UNIVERSITY OF MICHIGAN

ROGEL CANCER CENTER

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Patient-Centered, Team-Based Continuing Care After Breast Cancer Treatment: The *ConnectedCancerCare* Pilot Study

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Study Drug: ConnectedCancerCare Tool

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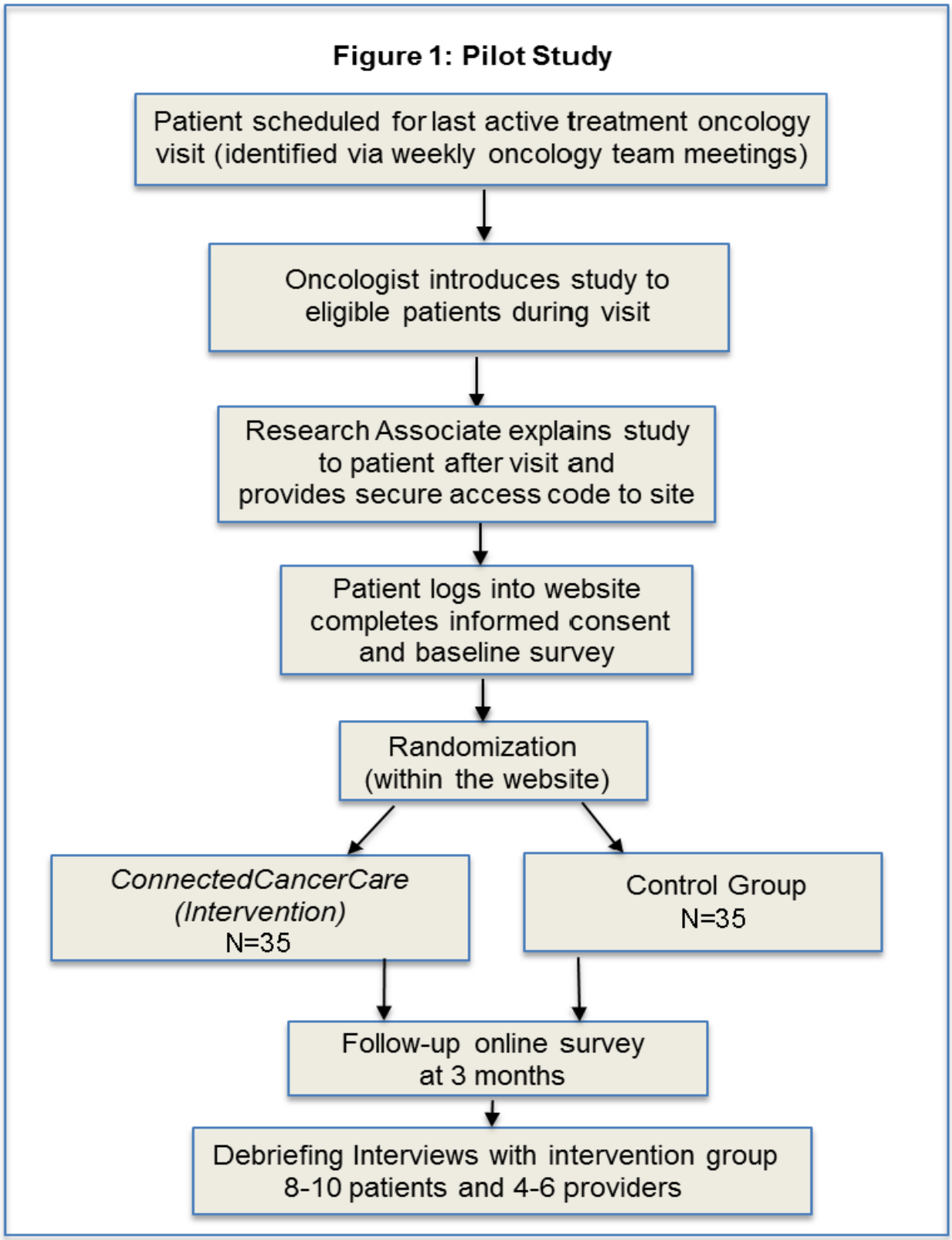
STUDY SCHEMA



STUDY ABSTRACT

The population of aging cancer survivors and their related healthcare needs are rapidly growing in the United States, necessitating the delivery of high-quality, team-based, patient-centered survivorship care long term. However, the delivery of this continuing care after treatment is complex and involves an increasing number of providers, which often results in uncoordinated, fragmented and/or duplicated care as a result. Promoting team-based, patient-centered continuing care after treatment is currently limited by coordination and communication challenges among providers, a lack of evidence about patients' preferences and expectations for their continuing care and few interventions to support the successful transition from primary treatment to survivorship.

The goal of this project is to pilot test a personalized, web-based navigation tool to support the transition from cancer treatment to survivorship that promotes team-based care. Using breast cancer as a model, this study will pilot test a patient-focused website to improve the quality of continuing care after primary treatment, by promoting the participation of the primary care provider in this care. Completion of this pilot study will inform future versions of the tool, as well as the full evaluation of the tool in a multi-site randomized control trial, with the ultimate goal of promoting team-based care plans for breast cancer survivors and informing policies to improve the quality of ongoing continuing care for cancer patients overall.

STUDY SUMMARY

Title	Patient-centered, team-based continuing care after breast cancer treatment: The *ConnectedCancerCare* Pilot Study
Phase	Pilot study
Objectives	**Aim 1**: To conduct a pilot evaluation to assess the feasibility and acceptability of a patient-centered, web-based navigation tool, *ConnectedCancerCare*, that supports the transition from breast cancer treatment to survivorship and promotes team-based survivorship care. **Aim 1A**: To assess the feasibility of recruiting at least 60 and up to 70 women with early-stage breast cancer who are completing primary treatment in the breast oncology clinic to the study. **Aim 2A**: To assess the acceptability of the CCC website among the 30 women randomized to the CCC intervention group. **Aim 2**: To explore whether CCC influences patient and provider communication about team-based survivorship care, patient-reported knowledge about team-based survivorship care and follow-up visit scheduling in primary care. **Aim 3**: To conduct debriefing interviews with participating patients and providers in the intervention group to inform the future evaluation and implementation of the tool.
Study Design	Pilot randomized control trial
Eligibility Criteria	1. Ability to voluntarily provide written IRB-approved informed consent and communicate satisfactorily with the investigator, to participate fully in the study, and comply with all its requirements. 2. Women diagnosed with Stages 0-II breast cancer

