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Results from a randomized trial of a web-based, tailored decision aid for women at high risk for breast cancer

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Abstract

Objective—To assess the impact of Guide to Decide (GtD), a web-based, personally-tailored decision aid designed to inform women’s decisions about prophylactic tamoxifen and raloxifene use.

Methods—Postmenopausal women, age 46–74, with BCRAT 5-year risk 1.66% and no prior history of breast cancer were randomized to one of three study arms: intervention ($n = 690$), Time 1 control ($n = 160$), or 3-month control ($n = 162$). Intervention participants viewed GtD prior to completing a post-test and 3 month follow-up assessment. Controls did not. We assessed the impact of GtD on women’s decisional conflict levels and treatment decision behavior at post-test and at 3 months, respectively.

Results—Intervention participants had significantly lower decisional conflict levels at post-test ($p < 0.001$) and significantly higher odds of making a decision about whether or not to take

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Competing interests
None declared.

prophylactic tamoxifen or raloxifene at 3-month follow-up ($p < 0.001$) compared to control participants.

Conclusion—GtD lowered decisional conflict and helped women at high risk of breast cancer decide whether to take prophylactic tamoxifen or raloxifene to reduce their cancer risk.

Practice implications—Web-based, tailored decision aids should be used more routinely to facilitate informed medical decisions, reduce patients' decisional conflict, and empower patients to choose the treatment strategy that best reflects their own values.

Keywords

Decision aids; Tamoxifen; Raloxifene; Breast cancer prevention; Tailoring

1. Introduction

Recent evidence suggests that approximately 15% of women aged 30–84 in the United States (US), more than 11.5 million women, may be at high risk of breast cancer [1], based on the National Cancer Institute Breast Cancer Risk Assessment Tool (BCRAT) 5-year absolute risk estimate [2,3]. For women who meet the high risk threshold of BCRAT 5-year risk 1.66% and are between the ages 40 and 74, the American Society of Clinical Oncology and National Comprehensive Cancer Network recommend that patients consider prophylactic treatment with tamoxifen or raloxifene to reduce the risk of invasive breast cancer in the future, although the latter is only recommended for postmenopausal women [4,5]. However, the decision to use prophylactic chemoprevention can be overwhelming to women, especially since there is not a clear right or wrong decision. The best decision for each woman must take into account the balance of potential risks and benefits, as well as one's own values and preferences. Thus, it is considered a preference-sensitive decision [6].

Decision aids are designed to help individuals make specific and deliberate choices about their care by providing accurate, balanced information on the options and outcomes to prepare individuals for decision making [7]. Ideally, the decision aid should also help individuals clarify their own values and better inform their personal choices [8]. Decision aids have been shown to increase individuals' knowledge of their options, provide evidence-based information about a health condition and the associated uncertainties, help patients recognize the value-sensitive nature of decisions, guide patients to consider which benefits and harms are most important to them, increase individuals' comfort with their personal choice, improve patient-provider communication about options, provide guidance in the steps of decision making and communication of their values, and enable patients to be active, informed participants [7,9].

The purpose of this study was to assess the impact of Guide to Decide (GtD) a web-based, personally tailored decision aid developed to inform women at high risk of breast cancer about the risks and benefits of prophylactic tamoxifen and raloxifene use [10]. The International Patient Decision Aid Standards (IPDAS) Collaboration suggests that the primary measure for evaluating patient decision aids should be decision quality, defined as the extent to which a patient's decision is informed and based on personal values. Furthermore, IPDAS recommended the need to assess patients' recognition that a decision needs to be made, appreciation of one's goals and values, and the importance of values in the decision [11]. Subsequently, to assess these key concepts of the patient decision making process, we aimed to evaluate the impact of the Guide to Decide on decisional conflict and treatment decision behavior (primary outcomes), and the association between these outcomes with patient satisfaction with the decision aid and preparation for decision making (secondary outcomes).

