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Journal Title: Contemporary Clinical Trials Communications

Volume: Volume 5

Publisher: Elsevier: Creative Commons Attribution Non-Commercial No-Derivatives License | 2017-03-01, Pages 123-132

Type of Work: Article | Final Publisher PDF

Publisher DOI: 10.1016/j.conctc.2017.02.001

Permanent URL: <https://pid.emory.edu/ark:/25593/s8f47>

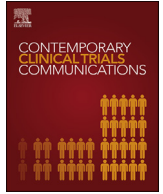
Final published version: <http://dx.doi.org/10.1016/j.conctc.2017.02.001>

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Study protocol: A randomized controlled trial of a comprehensive breast cancer treatment patient decision tool (iCanDecide)



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ARTICLE INFO

Article history:

Received 22 November 2016

Received in revised form

30 January 2017

Accepted 1 February 2017

Available online 3 February 2017

Keywords:

Breast cancer

Decision tool

Decision-making

Health communication

ABSTRACT

Background: Patients newly diagnosed with breast cancer face a series of complex decisions regarding locoregional and systemic treatment. There is a need to improve the quality of locoregional and systemic decisions for breast cancer patients, and to help patients understand the role of evaluative tests in this decision process. We are now conducting a randomized controlled trial (RCT) of an online decision tool—called iCanDecide, which we expect will help patients with these difficult decisions. Furthermore, the results of this RCT will be highly relevant to future breast cancer patients making these decisions and to their clinicians.

Methods: This is a two-arm randomized controlled trial with the target of 222 participants per arm. Participants are recruited from 25 surgical practices (total 40 surgeons) and 2 medical oncology practices (total 2 oncologists) in Michigan, Georgia, Tennessee, and California. Participants are newly-diagnosed female breast cancer patients between 21 and 84 years, with stage I-II invasive breast cancer or ductal carcinoma in situ (DCIS) and who are eligible for and considering either mastectomy or lumpectomy with radiation, and who may be eligible for adjuvant systemic treatment.

The RCT tests an interactive, tailored website, called iCanDecide (intervention arm), compared to a static version of the website (control arm). The static control arm is designed to include the same basic content as the intervention version, but without tailoring and interactive features. The primary outcome includes the rate of making a high-quality decision. The hypothesis is that patients randomized to the interactive version of iCanDecide will have higher rates of high quality decisions (informed and values-concordant), and will appraise their decision-making process more positively, for both surgical and systemic treatment.

Discussion: The goal of this study is to evaluate the impact of the iCanDecide interactive website on decision-making for locoregional and systemic breast cancer treatments. The results of this study will be important for future breast cancer patients and their clinicians as we determine how to better individualize decision making across this complex treatment landscape.

Trial registration: ClinicalTrials.gov ID NCT01840163.

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Abbreviations used: DCIS, Ductal Carcinoma In Situ; GEE, Generalized Estimating Equation; RCT, Randomized Controlled Trial; SEER, Surveillance, Epidemiology, and End Results Program.

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<http://dx.doi.org/10.1016/j.conctc.2017.02.001>

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1. Introduction

Patients newly diagnosed with breast cancer face a series of complex decisions regarding locoregional and systemic treatment. Currently many of these decisions do not meet the definition of a high-quality decision, defined as one that is both informed (i.e., based on an accurate understanding of the treatment risks and benefits) and values-concordant (i.e., consistent with the patients' underlying values for attributes of treatment) [1]. Moreover, the introduction of evaluative tests has made these decisions more complicated for many patients [2,3]. Decision aids and tools have been developed to help breast cancer patients with treatment decision making. While some have had positive impacts on knowledge about treatment options, most have not had a long standing effect on decision outcomes (e.g., decision satisfaction or regret) [4] and none have been specifically evaluated for impact on decision quality as defined above.

Furthermore, existing decision aids have not used tailoring to identify treatment-related knowledge deficits and provide patients with accurate information based on these deficits. In addition, no current tools provide tailored feedback to users based on stage of treatment planning, decision preparedness and/or their perceptions of their experience communicating about treatment with clinicians. A few have included a values clarification exercise, intended to elicit their values for treatment attributes (e.g., if they prefer to retain their natural breast or avoid radiation therapy) [5,6], but do not provide patients with direct feedback regarding which treatment attributes were most important to them and how these match existing treatments. Existing decision aids also do not have a focus on improving decision quality in both locoregional and systemic treatments. Finally, most of them were evaluated in academic settings, rather than community practices. Thus, there is a need to improve the quality of locoregional and systemic treatment decisions for breast cancer patients, and to help patients understand the role of evaluative tests in the decision process. Ensuring patients can deliberate effectively about these decisions, assert their views and communicate with their clinicians is likely to improve their overall decision preparedness and satisfaction.

This study will focus on improving individualized care by evaluating the impact of an innovative decision tool on locoregional

and systemic therapy decision making for newly diagnosed breast cancer patients diagnosed in community surgical practices. The online decision tool was developed and tested two years prior to launching the study [7]. Pilot data suggested that this tool has a positive impact on patient knowledge and decision outcomes. However, the prototype did not include key components necessary for improving decision quality, such as knowledge assessment and tailoring and patient activation. Further, the prototype was evaluated in academic settings and not in community practices where most breast cancer patients receive care.