	3. Women who are receiving care from a medical oncologist 4. Women who are completing their primary treatment for breast cancer and transitioning into survivorship
Statistical Considerations	As this is a pilot study, we will be primarily assessing whether the recruitment of at least 60 and up to 70 women is feasible, and whether the majority of participants (50%) report the tool is acceptable using descriptive statistics. We will assess differences in patient-reported outcomes between the intervention group and control group, but this is an exploratory analysis to guide future versions of the tool and our planned multi-site RCT. As such, a sample size of at least 60 women and up to 70 participants is sufficient to address our primary outcomes (see power calculation section).
Number of Participants	At least 60 and up to 70 women (30-35 intervention and 30-35 control arm)
Estimated Enrollment Period	9 months
Estimated Study Duration	12 months

1. Objectives/Specific Aims

The population of cancer survivors is expected to grow to nearly 19 million by 2024. Breast cancer makes up the largest proportion of cancer survivors (3 million) and most of these patients are over the age of 60 (72%), have survived at least 5 years (89%), and have other medical comorbidities (42%). Nearly all breast cancer survivors will continue to deal with treatment-related issues such as pain, fatigue and lymphedema, and most will also face other comorbid health concerns as they age. This necessitates the delivery of high-quality, team-based, patient-centered continuing care, defined as care that encompasses all aspects of care, not just that related to the breast. However, the quality of continuing care for breast cancer falls short of this goal due to: 1) a burden on patients to coordinate their own care, 2) an increasing number of providers involved in delivering care making coordination and communication more difficult, 3) increasing care fragmentation and duplication of services provided by primary care physicians (PCPs) and oncologists and, importantly, 4) a lack of evidence and interventions to support the successful transition from primary treatment to continuing care.

The National Academy of Medicine's report on the cancer delivery "system in crisis" calls for comprehensive, patient-centered, team-based continuing care models that promote cross-specialty provider collaboration (particularly between PCPs and oncologists) and decrease patient burden. Yet, providing high quality, team-based care through the transition to survivorship remains a challenge. Although prior research has identified provider-level barriers to providing team-based care, patients' knowledge of what encompasses continuing care is low, and little is known about patient preferences and expectations for who provides the various aspects of it. Informing patients about team-based continuing care and managing their related expectations is critical to improving care coordination, reducing fragmentation and inefficient use of services. While team-based care models offer promise for improving continuing cancer care, interventions that educate patients about continuing care needs and help them navigate the complexities of their cancer and comorbidity management are needed. Therefore, the goal of this study is to begin to address the existing gaps in the care of breast cancer survivors by building and evaluating an individualized, virtual navigation tool that promotes patient-centered, team-based, continuing care after breast cancer treatment. The specific aims of the study are as follows:

Aim 1: **To conduct a pilot evaluation to assess the feasibility and acceptability of a patient-centered, web-based navigation tool, *ConnectedCancerCare*, that supports the transition from breast cancer treatment to survivorship and promotes team-based survivorship care.** We will conduct a pilot randomized control trial of our prototype website ***ConnectedCancerCare*,** which is tailored to patient's knowledge about survivorship care guidelines and their preferences for their oncologist and primary care providers' roles in delivering their survivorship care. We will assess the feasibility of conducting a large-scale RCT in the future and the acceptability of CCC as outlined below in the following sub-aims:

Aim 1A: To assess the feasibility of recruiting at least 60 and up to 70 women with early-stage breast cancer who are completing primary treatment in the breast oncology clinic to the study. We will randomize 30-35 women into the intervention group who will view the CCC website and 30-35 women into the control group, who will view an online care plan document. ***H1a***: It will be feasible to deploy *CCC* in an academic breast clinic, as measured by the successful recruitment of at least 60 and up to 70 women (80%) into the study.

Aim 1B: We will assess the acceptability of the CCC website among the 30-35 women randomized to the CCC intervention group. ***H1b****: CCC* will demonstrate high usability among those who interact with it, as measured by patient-reported ratings of website usability (ease of use, time to completion, amount of information), usefulness, and whether they would recommend it to others.

Aim 2: To explore whether CCC influences patient and provider communication about team-based survivorship care, patient-reported knowledge about team-based survivorship care and follow-up visit scheduling with primary care. ***H2a***: Patients who view *CCC* will report greater knowledge about and better communication with their providers about team-based survivorship care when compared to the control group. ***H2b***: A greater proportion of patients who viewed CCC will report scheduling a follow-up visit with their PCP within 3 months compared to those who viewed the control website.

Aim 3: To conduct debriefing interviews with a sample of patients and their providers about their experiences with *ConnectedCancerCare*. We will debrief oncologists, PCPs and patients (in the intervention arm) about the usefulness of the tool and how to best implement it into practice. The results will then be used to further tailor and revise the tool and develop future evaluation plans, as well as guide post-evaluation implementation and ultimate incorporation into the electronic medical record.

Impact: The findings from this pilot study will directly inform future versions of the CCC intervention and support conducting a full-scale, multi-site, randomized control trial to evaluate whether CCC improves team-based care delivery for breast cancer survivors (planned R01 submission to NCI). More broadly, the findings from this study will also inform future survivorship care delivery strategies and will help guide interventions to improve the delivery and quality of survivorship care, both in breast cancer and other cancers.

2. Background and Significance

The growing number of aging cancer survivors face major challenges because their medical care is especially complex. The population of cancer survivors is expected to approach 19 million by 2024.hawley[1,2] Breast cancer makes up the largest proportion of survivors (3 million), the majority of which are over the age of 60 (72%) and have survived at least 5 years (89%).[1] Nearly all breast cancer survivors will continue to deal with treatment-

related issues such as pain, fatigue and lymphedema.[3-5] They will also face increasing comorbid health concerns as they age, as 42% have at least one comorbidity,[6] and on average are seeing 5-16 different doctors.[7] This obligates the delivery of high-quality, team-based, patient-centered and comprehensive care.