We hypothesized that the odds of having made a decision about whether or not to take prophylactic tamoxifen or raloxifene, at 3-month follow-up, would be higher among women who received the GtD; additionally, that women who received the GtD would report higher levels of post-test decisional conflict, since it is likely that these women would be unaware of their increased risk of developing breast cancer or the chemopreventive options prior to receiving the GtD. Further, we hypothesized that higher decisional conflict levels would be associated with lower patient satisfaction with the decision aid, and that higher levels of preparation for decision would be associated with higher odds of having made a decision about whether prophylactic tamoxifen or raloxifene, at 3-month follow-up.

2. Methods

2.1. Study design and intervention

Information about the study design, recruitment, study population and intervention has been previously described in detail [10]. In brief, upon obtaining IRB approval from the University of Michigan and the two recruiting sites, women at high risk of breast cancer (based on the National Cancer Institute Breast Cancer Risk Assessment Tool (BCRAT) 5-year risk 1.66%) were recruited from Group Health Cooperative (Seattle, WA) and the Henry Ford Health System (Detroit, MI) between August 2007 and March 2008. All women who were identified as meeting this BCRAT 5-year risk threshold, based on automated medical records at Group Health Cooperative and Henry Ford Health System, were mailed a study invitation letter, explaining that the study aimed to educate women about breast cancer chemoprevention, test an Internet-based information tool, and understand the best way to communicate breast cancer risk to women. Further, the invitation letter directed women how to log into the study website using a unique username and password to learn more about the study, be screened for eligibility, and enroll. Women were eligible if they were age 40–74, postmenopausal, not pregnant or nursing, had a BCRAT 5-year risk 1.66%, no prior history of breast cancer or chemoprevention, no contraindications for tamoxifen or raloxifene use, no terminal illness, and did not participate in the Study of Tamoxifen and Raloxifene (STAR) trial [12]. Eligible women provided consent via an online consent form.

Upon completing the eligibility and baseline questions, eligible participants were randomized to one of three study arms: intervention ($n = 690$), Time 1 control ($n = 160$), or 3-month control ($n = 162$). A block-randomized design was employed, using an automated algorithm, to ensure balanced distribution of participant characteristics across the three groups. Blocking was based on data collection site (Seattle vs. Detroit), race (White vs. Non-White), age (<60 vs. 60), and subjective numeracy (low vs. high). Intervention participants received the personalized GtD decision aid at baseline, followed immediately by a post-test survey and then a 3-month follow-up survey. Time 1 control participants completed the same 'post-test' questionnaire at baseline as the intervention group (excluding items assessing satisfaction with the decision aid) and the 3-month follow-up survey. After completion of the last survey, they received access to their tailored GtD decision aid. Participants in the 3-month control group completed an abbreviated 'post-test' survey (personality measures only) followed by the 3-month follow-up survey and access to the decision aid. The latter control group was used to address threats to internal validity, due to our concern that participants in the Time 1 control group would search the Internet for information about tamoxifen and raloxifene after answering questions about these drugs in the post-test survey, potentially impacting their answers at the 3-month follow up. Inclusion of the 3-month control arm allowed us to have a control group truly blinded to the concept of chemoprevention and to which we could compare the intervention group at 3 months.

Following completion of the post-test intervention, women were mailed a \$10 gift card to a store of their choice (i.e. Starbucks, Target, and a local grocery store). To encourage

completion of the 3-month follow-up surveys, participants were randomized to receive either a \$2 or \$5 bill as pre-incentive, included with a reminder letter to complete the online survey. Women who failed to complete the survey within about a week were sent a series of three emails over the following week asking them to log in and complete the brief assessment.

