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ORIGINAL REPORT

Improving Breast Cancer Surgical Treatment Decision Making: The iCanDecide Randomized Clinical Trial

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ABSTRACT

Purpose

This study was conducted to determine the effect of iCanDecide, an interactive and tailored breast cancer treatment decision tool, on the rate of high-quality patient decisions—both informed and values concordant—regarding locoregional breast cancer treatment and on patient appraisal of decision making.

Methods

We conducted a randomized clinical trial of newly diagnosed patients with early-stage breast cancer making locoregional treatment decisions. From 22 surgical practices, 537 patients were recruited and randomly assigned online to the iCanDecide interactive and tailored Web site (intervention) or the iCanDecide static Web site (control). Participants completed a baseline survey and were mailed a follow-up survey 4 to 5 weeks after enrollment to assess the primary outcome of a high-quality decision, which consisted of two components, high knowledge and values-concordant treatment, and secondary outcomes (decision preparation, deliberation, and subjective decision quality).

Results

Patients in the intervention arm had higher odds of making a high-quality decision than did those in the control arm (odds ratio, 2.00; 95% CI, 1.37 to 2.92; $P = .0004$), which was driven primarily by differences in the rates of high knowledge between groups. The majority of patients in both arms made values-concordant treatment decisions (78.6% in the intervention arm and 81.4% in the control arm). More patients in the intervention arm had high decision preparation (estimate, 0.18; 95% CI, 0.02 to 0.34; $P = .027$), but there were no significant differences in the other decision appraisal outcomes. The effect of the intervention was similar for women who were leaning strongly toward a treatment option at enrollment compared with those who were not.

Conclusion

The tailored and interactive iCanDecide Web site, which focused on knowledge building and values clarification, positively affected high-quality decisions largely by improving knowledge compared with static online information. To be effective, future patient-facing decision tools should be integrated into the clinical workflow to improve decision making.

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INTRODUCTION

Patients who are newly diagnosed with curable breast cancer face a complicated treatment decision-making process. This context has motivated initiatives to improve decision quality to ensure patients are informed of the tradeoffs with regard to the risks and benefits of different treatments, that their values are understood and incorporated into treatment decisions, and that they are prepared to engage their clinicians in decision -making.[1-3] Tools (ie, decision aids) have been developed to help patients manage treatment decision making after a diagnosis of breast cancer.[4-15] Few trials have evaluated breast cancer treatment decision tools in surgical practice.[5,15] Only one study has demonstrated the positive effect of a decision aid on a key aspect of decision quality, including knowledge and decision satisfaction,[10] whereas others have produced mixed results. The effect of existing tools is also limited by small patient samples from a single academic or a few clinical practice sites, as well as by the lack of attention to the variable decision workflow found in community practice. Despite the existence of many cancer treatment information Web sites and some online decision aids, there remain large gaps in

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a patient's level of knowledge about his or her treatment options, even after surgery.[16,17] Furthermore, patients themselves report a strong desire for assistance with cancer treatment decisions.

To address these gaps, we conducted a large randomized controlled trial of an interactive and comprehensive version of a decision tool, called iCanDecide, which covered both locoregional and systemic treatment decision making for patients with breast cancer, and was tailored to their age, race, timing of surgical consult, and values clarification feedback compared with a static version that emulated contemporary, quality Web sites typical of those available to patients; the iCanDecide intervention Web site is available online.[18] We hypothesized that patients with breast cancer who viewed the intervention version of iCanDecide would have higher rates of both aspects of a high-quality decisions, defined as a decision that is both informed and values concordant,[19] would be more prepared to make their treatment decisions, and would appraise their decisions more positively than patients who viewed the control version that was similar to quality contemporary Web sites.[3,20]

METHODS

Overall Design

This study was based a conceptual framework for improving decision making, informed by our preliminary studies and theory.[21-28] We performed a patient-level multisite randomized controlled trial in 22 surgical practices in four states from February 2014 to May 2016. Eligible consenting patients within each practice were randomly assigned to the intervention (tailored and interactive) or control (static information) version of the iCanDecide Web site. The study received institutional review board approval from the University of Michigan and the participating practices. The protocol was published before the completion of recruitment.[28]

Practice Recruitment

We recruited practices directly in geographic areas with diverse populations. Each practice, which ranged from one to five surgeons, received $1,000 for participation and was visited by the study team to provide training. Practices were responsible for having someone (eg, a surgeon or nurse) offer study information packets to eligible women and for providing monthly recruitment reports. Practices were given iPads to encourage participation from patients with limited access to the Internet.