As a result of concerns regarding the quality of cancer care and the rising costs associated with its delivery in the United States, The National Academy of Medicine's (Academy, formerly IOM) released a report in 2013 highlighting the cancer delivery "system in crisis" and calling for comprehensive, patient-centered, team-based continuing care models that promote cross-specialty provider collaboration and decrease patient burden.[2] The report highlights the explicit goal of providing team-based care to cancer survivors in which members of the cancer team coordinate with primary care to implement care plans and deliver efficient and patient-centered care. Further supporting team-based care models are provisions for patient-centered medical homes and Accountable Care Organizations in the Affordable Care Act, which promote and incentivize a collaborative model of care.[8] These provisions support oncology providers partnering with primary care and geriatric providers in new ways and integrating primary care into cancer care delivery throughout the continuum of disease.[9] In addition, one of the conceptual goals of survivorship care plans (SCPs) is to promote collaboration and communication between the providers involved in delivering this care.[10] However, despite high satisfaction among patients, receipt of care plans has been limited,[11,12] and when evaluated, SCPs were not found to improve care coordination and quality.[13] Nor have these plans eliminated the patients' confusion around the coordination of team-based continuing care and which provider is delivering it.[14] It is possible that the reason that SCPs have not been successful to date is in part driven by the fact that they are not patient-centered enough, and aren't promoting team-based care as they were intended to do conceptually. Despite these challenges, SCPs have wide support including recommendations from the Academy and the American College of Surgeons Commission on Cancer (ACSCoC). As such, the use of SCPs is starting to be required for ACSCoC cancer program accreditation.[15]

Despite these recommendations, policy provisions and the creation of SCPs, it remains very challenging to provide high-quality, patient-centered, team-based care through the transition to survivorship. The often chaotic delivery of cancer care is in part driven by the increasing number of providers involved in delivering the care, the increasing number of comorbid conditions the patients are managing as they age and the burden put on patients to coordinate their ongoing care, often with little support or guidance. Workforce shortages further complicate these issues, as significant shortages in both oncology and primary care physicians are expected by 2020.[16] As patients go through care transitions, such as transitioning from primary treatment to continuing care, they are at increased risk of experiencing fragmented or duplicated care such as repeated or missed clinic visits, lab and imagining tests.[17] Because of these challenges, continuing to provide cancer care without successfully sharing care between specialties such that communication and coordination are improved is not sustainable, and puts the patient at high risk of poor quality outcomes.[2]

The success of these care models is dependent on understanding the factors that promote or inhibit them. Previous research suggests that primary care physicians (PCPs) and oncologists differ in their knowledge, attitudes and practices as it relates to continuing care.[18,19] Findings from the Survey of Physician Attitudes Regarding the Care of Cancer Survivors Study (SPARCCS) suggest the majority of oncologists prefer an oncology dominant model of care whereas PCPs prefer a PCP/shared care model.[19] Also, clinicians from both specialties are uncertain about what roles they should play in delivering continuing care, which may lead to duplication or omission of important medical services.[19] While previous studies have identified provider-level barriers to implementing team-based continuing care, there remains a large gap in our understanding about what patients perceive, understand and expect about it. This inhibits

our ability to successfully engage and inform them about their ongoing care needs and sufficiently support them as they complete primary treatment.

To successfully promote team-based continuing care models that are truly patient-centered, we must partner with patients in managing their survivorship care. This requires providing patients with patient-centered, reliable information that helps them to navigate the transition to survivorship and centrally participate in managing their care going forward. Yet, we know very little about patients' preferences and expectations with regard to their continuing care after treatment, particularly as it relates to the role of the PCP. Focus group data suggests that patients feel that their care is in part their responsibility, are open to having PCPs manage aspects of it, but report hesitation and uncertainty about the role that PCPs play in delivering this care.[20] As a result, many survivors report that they continue to receive care and reassurance from their cancer specialist rather than their PCP.[20] Assessment of patients' attitudes, beliefs and knowledge about team-based continuing care in population-based samples does not currently exist despite qualitative findings that suggest that they may be important barriers to best practices. This lack of understanding hinders our ability to design patient-centered interventions that promote team-based care and improve continuing care quality and coordination. While team-based care models offer promise for improving continuing care, without an understanding of the factors that promote or inhibit them, and the preferences and expectations of those involved, these models will not be effective and our ability to design interventions to promote team-based care will be limited.

Therefore, **the goal of this study is to conduct a pilot evaluation an individualized, virtual navigation tool that promotes patient-centered, team-based, continuing care after breast cancer treatment.** The study objectives address the large gaps in the evidence and the need to develop interventions to improve the quality of collaborative care after cancer treatment. Breast cancer is an excellent model for this work, as the transition from treatment to survivorship is particularly complex with patients remaining on protracted adjuvant therapies. In addition, the findings from this study will also be applicable to other cancer survivors as they transition to survivorship.

3. Preliminary Data

There are untapped opportunities for PCPs to take on a larger role in survivorship care. Our previous findings in the iCanCare Study suggest that PCPs are more involved in care during cancer treatment than previously understood. Most women with early-stage breast cancer reported high primary care quality (as measured by access and relationship with the PCP) during their initial cancer treatment. In addition, the majority reported seeing their current PCP for more than 2 years, and that their PCPs were engaged in and informed about the cancer care they were receiving during treatment. However, almost a quarter of women reported low PCP engagement in and communication about the cancer care during treatment, despite reporting high primary care quality. While our findings suggest PCPs are quite engaged in cancer care during treatment, another recent study from Canada suggests that patient contacts with their PCPs decreased over time in survivorship and were lowest in the adjuvant treatment phase.[21] Prior work from our group also suggests that PCP involvement may be lower later in survivorship, as only a quarter of women with early-stage breast cancer reported they were followed by a PCP 4 years after diagnosis.[22]

There is a need to clarify provider roles during survivorship. Because prior cancer care delivery research has focused on characterizing utilization in survivorship, it remains unknown what aspects of care PCPs are handling vs. what aspects oncologists are handling in survivorship. This has led a lack of clarity regarding provider roles in survivorship care. As a result, current guidelines fall short of clearly delineating which specialty should handle the

various aspects of care. This has led to confusion among both patients and providers.[23] Our prior work in the iCanCare Study supports this, as the majority of women with early-stage breast cancer preferred their oncologists handle multiple aspects of their survivorship care that PCPs typically deliver (e.g. screening for other cancers and comorbidity management).[24]

In addition, this ongoing lack of clarity about provider roles in survivorship may result in clinicians providing care outside the scope of their specialty. Our preliminary oncologist data from iCanCare suggests that this may be the case, as most medical oncologists reported often having problems in avoiding duplication of care with PCPs as well as coordinating care for existing or new comorbidities. Importantly, over one third of oncologists reported problems even determining whether they or the PCP should provide general preventive care. Others have reported similar findings, specifically with respect to oncologists providing the majority of survivorship care.[25] Therefore, oncologists may not only continue to dominate surveillance services and cancer-related follow-up, they may also be delivering aspects of care that PCPs or other specialists typically deliver.