We are now conducting a randomized controlled trial (RCT) of an updated and enhanced version of this online decision tool—called iCanDecide—in newly diagnosed patients (expected N = 444) with invasive early stage breast cancer or DCIS in community practices, compared with the static version initially developed in our pilot study. Patients that view the iCanDecide website are being randomized to either the enhanced interactive, tailored version (intervention) or a non-tailored, static version (control). Thus, all participants in the trial receive information to help them with their treatment decision; but delivered in different ways. As noted above, the primary outcome is a high-quality decision (defined as an informed and values concordant treatment choice) [1] for both locoregional and systemic breast cancer treatments. The hypothesis is that patients randomized to the interactive version of iCanDecide will have higher rates of high-quality decisions. The secondary hypothesis is that patients in the intervention arm will appraise their decision-making process (decision preparedness, deliberation, and satisfaction) more positively, for both locoregional and systemic treatment (see Fig. 1).

The results of this RCT will be highly relevant to future breast cancer patients making these decisions and to their clinicians. The aims are:

Aim 1: To evaluate the impact of an online comprehensive decision tool (iCanDecide) on decision making for locoregional treatment among newly diagnosed patients with early stage breast cancer, compared to standard online information.

H1a. Patients in the intervention arm will have a higher rate of high-quality decisions about locoregional treatment (i.e., accurate knowledge about treatment options and their risks and benefits

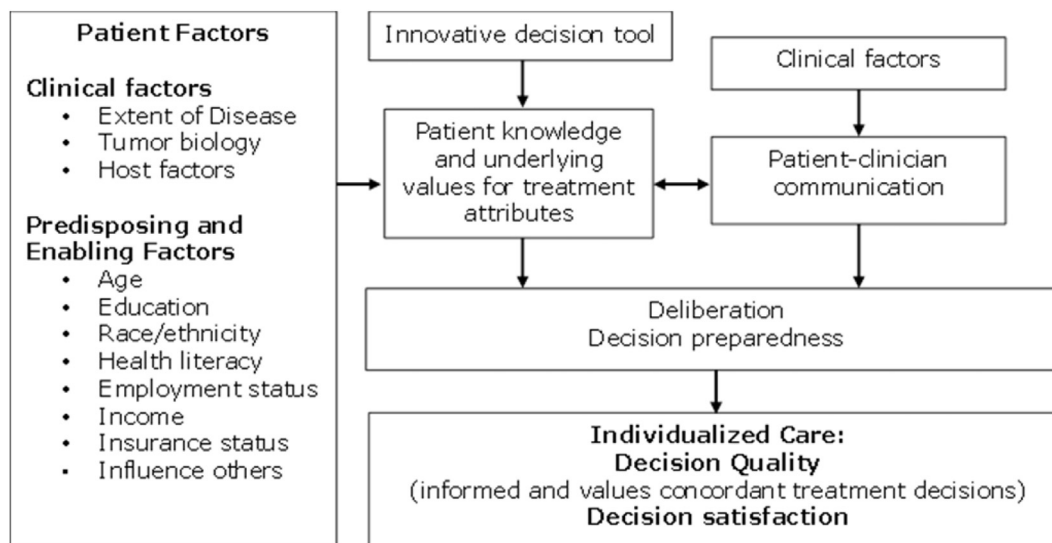


Fig. 1. Shows the conceptual framework for the hypothesized association between the interactive version of iCanDecide and the primary outcomes of the study. This model is informed by several existing theories, including the Health Belief Model, Social Learning Theory, the Behavioral Model of Health Services Utilization [8–11] and by our preliminary studies [8,12–15].

and a higher rate of values-concordant treatment decisions).

H1b. Patients in the intervention arm will report more positive appraisal of the locoregional treatment decision-making process (decision preparedness, deliberation and satisfaction).

Aim 2: To evaluate the impact of the iCanDecide tool on decision making for adjuvant systemic therapy among newly diagnosed patients with early stage invasive breast cancer, compared to standard online information.

H2a. Patients in the intervention arm will have a higher rate of high-quality decisions related to adjuvant systemic therapy (i.e., accurate knowledge of treatment options and their risks and benefits and a higher rate of values-concordant treatment decisions).

H2b. Patients in the intervention arm will report more positive appraisal of the systemic therapy decision-making process (decision preparedness, deliberation and satisfaction).

2. Methods/design

The purpose of the study is to deploy and evaluate an innovative decision tool (iCanDecide) designed to improve locoregional and systemic breast cancer treatment decision making. The study is a 2-armed randomized controlled trial (RCT) of a tailored and interactive version of iCanDecide (intervention) versus a static version (control) for newly diagnosed breast cancer patients. After enrollment and informed consent is completed online, participants complete a short baseline survey, and are then electronically randomized on the website to the intervention or control versions of iCanDecide. The study protocol described received approval from the University of Michigan (UM) Institutional Review Board (HUM00062261). At this point in the study, practice recruitment is completed, while participant data collection is ongoing, with analysis to follow.

2.1. Setting overview

Twenty-five surgical practices (total 40 surgeons) and two medical oncology practices (total 2 oncologists) agreed to participate in recruiting patients for the study. These practices are located primarily in Michigan and Georgia, with one in Tennessee, and one in California. Of the participating practices, 12 are private practices, 12 are community-teaching hospitals, and 2 are not-for-profit hospitals. Thirty participating surgeons specialize in breast cancer care; the remaining ten are general surgeons that see breast cancer patients less frequently. The UM Institutional Review Board (IRB) determined that these sites were “not engaged in research” due to the fact that the only activity being conducted at each site is to offer study materials (packet) to eligible patients (by a physician, nurse or staff person, as described in “patient recruitment” below). The study packet (described below) provides all information for patients to decide whether or not to enroll, and all patient information is entered directly into the website by patients themselves.