Participants and Procedures

Eligible patients were women with a new diagnosis of early-stage (I to II) breast cancer between the ages of 21 and 84 years who had not yet received surgical treatment and who did not have a contraindication for either mastectomy or breast conservation therapy. Women who received neoadjuvant chemotherapy were eligible if actively considering surgical options. We used a flexible approach to enrollment—patients could enroll before or after their first surgical consultation visit—on the basis of extensive pilot work with surgical practices. Only one practice (n = 2 enrolled patients) opted to invite patients before surgical consultation.

The study packet included an introductory letter, Web site login information, and $20. Once logged in, participants consented online, completed a short survey, and were allocated to a study arm using random assignment stratified by site, age, race, education, and the timing of surgical consult. Two weeks after enrollment, women with invasive breast cancer were encouraged to log back into the tool to view a systemic treatment module. The first follow-up survey was mailed 4 weeks after enrollment, with a second survey mailed 9 months later. A modified Dillman method[29] was used to encourage survey completion at each time point (mailed survey, telephone reminder, resending survey, and telephone option). This work reports the results of the first follow-up survey.

Intervention and Control Arms

Participants were randomly assigned online to either an interactive and tailored iCanDecide Web site (intervention) or to the static iCanDecide Web site (control). Both versions were based on an existing prototype[3] that was developed according to criteria outlined by the International Patient Decision Aids Standards[30] using user-centered design.[31] Both versions were based on extensive piloting feedback from clinicians and patients with breast cancer. Patients were blinded to the true intervention arm as both versions had the same name and included quality information about the key content areas for locoregional and systemic treatment. The intervention included several innovative features designed to align with components of a high-quality decision, which included a knowledge-building module that systematically delivered information to participants about key content areas (survival outcomes, risk of local recurrence, radiation, recovery from surgery, need for additional surgery, genetic testing, reconstruction, and bilateral mastectomy), a values-clarification and feedback exercise that used conjoint analysis[3] to assess the importance of four key attributes of treatment (radiation therapy, keeping the natural breast, need for additional surgeries, and cosmetic outcome),[32,33] and a patient activation module that used testimonials that were tailored to age, race, and the timing of surgical consult. The control version emulated contemporary, quality Web sites that are typical of those available to patients.

Primary Outcome Measures

Outcomes were selected on the basis of our framework and their relevance to treatment decision making. The primary outcome, measured via patient report from the first follow-up survey, was a high-quality locoregional treatment decision that consisted of two components, which were accurate knowledge about the risks and benefits of treatment option tradeoffs, and that the chosen treatment was concordant with patient values.[19] We assessed each component separately because they are distinctly different constructs with different clinical practice implications. Knowledge was measured by using a validated five-item knowledge scale for locoregional treatment[19] that was adapted from a prior 12-item knowledge scale.[32] We used a prespecified cutoff of $> 80\%$ to determine a clinically meaningful level of high knowledge. Values-concordant treatment was determined by using a validated five-item question set[19] that assessed the importance to the patient to achieve certain outcomes (eg, keeping the natural breast and/or avoiding radiation) on a scale from 0 to 10. This question set was asked before the patient logged off the Web site. We modeled these attributes to generate a predicted probability of preferring breast conservation or unilateral or bilateral mastectomy. If the prediction aligned with the treatment received, this was considered concordant, otherwise it was considered nonconcordant.

Secondary outcomes included patient preparation for decision making, the extent of deliberation, and subjective decision quality (SDQ). Preparation for decision making was measured by using a validated scale that assessed the degree to which participants felt the Web site prepared them for making their treatment decision.[34] We assessed deliberation (the degree to which patients spent time thinking through the options)[35,38] and SDQ by using measures that were developed and validated by our team.[36-38] All were measured on continuous scales and standardized to ranges from 1 to 5.