The GtD was designed from a more practice-based framework, trying to understand risk communication. The GtD was based on previous work looking at deficiencies with decision aids in prostate cancer and attempts to address those areas that were lacking when trying to assess issues in presenting risks and benefits [13]. Within the GtD, participants received information about breast cancer (in general), their individual absolute risk of developing breast cancer (BCRAT 5-year risk score) and information on the risks and benefits of tamoxifen and raloxifene. Information on the risks of both drugs was tailored to each woman's age and race/ethnicity, while the benefits of the drugs were tailored based on the BCRAT risk score. This study assessed the Guide to Decide (GtD) version 2, which was based largely on the GtD version 1 that provided information on tamoxifen only. That decision aid had undergone focus group testing, 1-on-1 cognitive interviews, and went through a randomized controlled trial. GtD2 then added information on raloxifene, added communication factors, and pilot tested using cognitive interviews. All content was written in English at an 8th grade reading level, equivalent to that of a 13-year old in the US

2.2. Key measures

2.2.1. Decisional conflict—Decisional conflict was measured at post-test survey using the 16-item Decisional Conflict Scale (DCS) [14]. This measure is used to assess patients' uncertainty in making health-related decisions, the factors that contribute to this uncertainty, and perceived effective decision making. It is composed of five subscales: informed, values clarity, support, uncertainty, and effective decision. In the present study, both total DCS and individual subscale scores were calculated as specified by O'Connor et al. [15]. Previously reported findings from the Guide to Decide study calculated decisional conflict such that higher scores corresponded to lower decisional conflict levels [10].

2.2.2. Participant satisfaction and identification with decision aid—Participant satisfaction with the GtD decision aid was measured at post-test using seven items. Four of the items were rated on a 7-point Likert scale ranging from 'completely disagree (1) to "completely agree (7): (1) "I felt that the risk/benefit numbers I received were "my numbers" (not other people's)", (2) "I found the decision guide to be written personally for me", (3) "I felt that the information in this decision guide was relevant to me", and (4) "I felt that the information in this decision guide was designed specifically for me". The question "How trustworthy was the decision guide?" was measured on an 11-point Likert scale ranging from ("not at all trustworthy" (0) to "extremely trustworthy" (10)). The remaining two items: "The program included some numerical information about how likely a women would be to experience side effects of tamoxifen or raloxifene. How easy or difficult was it to understand?" ("very difficult to understand" (1) to "very easy to understand" (4)); and "Would you recommend this program to a close friend or family member?" ("definitely would not recommend" (1) to "definitely would recommend" (5)).

2.2.3. Preparation for decision making—The Preparation for Decision Making (PrepDM) Scale [16,17] was used to evaluate participants' perceived preparation to make a decision about taking a chemopreventive agent to reduce their risk of future breast cancer. The PrepDM has been previously validated and shown to have good reliability [17,18]. PrepDM scores were calculated as specified by the scale's authors [16].

2.2.4. Stage of decision making—Participants' decision making behavior was measured in the 3-month follow-up survey using two items. First, participants were asked, "Have you made a decision about whether or not to take a breast cancer prevention drug as a way to prevent breast cancer?" For this analysis, we collapsed responses into two categories: "made a decision" (i.e. decided to not take either tamoxifen or raloxifene/decided to take tamoxifen/decided to take raloxifene) or "not made a decision." Individuals who reported that they had not made a decision whether or not to take a breast cancer drug were subsequently asked, "How close are you to making a decision about whether to take a breast cancer prevention drug as a way to prevent breast cancer?" Response options for the latter question were based on a 4-point scale, with prompts at each extreme of the scale only; specifically, (1) "Not at all close to making a decision," (2), (3), (4) "Extremely close to making a decision." Scale options 2 and 3 did not have any prompts associated with them.

2.3. Statistical analyses

All results were based on data obtained from participants' self-reported responses to the online questionnaires. Descriptive statistics were used to assess participants' baseline sociodemographic characteristics and BCRAT 5-year risk score. To assess the impact of the GtD on participants' decisional conflict, we used multivariate linear regression to compare post-test DCS and decisional conflict subscale scores between intervention and Time 1 control participants, adjusting for age, race (White/non-White), education (high school diploma/GED, some college/trade school, and bachelor's degree or higher), and BCRAT 5-year risk score; these baseline covariates were included in the multivariate linear regression to improve estimate precision [19]. We ran separate models for the overall DCS and subscale scores. Similar multivariate linear regression models were used to examine the association between DCS (total and subscale scores) and the seven patient satisfaction measures adjusting for age, race, education and BCRAT risk score.