2.2. Practice recruitment

Surgical practices were recruited to the study in two ways. The primary method for recruitment was to identify community-based surgeons in practices in the Detroit and Atlanta SEER (Surveillance, Epidemiology, and End Results Program) catchment areas. A strength of focusing in these geographic locations and in community practices is the ability to identify and recruit a breast cancer patient population more representative of the U.S. breast cancer population than can be obtained from academic clinical settings.

These surgeons were mailed an invitation letter and study fact sheet; a study coordinator would then follow up by phone in order to verify that the practice had received the letter and would also request to set up a phone call or meeting with someone from the practice (surgeon, nurse or practice manager) and the UM study team (principal investigator and study coordinators). During this initial presentation, the study team would describe the project in detail to providers and staff, which included informing the practices of what was expected from participating sites: to identify eligible patients and offer a study packet (as described in “patient recruitment” section below), and to report back to the study team the total number of packets given out, as well as the total number of new breast cancer patients seen per month. Of note, the study is designed to be as flexible and as easily integrated into the clinical workflow as possible, therefore study packets may be offered to patients either before or after the visit with the surgeon, and may be handed out by anyone in the practice including the surgeon him/herself, nurse or manager. Practices are also informed that iPads will be made available if there are concerns that the patient population may not have access to the internet at home.

Following the presentation, a study coordinator would then follow up with the practice in order to answer any questions and begin the process of initiating the practice to the study.

In addition to the method described, there were some surgeons that became interested in participating in the project after hearing the principal investigator present the study at various conferences. In this case, the process for initiating the interested surgeon's practice as a study site followed as above in terms of meeting and presenting to the practice by the study team and confirming their participation.

Once a practice was confirmed as a study site, defined as the surgeon(s) and practice managers agreed to participate, they received a \$1000 payment as a thank you for their time and efforts.

2.3. Study patient population and eligibility criteria

As noted above, this RCT is designed to flexibly adapt to the workflow of the participating practices, and as such, participant recruitment methods will vary across participating practices. Therefore, practices who agree to participate may decide to offer study packets to patients before or after their visit with the surgeon. Study packets may be handed out by the surgeon him/herself, nurse or practice manager depending on who interacts with the patient at the time point when a packet may be offered. Furthermore, it is anticipated that some practices will recruit more participants than others, since recruitment will be proportional to the volume of breast cancer patients in each practice and seen by each surgeon (i.e., those physicians specifically in breast cancer care practices will most likely see more breast cancer patients than physicians in general practices). Practices with lower socioeconomic patient populations may recruit fewer participants due to this being an online intervention (requiring access to the internet and basic knowledge of website navigation). Importantly, however, the study team can offer iPads to practices where this may be an issue to ensure that all potential participating patients can have access to the program. Whether or not the practice utilizes iPads will be assessed throughout the course of the study.

The inclusion criteria are:

- Newly-diagnosed female breast cancer patients, ages 21–84, with stage I-II invasive breast cancer who are eligible for and considering either mastectomy or lumpectomy with radiation, and who may be eligible for adjuvant systemic treatment
- Two discretionary enrollment criteria include:

- Patients with DCIS (stage 0 breast cancer) may be enrolled into the study if they are eligible for and considering either mastectomy or lumpectomy with radiation.
- Patients taking neoadjuvant chemotherapy (chemo prior to surgery) may be enrolled into the study if they are eligible for and considering either mastectomy or lumpectomy with radiation.
- English speaking

Patients for whom there is only one good surgical option or any other clinical/non-clinical reason for which the surgeon determines the patient is not eligible for the study will not be offered a study packet by their provider.

2.4. Potential risks and protection of human subjects

Risks to participants in this study are minimal. The intervention is an educational website similar to the type of information patients seek on their own or receive from their surgeon or medical oncologist. Participation is entirely voluntary, and participants may also opt out at any time. Breast cancer patients will be experiencing emotional distress due to their diagnosis; this is one reason for allowing the patient's own clinical breast care team (surgeon, oncologist, nurse, etc...) to introduce the study. Clinicians may decide against introducing the study to a patient in extreme distress. In addition, all subjects are provided with the contact information of the study coordinators and are encouraged to contact them should any questions about the study arise. The introductory letter clearly states that participation is voluntary and it will not affect the participant's medical care. This information is repeated in the online consent form.

If participants need support after reviewing information on the website about their disease and treatment, or want further clarification of any issue, they may contact the study team for instructions on where to access additional emotional support. If participants have any questions or concerns it will be addressed by the appropriate investigator in a sensitive and professional manner. The online informed consent form encourages patients to follow up with their healthcare provider for specific health-related questions. It also instructs them to contact the UM Institutional Review Board (including providing the phone number to do so) if they are concerned about their rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s).

2.5. Data safety and monitoring

Patients voluntarily logging into the iCanDecide decision tool complete an online informed consent. After consenting, participants are directed to create an account on the website (during which they voluntarily provide name and contact information to the study team for follow-up). At no time does the practice directly provide patient health or identifying information to the study team. All follow-up contact with the patient (including surveys) is done using contact information entered by the participant directly into the website after they have consented. Those who will have access to the study data are the study principal investigator, co-investigators and study coordinators.

This study is monitored in accordance with the approved UM Comprehensive Cancer Center Data and Safety Monitoring Plan. The study specific Data and Safety Monitoring Committee, consisting of the protocol investigators, data manager or designee, and other members of the study team involved with the conduct of the trial, will meet every two weeks depending on the activity of the protocol. The discussion will include matters related to addressing

any adverse events that could result from study participation, validity and integrity of the data, enrollment rate relative to expectations, characteristics of participants, retention of participants, adherence to the protocol (potential or real protocol deviations) and data completeness.