Patient Factors

Factors were obtained from the login survey and included age, race, education level, and partnered status, and whether the patient had seen her surgeon yet (yes or no). We also assessed the patient's decision trajectory at enrollment by asking whether she was leaning toward a certain treatment option (mastectomy, lumpectomy, other, or not leaning) and whether she felt sure of the best treatment choice for her (yes or no). We combined these

two questions into a binary measure—leaning strongly toward a treatment option (yes to leaning and to being sure) versus other combinations.

Web Site Use and Satisfaction

Patients were asked to indicate whether they thought the Web site was easy to use, helpful in decision making, helpful in thinking about pros and cons, and whether they would recommend it to other patients with breast cancer. Participants were also asked to rate their satisfaction with regard to the Web site's length and the amount of information available. Finally, we asked whether patients contacted their surgeon's office after viewing the Web site (yes or no).

Sample Size

Our prior research provided the assumptions with which to determine the sample size for this study.[16,27,39,40] We estimated a need to recruit 222 patients per arm (N = 444). Assuming that 76% of participants would complete the primary outcome assessment, this would result in a final sample size of 340 (170 patients per arm), which would ensure 80% power ($\alpha = .05$) to detect differences of 10% to 15% in high-quality decisions between patients in the intervention and control arms with an intracluster correlation of 0.01 to 0.04. We exceeded the recruitment goal to increase the power to detect differences in secondary outcomes. Data remained blinded and locked until after all data collection was completed.

Statistical Methods

All primary analyses were prespecified and followed the published protocol.[28] We used an intention-to-treat analysis such that all patients who were randomly assigned were included in analyses.[41] We first examined whether random assignment balanced the distribution of demographic and clinical factors across two arms. Because these covariates are balanced across two arms, we conducted unadjusted analyses of the primary outcome (high-quality decision) and its two components—knowledge and values-concordant treatment—using generalized linear mixed models with logit link function to evaluate the effect of intervention. We then conducted unadjusted analyses of secondary outcomes to evaluate the hypothesis that patients in the intervention arm would have higher rates of deliberation, decision preparation, and SDQ than patients in the control arm, using linear mixed models.

In adjusted analyses of primary and secondary outcomes using mixed models, we considered patient age, race, education, marital status at enrollment, cancer stage (ductal carcinoma in situ *v* not), and treatment received (mastectomy *v* not) as covariates in the models. Participants with missing items for outcomes or covariates (≤ 5%) were excluded from analyses.

In post hoc unadjusted analyses, we examined the association between the study arm (intervention *v* control) and the two outcomes significant in the primary and secondary outcomes analyses—knowledge and decision preparation—separately by baseline treatment decision trajectory, and we evaluated the interaction between decision trajectory and study arm. We used generalized linear mixed models for knowledge and linear mixed models for decision preparation. Detailed analyses can be found in the Data Supplement. Analyses were performed by using SAS (SAS/STAT User's Guide, Version 9.4; SAS Institute, Cary, NC).

RESULTS

Participant Characteristics

Study packets were distributed to 1,084 patients, of whom 567 (52.3%) visited the Web site and, of these, 537 (94.7%) were eligible, created an account, and completed an enrollment survey (Fig 1). The response rate to the first follow-up survey was 92% (n = 496) in both the intervention (n = 245) and control (n = 251) arms. Nonrespondents to the survey were more likely to be black and not married ($P < .05$), but similar with regard to other demographic factors. Study arms were balanced with regard to demographic and treatment factors. Approximately two thirds of patients were strongly leaning toward a treatment option at enrollment in each study arm. The majority of patients in both arms completed their respective Web site review, but completion rates in the intervention arm were higher in white patients than in minority patients (95.3% *v* 78.8%, respectively; $P < .001$). Patients in the intervention arm spent, on average, 46 minutes reviewing the Web site compared with 21 minutes for patients in the control arm (Table 1).

Outcomes Analyses

Overall, compared with patients in the control arm, more patients in the intervention arm achieved a high-quality decision (49.6% *v* 33.3%; $P = .0004$) and had high knowledge (60.7% *v* 42.5%; $P < .001$). There was no difference in values-concordant treatment outcome between arms (78.6% in the intervention arm, and 81.4% in the control arm; $P = .45$).

Primary outcomes analyses found that patients in the intervention arm had higher odds of making a high-quality decision than patients in the control arm (odds ratio [OR], 2.00; 95% CI, 1.37 to 2.92; $P = .0004$), as well as of high knowledge (OR, 2.19; 95% CI, 1.51 to 3.18; $P < .001$), but not of values-concordant treatment. Patients in the intervention arm also more often had high decision preparation than did patients in the control arm (estimate, 0.18; 95% CI, 0.02 to 0.34; $P = .027$). There were no differences in deliberation or SDQ by arm (Table 2). In multivariable analyses, patients in the intervention arm had significantly higher odds of a high-quality decision (OR, 1.94; 95% CI, 1.31 to 2.86), high knowledge (OR, 2.18; 95% CI, 1.47 to 3.24), and higher decision preparation (estimate, 0.18; 95% CI, 0.024 to 0.34; Table 3).

Post Hoc Analysis

The effect of being in the tailored and interactive iCanDecide arm, relative to the control arm, on high knowledge was similar for women who strongly leaned toward a treatment at enrollment compared with those who did not (OR, 2.29; 95% CI, 1.44 to 3.65 *v* OR, 2.20; 95% CI, 1.10 to 4.39; Fig 2). There was a similar effect for decision preparation (estimate, 0.27; 95% CI, 0.02 to 0.52 for strongly leaning; estimate, 0.14; 95% CI, −0.06 to 0.34 for not strongly leaning; results are reported in the Data Supplement). No significant interactions were observed between decision trajectory and intervention arms for both knowledge and decision preparation.

Patient Appraisal of the Web Sites

Nearly 90% of patients in both arms reported that the Web site was easy to use, 60% said it was helpful in their decision making, and most (85.1% in the intervention arm, and 79.4% in the control arm) would recommend it to others. More patients in the intervention arm reported that the Web site helped in thinking about the pros and

