of patients' participation in medical decision-making,[22] and the development of informed consent processes,[23] information booklets have been widely used but rarely assessed in national multi-centre surveys. As in two previous studies[10,11] on satisfaction with information provided, the booklet was found in the present study to have a positive impact. Other factors determining the satisfaction level include the size of the centre, and the fulfilment of patients' expectations. The latter is thought to contribute to satisfaction.[24].

The decision to undergo genetic tests rated very high. This can be explained by the fact that all these women fulfilled the inclusion criteria for genetic testing and the tests had already been proposed to them by a cancer geneticist. The significant increase in this decision, observed during the experimental

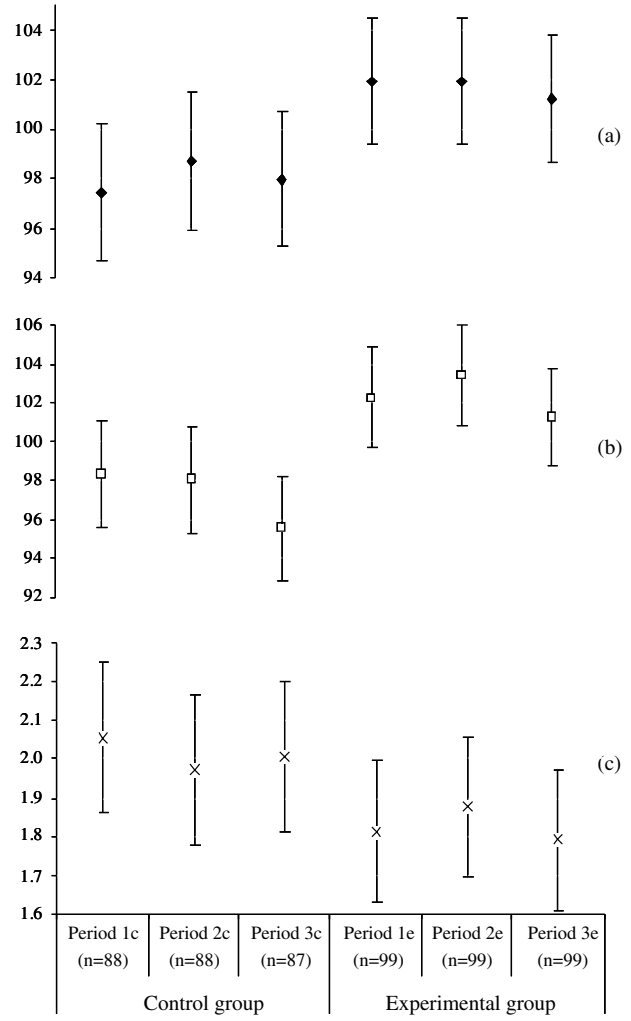

Fig. 2 – Time-trends for the three main outcomes: (a) satisfaction with the information provided, (b) knowledge, and (c) decisional conflict scale uninformed subscore. To check the existence of spontaneous time-trends, each group was divided into three consecutive periods with equal sample sizes. Period 1c = [June 2001, November 2001], Period 2c = [November 2001, Mars 2002], Period 3c = [Mars 2002, September 2002], Period 1e = [September 2002, December 2002], Period 2e = [December 2002, March 2003], and Period 3e = [April 2003, July 2003]. Mean values are provided with their 99% confidence intervals.

period, was likely to be due to a time-trend instead of an effect of the intervention itself. One means of exploring the quality of decision-making is to measure the decisional conflict involved, which has rarely been done in this context. The booklet provided general standardized information. The impact expected and confirmed by the results therefore mainly showed up in the DCS uninformed subscale, which is that most frequently affected by decision aids.[25] The overall scale showed no significant decrease in the level of decisional conflict in this group, but a "dose–response" relationship was observed after these patients had been given the booklet (Table 4). These results are consistent with the lack of effect of an information booklet previously observed on the uncertainty DCS subscale.[11] Another study showed the existence of a slightly lower but significant level of DCS in a group receiving counselling than in a group using only a computer-based decision aid.[8]

The present results confirm that a booklet can have a positive, although modest, impact on knowledge.[9–13] This low impact may be explained by the fact that the booklet was given as a complement to a one-hour cancer genetic consultation. A multidimensional method has been developed for measuring informed choice, based on patients' knowledge, attitudes, and behaviour,[26] since measuring informed choice via knowledge indicators alone did not seem to give an exhaustive picture of the issue at stake.[26] However measuring an informed decision in a very homogeneous population such as the one we studied, i.e., a population in which the test is medically indicated and acceptable for the overwhelming majority, does not do away with the need for the decision to be informed. Including the conflicting aspects of the decision-making process seemed to be an interesting way of assess the quality of the informed consent process.

In general, patients seem to want as much information as possible, and generally prefer the written form rather than group meetings or telephone discussion groups.[27] Other permanent self-administered forms of support such as videotapes[11] or computer programs[8] have been used. Despite the increasing use of internet, only 49% of our sample had a personal computer with an internet connection (data not shown). Information booklets are particularly useful because they can be handed over directly by practitioners, which is expected to increase their impact.[7] On the other hand, the complementarities of standardized booklets and more personally tailored information, such as that normally delivered during genetic counselling should be highlighted.[13]

We used a quasi-experimental design. A randomised controlled trial was not feasible for two reasons: (1) after being published, the Patient Information Booklet was available on the internet, which increased the risk that a randomised control group might have access to it; (2) since the booklet took a long time to draw up (1996–2002), cancer geneticists wanted to distribute it as soon as possible and were unwilling to adopt the randomisation design, especially as it has been previously reported that booklets of this kind often have a positive impact. The design adopted was compatible with prospective data collection, starting before the booklet became available, and this made it possible to control the time of the booklet's release. The absence of spontaneous time-trends for the main outcomes (Fig. 2) and the "dose–response" relationship observed (Table 4) provides evidence that the changes observed were more likely to be attributable to the booklet than to other contemporaneous event. Measuring knowledge before the consultation to compare its baseline level for the control versus the experimental groups would have modified the context of the routine practice of the consultation, and results would not have indicated the situation in normal clinical practice. Satisfaction with the process and decisional conflict about testing had to be assessed after the consultation.

Patients' information booklets are appreciated by patients and can improve their informed choice for genetic testing. Information sharing is the first step towards reaching an

Table 5 – Logistic regression analysis predicting satisfaction with information provided (⩾105; n = 503) and decisional conflict scale uninformed sub-score (⩾2; n = 525)

Predictive variables	Step	Satisfaction with information provided ⩾105[a]			Decisional conflict scale uninformed subscore ⩾2[b]		
		Adjusted OR	(99%CI[c])	*P*-value	Adjusted OR	(99%CI)	*P*-value
Constant	1	0.06		<0.001	0.78		0.529
Centre	–			0.011			0.093
1 cancer geneticist		1	Referent		1	Referent	
⩾2 cancer geneticists		0.58	(0.33–1.00)		0.68	(0.37–1.23)	
CES-D	–			0.751			0.010
<23		1	Referent		1	Referent	
⩾23		1.08	(0.59–1.95)		0.56	(0.32–1.00)	
Group	2			<0.001			0.003
Control		1	Referent		1	Referent	
Experimental		2.90	(1.68–5.03)		1.88	(1.08–3.27)	
Good relationship with doctor	–			0.060			0.044
Partly		1	Referent		1	Referent	
Absolutely		3.30	(0.65–16.91)		2.05	(0.82–5.15)	
Expectations satisfied	–			<0.001			<0.001
Partly		1	Referent		1	Referent	
Absolutely		5.27	(2.90–9.59)		2.64	(1.48–4.71)	
Education	–			Not entered			0.004
Lower or equal to high school					1	Referent	
Higher than high school					1.95	(1.08–3.52)	

a Nagelkerke's $R^2 = 0.270$.
b Nagelkerke's $R^2 = 0.177$.
c CI, confidence interval.

Table 6 – Multiple linear regression analysis of knowledge (n = 527)

Predictive variables	Step	ΔR^2	Final β	*P*-value
Constant	1		100.14	<0.001
Centre ⩾2 cancer geneticists	–	0.001	−0.30	0.725
CES-D ⩾23	–	0.019	−2.05	0.023
Education > high school	2	0.058	4.26	<0.001
Experimental group	3	0.030	3.66	<0.001
Age	4	0.026	−0.15	<0.001
Monitoring – blunting	5	0.011	0.47	0.010
Total		0.146		

informed decision between a woman, her doctor and possibly the patient's family.[22] Standardizing the delivery of information, designed to complete cancer genetic consultations in the form of a document validated both by doctors and patients, seems to be a promising method of improving patients' satisfaction and saving health care resources. Organizing its distribution via a national network of consultants may also reassure "at risk" families in a given country that considerable coordination is going on among health care providers.

Conflict of interest statement

None declared.

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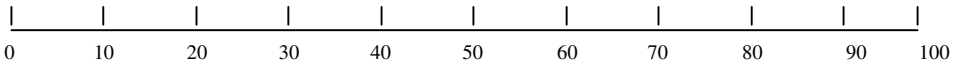
Appendix 1. Patient information booklet

A multidisciplinary task force including doctors, psychologists, research workers, and women, drew up this booklet between 1996 and July 2002. This 32-page coloured booklet is divided into eight chapters focusing on various aspects such as genetic transmission, testing, and screening. It can be found on the FNCLCC (National Federation of French Cancer Centres) website (http://www.fnclcc.fr/fr/sor/pdf/patient/ssp_familial_integral.pdf). More than 10,000 copies have been printed and it was distributed in 2004 to consultation centres all over France. The main objective of this booklet was to provide a complementary genetic counselling tool and to help patients to make informed decisions about undergoing genetic testing. When the French Cancer Genetic Network considers the booklet to be outdated, they will contact the FNCLCC to renew it. Next revision is likely to occur by 2007.

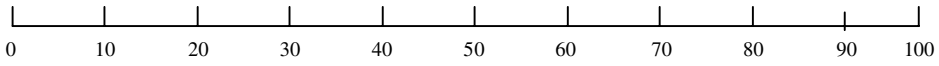
Appendix 2. Knowledge questionnaire

Here are a few questions about the information you have been given.

Out of every 100 women in the general population, how many will have breast cancer at some point in their lifetime?



Among 100 women with a genetic predisposition to breast cancer, how many will have breast cancer at some point in their lifetime?



If a genetic predisposition to breast cancer is detected in a woman, what is the risk that her children may have the same predisposition?

☐ *no risk*
☐ 1/2
☐ 1/4
☐ *will definitely have the predisposition*
☐ *I don't know*

If a genetic predisposition to breast cancer is detected in a man, what is the risk that his child may have the same predisposition?

☐ *no risk*
☐ 1/2
☐ 1/4
☐ *will definitely have the predisposition*
☐ *I don't know*

Please read the following case descriptions and answer the questions:

"Mrs. Y developed breast cancer a long time ago. Some of her close family relatives have also had breast cancer. She underwent a genetic test to find out about the risk run by her daughter. A **BRCA1** *mutation breast cancer predisposition has been observed in the tests on Mrs. Y's blood sample.*

Her daughter, who was 25 years old, asked to have a genetic test, and no familial mutation was detected."

Do you think the surveillance of Mrs. Y's ***daughter*** *will be the same as that applied to a woman:*

☐ *with a genetic predisposition to breast cancer*
☐ *with no genetic predisposition*
☐ *I don't know*
☐ *other response: . . .*

Mrs. Y would like to know about her risk of breast cancer recurrence. In comparison with a woman of the same age with the same type of cancer but no genetic predisposition, do you think her risk is:

☐ *lower*
☐ *equal*
☐ *higher*
☐ *I don't know*

Let's talk about another story:

Miss X developed breast cancer at the age of 32, and her mother and sister also developed breast cancer before the age of 40. Miss X is the first member of her family to have had genetic testing for breast cancer predisposition. The test did not show the existence of a **BRCA1** *or* **BRCA2** *mutation.*

Do you think the surveillance of Miss X's ***daughter*** *will be the same as that of a woman:*

☐ *with a genetic predisposition to breast cancer*
☐ *with no genetic predisposition*

☐ *I don't know*
☐ *other response: . . .*

Miss Y would like to know her risk of breast cancer recurrence. In comparison with a woman of same age with the same type of cancer but no genetic predisposition, do you think her risk is:

☐ *lower*
☐ *equal*
☐ *higher*
☐ *I don't know*

In the case of women less than 40 years old with a genetic predisposition to breast cancer, an annual mammography started at the age of 30 would make it possible to detect:

☐ *any occurrence of breast cancer*
☐ *most occurrences of breast cancer (more than half)*
☐ *some occurrences of breast cancer (less than half)*
☐ *we don't really know what percentage would be detected*
☐ *I don't know*

In the case of women with a genetic predisposition to breast cancer, preventive mastectomy would prevent:

☐ *all occurrences of breast cancer*
☐ *most occurrences of breast cancer (more than half)*
☐ *some occurrences y of breast cancer (less than half)*
☐ *we don't really know what percentage would be prevented*
☐ *I don't know*

In the case of women with a genetic predisposition to ovarian cancer, preventive ovariectomy would prevent:

☐ *all occurrences of ovarian cancer*
☐ *most occurrences of ovarian cancer (more than half)*
☐ *some occurrences of ovarian cancer (less than half)*
☐ *we don't really know what percentage would be prevented*
☐ *I don't know*

In France, insurance companies ("life- or lending" insurance companies) are entitled to do the following: (you can give several answers, if applicable)

☐ *to ask a patient to undergo genetic tests*
☐ *to ask for genetic test results*
☐ *to ask whether you have given all the health information you have about yourself*
☐ *to ask whether you have had a blood sample analyzed to identify risks*
☐ *I don't know*
☐ *other response: . . .*

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