To examine whether the GtD had an impact on self-reported decision making, we used a two-step modeling approach. First, logistic regression was used to assess whether there was a difference between the intervention, Time 1 control, and 3-month control participants in having made a decision about whether or not to take tamoxifen or raloxifene at 3-month follow-up. Second, among those participants who had not made a decision at 3-month follow-up, ordered logistic regression was used to examine self-reported stage of decision making at 3-month follow-up between the intervention, Time 1 control, and 3-month control participants. We then examined whether the decision aid was more helpful to those participants who had not made a decision and, thus, were actively considering their options at 3-month follow-up. To accomplish this, we assessed the association between post-test PrepDM scores and treatment decision making behavior among intervention participants, using the same two-step modeling approach; specifically, post-test PrepDM scores was used as the predictor in both the logistic and ordered logistic regression models. All statistical analyses were done using Stata/SE 10.1 (Stata Corporation, College Station, TX, USA).

3. Results

3.1. Participants' baseline characteristics and response rates

Participants' baseline demographic characteristics are described in Table 1. Intervention and control group participants were similar in age, race/ethnicity, educational attainment and BCRAT 5-year risk score at baseline. In general, participants were predominately non-Hispanic White (96.1%) and well-educated (65% with a bachelor's degree or higher), with a mean age of 61.8 years (standard deviation (SD) = 5.2) and mean BCRAT 5-year risk of 2.6% (SD = 1.2).

Overall, 1039 women provided informed consent and were randomized (Fig. 1). During the study, 27 control participants received the GtD following the post-test, in error, rather than after the 3-month follow-up survey, as designed. Accordingly, these participants were excluded from analyses. For this study, we assessed a sample of 1012 participants (84.5% of consenting participants) who completed the 'post-test' survey, among whom 585 participants (48.9% of consenting participants) completed the 3-month follow-up survey. Our analyses indicated that participants who responded to the 3-month survey were similar to non-responders, with the exception that a greater proportion of 3-month respondents had a college degree (71.1% vs. 58.8%, respectively, $p < 0.001$). To gain an understanding about the time to complete the decision aid, we examined how long intervention group participants spent online. On average, individuals spent 49 min (range = 15–173 min) reviewing the decision aid and completing the embedded post-test.

3.2. Decisional Conflict Scale and decisional conflict subscale scores

Table 2 describes the Decisional Conflict Scale (DCS) total and subscale scores of intervention and control group participants at post-test, adjusting for age at enrollment, race, education and baseline BCRAT 5-year risk score. Intervention group participants had significantly lower total DCS scores ($p < 0.001$), as well as significantly lower scores on the uncertainty ($p < 0.001$), informed ($p < 0.001$), values clarity ($p < 0.001$), support ($p < 0.001$), and effective decision ($p < 0.001$) subscales compared to control group participants.

3.3. Patient satisfaction with the decision aid

Patient satisfaction with the Guide to Decide was measured at post-test among intervention group participants. Overall, participants' responses trended toward higher satisfaction on each measure: The risk/benefit numbers I received were "my numbers" (mean = 5.3, s.e. = .06; 1–7 point scale); The GtD was written personally for me (mean = 4.4, s.e. = .06; 1–7 point scale); The information in the GtD was relevant to me (mean = 5.1, s.e. = .06; 1–7 point scale); The information in the GtD was designed specifically for me (mean = 4.2, s.e. = .06; 1–7 point scale); How trustworthy was the GtD (mean = 7.2, s.e. = .08; 0–10 point scale); How easy/difficult was it to understand numerical information in the GtD (mean = 3.7, s.e. = .03; 1–4 point scale); Would you recommend the GtD to a close friend or family member? (mean = 3.9, s.e. = .03; 1–5 point scale); results not shown.

3.4. Association between decisional conflict and patient satisfaction with the decision aid

Among intervention group participants, higher post-test DCS scores were associated with significantly lower satisfaction with the decision aid at post-test (Table 3). Specifically, on six of the seven satisfaction items, increased decisional conflict levels at post-test were associated with significantly lower satisfaction with the decision aid. No significant association was found between DCS and participants' willingness to recommend the decision aid to a family member or close friend. The same trend was found with each of the decisional conflict subscale scores (results not shown).

3.5. Stage of decision making and preparation for decision making

At 3-month follow-up, a significantly greater proportion of intervention group participants (44.8%; $p < 0.001$) had made a decision about whether or not to take a breast cancer chemoprevention drug compared to Time 1 control group (65.7%) and 3-month control group participants (70.0%, results not shown). The odds of having made a decision at 3-month follow-up were lower for participants in both control groups compared to intervention group participants, Time 1 control (OR = 0.42 [95% CI: 0.27–0.67]; $p < 0.001$) and 3-month control (OR = 0.35, [95% CI: 0.22–0.56]; $p < 0.001$) (Table 4).

Fig. 2 shows the distribution of participants' stage of decision making, among those participants who had not made a decision by 3-month follow-up. A significantly greater proportion of Time 1 control group and 3-month control group participants reported to be in Stage 1 "Not at all close making a decision" compared to intervention group participants ($p < 0.05$). Participants in the 3-month control group had significantly lower odds of being closer to making a decision compared to intervention group participants (OR = 0.33 [95% CI: 0.17–0.65]; $p = 0.001$; Table 4). There was no statistically significant difference in self-reported stage of decision making between Time 1 control and intervention group participants who had not made a decision by 3-month follow-up.

Among intervention group participants, higher post-test PrepDM scores were associated with significantly decreased odds of having made a decision about whether to take a breast cancer chemoprevention drug at 3-month follow-up (OR = 0.99, [95% CI: 0.98–1.0], $p = 0.03$; Table 5). Of those intervention participants still in the decision making process at 3-month follow-up, individuals with a higher PrepDM score at post-test had increased odds of being farther along in the decision making process (OR = 1.04, [95% CI: 1.02–1.06]; $p < 0.001$). Fig. 3 shows the mean post-test PrepDM scores among intervention participants in each stage of the decision making process who had not made a decision at 3-month follow-up.

Post hoc analyses to assess post-test PrepDM scores between intervention group participants who completed the 3-month follow-up test and those lost to follow-up found no significant differences between groups (results not shown).

4. Discussion and conclusion

4.1. Discussion

We found that women who received the GtD decision aid had greater odds of making a decision or were closer to making a decision about whether to take prophylactic tamoxifen or raloxifene than women who did not receive the decision aid. Furthermore, contrary to our hypotheses, women in the intervention group had significantly lower decisional conflict levels. In fact, mean decisional conflict scores among women receiving the decision aid were less than half that of Time 1 control participants (22.0 vs. 55.7, respectively), with women in latter group among those who did not receive information or knowledge about the chemoprevention drugs.

These findings provide further support for the benefit of decision aids among individuals facing complex health decisions [8]. Evidence suggests increased decisional conflict is associated with a higher likelihood of delayed decisions and wavering between choices [20], with decisional conflict scores of less than 25 associated with implementing decisions, whereas scores higher than 37.5 are associated with decision delay or feelings of uncertainty about decision implementation [15]. Our study supports this previous research, finding that women in Time 1 control had lower odds of having made a decision about taking prophylactic chemoprevention compared to intervention participants. Moreover, among women who had not made a decision, participants in the 3-month control had lower odds of being close to making a decision compared to those in the intervention group. Additionally, our study expands on previous studies evaluating the effectiveness of decision aids [17], by using a novel, two-step approach for assessing patients in different stages of the decision making process.

We found that lower levels of decisional conflict were associated with significantly increased patient satisfaction with the decision aid. Intervention group participants with lower decisional conflict were more likely to report that they felt the GtD was written

personally for them, designed specifically for them, relevant, trustworthy, and that the risk/benefit number presented were “my numbers” (not other people’s) and easy to understand. Consequently, these findings suggest that decisional conflict may be associated with the patients’ ability to identify with, understand, and relate to the information presented in the decision aid.

In addition, our results on the PrepDM scores of women who received the decision aid support previous findings suggesting decision aids may be more useful to individuals who are actively considering a decision [17]. Subsequently, GtD may be more helpful to women who are still contemplating the decision about whether to take prophylactic chemoprevention compared to those who have already made a choice or are not at all close to making a decision. These results highlight that the timing of a decision aid intervention in the care pathway may affect the usefulness of decisional support to a patient.

4.1.1. Strengths and limitations of the study—The Guide to Decide was the first randomized trial of a breast cancer chemoprevention decision aid following the results of the STAR trial [10]. Our study evaluated the effects of the GtD on various aspects of participants’ decision making process, contributing valuable information to an area of research that Sivell et al. [21] suggest only one other such study exists. Furthermore, unlike many other prior studies, we followed the International Patient Decision Aid Standards (IPDAS) Collaboration guidelines for assessing the quality of decision making, by examining the extent to which participants’ reported recognizing that a decision needs to be made, making an informed decision, as well as acknowledging one’s goals and values, and the importance of incorporating personal values in the decision [11]. Consequently, our study on the impact of the GtD reflects an evidence-based approach and shift in paradigm of how researchers may examine the effectiveness of decision aids on the quality of patient decision making.

While our study adds to the current literature, there are also some pragmatic limitations to be considered. First, this study was conducted in an educated, predominately White, insured population of women aged 40–74 years; therefore, the results may not generalize to women who are uninsured, lower SES, from other racial/ethnic backgrounds, or outside the sample age limit. Second, the use of a web-based decision aid may create a selection bias, since individuals without computer access were not eligible for this trial and women not comfortable using computers or the Internet may have chosen not to pursue enrollment. As such, the results may not generalize to those who do not use the Internet or are not comfortable with this technology. Third, some experts contend that reducing decisional conflict should not necessarily be an explicit goal of decision aids, because sometimes increased awareness of tradeoffs may cause patients to feel more conflicted [22]. These experts argue that the goal of decision aids is to inform people about their choices regardless of whether that increases or decreases conflict. Nevertheless, our study shows that the GtD informs patients about tradeoffs while, at the same time, reducing decisional conflict. Finally, the results may be specific to the GtD tool and not generalize to other decision aids. Despite these limitations, we believe the results do generalize to the intended audience (insured post-menopausal women at risk for elevated risk for breast cancer who are comfortable using the Internet and eligible for breast cancer chemoprevention). Moreover, the results provide important insight into the value that decision aids can have in helping women make informed decisions regarding their care.

5. Conclusion

Overall, our findings indicate that receiving an online decision aid may help women at high risk for breast cancer make a decision, or be further along in the decision making process, as

well as reduce decisional conflict about future prophylactic tamoxifen or raloxifene use to reduce their cancer risk.

5.1. Practice implications

Patient involvement in decisions about their health has become increasingly important, with patient-centered care recognized as a primary domain of quality health care [23,24]. Engaging patients in their own decision has the greatest potential to help guide medical decisions that incorporate individuals' preferences, needs, and values, as well as lead to increased satisfaction with one's health care and better quality of life [25,26]. However, patients must understand the facts relevant to their medical decision in order to be effective advocates and make informed decisions [27]. Accordingly, for women at high risk of developing breast cancer, the decision to use tamoxifen or raloxifene as a prophylaxis is a preference-sensitive decision; that is, it involves weighing trade-offs between the risks (inconvenience, health care costs, and a number of potential side effects) and benefits of the treatment (the chance that the drug will reduce one's risk of developing breast cancer). Further, each woman must weigh these relative risks and benefits for herself and make a decision that is aligned with her own values and preferences; there is no single right or wrong answer.