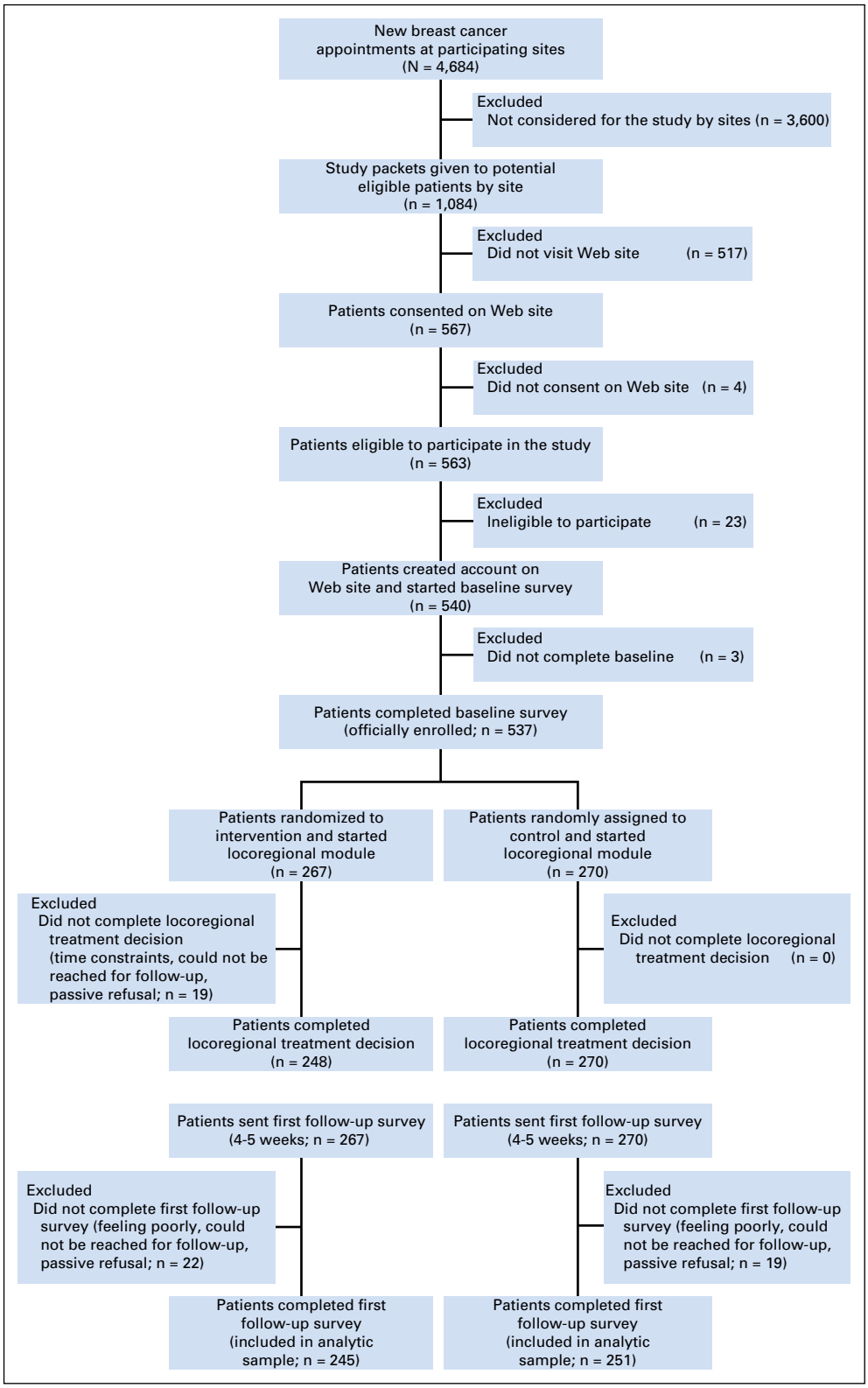

Fig 1. Patient flow diagram.

cons that mattered most than did patients in the control arm (79.2% *v* 67.0%; $P = .039$). More patients in the control arm reported that the length was just right (85.6% *v* 75.0%; $P = .04$), but similar numbers reported that the amount of information was just right (79.9% in the intervention arm, and 75.8% in the control arm; $P = .08$). Finally, there was a trend toward more patients in the intervention arm contacting their surgeon's office after using the Web site (31.2% *v* 20.9%; $P = .12$).

Table 1. Demographic and Other Characteristics Among Patients Who Enrolled in the iCanDecide Study (N = 537)

Characteristic	Control Arm (n = 270)	Intervention Arm (n = 267)
Mean age at diagnosis (SD), years	57.0 (10.9)	56.5 (10.7)
Race		
White	212 (79)	210 (79)
Black	45 (17)	42 (16)
Other (Asian, Hispanic, American Indian, other/multiracial)	13 (5)	15 (6)
Education		
High school graduate or less	58 (21)	57 (21)
Some college or college graduate	145 (54)	148 (55)
Some graduate school or completed graduate school	67 (25)	62 (23)
Married/partnered		
No	83 (31)	64 (24)
Yes	187 (69)	203 (76)
Leaning toward treatment option and sure about choice		
No	95 (35)	89 (33)
Yes	175 (65)	178 (67)
Treatment received		
Lumpectomy	165 (61)	170 (64)
Unilateral mastectomy	28 (10)	28 (10)
Bilateral mastectomy	50 (19)	44 (16)
Other/missing data	27 (10)	25 (9)
Reconstruction received		
No	185 (69)	183 (69)
Yes	60 (22)	59 (22)
Missing data	25 (9)	25 (9)
Neoadjuvant chemotherapy received		
Yes	23 (9)	26 (10)
No	227 (84)	219 (82)
Unknown/missing data	20 (7)	22 (8)
Paradata		
Mean locoregional Web site module completion time (SD), minutes	21 (17)	46 (27)
Patients who completed the locoregional Web site module	270 (100)	248 (93)

NOTE. Data are given as No. (%) unless otherwise noted.
Abbreviation: SD, standard deviation.