2.6. Patient recruitment and consent

This RCT was designed to flexibly adapt to the needs of each practice. This was done deliberately based on our pilot work that revealed that there is variation in how surgeons in community practices meet with newly diagnosed patients. Some deliver the diagnosis on the telephone, some deliver the diagnosis at the first visit, while other patients receive the diagnosis elsewhere and follow up with the surgeon. Surgeons in our pilot study had differing views on when they felt a decision tool would be most useful. Therefore, we purposely designed the website so it could be viewed either prior to or after seeing the surgeon. We also designed the study so that the introductory packet could be given to patients by the surgeon, or someone else in the practice (such as nurse or assistant).

Aside from these differences, the method for identification and recruitment of patients is the same. At all practices, potentially eligible patients are identified by a practice member and offered a study packet. Patients may choose to accept or decline the packet. The study packet includes the following: 1) introductory letter signed by the Principal Investigator and the associated clinician or practice group, and includes local study team contact information; 2) log-in instructions for the iCanDecide website; and 3) a \$20 gift.

After accepting a study packet, the patient decides whether or not to enroll in the study. At no time does the clinic transmit patient health or personal information to the study team.

Enrollment can be done at home or in the clinic via the iPad (provided to practices by the study team) and occurs when the patient follows the web link to the iCanDecide website and uses the access code provided with their study packet. Once an access code is entered, the participant will see a "pop-up window" with a brief overview of the study and the steps involved in participation. Potential participants are told there are two different versions of a breast cancer treatment website, and each takes differing amounts of time to view with a minimum time of about 30 min. Once this pop-up window is closed, the participant will be able to view the online consent form. She must select "yes" to participating in a research study in order to proceed further on the website. If the patient would not like to participate, they are instructed to close their browser. Those who consent will proceed as described below.

2.7. Participant eligibility, account creation, and baseline survey

After consent, participating patients will answer a few baseline questions to reassess eligibility. In the majority of cases, the participants are pre-screened by their clinician before being given a packet. However, in the rare chance that a packet is given to an ineligible patient (not within the age criteria, does not read/speak English), these questions will stop them from advancing further and thank them for their interest.

Following eligibility screening, the participant will create an account on the website. This includes providing the following information: first name (required), last name (required), username and/or e-mail address (at least one field is required), create a password (required), street address (required, used for survey follow-up), and phone number (optional). The participant is also asked to provide a security question and answer to help protect their account. The participant then proceeds to the remaining baseline survey (part of the locoregional treatment section, Time 1a

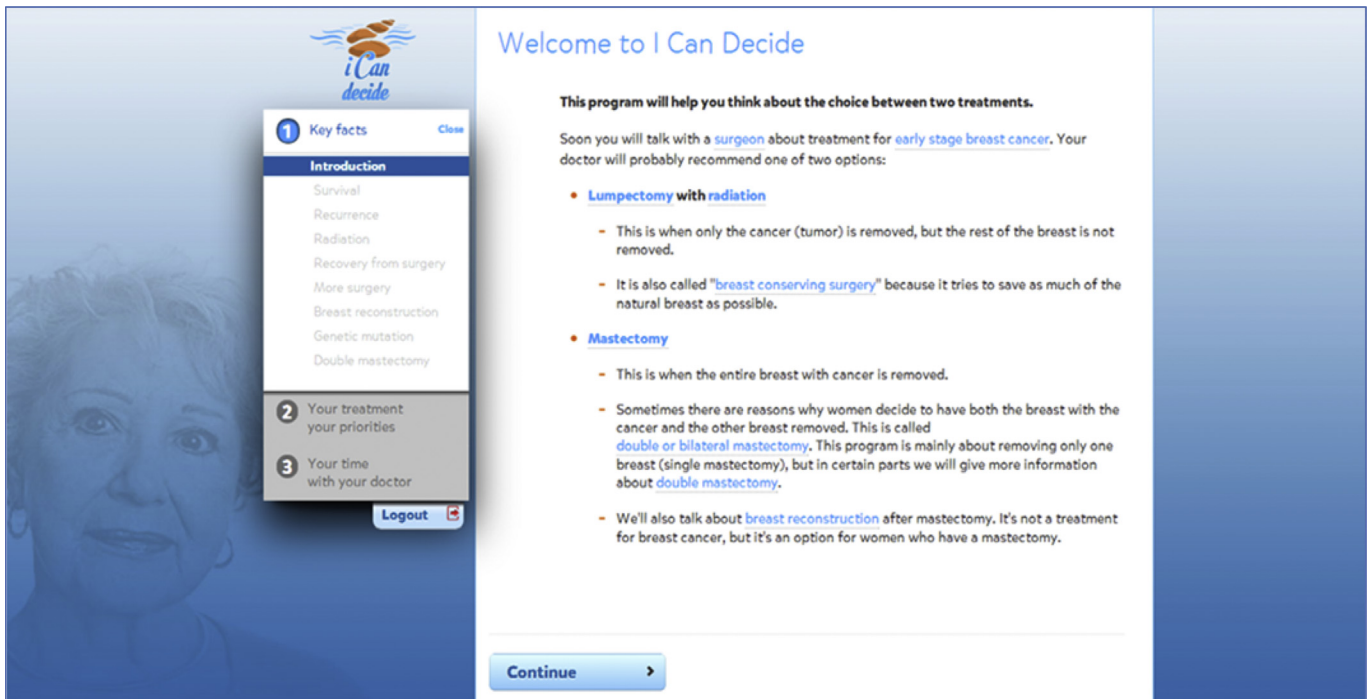


Fig. 2. A screen from the iCanDecide participant interface.

or T1a) which will assess demographics, clinical, decision and communication context variables.