Personalized decision aids should be used more routinely with some patient groups to facilitate such informed medical decisions, reduce patients' decisional conflict, improve communication, and empower patients to choose the treatment strategy that best reflects their own values. GtD was developed as a decisional support tool that uses web-technology to provide useful information to women at high risk of developing breast cancer that can be accessed in the comfort of their own home, alone or with key members of their social support system, where patients are likely to be less distressed, and which may further improve understanding [28].

I confirm all patient/personal identifiers have been removed or disguised so the patient/person(s) described are not identifiable and cannot be identified through the details of the story.

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Fig. 1.
Guide to Decide consort diagram.

Fig. 2.

Participants' stage of decision making at 3-month follow-up. *Notes:* Percentages based on those participants who reported to have not made a decision about whether or not to take a chemoprevention drug at 3-month follow up (intervention group $n = 171$, Time 1 control $n = 67$, and 3-month control $n = 70$).

Fig. 3.

Stage of decision making and preparation for decision making among intervention group participants in the decision making process. *Notes:* The F -statistic is based on the F -test for trend. Estimated values are the mean preparation for decision making (PrepDM) score, at post-test, among intervention group participants in each stage of the decision making process, who had not made a decision about whether or not to take a breast cancer chemoprevention drug at 3-month follow-up survey. All responses are based on intervention group participants with a valid (non-missing) post-test PrepDM score ($n = 169$).

Table 1

Baseline characteristics of participants.

Characteristic	Intervention (n = 690)		Time 1 control (n = 160)		3-month control (n = 162)		p value
	Mean [95% CI]		Mean [95% CI]		Mean [95% CI]		
Age, years	61.7 [61.3, 62.1]		62.0 [61.2, 62.9]		61.5 [60.6, 62.4]		0.63
	n (%)		n (%)		n (%)		
Race/ethnicity							
Non-Hispanic White	660 (95.7)		152 (95.0)		156 (96.3)		0.96
Asian/Pacific Islander	13 (1.9)		3 (1.9)		2 (2.5)		
Native American	8 (1.2)		3 (1.9)		1 (0.6)		
Black	3 (0.4)		1 (0.6)		0 (0.0)		
Hispanic	3 (0.4)		1 (0.6)		1 (0.6)		
Other	3 (0.4)		0 (0.0)		0 (0.0)		
Educational attainment							
High school diploma/GED	50 (7.3)		9 (5.6)		14 (8.7)		0.77
Some college/trade school	179 (26.1)		45 (28.1)		46 (28.6)		
Bachelors degree or higher	456 (66.6)		106 (66.3)		101 (62.7)		
	Mean [95% CI]		Mean [95% CI]		Mean [95% CI]		
5-Year BCRAT risk score	2.67 [2.58, 2.76]		2.60 [2.43, 2.76]		2.81 [2.52, 3.10]		0.32

Notes: Abbreviations: 95% CI = 95% confidence interval.

All estimates are based on participants who have a valid (non-missing) response to each variable.

Table 2Participants' Decisional Conflict Scale and subscale scores^a

Characteristic	Intervention (<i>n</i> = 690)	Time 1 control (<i>n</i> = 160)	<i>p</i> value
	Mean [95% CI]	Mean [95% CI]	
Total decisional conflict score	22.0 [18.8, 25.1]	55.7 [38.9, 72.5]	<0.001
Uncertainty subscore	37.4 [32.7, 42.0]	73.2 [48.5, 98.0]	<0.001
Informed subscore	8.69 [5.46, 11.9]	57.4 [40.3, 74.6]	<0.001
Values clarity subscore	12.6 [8.9, 16.4]	47.7 [27.8, 67.6]	<0.001
Support subscore	18.1 [14.6, 21.6]	43.3 [24.8, 61.8]	<0.001
Effective decision subscore	30.0 [26.1, 33.9]	55.5 [34.8, 76.3]	<0.001

Notes. Abbreviations: 95% CI, 95% confidence interval.

Estimates derived from multivariate linear regression, adjusting for age, race, education, and baseline BCRAT 5-year risk score.

^aTotal decisional conflict and subscale scores based on participants' responses to the Decisional Conflict Scale at post-test.

Table 3

Association between decisional conflict and satisfaction with the decision aid^a

Participant satisfaction item	Total DCS score (<i>n</i> = 690)	
	β (SE)	<i>p</i> value
The risk/benefit numbers I received were “my numbers” (not other people’s)	−0.02 (0.004)	<0.001
The GtD was written personally for me	−0.01 (0.004)	<0.001
The information in the GtD was relevant to me	−0.01 (0.003)	0.007
The information in the GtD was designed specifically for me	−0.01 (0.004)	0.001
How trustworthy was the GtD	−0.01 (0.005)	0.002
How easy/difficult was it to understand numerical information in the GtD	−0.004 (0.001)	0.003
Would you recommend the GtD to a close friend or family member?	−0.002 (0.002)	0.291

Notes: Abbreviations: β , beta estimate; SE, standard error.

^aEstimates presented were obtained by multivariate linear regression analyses of total DCS score (predictor of interest) and patient satisfaction measures (modeled separately), adjusting for age, race, education, and BCRAT risk score as covariates; analyses among intervention group participants only.

Table 4

Impact of the Guide to Decide on treatment decision behavior.

Treatment arm	Made a decision about whether to take breast cancer prevention drug ^a		
	OR	95% CI	p value
Intervention (<i>n</i> = 383)	Ref.	–	–
Time 1 control (<i>n</i> = 102)	0.42	0.27–0.67	<0.001
3-month control (<i>n</i> = 100)	0.35	0.22–0.56	<0.001
Had not made a decision about whether to take breast cancer prevention drug. Self-reported stage of decision making (I–IV) ^b			
	OR	95% CI	p value
Intervention (<i>n</i> = 171)	Ref.	–	–
Time 1 control (<i>n</i> = 67)	0.65	0.36–1.16	0.146
3-month control (<i>n</i> = 70)	0.33	0.17–0.65	0.001

Notes: Abbreviations: 95% CI, 95% confidence interval.

^a Estimates obtained from logistic regression analysis of having made a decision about whether or not to take a breast cancer prevention drug at 3-month follow-up between intervention arms; analyses based on those participants with a valid (non-missing) response.

^b Estimates obtained from ordered logistic regression analyses, among participants who had not made a decision about whether to take a breast cancer prevention drug at 3-month follow-up, with self-reported stage of decision making (I–IV) as the outcome and intervention arm as predictor.

Table 5
Association between preparation for decision making and treatment decision behavior.

Made a decision about whether to take breast cancer prevention drug ^a		
OR	95% CI	p value
PrepDM Score ^b	0.99	0.98–1.00
Had not made a decision about whether to take breast cancer prevention drug. Self-reported stage of decision making (I–IV) ^c		
OR	95% CI	p value
PrepDM Score ^b	1.04	1.02–1.06
		<0.001

Notes: Abbreviations: OR, odds ratio; 95% CI, 95% confidence interval.

^a Estimates obtained from logistic regression analyses, with having made a decision about whether to take a breast cancer prevention drug at 3-month follow-up as the outcome and post-test PrepDM score as predictor.

^b Among intervention group participants only who had not made a decision about whether or not to take a breast cancer chemoprevention drug at 3-month follow-up survey (*n* = 171).

^c Estimates obtained from ordered logistic regression analyses, among participants who had not made a decision about whether to take a breast cancer prevention drug at 3-month follow-up, with self-reported stage of decision making (I–IV) as the outcome and post-test PrepDM score as predictor.