DISCUSSION

We found that an interactive and tailored breast cancer treatment decision tool improved decision quality and prepared patients for decision making compared with a high-quality static information Web site. This suggests that an interactive design is important to enhance the potential benefit of decision tools in practice. Most patients completed the components of the intervention Web site and positively appraised its ease of use and salience for treatment decision making.

The improvement in decision quality stemmed largely from improvements in knowledge about the risks and benefits of treatments. This is promising as the knowledge-building module was developed to address large deficits in knowledge about treatment after the diagnosis of curable breast cancer,[16,43-45] and incorporated interactive learning principles. Our results are consistent with those reported by others who found that decision aids have a positive effect on knowledge.[46] Of importance, we observed improvements in knowledge and decision preparedness regardless of the patient's decision trajectory at the time of enrollment (strength of leaning toward a treatment). This suggests that tools can be deployed flexibly in practice even after the first visit, with positive effects on decision outcomes. At the same time, our study highlights persistent gaps in decision making about treatment; approximately 40% of patients in the intervention arm did not achieve high knowledge about treatment tradeoffs, and 60% did not achieve high decision preparation, which suggests that there is still considerable room for improving the decision-making process.

Being in the intervention arm did not affect values-concordant treatment, which was generally high across arms (> 80%). This is consistent with a recent review of decision aids that found little evidence that decision aids influence the receipt of values-congruent treatment.[15] This supports the importance of knowledge as a key component of high-quality decisions, as uninformed values-driven choices have been shown to be associated with more extensive treatment.[17]

The high rate of values-concordant treatment that was observed in the study may be a result, in part, of patients already having clear treatment preferences after their surgical visit, when virtually all patients in our study viewed the Web sites. Whereas the ideal time to support shared decision making may be before consultations, we found that few surgeons are willing to provide patients with previsit materials about the treatment of breast cancer. Although electronic health systems may improve this process,[47] our results underscore the importance of offering tools even after surgical consults, when patients are often still making these critical decisions.

Table 2. Primary and Secondary Outcomes by Study Group (n = 496)

Outcome	Intervention (n = 251) % (No.)*	Control (n = 245) % (No.)*	Intervention *v* Control OR (95% CI)†	*P*†
Primary				
High-quality decision (high knowledge plus values-concordant treatment)	49.6 (113)	33.3 (80)	2.00 (1.37 to 2.92)	.0004
High knowledge	60.7 (148)	42.5 (105)	2.19 (1.51 to 3.18)	< .001
Values-concordant treatment	78.6 (180)	81.4 (197)	0.86 (0.54 to 1.35)	.45
	Mean (SD)	Mean (SD)	Coefficient (95% CI)	
Secondary				
Decision preparation	3.9 (0.9)	3.7 (0.9)	0.18 (0.02 to 0.34)	.027
Deliberation	3.9 (0.8)	3.9 (0.8)	0.07 (−0.09 to 0.20)	.45
Subjective decision quality	4.5 (0.5)	4.4 (0.6)	0.06 (−0.04 to 0.16)	.25

Abbreviations: OR, odds ratio; SD, standard deviation.
*The denominators of percentages vary slightly as a result of missing values.
†Generalized linear mixed models with logit link were used for primary outcomes, and linear mixed models were used for secondary outcomes.

Table 3. Adjusted Models of Association Between Outcomes and Study Group

Variable	High-Quality Decision (n = 493), OR (95% CI)	High Knowledge* (n = 493), OR (95% CI)	High Decision Preparation† (n = 488), Estimate (95% CI)
Intervention study group (*v* control)	1.94 (1.31 to 2.86)†	2.18 (1.47 to 3.24)†	0.18 (0.038 to 0.34)‡
Age (in 10 years)	0.78 (0.64 to 0.95)‡	0.60 (0.49 to 0.74)†	0.89 (0.010 to 0.17)‡
White (*v* other)	1.44 (0.84 to 2.46)	2.26 (1.32 to 3.85)§	−0.39 (−0.60 to −0.18)†
College graduate school (*v* college or less)	1.88 (1.10 to 3.23)‡	2.13 (1.27 to 3.57)§	−0.036 (−0.24 to 0.17)
Married/partnered (*v* not)	1.49 (0.90 to 2.46)	1.79 (1.10 to 2.90)‡	0.096 (−0.09 to 0.29)

NOTE. Generalized linear mixed models with logit link function were used to model high-quality decision and knowledge, and linear mixed models were used for decision preparation, accounting for patient clustering within practices. Results are similar when we included clinical factors (stage and treatment), and when we excluded patients who had neoadjuvant chemotherapy treatment or adjusted for the timing of the surgeon visit or baseline treatment decision leaning.
Abbreviation: OR, odds ratio.
*High knowledge: a cutoff of ≥ 80% correct; decision preparation: the higher the value, the more prepared for decision making.
†$P < .001$.
‡$P < .05$.
§$P < .01$.

As with other interactive decision aids, there was a potential patient burden associated with the intervention version of iCanDecide. Patients spent, on average, more than 40 minutes completing the tool, which included several interactive components. Patients had the option to participate at the clinic via an iPad, but nearly all chose to view it at home. Yet no patient expressed concerns about the length, and more patients in the intervention arm reported that the Web site helped them think about the pros and cons of treatment. Although the interactive nature of the intervention arm may have better personalized the Web site, interactivity can be confusing and cumbersome if not developed with high-quality standards as done in our study.[31] Decision tools that engage patients at their desired level may be most effective. The race disparity in the completion rates in the intervention arm underscores the need to build tools that minimize cognitive burden and maximize usability across all types of patients.

Strengths of this study include the large sample size, high participation rates, the community-based deployment, and validated measures of decision quality. Yet there were some limitations. Whereas there was no true usual care arm in the study, many patients with breast and other cancers seek information online after their diagnosis to get information about treatment.[48] Although we achieved good representation of patients across subgroups, there remain limits to generalizability to all racial and socioeconomic groups. Some women with limited access or lower facility with the Internet may not have enrolled in our study, despite providing practices with an iPad. Whereas the iCanDecide intervention included innovative features, it was not possible to include all patient values in the values clarification exercise. Finally, characteristics of the 48% of women who were invited but did not enroll are unknown.

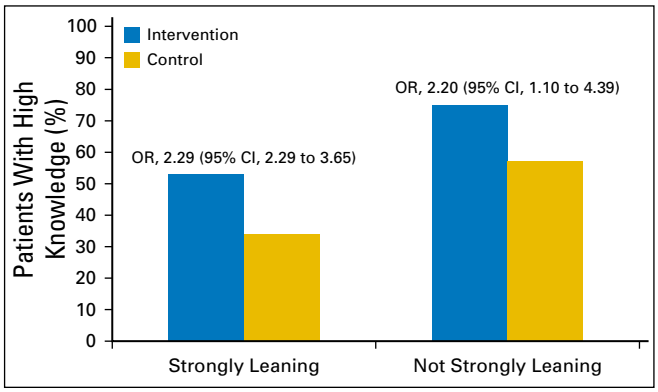

Fig 2. High knowledge by decision trajectory status and study group. Odds ratios (ORs) were obtained using generalized linear mixed models for knowledge comparing the intervention arm with the control group.

Treatment decision making after a breast cancer diagnosis is complex and unfurls variably across patients and practices.[49] We found that a tailored, interactive version of a patient-facing decision tool—iCanDecide—delivered flexibly in this context can improve key aspects of decision making. Our results underscore the demand for such tools on the part of patients with newly diagnosed breast cancer. Yet our study suggests important areas for future work to optimize informed decision making and patient appraisal of the process, including fully integrating the tools into clinical workflows to better engage clinicians in discussions with their patients, and comparing decision aids with other approaches, such as patient personal coaching.[46,50] Implementation studies are needed to better determine how to deploy and evaluate such tools as iCanDecide in the context of surgeon and practice variation. Innovative strategies are needed to ensure that these tools can be broadly deployed to improve patient-clinician decision making.

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Disclosures provided by the authors are available with this article at jco.org.

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Manuscript writing: All authors
Final approval of manuscript: All authors
Accountable for all aspects of the work: All authors

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