2.8. Randomization

Following the completion of the baseline survey, the website program will randomize patients into one of the two arms as described: intervention (interactive iCanDecide) or control (static iCanDecide). The randomization is stratified by location, race, education, if they have seen their surgeon, and age to certify equal proportions of the participants by these factors in both arms.

2.9. Intervention and control conditions

Overview: Both the intervention and control websites include similar content, though the content is delivered differently. Both include information about the disease of breast cancer, and about locoregional and systemic treatment options (see Fig. 2). Each version delivers the content about locoregional and systemic

treatment in two distinct content modules. The locoregional module is viewed immediately after logging in, while the systemic module is made available two weeks later (see Fig. 3). This delay in offering content on systemic treatment was purposely done as part of this study to ensure patients would be able to focus on specific decisions happening at different points in time, rather than become overwhelmed with all treatment information at one time. While both intervention and control arms include the two content modules, the intervention version has tailored and interactive features that we believe will improve decision making when compared to delivery of this content in a more standard, static way as in the control version. Participants are not required to complete either version of the website in one sitting, and are able to re-log in later (previously entered information is saved). While we will be collecting information on total time spent on the websites, we will be able to determine if the participant viewed the website more than once.

Intervention: The iCanDecide intervention website is a tailored, interactive and comprehensive online breast cancer treatment

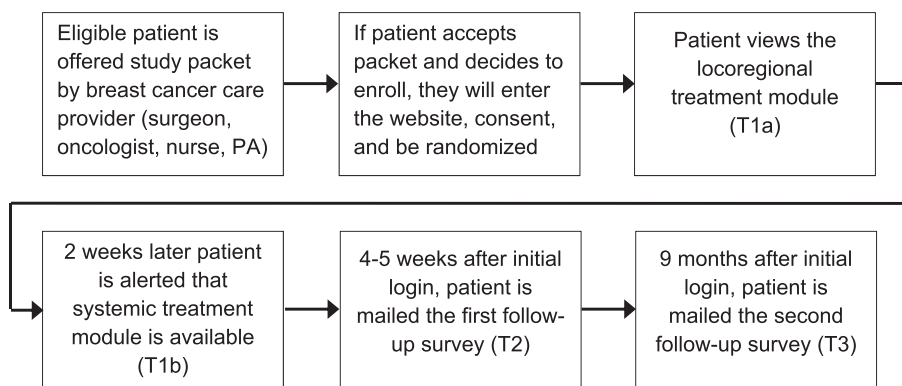


Fig. 3. Study flow diagram.

decision tool. A prototype of the website was developed by the UM Center for Health Communications Research team under the direction of the Principal Investigator and other health care professionals in this field, and was pilot-tested in a small study conducted at two cancer centers from 2011–12⁷. Based on this pilot study and other work, the team has updated iCanDecide to include key features believed to be necessary to improve decision-making outcomes in breast cancer patients. These features are further described below.

The iCanDecide intervention version is delivered to participants in a linear format, to ensure that they receive all content and features of the tool and are not able to skip around as in a typical website. The key innovations of this version are:

- “Knowledge building” section that delivers information in a way that helps patients understand the basic “key facts” related to their treatment options and also queries their understanding after each “key fact.”
- “Your priorities” section that contains a values clarification exercise (conjoint analysis) with real-time feedback to patients regarding the factors most important to them in treatment decision making. This section also contains an exercise to review other factors and preferences that influence a patient’s decision making.
- “Communicating with your doctor” section with tailoring to help guide patients talk with their clinicians

Control: The comparison in this study is a static version of the iCanDecide tool, also delivered online. This static version offers similar content but without the tailored and interactive features of the intervention version. It is designed to mirror typical self-navigated websites available to patients with a breast cancer diagnosis. Participants are able to navigate the information using left side menu and are not taken through the site in a linear way.

2.10. Participant monitoring and module follow-up

Study coordinators know when a new participant has enrolled by checking the administration console that is linked to the iCanDecide website. Each coordinator has their own login credentials. Some of the basic features of the admin console include: creating study locations (when new practices decide to participate), creating the participant access codes as mentioned above, and follow-up tracking. The follow-up tracking portion displays the name of the participant, the study ID (access code), the practice name that recruited them (the practice name is linked to the participant’s access code in order to track enrollment from each site), the participant’s contact information (email, phone, address), the randomization arm, date/time they created their account and which sections of the modules (both locoregional and systemic) the participant has completed. For participants that have not completed the locoregional module within one week of creating their account, the study coordinators remind participants by email and phone that there is information remaining which they can review. Systemic module follow-up (outside of the emails automatically sent to participants) is combined with survey follow-up and described below.

2.11. Paradata collection

We will be collecting “paradata”—data related to the usage of the websites—for participants in both intervention and control arms. This data will be used in additional analyses following the primary outcome analyses that is described below. This data related to website usage is stored on servers at the coordinating center.

Paradata to be collected for both groups including total time spent on the website (measured at the timepoint that the preferences questions are completed), time spent per page viewed, and use of “drill downs” (or clicks to see additional or more information about a topic). For intervention participants, there is an interactive exercise to assess their values for treatment attributes; we will collect time spent on this exercise as well as the specific output that links their values to existing treatment options.