Significant disparities exist in the quality of breast cancer care. Our research group, the Cancer Surveillance and Outcomes Research Team (CanSORT), has extensive experience in conducting population-based studies of diverse cancer patients, their caregivers and clinicians focused on examining disparities in the quality of cancer treatment and outcomes. This work has directly informed multiple patient-level interventions focused on improving the quality of cancer care.[26] Our prior research has also demonstrated important sociodemographic disparities in the breast cancer treatment decision-making process[27-29] and outcomes after treatment,[22] including financial toxicity,[30-32] worry about recurrence[33] and quality of life[34] years after initial treatment, notably among black and Latina women.[35-37] Our population-based research directly informs our intervention research and has led to the development and successful evaluation of a multi-site randomized control trial of a patient decision aid for breast cancer treatment, led by Dr. Wallner's mentor, Dr. Sarah Hawley. The *ConnectedCancerCare* pilot study will be modeled after the pilot approach used to support this study, which ultimately led to the successful recruitment of over 500 patients across multiple clinic sites across the US for the full-scale RCT.[38]

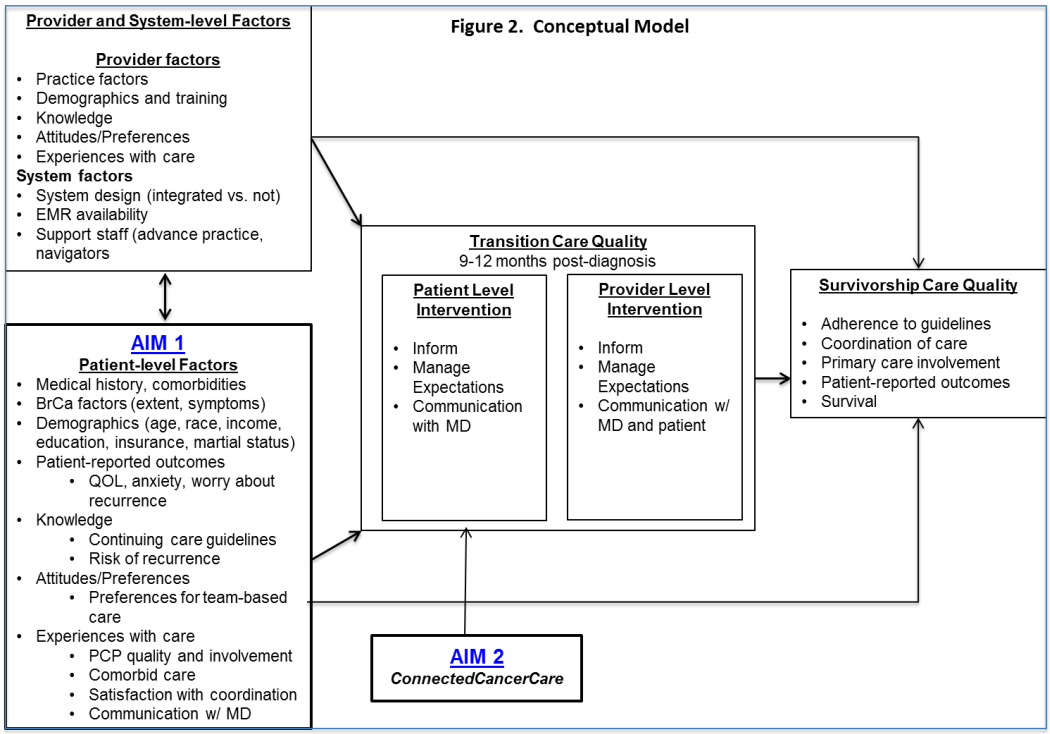
Beta Testing. Usability testing of an early version of the *ConnectedCancerCare* website was conducted with early stage breast cancer patients (n= 4; age range: 33-50 years) who had recently completed active treatment and were in continuing/survivorship care. Patients were identified via outreach with the Breast Cancer Advocacy Committee at UM Rogel Cancer Center. Participants met with a team of developers and designers in the Center for Health Communications Research (CHCR) to go through the website and think out loud about the navigation, flow, usability and drafts of the content. While viewing the beta website on a laptop computer, patients were asked about the ease of navigation and functionality of the site; clarity of links to sections; expectations and satisfaction with information under specific sections; the value of a "to-do" vs. checklist; knowledge of medical team members' roles in their survivorship care; and general questions pertaining to the overall look and feel of the site and what they liked and/or disliked in viewing all the website pages.

Based on their feedback, *ConnectedCancerCare* was enhanced as follows: 1) "to-do" list was combined into the patient checklist and renamed "My Next Steps," 2) information sections were renamed to clarify content (i.e. My primary care doctor became Primary care during survivorship), and 3) greater emphasis was added to onboarding patients and explaining the importance of scheduling a PCP appointment. The modifications made as a result of user testing will provide patients with a better understanding of the primary purpose of the website (i.e. PCP involvement in survivorship care).

Patients also made suggestions for future enhancements to the CCC site which included: expanding the resources section, additional tailoring to specific patient needs, providing a feature to help patients locate a PCP, and integrating the site with the patient portal. These suggestions, combined with feedback we receive from pilot participants who participate in the debriefing interviews, will help inform future enhanced versions of the CCC tool.

4. Methods

Conceptual Model. The overall conceptual model for this study was informed by the Chronic Care Model[39] and prior research by our team about treatment decision making, care coordination and the interplay between the health care system, patients and providers during cancer treatment.[27,28,33,40-42] (Figure 2)



4.1. Design

The proposed study is a randomized control pilot trial of at least 60 and up to 70 women newly diagnosed with early-stage breast cancer who are finishing primary treatment. Participants will be randomized either to the intervention arm (CCC website that will provide information on team-based follow-up care for both cancer surveillance and preventive care) or the control arm (static online survivorship care plan template which was adapted from the ASCO breast cancer survivorship template). The feasibility and acceptability of the tool and correlations with patient-reported outcomes will be assessed 3 months following the completion of the baseline survey. A sample of 8-10 patients in the intervention arm will then be invited to participate in debriefing interviews to collect feedback regarding their experience with the CCC tool. We will also ask for feedback from 4-6 providers (2-3 medical oncologists and 2-3 PCP's) whose patients participated in the study. Due to time and budget constraints, we are only able to include a sample of patients and providers in our debriefing interviews.

4.2. Subject Recruitment

Since this pilot study is testing a behavioral intervention and not a therapeutic intervention, the following outlines our standard approach to recruitment and enrollment of subjects, which have been successfully used in prior studies of UM breast cancer patients. For subject recruitment,

we will follow the approach used previously by Dr. Hawley in her iCanDecide recruitment (HUM 62261). The iCanDecide Study was a two-armed randomized controlled trial of an interactive and tailored website with the goal of helping newly diagnosed and early stage breast cancer patients make informed treatment decisions. Employing the same recruitment strategy as used in the pilot study for iCanDecide, a trained clinical research associate will recruit a sample of at least 60 and up to 70 women from the University of Michigan Breast Cancer Clinic who are completing primary treatment for early-stage breast cancer, ages 21-84, and finishing their active treatment visits with their medical oncologist. A study coordinator will identify eligible patients for the pilot testing by reviewing MiChart scheduled oncology visits for patients nearing the end of their treatment and reports from the breast oncology meetings. Patients' eligibility for participation in the study will be verified with the UM breast oncology care team and the PI. Once an eligible patient is identified as being at the end of their primary treatment, the study coordinator will identify their next scheduled visit with medical oncology and plan to be there in person to initiate recruitment. At that visit, the study will be introduced to the patient by the attending oncologist, and those who are interested in participating will then meet with the study coordinator to discuss the following packet of materials: (1) a cover letter written at a 6th grade reading level containing instructions, information about the study including the risks and benefits, their rights as participants and that participation is voluntary; (2) log-in information to access the website which contains the informed consent for them to complete; (3) a copy of the informed consent which they will complete online; (4) information about how to receive a $20.00 electronic Amazon gift card once subjects have completed the online baseline questionnaire, (5) a local telephone number to call with questions or concerns, and (6) an additional $20 Amazon gift card included in the study packet to encourage enrollment of participants. For patients' convenience, the study coordinator will provide patients' with the option to view the CCC website or access it via a laptop computer or ipad. When a patient logs into the website, she will be asked to verify personal information and complete the informed consent. The PI and study coordinator(s) will verify subjects' enrollment into the study via their online completion of the consent form and baseline questionnaire, as indicated on the CCC Administrative Dashboard.

This process will request contact information, including providing an address and telephone number to support following up after the follow-up survey has been emailed to participants if needed, sending the electronic gift card to participants via email, and contacting those interested in participating in debriefing interviews at the completion of the study.

Inclusion Criteria:

1. Ability to voluntarily provide written IRB-approved informed consent and communicate satisfactorily with the investigator, to participate fully in the study, and comply with all its requirements.
2. Women diagnosed with Stages 0-II breast cancer
3. Women who are currently receiving care from a breast oncologist at UMCCC
4. Women who are completing their primary treatment for breast cancer and transitioning into survivorship
5. Access and ability to use the Internet

Exclusion Criteria:

1. Women who are unable to speak and/or read English

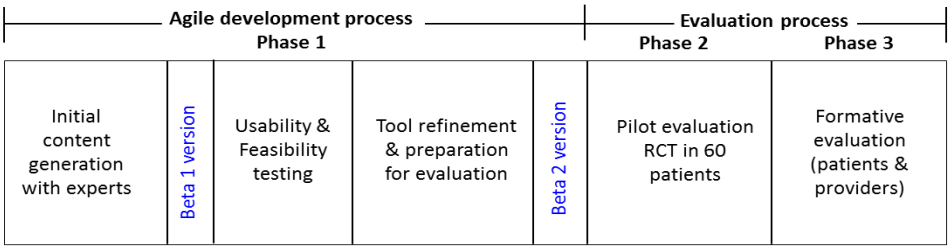
4.3. Subject Selection

After completion of the baseline questionnaire**,** participants will be randomized to either enter the *ConnectedCancerCare* website (n=30-35), or a static website (n=30-35) which contains a brief survivorship care plan template in PDF format (see Appendix). We will employ block randomization, with a block size of 6 (10-12 blocks total) to ensure that the study group assignments are equally distributed throughout recruitment.

4.4. Intervention (*ConnectedCancerCare*)

Overview: The CCC tool is a personalized, navigation website that is tailored to patients' preferences for provider roles in follow-up care, their satisfaction with their current PCP, and their worry about cancer recurrence. This pilot study is designed to determine whether an informative and tailored website can assist in guiding patients to utilize team-based care for their follow-up cancer care. The tool involves a website and text-based reminder system to help patients transition from active cancer treatment to ongoing/survivorship, team-based care and includes three research phases: 1) baseline survey and 2) 3-month follow-up survey among all participants; and 3) patient/provider interviews among a sample of participants in the intervention arm to assess patients' understanding of survivorship care, usage of the website, and increased knowledge of team-based survivorship care as a result of using the tool. This tool was developed by the UM Center for Health Communications Research (CHCR) under the direction of the PI, Dr. Wallner, with input from oncologists, primary care physicians and other study co-investigators, and then beta tested among breast cancer patients. We believe this tool will be of benefit to patients comfortable using the internet and to clinicians who value additional information about their patients' preferences and concerns.

Figure 3. CCC Development and Evaluation



Development: CCC was developed using "agile development",[43-45] which included content development and usability testing as used previously by the investigators in a trial of a patient decision aid for breast cancer treatment.[26] CCC was developed using an iterative, agile cycle, which included planning (content decisions), design (graphical display and media elements), development (programming) and testing (feedback from stakeholders on draft versions). Testing included an iterative process of tailoring, timing, data, and functionality. The next phase (Phase 2) includes the pilot evaluation detailed in this protocol (Figure 3).

Figure 4. Anticipated CCC content

Questionnaire Module
Preferences for who handles continuing care-
Knowledge of survivorship guidelines
Concerns regarding survivorship care
Patient history (i.e. comorbidities)
Healthy Lifestyle Behaviors (smoking, diet, exercise)

Inform Module
Inform about survivorship guidelines
Inform about healthy living during survivorship

Tailored Educational Module
Clarify provider roles
Promote team-based care
and **communication** with provider
(via tailored checklist)
Link to BTP lifestyle interventions

Calendar/Reminder Integration
Email reminders and calendar prompts for:
PCP and Oncology follow-up visits (3-6 months)
1st mammogram (1 year)

Content: The content of the *CCC* navigation tool was developed by Drs. Wallner and Hawley, along with clinical experts in the UM-RCC and CHCR. The development built upon the existing programming of the iCanDecide tool, a novel treatment decision-making tool developed by Dr. Hawley, which recently was evaluated in a full-scale randomized control trial with 500 patients (REF). *CCC* includes content focused on four areas as outlined in the conceptual model:

1) **Inform:** This section provides the patient with key facts about survivorship guidelines and what to expect from team-based care.

2) **Clarify:** This section provides tailored content to clarify appropriate provider roles in delivering team-based care based on their collected preferences. The preferences outlined in the questionnaire section are used to tailor the content on this page.

3) Communicate: This section promotes communication with the oncologist and PCP about this topic and includes tips and suggestions on how to communicate with their physicians and get the most out of their clinic visits.

4) **To do list for follow-up care and reminders**: This sections outlines for patients what services they will need during survivorship, based on clinical guidelines. Customized alerts will be sent to participants to remind them to schedule their follow-up visits with their PCP, according to the guideline-recommended schedule and to complete their follow-up survey. A total of three reminders for each event have been built into the website program, and subjects are given the choice of how they want to receive reminders (i.e. text or email). Currently, the ConnectedCancerCare website is not linked to MiChart; however, that is a desired feature for future development.

Screen shots of the website content and information on how to access the website directly are included in Appendices 5.

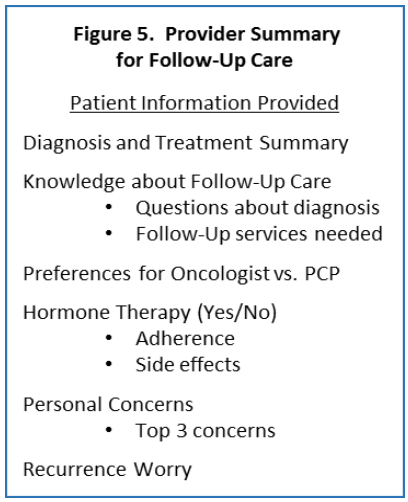
4.4.1. Baseline Questionnaire: After completing the online consent, patients will begin the online questionnaire which collects information that is used to tailor the content of the website. The survey is included in the Appendix. Measures used to tailor the website content include the following:

a. Knowledge of guidelines for breast cancer follow-up screening and preventive care
b. Current PCP (yes/no)
c. Preferences for providers in team-based (PCP or oncologist)
d. Satisfaction with care coordination at the time of transition
e. Communication with providers about continuing care
f. Worry about recurrence

We will also ask patients to provide the contact information for their medical oncologist and primary care physician as part of the baseline questionnaire, which will be used to fax a provider summary to both physicians' offices. The research coordinator will then verify this contact information using MiChart and the internet (for address verification) as needed.

4.4.2. Provider Summary: The results of the baseline questionnaire will populate a short patient summary and highlight any critical misconceptions, or expectations the patient has about her care and who will be managing it, any gaps in knowledge she has about follow-up care, and a short checklist for her to use to guide her continuing care. Providers of patients randomized to the CCC intervention website will receive a summary based upon patients' answers to the baseline questionnaire for the six areas outlined in the Provider Summary. They include: 1) patient diagnosis and treatment; 2) knowledge of follow-up care; 3) preferences for follow-up care from PCP vs. Oncologist; 4) hormone therapy requirement; 5) personal health concerns; and 6) level of recurrence worry. Providers of patients in the control group will not receive a summary report for these patients.

Figure 5. Provider Summary for Follow-Up Care



4.4.3. Follow-up Questionnaire: At three months, patients in both groups (intervention and control) will be emailed and prompted to complete a brief, online survey by logging back into the *CCC* website. The survey includes multiple measures of acceptability and usability in the intervention group only (primary outcomes) as they relate to viewing the tool (described in detail in section 5 below). Also, we will explore the influence of the intervention on secondary patient-reported outcomes including whether they scheduled a visit with their PCP and their knowledge about continuing (survivorship) care, as outlined in section 5 below.

4.4.4. Patient Contacts: If a patient decides to participate, they will log into the CCC website using the unique assigned ID access code provided with the recruitment letter. Upon initial login, they will consent online, create their account (by inputting their email and phone number) and begin the baseline survey. They will receive one automated email reminder 2 days later if the baseline questionnaire is not completed, and up to 2 personalized phone contacts from the study coordinator within 14 days if the baseline questionnaire remains uncompleted. Upon completion of the baseline questionnaire, participants randomized to the intervention arm will receive weekly reminders via email, and possibly text messages if they opted into texting at account creation to make an appointment with their PCP. Three months from baseline completion, participants will receive a 1-week advance alert email (and a text if they opted in) for the follow-up questionnaire, followed by a second email alert in the next week, indicating the survey's availability on the CCC website. Participants will receive one automated email reminder 5 days later if the follow-up questionnaire is not completed. We will employ a modified version of the Dillman method, which includes up to 3 contacts for follow-up to maximize response rates and to identify non-respondents, that has proven to be successful in our previous work.

4.4.5. Debriefing Interviews: A sample of 8-10 patients who participated in the pilot testing and 4-6 of their physicians (2-3 medical oncologists and 2-3 primary care physicians) will be contacted via phone and invited to participate in debriefing interviews about the usefulness of the tool and future implementation strategies. A question will be included at the end of the follow-up survey which solicits their interest in being contacted after the study ends to discuss their experience with *ConnectedCancerCare* in more detail. For those who respond yes, we will select the first 8-10 people and contact them via phone to conduct a brief 20-minute audiotaped, interview (questions are in the Appendix), to gather their feedback about their experience with the tool.

4.5. Time and Events Table

Study Events	**Pre-study** (after completing primary treatment)	**Time 1** (When viewing the website initially)	**Time 2** 3 months post-baseline questionnaire completion)	**Time 3** 1-3 months post-follow-up questionnaire completion)
Informed Consent	**X**			
Baseline Questionnaire	**X**			
Randomization		**X**		
View intervention or control website		**X**		
Follow-up questionnaire			**X**	
Debriefing Interviews				**X**

5. Measures

The measures described in detail below were selected after literature review, and were directly informed by our conceptual model and the results of our prior work and pilot data. The measures are described by specific aim below:

Aim 1A: Feasibility
Feasibility will be defined by the successful recruitment of at least 60 women with half randomized to the intervention website and half to the control website over a 9-month time period. Based upon positive response rates of patients in previous studies of survivorship interventions and the iCanDecide pilot trial, we anticipate approaching approximately 87 women in order to achieve a similar response rate of 80% enrollment (n=70). We will also assess the proportion of those successfully recruited who complete the baseline survey and the follow-up survey. In addition, we will capture paradata including participants' average number of page views, and average time on website.

Aim 1B: Acceptability
Acceptability and usability will be defined by asking participants in the intervention arm to rate their experiences with the tool on 5 point Likert-type scales, as follows: (1) CCC was easy to use, (2) CCC was helpful during my transition to survivorship, (3) CCC helped me think about when to see my PCP and when to see my oncologist, (4) I would recommend CCC to other patients, (5) The time it took to go through the website (6) The amount of info.

Based on our prior work, we will use a cut off of 50% of more reporting a score above 3 as acceptable within that domain. We will also examine the distributions within each domain and determine how we can make the next versions of the tool more acceptable to patients as needed. We will then create a summary score of acceptability by averaging the responses to the 6 items, with a score of 3 or more indicating the tool was acceptable to the majority of patients.

Aim 2: Exploratory patient-reported outcomes
We will collect patient-reported outcomes in both the intervention and control groups. We will then explore whether the intervention (compared to control) is correlated with the following measures: Knowledge about continuing care guidelines measured by items used in our previous studies adapted to continuing care (categorical);[27] Preferences for team-based care (PCP or oncologist); Satisfaction with care measured by a care coordination question used in previous CanSORT studies tailored to the timing of transition (categorical);[40] Communication with providers about continuing care measured by an item from the SPARCCS adapted to the patient perspective (categorical).[18,25] We will explore follow-up visit scheduling (yes/no) using patient-reported measure of whether or not they have scheduled a visit with their PCP since viewing the tool (or control). We will also ask patients whether they have seen their oncologist (yes/no) since viewing the tool and verify their responses using MiChart data.

Aim 3: Debriefing interviews
Guiding questions with prompts will be used to obtain patient and provider feedback (See Appendix for draft interview guide). Patients will be asked about the content of the tool, how they used the tool (or not), and whether it improved their care transition experience. In addition to these questions, providers will also be asked about their experience with the tool summary, how well it fit into their clinical practice, with the goal of understanding how to best imbed the tool into current clinical work-flow.

6. Procedures

6.1. Data Management: We use established human subjects' protection protocols that address the limited use of personal health information, transfer of de-identified datasets within our

institution, storage of information from various data sources and surveillance and response to adverse events. The primary risks of the study are related to breaches in confidentiality and patient concerns about the use of their medical information. We have a long track record of employing the highest standards of patient confidentiality. However, we will respond promptly to any patients or providers who contact the staff or investigators about any concerns related to the study.

For pilot testing, the study coordinator will assign a unique study ID to each potential participant. A secure, unique ID access code generated by the website will be used by the participants when they log into the website. Access to the password protected, encrypted, study database will be restricted to the principal investigator and selected members of the study staff. For the physician interviews, the digital recordings and transcripts will also be de-identified and stored in password-protected files, which will only be accessible to the principal investigator and study staff. Patient and provider contact information will be kept in encrypted and password-protected files and used until the study and reporting is completed. The research data, which includes health-related data about the participants collected through the CCC intervention, will be stored for the required 7 years in a secured online server after which time the online data files will be electronically and securely deleted from the server, destroying all data.

Weekly meetings with Dr. Wallner and the study staff will address any adverse events that could result from pilot study participation (e.g. increased anxiety) and patient and physician interview participation. These are anticipated to be rare and will be handled on an individual basis. Any adverse events will be reported to the IRBMED of the University of Michigan according to current IRBMED reporting guidelines.

7. Data Analysis Plan

Aim 1a: Feasibility
To determine feasibility, we will first assess whether we were successfully able to recruit 80% of our target population (N=87) into the study to achieve a maximum sample size of N=70. We will then generate descriptive statistics of the feasibility measures described above, including % of patients who complete each questionnaire, and average number of page views and time on website.

Aim 1b: Acceptability
The distribution within each of the 5 measures of acceptability will be determined and mean scores >3 within each domain will be examined. For any domain that has a mean score below 3, we will then use that information to inform future adaptations of the tool to increase the acceptability. The distribution of the acceptability summary score of will then be assessed and the proportion of patients with a score of 3 or more will be calculated.

Aim 2: Exploratory Patient-Reported Outcomes
We will then explore comparing knowledge, satisfaction, communication and utilization among the 30-35 women who engaged with the tool to the 30-35 who received the standard of care using chi-square tests and two-sided student t-tests where appropriate. This is designed to be a pilot study to determine if patients who engage with tool score higher on key knowledge, communication, and satisfaction items compared to those who received the control.

Aim 3: Patient and Provider Debriefing Interviews
To better understand what worked and did not work following the pilot testing and the underlying mechanisms of the intervention, we will conduct a formative assessment with both patients and

providers who had a patient who enrolled in the study. All interviews will be audio recorded and transcribed and analyzed using Dedoose and NVivo software. The investigator team will review the transcripts to identify overall themes which will help to refine the tool as needed and guide the future implementation of it into a broader system-level tool used in clinical practice.

7.1. Power Calculations

We hypothesize that 50% of more of our sample will report an acceptability score of 3 or higher. With a sample size of 30 in the intervention group, we can obtain a two-sided 95% confident interval with a width equal to 0.374 when we assume 50% patients will report the tool being acceptable and usable. Since 0.375 is a clinical meaningful and a reasonable width for confidence intervals, we show that our study will have sufficient power to examine the extent of acceptability and usability among patients regarding our intervention tools.

8. Protection of Human Subjects

Risks to Human Subjects: Risks to participants in this study are minimal, since this is an informational and educational tool similar to the type of information patients seek on their own or receive from their oncologist or primary care physician. The website-based navigation tool being studied contains similar educational content found in survivorship care guidelines available on the internet or from their medical oncologist. It is possible breast cancer patients may be experiencing distress or anxiety as they complete their primary treatment, however, all subjects will be informed that participation is completely voluntary, that they may drop out at any time, and it will not affect their medical care, as stated in the informed consent form. Upon initial login they will be asked to consent prior to viewing information on the website. The consent form will explain that their clinician will be able to view their own patients' responses on the dashboard website.

After consenting, patients will be directed to complete a **baseline survey**. As in our prior work, the survey will be kept as brief as possible to minimize participant burden. Our experience has found participants and non-participants view this type of research very favorably and are eager to provide feedback on the development of these types of tools, as evidenced by many moving comments about our prior studies and high response rates. There is a very small possibility that information on the website may upset patients. If patients do need support or want further clarification, the principal investigator will address it in a timely and professional manner. For **debriefing interviews,** we will use trained qualitative researchers to ensure appropriate questions are asked, and that patients and physicians are comfortable with the process. They will be informed up front in the consent form that interviews will be audio recorded. There is a very small possibility that the questions asked during the interviews may upset physicians. If patients or physicians require additional support or want further clarification, the principal investigator will address it in a timely and professional manner.

> Patient eligibility criteria: Patients eligible for the study will be female breast cancer patients age 21-84, with stage I-ll (including DCIS) invasive breast cancer who have recently completed active cancer treatment(s) and are transitioning to follow-up care with their oncologist and PCP.
>
> Vulnerable populations: There is no inclusion of fetuses, neonates, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations, except that it is possible that a subject might be pregnant. Because this involves surveys and reviewing an informational website, it should have no additional risk for a pregnant woman.
>
> Excluded are: Patients for whom there is a clinical/nonclinical reason for which the surgeon determines the patient is not eligible for the study; patients who do not have internet access or email addresses, and patients who do not read or speak English.

Patient Recruitment for Pilot Testing Patients will be recruited through the Breast Cancer Clinic at the University of Michigan Rogel Cancer Center. Patients eligible for the pilot testing will be those who have recently finished their primary treatment for newly-diagnosed stage I-II female breast cancer and have scheduled their transition visit with the medical oncologist. For the pilot, we will recruit English speaking women with internet access.

Patient and Physician Recruitment for Debriefing Interviews: As stated in section 4.4, a convenience sample of 8-10 patients who participated in the intervention arm and answered that they were willing to be contacted for additional information regarding their experience with using the website on the follow-up survey will be invited to participate in debriefing interviews. We will contact these participants via email and invite them to participate in the debriefing interviews about the usefulness of the tool and future implementation strategies. Debriefing interviews will also be held with 4-6 of their physicians (2-3 medical oncologists and 2-3 primary care physicians) to obtain their views on the usefulness and usage of the tool by their patients and future enhancements.

Sources of Materials: All data to be used in this project will come from: 1) electronic patient surveys (pilot testing), 2) MiChart patient records (participant eligibility), and 3) patient and provider interviews. Survey data will include baseline data collected through the navigation tool, and then follow-up survey data for participants in the intervention three months later. Digital audio recordings will be taken during each physician and patient debriefing interview to be transcribed and analyzed.

8.1. Adequacy of Protection Against Risks: We use established human subjects' protection protocols that address the limited use of personal health information, transfer of de-identified datasets within our institution, storage of information from various data sources and surveillance and response to adverse events. The primary risks of the study are related to breaches in confidentiality and patient concerns about the use of their medical information. We have a long track record of employing the highest standards of patient confidentiality. However, we will respond promptly to any patients or providers who contact the staff or investigators about any concerns related to the study.

9. Data Safety and Monitoring

9.1. Data Security and Confidentiality: For pilot testing, the study coordinator will assign a unique study ID access code to each potential participant. This study ID will be used by the participants when they log into the website. Access to the password protected, encrypted, database will be restricted to the principal investigator and selected members of the study staff. For the physician interviews, the digital recordings and transcripts will also be de-identified and stored in password-protected files, which will only be accessible to the principal investigator and study staff.

9.2. Project Data Management and Coordination: Weekly meetings with Dr. Wallner and the study staff will address matters related to the safety of study participants, validity and integrity of the data, recruitment rate relative to expectation, adherence to the protocol, data completeness, and any adverse events that could result from pilot study participation (e.g. increased anxiety), patient and physician usability testing, or interview participation. These are anticipated to be rare and will be handled on an individual basis. At these regular meetings, the protocol specific Data and Safety Monitoring Report will be completed and signed by the Principal Investigator or by one of the study coordinators.

9.3. Data Safety Monitoring Plan (DSM): This study will be monitored in accordance with the NCI approved University of Michigan Rogel Cancer Center Data Safety and Monitoring Plan. The PI for the study will oversee the data safety and monitoring issues, working closely with study staff and the group's biostatistician. Datasets will be managed by Drs. Wallner and Hawley with guidance for the bio-statistical core by Dr. Li for the *ConnectedCancerCare* (CCC) Study. We do not anticipate many adverse events from voluntary participation in this minimal risk study. Viewing the intervention is educational, and should not cause undue anxiety, concern or worry. The intervention is similar to information available on the internet, or from their clinician's office with the exception that the navigation tool provides more tailored information for patients to understand the components of their ongoing continuing care. The CanSORT Data Safety and Monitoring Board for this study will consist of those individuals identified as co-investigators for this study: Drs. Katz, Hawley, Ayanian, and Sales. Data issues, including recruitment, enrollment and attrition will be discussed, as will any adverse events. The DSM board will meet monthly or more frequently if deemed necessary to discuss matters related addressing any adverse events that might result from study participants' adherence to the protocol, and data completeness.

Any adverse events, including increased participant anxiety or other concerns, will be immediately reported to the PI, discussed via weekly staff meetings between the PI and study staff. Data Safety and Monitoring Reports will also be submitted to the University of Michigan Rogel Cancer Center Data and Safety Monitoring Committee (DSCM) every six months for review.

The study itself does not provide treatments of any kind; this is done by the clinicians as is usual care. No products, medications or tests are being delivered as part of this study.

10. Adverse Event Reporting

While we do not anticipate many adverse events from participation in this minimal risk study, possible adverse events could include increased anxiety about breast cancer follow-up care from participating in the study. If desired by the participant, referral to counseling or support services can be made. We anticipate that any anxiety caused by the program will be minimal, and could be addressed by website reminders to patients to discuss concerns with their clinicians. All participants will have a UM oncology specialist working with them to transition them to survivorship care. We will provide a contact sheet to the clinicians and patients, so they can reach the study team at any point with questions or concerns. We will follow IRBMED guidelines for reporting.

10.1. Pilot Test Safety We do not anticipate many adverse events for participants in this study. This is a minimal risk study and participation is voluntary. Viewing the intervention is educational, and should not cause undue anxiety, concern or worry. The intervention is similar to information they would obtain online if searching on their own, or from their clinician's office. The exception is that the navigation tool provides more tailored information, which should make it easier for patients to understand the components of their continuing care. It is possible that viewing the tool ahead of their visit with the oncologist could increase anxiety about discussing their follow-up care. Should increased anxiety occur, the following will be done to address and ameliorate concerns: 1) the participant has the chance to discuss these issues with his or her oncologist at the transition visit; 2) the clinician will report to us any issues that appear to be related to the study and are concerning; 3) participants may contact the study team at any time to express questions or concerns, in which case the study PI and/or local staff will refer them to appropriate counseling and/or discuss their concerns with them at that time, and 4) the participant may choose to stop participation in the study. Any adverse event such as this will be discussed via weekly staff meetings between the PI and study staff; such events will be recorded by the PI and

reported to the study sponsor. Adverse events will only be reported to the UM IRBMED according to the Standard AE reporting guidelines. Should there be concerns that are not sufficiently addressed (i.e. frequently occurring AEs), the protocol will be modified. