

Informed Choice in Mammography Screening

A Randomized Trial of a Decision Aid for 70-Year-Old Women

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Background: Many women who have participated in mammography screening are now approaching 70 years of age. These women are advised to consider both the benefits and harms of continuing to be screened. Doing so may be difficult for individual women, and there are no evaluated decision support tools to assist them.

Methods: To assess the effect of a decision aid (DA) about whether to continue or stop mammography screening for women aged 70 years, a population-based, randomized controlled trial was conducted in New South Wales, Australia. Women aged 70 years who had regularly participated in mammography screening were eligible to participate in the trial. Women received a DA providing balanced, quantitative information or standard information available from the screening program. The main outcomes were the percentage of women making an informed choice about whether to continue or stop screening and the percentage of women participating in the screening.

Results: Women who received the DA (the interven-

tion group) were better informed than the control group (mean increase in knowledge score out of 10, 2.62 for the intervention group vs 0.68 for the control group; $P < .001$), and a significantly greater percentage made an informed choice (73.5% vs 48.8%; $P < .001$). The DA did not increase anxiety and slightly reduced decisional conflict. There was no difference in the percentage of women who participated in screening within 1 month.

Conclusions: This DA increased knowledge and assisted women to make an informed choice. It did not alter participation in screening. The DA is an effective way to assist women to make a decision about continuing mammography screening and seems to be a feasible intervention within a population screening program.

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MAMMOGRAPHY SCREENING reduces mortality from breast cancer, but it also has important downsides, including overdetection (and overtreatment) of in situ and invasive breast cancer and extra imaging and biopsies for abnormalities that

*For editorial comment
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are benign (false positives).¹ As such, screening is generally recommended for women aged 50 to 69 years, but for women 70 years or older, in whom the benefit-harm ratio declines, recommendations are less clear cut. For example, the US Preventative Services Task Force notes that a mortality benefit from screening is still likely for women older than 70 years, if life expectancy is not compromised by co-

morbid disease.² In particular, there are concerns about detecting and treating cancers in older women, which, without screening, would not have affected patients' health or life expectancy.

As women who began screening in their 50s and 60s now approach age 70 years, the issue of whether to continue screening past age 70 years is one of increasing relevance. In screening programs in the United Kingdom, Canada, and Australia, once women turn 70 years of age (or 75 years in some areas), they are no longer invited but are still eligible to be screened if they wish.³⁻⁵ Guidelines state that participants in screening programs should be given balanced information^{6,7} and that the decision to continue or stop mammography screening should be made by the individual after careful consideration of the possible benefits and harms.⁸⁻¹⁰ However, little information is available to help women make this choice,^{11,12} with several

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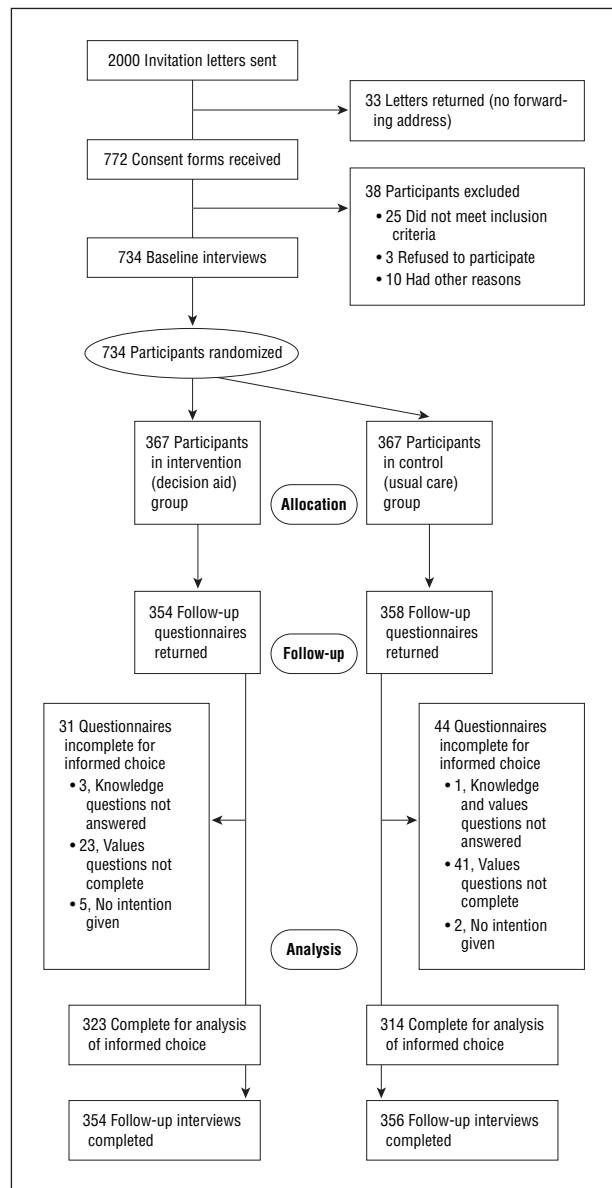


Figure 1. Flowchart of study.

reviews¹³⁻¹⁵ demonstrating that the available information is biased and insufficient for informed decision making. There are also concerns that disclosure of the downsides of mammography screening might have a negative impact on participation rates.¹⁶ In previous articles we suggested ways to provide balanced information about cancer screening,¹⁷ provided numeric estimates of the outcomes of mammography screening for Australian women aged 40 to 80 years,¹ and subsequently developed a decision aid on the pros and cons of continuing mammography screening for women aged 70 years. (Decision aids assist people to make informed decisions by providing information on the relevant options and outcomes.¹⁸ They have been shown to improve patients' knowledge, clarify values, reduce decisional conflict, and encourage users to take a more active role in decision making without increasing anxiety.^{11,18})

In Australia, mammography screening is offered free of charge through a national population program, Breast-

Screen Australia, which women access directly (without physician referral). The national policy is to invite all women aged 50 to 69 years by personal letter, with reminder letters every 2 years. Approximately 60% of women aged 60 to 69 years participate in the program,¹⁹ but there is no national policy on whether to continue inviting them after they reach 70 years of age. Until 2005 in New South Wales (NSW) (the most populous Australian state), women continued to receive invitations indefinitely. However, in late 2005, a policy decision was made to cease invitations to women aged 70 years. Women were advised that they would no longer receive invitations, but they could continue screening if they wished. This provided an opportunity to evaluate our decision aid in a population sample of women facing this decision.

We assessed the impact of the decision aid on the percentage of women who (1) make an informed choice about whether to continue or stop screening and (2) participate in screening.

The secondary aims were to (1) assess the impact of the decision aid on women's decisional conflict and anxiety about breast cancer and (2) explore the relationship between a woman's decision to continue or stop screening and her objective and perceived risk of breast cancer and self-assessed health.

METHODS

STUDY DESIGN, PARTICIPANTS, AND BASELINE MEASURES

We evaluated the decision aid in a randomized controlled trial (Figure 1). Potential participants were selected at random from BreastScreen NSW (part of BreastScreen Australia) records and sent an invitation to join the study. Owing to ethics committee requirements, women had to return a signed consent form in response to this invitation in order to participate. Women were eligible to participate if they were aged 70 to 71 years, had undergone 2 screening mammograms in the past 5 years, were due for their next mammogram within the next 3 months, and had not previously been diagnosed with breast cancer.

A baseline structured telephone interview was conducted, and once eligibility was confirmed, women were randomized to receive a decision aid or usual care (hereinafter, intervention and control groups, respectively) by interview staff who accessed a previously concealed computer program, which assigned allocations in accordance with a simple randomization schedule.

INTERVENTION GROUP

The decision aid was developed using the Ottawa Framework.²⁰ Screening outcomes were based on numerical estimates derived from a Markov model by Barratt et al.¹ The model estimated outcomes for Australian women who either continue screening for another 10 years (from age 69 to 79 years) or stop screening at 69 years, having previously been regular participants in screening. The model assumed a 37% relative risk reduction in breast cancer mortality for screened women, which includes adjustment for 100% participation in screening,²¹ and allowed for the impact of declining life expectancy with age on the benefit of screening. The current life expectancy for 70-year-old Australian women is 16 years.