2.12. Data collection

This is an intent-to-treat RCT, thus all enrolled subjects receive the follow-up assessments (first and second follow-up surveys) regardless of the degree to which they used the website (intervention or control arm). The first follow-up survey (Time 2 or T2) is used to collect our primary outcome for specific aim 1 (see Table 1 for measures) and is sent at 4–5 weeks after initial enrollment (we are estimating that most participants will have had or will shortly undergo their surgical treatment option at this time). The second follow-up survey (Time 3 or T3) is used to collect our primary outcome for specific aim 2 and is sent at 9 months post enrollment. The follow-up surveys are mailed to the address provided by the participant and contain a cover letter, de-identified survey (with access code/study ID), return envelope, and \$20. At the time a survey is mailed, an email alert is sent by a study coordinator to the participant to make them aware this packet will arrive soon. Approximately 2–4 weeks after a survey is mailed, follow-up procedures will begin. Initial reminders are sent by email and ask the participant to confirm receipt of the survey. If no response is received via email, coordinators follow up by phone (if phone number was provided) over a span of several weeks as not to burden the participant (maximum of three attempts).

Two weeks after initial enrollment (the date of account creation), participants in both arms are invited via an automatic email to re-visit iCanDecide (intervention or control version) and proceed through the second module on systemic chemotherapy, if they are considering that treatment. They will receive a final reminder via email of the systemic module at 4 weeks as well. Participants use the username and/or e-mail address and the password that they created to log back into the website. There is a brief eligibility section which asks if they have been told by their doctor that their breast cancer is ductal carcinoma in situ (DCIS) or Stage 0 cancer. Participants that select “yes” are unable to proceed to this section of the website, but are told to talk to their doctor if they have questions about systemic therapy. Participants that select “no” proceed through the module.

Participants in both arms complete a brief baseline survey at the beginning of the systemic treatment section (Time 1b or T1b). The intervention version of the systemic module mirrors that of the locoregional module (knowledge building, values assessment, patient activation), and the control version provides static information on systemic chemotherapy, similar to the format of the locoregional control version.

2.13. Measures

As mentioned above in Section 1, the primary outcome is a high quality decision, which consists of 2 components: 1) informed (i.e. accurate understanding about treatment options and risks and benefits), and 2) values concordant (i.e. treatment is consistent with the underlying values of the patient) [1]. Patient knowledge and understanding will be assessed using an adapted version of an existing 12-item scale specifically developed to assess knowledge about both locoregional and systemic therapy [1]. Locoregional treatment knowledge will be assessed in the Time 2 survey, and

Table 1
List of instruments. Gives an overview of the measures used in the study surveys by specific aim and survey time point.

| Primary outcomes measures | Instrument name | Specific aim | Survey |
|---------------------------------|--|---|---|
| Decision quality | Preference for Treatment Measures [16] Breast Cancer Knowledge Measure [1] | SA1 SA1,2 | T1a T2, T3 |
| Decision satisfaction | Decision Satisfaction Scale [18] | SA1,2 | T2, T3 |
| Deliberation | Breast Cancer Treatment Deliberation Scale [20] | SA1,2 | T2, T3 |
| Decision Preparedness | Decision Preparedness Scale [17] | SA1,2 | T2, T3 |
| Other measures | | | |
| Decision tool use | Decision Tool Ease of Use Measure | SA1,2 | T2, T3 |
| Receipt tests and treatments | Breast MRI and Other Imaging Tests Measures Germline Genetic Testing Measures Tumor Genomic Testing Measures Chemotherapy Decision Context Measures Systemic Therapy Receipt Measures Reconstruction Decision Context Receipt Measures Radiation Therapy Receipt Measures Surgical Decision Context Measures Surgical Treatment Receipt Measures | SA1 SA1,2 SA2 SA2 SA2 SA2 SA2 SA1,2 SA1,2 | T2 T2, T3 T3 T1b, T3 T3 T3 T3 T2, T3 T2, T3 |
| Patient attitudes | Risk of Recurrence Estimates Measure [1] Worry About Recurrence Measure [21] | SA2 SA2 | T3 T3 |
| Clinician-patient communication | Communication Preferences Measure [22] Modified Health Care Climate Questionnaire (mHCCQ) [23] Modified Control Preferences Measure [24] | SA2 SA1,2 | T3 T2, T3 T1a |
| Quality of life | PROMIS® v1.1 Global Health Short Form [25] | SA2 | T3 |
| Demographics | Basic demographic information | | T1a |

systemic knowledge in the Time 3 survey. To determine if patients are informed, knowledge will be categorized into high (>80% correct on knowledge questions, or an “informed” patient) vs. low knowledge. Values concordance will be determined by comparing the treatment the participant actually received (reported on the T2 survey) with a validated set of “preference for treatment” items [16] that are assessed during the use of the tool in both intervention and control arms. These preference questions were developed specifically for assessing concordance between values and treatment received in breast cancer patients [16]. A high quality decision will then be determined by combining knowledge (high/low) with values concordance (yes/no) to create a binary outcome (high quality defined as high knowledge/informed and values concordant treatment vs other groups). The secondary outcomes related to patient appraisal of the decision-making process will include three measures: 1) the validated decision preparedness scale [17], 2) an adapted version of the validated decision satisfaction scale [18], and 3) a scale developed by our team based on measures of public deliberation to assess treatment deliberation [19]. These outcomes will be assessed for both locoregional and systemic breast cancer treatments (see Table 1).

Because of the nature of recruitment which will occur at the community sites, the study team is not able to collect information about patient treatment other than what is reported by patients at the time of log in or on the follow up surveys. At no time will the clinic be asked to transmit patient health or personal information to the study team. Thus information on prior treatment, including treatment for other comorbid conditions will not be available. Because clinical teams will be recruiting only patients with a new diagnosis of breast cancer, we expect there will be few (if any) patients who have had already received treatment for breast cancer. Prior treatment for other cancer(s) is allowable, unless the patient cannot choose between lumpectomy with radiation or

mastectomy in which case she would not be identified as eligible by the clinical team.

We will also collect a surgeon identifier for each patient enrolled into the study to allow us to adjust for any clustering at the surgeon level. Because we are recruiting patients from surgical practices, we are only able to include a surgeon identifier, but are not able to include a medical oncologist identifier.

3. Analysis

Overview: The overall analytic plan is guided by the conceptual framework (Fig. 1). We are primarily interested in the degree to which the intervention arm of the iCanDecide tool (interactive and tailored) improves high-quality decisions for locoregional and systemic therapy in newly-diagnosed breast cancer patients relative to the control arm (untailored, static information). We are secondarily interested in the degree to which the tool improves patient appraisal of decision making (decision satisfaction, decision preparedness).

The data for each variable will be examined to identify potential outliers and deviations from statistical assumptions. For continuous variables, we will check the normality assumption using QQ-normal plots and perform appropriate application of the normalizing transformation such as log transformation. We will then describe all variables (Table 1) by intervention and control group. We will evaluate the distribution of patient demographic and clinical factors by condition to ensure the success of randomization. We expect randomization to be successful because patients are randomized online at the time of log in. Should we see differences in groups according to patient demographic or clinical factors, we will adjust for these during the primary outcome analysis. We will also describe the “paradata” (total time on website, time spent on page, use of drill downs, etc.) by intervention and control condition

for inclusion in additional analyses as outlined below.

For each aim, the main outcome analysis will be intent-to-treat and we will include each patient in the analysis for whom we have primary outcome data. We expect that missing response values will be low (<5% based on prior work), however we will examine the distribution of missing values and explore factors that may predict missingness. We will further conduct sensitivity analysis by running the models only among patients with complete data for all outcomes. Analyses will be done using Stata 11.1 or SAS 9.2.

Aim 1: To evaluate the impact of an online comprehensive decision tool (iCanDecide) on decision making for locoregional treatment among newly diagnosed patients with early stage breast cancer, compared to standard online information.

We will compare iCanDecide-intervention (tailored and interactive) vs. iCanDecide-control (standard) on the primary outcomes of high-quality decisions and appraisal of the decision-making process (decision preparedness, decision satisfaction and deliberation) related to locoregional treatment post intervention. A high quality decision will be defined and categorized as described above into a dichotomous variable (high quality vs. lower quality).

We will conduct modeling in three steps, each using a generalized linear mixed model [26] or generalized estimating equation (GEE) [27,28] approach with logit link function. First we will model a high quality decision (vs. lower quality), with intervention group as the primary covariate. Second, we will run the model adjusting for potential clustering at the surgeon level by including the surgeon identifier. Third, we will include additional covariates that may influence high quality decisions, specifically patient demographic (age, education, race/ethnicity, marital status) and clinical factors (stage and treatment received).

For H1b, the 3 elements of patient appraisal of decision making for locoregional treatment (decision preparedness, satisfaction and deliberation) are all continuously measured so we will use a linear mixed model or GEE with a normal link function to model each of these outcomes. We will then follow the 3-step modeling approach outlined above.

Aim 2: To evaluate the impact of the iCanDecide tool on decision making for adjuvant systemic therapy among newly diagnosed patients with early stage invasive breast cancer, compared to standard online information.

For this aim, the analysis population includes those eligible for chemotherapy, which we expect to be about 85% of patients who enroll into this study. We will compare the effect of the tool on high-quality decisions and decision preparedness, decision satisfaction and deliberation related to systemic treatment. The analysis plan and modeling will follow that described above in the Aim 1 analysis, with the exception of the inclusion of a clinician identifier since we are not able to collect medical oncologist identifier information in this study.

Additional analyses: For both Aims, following the primary analysis and hypothesis testing, we will include “paradata” in our models to assess whether the level of engagement with the tool was associated with any observed differences in our outcomes. We will run the models specified above including the paradata available for both groups (total time spent on website, time spent per page, and use of drill downs).

Among intervention participants, we will report the results of the values clarification exercise. This will include the overall attributes ratings across all intervention participants, and the treatments associated with these value ratings. We will further describe the total time taken to complete this exercise.

3.1. Power and sample size

While our prior research provides an estimate of the proportion

of current breast cancer patients whose treatment decision is informed, to our knowledge there is no data regarding the degree to which current decisions for breast cancer treatment are high-quality. We thus developed a proxy measure to calculate a sample size that will provide with reasonable power to observe differences between groups. This measure was taken from our prior work and defined as the proportion of patients who made an informed decision and reported high satisfaction with the surgical decision [29–31]. We determined that approximately 30% of patients fall into this group. Thus, we estimate for this study that rates of a high-quality decision in both groups prior to the study would be approximately 30%. We estimate that both groups will improve in rates of high-quality decisions, since both are viewing information; but we expect the intervention group will improve significantly more than the control group. We thus have estimated that rates of high-quality decisions in the intervention group post-intervention will be between 50 and 60%, while the control group will be 30–40%. We have recruited 42 physicians at 26 practices. While there are data specifically about clinician ICCs for a high-quality decision, there is one large study (over 9000 patients) that reported ICCs for satisfaction with doctor-patient communication at the doctor, practice, and health plan level. In that study, satisfaction with doctor-patient communication had an ICC of 0.04 at the physician level after stratifying for practice [20]. By adjusting for patient characteristics (e.g. age, education, race/ethnicity) that may vary across surgeons (since surgeons may have patient populations that differ according to these characteristics), we should be able to reduce that still further. We calculate the required sample size for each group to achieve 80% power and significance level of 0.05 for a two-sided test for a range of intra-cluster correlation coefficients (ICCs). We will plan to recruit at least 222 per group ($N = 444$). We expect about 10% will not complete Time 2, and another 15% will not complete the Time 3 follow-up survey, based on our prior work. This attrition will result in a final N of 340 (170 per group), which will allow us to have 80% power ($\alpha = 0.05$) to detect differences of 15–20% in high-quality decisions between intervention and control subjects assuming low to moderate ICC ($0.01–0.04$)²⁰. Because close to 100% of patients with invasive breast cancer will be faced with a decision about adjuvant systemic therapy, we will be sufficiently powered to detect differences in this outcome as well.

4. Discussion

4.1. Rationale for trial

The iCanDecide trial has the potential to increase the quality of decision making across the continuum of treatment, from locoregional to systemic therapy, for patients with breast cancer. Existing decision tools directed toward early stage breast cancer treatment are limited in how they provide information about treatment options to patients, and the lack of values clarification and patient-clinician activation components. The project plans to compare the iCanDecide interactive tool that fills these gaps in existing tools, to a static version of iCanDecide, similar to typical information found online. This trial is needed to better understand how the proposed decision tool innovations—knowledge building, values clarification and real time feedback and patient activation—can help improve the quality of treatment decisions for patients. By conducting our study in primarily two distinct geographic areas and focusing on recruiting from community based surgical practices, we believe we can recruit a diverse and more generalizable population of breast cancer patients than studies that have been conducted only in academic settings. The iCanDecide tool, if shown to be effective, can be easily integrated into the routine of a variety of clinical practices

to help clinicians individualize treatment decisions for newly diagnosed patients with breast cancer and to help patients make high-quality decisions about their care.

4.2. Dissemination

The participating practices (including providers and staff) will receive monthly newsletters updating them about the study. Upon completion of patient recruitment, participating providers will have the option to continue offering the iCanDecide interactive website to their patients as an ‘information only’ site. Furthermore, after the final mailings of the second follow-up survey, the participants will receive a newsletter summarizing some of the study findings. Upon completion of the trial, the study team plans to present findings at national meetings and publish results in clinical journals.

4.3. Future directions

The iCanDecide patient version tool has been designed to help improve the quality of treatment decision making for patients with breast cancer. We believe that by partnering with community based practices in primarily two distinct geographic areas will increase the generalizability of our sample to be more representative of U.S. women with breast cancer. Yet further work is needed to conduct similar studies of decision making tools in different settings, particularly those with larger numbers of underserved and vulnerable populations. Furthermore, additional work is needed to connect output from the patient-facing decision tool to the clinical team, who can review and circle back to a patient on these important issues. Next steps after our initial iCanDecide aims are met include developing and piloting a “clinician dashboard” prototype in order to meet these patient-provider communication needs. If effective, we plan to expand the implementation of iCanDecide into a broader set of clinical practice settings by partnering with groups such as the National Cancer Institute Oncology Research Program (NCORP).

Competing interests

The authors declare that they have no competing interests.

Funding

This research was supported by the National Cancer Institute of the National Institutes of Health (P01CA163233) and the University of Michigan Comprehensive Cancer Center Support Grant (5 P30 CA46592).

Acknowledgements

We would like to acknowledge the significant contributions of our participating practices from Michigan (Drs. Shannon Bongers, Nayana Dekhne, and Nicole Walker from Beaumont Health System; Drs. Eric Brown and Linsey Gold at Comprehensive Breast Care; Drs. Jeffrey Falk and Cheryl Wesen from Michigan Breast Specialists at St. John Providence; Dr. Narendra Gohel affiliated with St. John Providence; Dr. David Siegel affiliated with St. John Macomb – Oakland; Dr. Keith Hinshaw from Rochester General Surgery; Dr. Pamela Johnson; Dr. Amy Kirby affiliated with St. Joseph Mercy Oakland; Dr. Raouf Mikhail affiliated with Hurley Medical Center; and Drs. Jessica Bensenhaver, Jacqueline Jeruss, Lisa Newman, and Michael Sabel from the University of Michigan Cancer Center); from Georgia (Dr. Jennifer Amerson from Breast Care Specialists; Drs. William Barber, Amanda Morehouse, and Erin Bowman from

Atlanta Breast Care; Drs. Sheryl Gabram, Joel Okoli, and Derrick Beech at Grady Memorial Hospital/Emory; Dr. Cheryl Jones at Georgia Cancer Specialists affiliated with Northside Hospital; Dr. John Kennedy from Dekalb Surgical Associates; Drs. Keith Martin and Thomas Woodyard affiliated with Coliseum Health System; Dr. Monica Rizzo from Emory Healthcare; Drs. David Ruben, Patrick Luke, and Iqbal Garcha affiliated with Northside Hospital); from Tennessee (Drs. Alyssa Throckmorton and Lindi VanderWalde at Baptist Medical Group - Memphis Breast Care) and from the Los Angeles area (Drs. Deanna Attai and Maurice Berkowitz affiliated with the University of California, Los Angeles Health System).

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