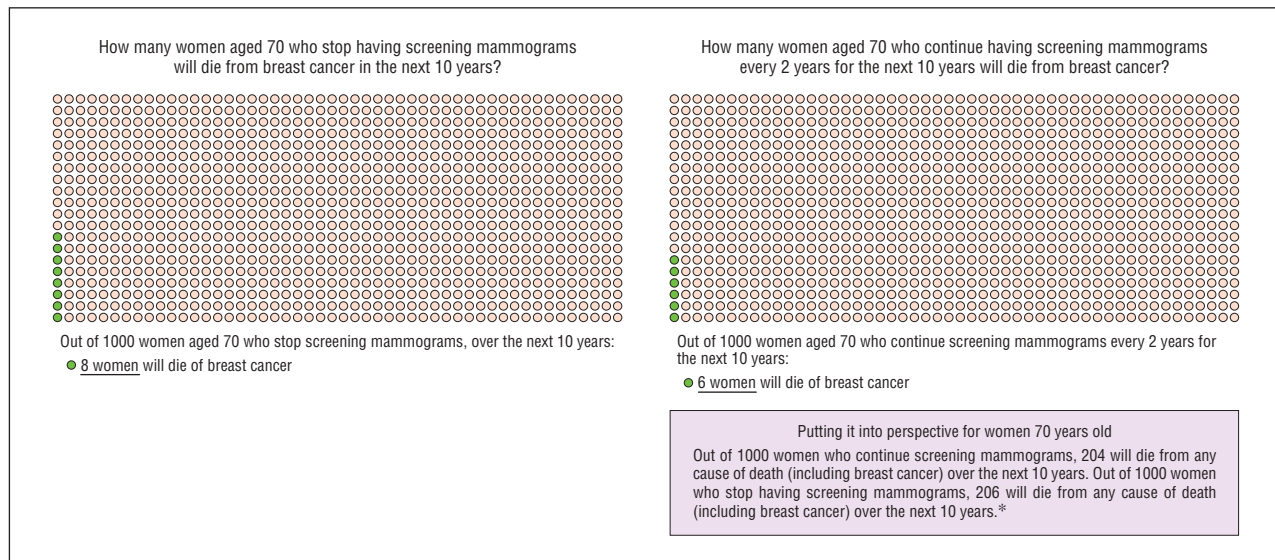


Figure 2. Extract from the decision aid: deaths from breast cancer and all causes for those who stop and those who continue mammography screening. The asterisk indicates that the reader should refer to the model of Barratt et al.¹

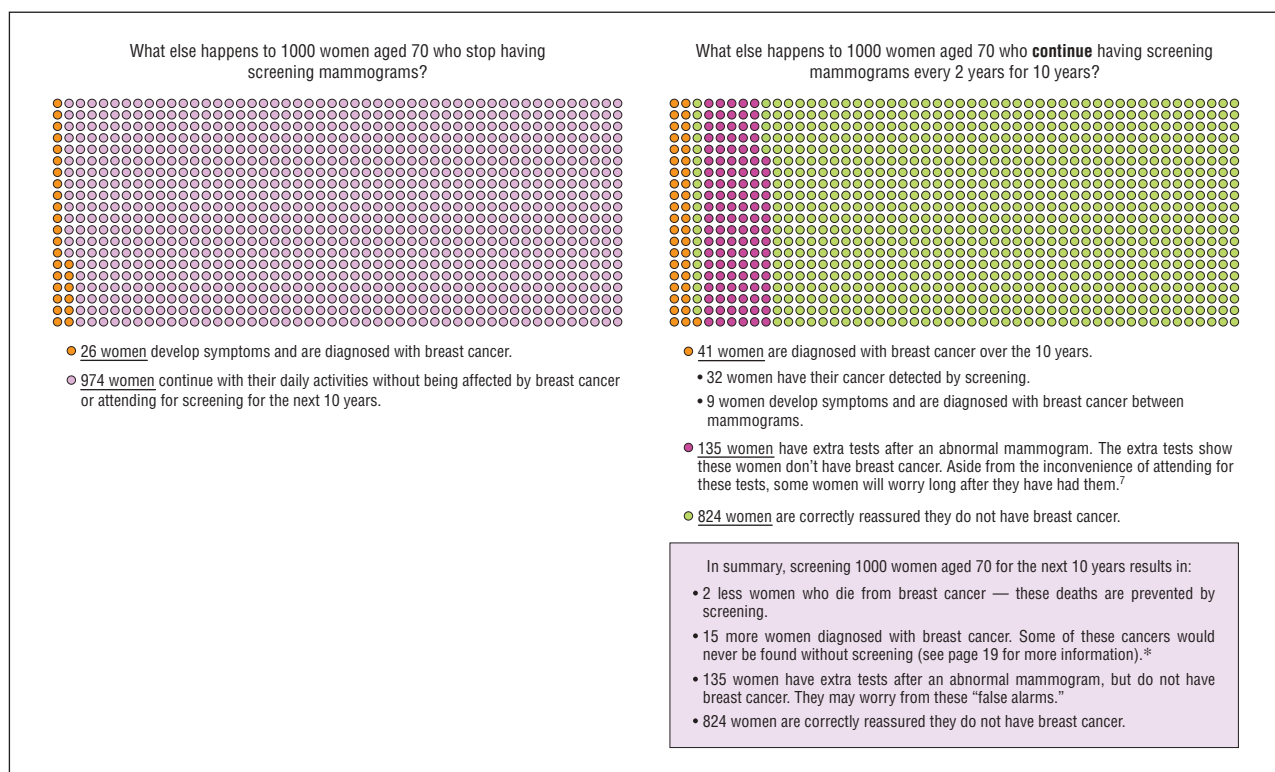


Figure 3. Extract from the decision aid: other outcomes for those who stop and those who continue mammography screening. Asterisk (“see page 19 for more information”) refers to page 19 in the decision aid, which provided more information about cancers that may never affect a person’s health (Figure 4).

In pilot testing of the decision aid (with 29 women aged 70-71 years), 15 women felt the decision aid was balanced and fair, 7 women felt it was biased toward screening, and 7 felt it was biased toward stopping screening. The women rated the decision aid as being clear (28 of 29), understandable (28 of 29), about the right length (25 of 29), and containing about the right amount of information (21 of 29).²² This contrasted with an earlier review²² by screening service staff who were concerned that the decision aid might be too detailed and was biased against screening. They thought that numeric information about over-

detection, false positives, and follow-up imaging and biopsies should be removed because it might worry women. Based on the feedback from women, however, we kept this information in the decision aid.

The decision aid was a self-administered, paper booklet that consisted of 2 sections (information and a worksheet with a values clarification exercise) and an appendix. The information section described the options (to continue or stop screening) and the chances of each of the possible outcomes of each option (**Figure 2** and **Figure 3**).

FOLLOW-UP AND OUTCOME MEASURES

Follow-up data were collected by a self-completed, mailed questionnaire that measured knowledge, attitudes, and intentions with respect to screening mammography, breast cancer worry, decisional conflict, and anxiety.

One month after the questionnaire was returned, the women were contacted for a follow-up telephone interview to ascertain whether they had attended for screening or had made an appointment to be screened. The interviewers were blinded to group assignment.

Primary Outcome Measures

Because the aim of the decision aid was to support women in making an informed choice, our primary outcomes were (1) informed choice and (2) participation in screening. We followed the general approaches suggested by O'Connor²³ and Marteau et al,²⁴ which encompass sufficient knowledge, clearly defined values, and an expressed intention regarding future mammography screening. Participation was selected as an outcome because our partner, BreastScreen NSW, needed to know whether the decision aid would have an impact on demand for services as part of planning for future distribution. Participation was assessed both as (1) intention to be screened immediately after intervention and (2) self-reported attendance at screening 1 month after intervention.

Nine knowledge questions were designed for this study because we could not find any published items that we felt adequately measured knowledge in this age group, particularly regarding the increased chance of a breast cancer diagnosis. Our items included 4 concept questions and 5 numeric questions. Answers to questions were scored using a marking scheme developed a priori to give a score of 0 to 10. Following the approach described by Marteau et al,²⁴ it was decided a priori that a score of 6 or higher would be considered "adequate" knowledge. We pilot tested the questions in a sample of 70 women, after which minor modifications were made. (Full details of the knowledge questions and the marking scheme are available at http://www.health.usyd.edu.au/shdg/resources/decision_aids.php.)

We used the values clarity subscale of the decisional conflict scale,²⁵ on which scores range from 0 to 100 (a score of 25 or less indicates clear values). Intention with respect to future screening was measured using a 5-point Likert scale with anchors of attending mammography screening every 2 years and no longer attending screening.

Women were classified as making an informed choice if they had adequate knowledge and clear values and expressed an intention to either continue or stop mammography screening (ie, they were not undecided).

Secondary Outcome Measures

Secondary outcomes were decisional conflict (Decisional Conflict Scale²⁵) and anxiety (State-Trait Anxiety Inventory²⁶ and a question asking specifically about breast cancer worry²⁷).

We also explored women's attitudes toward screening,^{24,28} the relationship between women's objective (using

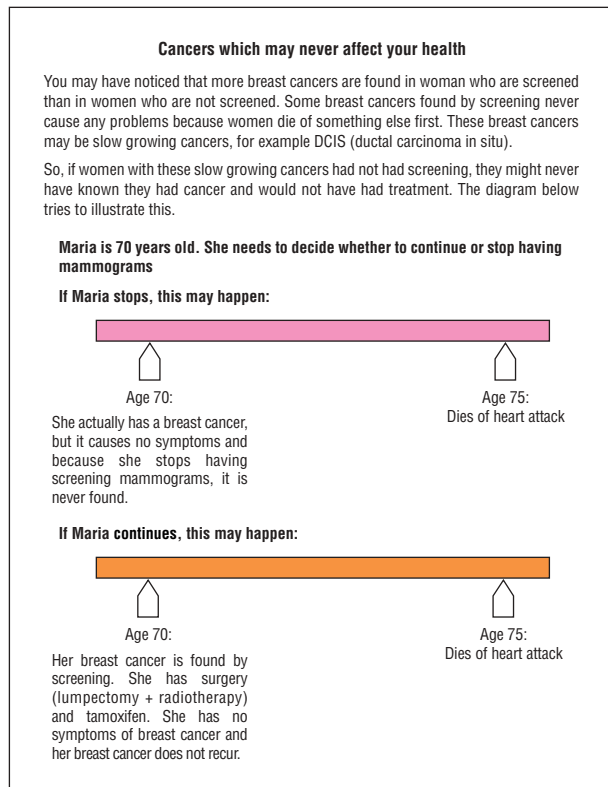


Figure 4. Extract from decision aid appendix: Cancers which may never affect your health.

This section was developed in accordance with guidance on risk communication about screening decisions.¹⁷ The chance of each outcome was expressed as an event rate per 1000 women screened every 2 years over 10 years, starting at age 70 years, using "1000-face" diagrams (Figure 2 and Figure 3).

The worksheet contained a values clarification exercise and examples of how other women had completed the values clarification exercise. These were based on women's responses during development.

The appendix contained an explanation of the possibility of detecting a type of breast cancer that might not affect a woman's health (Figure 4). It explained that this breast cancer might be low grade and might not progress to clinically relevant disease within the woman's lifetime even if left undetected and untreated. The concept was illustrated by a diagram representing a woman who may decide to be screened and will then have a breast cancer found by screening and treated. Alternatively, the same woman may choose not to be screened, and her breast cancer will remain undetected (and untreated). Regardless of her choice, she dies at the same time of heart disease. The appendix also contained additional information that the women who participated in the pilot testing felt was important (effects of radiation and risk factors for breast cancer) and references for information in the decision aid.

CONTROL GROUP

The standard BreastScreen NSW brochure contained a small amount of information regarding screening at different ages. It was selected because it was the only BreastScreen NSW brochure that contained any information specifically for women aged 70 years. It provided no numeric information about the outcomes of screening.

the model of Gail et al²⁹) and perceived risk³⁰ of breast cancer, their intentions with respect to mammography screening, and the relationship between self-assessed health (using the 36-item short-form survey³¹) and intentions.

STATISTICAL ANALYSIS

A total of 313 women per group were required to detect a 10% change in the percentage of women making an informed choice (80% power; significance level, $P=.05$; 2-sided t test). The 2-sided t test was used to compare the difference in the mean change in knowledge scores between the intervention and control groups, continuous variables at baseline, and continuous variables measured only at follow-up. The percentage of women who had made an informed choice were knowledgeable and had clear values after intervention were compared using the χ^2 test.

Logistic regression was used to determine whether the decision aid reduced indecision, and, among those who had made a decision, whether the decision aid was associated with choosing to continue or stop screening. The effect of objective and perceived breast cancer risk and of self-assessed health on screening intentions before and after the intervention were also examined with logistic regression models. We used SAS statistical software (version 9.1; SAS Inc, Cary, North Carolina) to calculate all statistics.

The NSW Department of Health and the University of Sydney human research ethics committees approved this study. The trial was registered with the Australian Clinical Trials Registry and the Clinical Trials Registration System.

RESULTS

PARTICIPATION AND COMPLETION RATES

The trial was conducted from August 2005 to June 2006. In response to the 2000 mailed invitations, 39% of women returned signed consent forms. A total of 734 women were randomized, and 710 (97%) completed the trial (Figure 1).

RANDOMIZATION AND BASELINE CHARACTERISTICS

Table 1 shows baseline characteristics of the 734 women who participated in the trial. Key characteristics (age, knowledge of and intentions with respect to mammography screening, breast cancer worry) were similar in both groups, and most women intended to continue screening.

PRIMARY OUTCOMES

Knowledge and Clarity of Values

There was a large and statistically significant increase in knowledge in the intervention group (see **Table 2** for

Table 1. Baseline Characteristics of the Intervention Group (IG) and Control Group (CG)^a

Characteristic	IG (n=367)	CG (n=367)
Age, mean (SD), y	70.4 (0.7)	70.3 (0.6)
Education, No. (%) ^b		
None	1 (0.3)	1 (0.3)
Any	279 (76)	260 (71)
Post-high school	87 (24)	105 (29)
Country of birth		
Australia	294 (80)	292 (80)
United Kingdom or Ireland	38 (10)	38 (10)
Other	35 (10)	37 (10)
Main language spoken		
English	352 (96)	350 (95)
Bilingual (English and other)	8 (2)	7 (2)
Other	7 (2)	10 (3)
Worry about breast cancer		
None	169 (46)	162 (44)
A bit	181 (49)	170 (46)
Quite	9 (2)	28 (8)
Very	8 (2)	7 (2)
Intention regarding future screening mammograms		
Undecided	60 (16)	44 (12)
Decided	307 (84)	323 (88)
Stop screening	23 (6.3)	38 (10.4)
Continue screening	284 (77.4)	285 (77.7)
Knowledge scores, mean (SD) ^c		
Numerical	1.14 (0.97)	1.16 (0.96)
Concept	3.74 (0.99)	3.80 (1.01)
Total knowledge score	4.88 (1.57)	4.95 (1.56)

^aData are given as number (percentage) except where indicated.

^bOne is missing (in CG).

^cMaximum numerical and concept knowledge score, 5; maximum total score, 10.

P values). The percentage of women considered to have adequate knowledge (who had a score of at least 6 of 10) was 76.6% in the intervention group compared with 56.9% in the control group ($\chi^2=31.15$; $P<.001$).

The women in the intervention group had clearer values; the mean scores were 19.51 for the intervention group and 22.59 for the control group ($t_{545}=2.27$; $P=.02$).

Intentions Regarding Future Mammography Screening

Women in the intervention group were less likely to be undecided (odds ratio, 0.32 [95% confidence interval, 0.17-0.63]; $P<.001$). Among those women who had made a decision regarding screening, the decision aid did not alter the odds of intending to stop screening (odds ratio, 1.28 [95% confidence interval, 0.63-2.61]; $P=.50$).

Informed Choice

Informed choice was determined for all women whose knowledge and values were evaluated and who had indicated intention regarding future screening immediately after intervention (323, intervention group; 314, control group). Women who were undecided (35 [11%] in the control group, and 14 [4%] in the intervention group)

Table 2. Primary Outcomes for Intervention Group (IG) and Control Group (CG)^a

Outcome	IG	CG	Difference	P Value
Knowledge	(n=351)	(n=357)		
Change in total, mean	2.62	0.68	1.94	<.001
Change in concept, mean	0.66	0.38	0.29	<.001
Change in numerical, mean	1.95	0.30	1.65	<.001
Knowledgeable (total score > 50%), %	76.6	56.9	19.8	<.001
Values clarity	(n=331)	(n=315)		
Mean score	19.51	22.59	-3.08	.02
With clear values (< 25), %	89.4	81.3	8.2	.003
Intention	(n=349)	(n=356)		<.001
Undecided ^b	17 (4.9)	36 (10.1)		
Decided	332 (95.1)	320 (89.9)		.46
Decision	(n=322)	(n=320)		
Will stop screening ^c	33 (9.5)	33 (9.3)		
Will continue screening	299 (85.7)	287 (80.6)		
Informed choice	(n=309)	(n=279)		
Informed	227 (73.5)	136 (48.8)	24.72	<.001
Participated in screening, self-reported at 1-mo postintervention	(n=354)	(n=356)		.84
Screened	21 (5.9)	25 (7.0)	-1.09	
Unscreened, but have made appointment, or planning to make appointment	268 (75.7)	266 (74.7)	0.99	
Unscreened	65 (18.4)	65 (18.3)	0.10	

^aData are presented as number (percentage) except where noted.

^bOdds ratio, 0.32, adjusted for intention before the intervention.

^cOdds ratio, 1.28.

were considered not to have made a choice and were excluded from this analysis. Of those who expressed an intention either to continue or stop screening (309 in the intervention group, 279 in the control group), 73% of women in the intervention group compared with 49% of women in the control group made an informed choice ($\chi^2=37.92$; $P<.001$).

Participation in Screening

At 1 month after intervention there was no difference in the percentage of women who had participated in screening between groups. Few women had actually attended a screening, but most indicated that they were in the process of arranging to be screened.

SECONDARY OUTCOMES

The decision aid slightly lowered decisional conflict on the Informed subscale and Value subscale, but total decisional conflict was not lower. The decision aid did not make women more anxious, and approximately 95% of all women remained positive toward screening (**Table 3**).

None of the 3 factors—perceived breast cancer risk, objective breast cancer risk, or self-assessed health—was associated with intending to continue screening before ($P=.35$, $.60$, and $.82$, respectively) or after intervention ($P=.06$, $.62$, and $.90$, respectively).

COMMENT

Our decision aid increased the percentage of women who were able to make an informed decision to either continue or stop screening from 49% to 73%. It increased knowledge, reduced indecision regarding future screen-

ing, and did not increase breast cancer anxiety. To our knowledge, this is the first study to evaluate a decision aid about the pros and cons of screening mammography with women at the point of decision making, and it is therefore the first to demonstrate that a decision aid can be effective in assisting women to make a decision about screening mammography. In particular, we note that ours is the first evaluated decision aid about breast cancer screening that explicitly acknowledges and attempts to explain to women the possibility of overdiagnosis and overtreatment of breast cancer occurring as a result of screening.

The study found that adequately informing women about these issues did not have any effect on participation rates. This may be reassuring for countries with publicly funded screening programs that previously have opted to provide information to encourage women to attend.^{16,32}

The study design was strong (a randomized controlled trial), which allows us to be confident that the impacts on knowledge and informed choice are attributable to the decision aid. The study met criteria for a high-quality trial: randomization with allocation concealment and a high follow-up rate after randomization (97%). Our sample consisted of women who had been regularly participating in screening for some years. Although such women may be different from the general population, they are the appropriate population in which to test this decision aid because they are the group facing the decision addressed by it. Owing to ethics committee requirements at our institution, the trial had to be conducted on an “opt-in” basis. Given the recruitment difficulties inherent in such a design and compared with other similar studies,³³ we think that 39% is a reasonable initial participation (consent) rate. We ac-

Table 3. Secondary Outcomes for Intervention Group (IG) and Control Group (CG)

Outcome	IG	CG	Difference	P Value
Anxiety ^a	(n=321)	(n=315)		
STAI, mean	29.61	29.34	0.26	.76
Worry about breast cancer, No. (%)	(n=343)	(n=350)		NA
None	124 (36.2)	137 (39.1)	-13.0	
A bit	189 (55.1)	168 (48.0)	21.0	
Quite	19 (5.5)	30 (8.6)	-11.0	
Very	11 (3.2)	15 (4.3)	-4.0	
Change in worry, No. (%)	(n=343)	(n=350)		.30
Less worried	41 (12.0)	56 (16.0)	-15.0	
No change	217 (63.3)	214 (61.1)	3.0	
More worried	85 (24.8)	80 (22.8)	5.0	
Decisional conflict, mean ^b	(n=315)	(n=295)		
Total	20.06	21.89	-1.83	.12
Informed subscale (IG, n=334; CG, n=316)	20.78	23.26	-2.48	.05
Value subscale (IG, n=331; CG, n=315)	19.51	22.59	-3.08	.02
Support subscale (IG, n=321; CG, n=309)	20.90	22.98	-2.08	.10
Uncertainty subscale (IG, n=331; CG, n=316)	22.23	22.65	-0.42	.79
Effective decision subscale (IG, n=331; CG, n=314)	18.41	19.19	-0.78	.52
Attitudes ^c	(n=321)	(n=313)		
Mean score	81.37	83.53	-2.16	.07
Positive toward screening, %	94.7	95.9	-1.10	.50

Abbreviation: STAI, State-Trait Anxiety Inventory.

^aSTAI scale: 20-80; the higher the score, the greater the level of anxiety.

^bDecisional conflict scale: 0-100; 0=no decisional conflict, 100=extreme decisional conflict. Subscales: 0-100, where 0=extremely informed, extremely clear about personal values, extremely supported in decision making, extremely certain about best choice and a good decision.

^cAttitudes scale: 0-100; the higher the score, the more positive the attitude toward mammogram screening.

knowledge that the women who participated are those who were most interested in making an informed choice about whether to continue screening. It therefore seems reasonable to assume that the results are generalizable to women for whom the decision is relevant and who are interested in exploring their options and making an informed choice. Furthermore, we emphasize that the initial participation (consent) rate (which occurred prior to randomization) affects only the generalizability of the results, not the validity of the trial, because follow-up rates after randomization were very high.

Many decision aids are studied in trials involving individuals in consultation with their physicians. Although women may discuss breast screening with their physicians, many women will make the final decision about whether to be screened independently of their physicians, especially in countries where population breast screening programs are implemented. Thus, our decision aid was designed as a tool to be used independently by women, without necessarily assuming any input from their physician. The study supports the application of decision aids to such a setting. We believe the results are therefore particularly relevant to countries that provide population screening programs, such as Canada, the United Kingdom, and many European countries. We note, however, that even in countries without population screening programs, women are increasingly likely to make decisions about screening in the absence of input from their physicians as the trend toward more active consumer involvement in health care decision making increases.³⁴

In conclusion, this study has demonstrated that a decision aid about mammography screening increased

knowledge and enabled more women to make an informed choice about screening. It did not adversely affect women in terms of causing anxiety and decisional conflict about screening and did not affect participation rates. Screening programs should consider providing women older than age 70 years with evidence-based information, such as this decision aid, to assist them in their decision making.

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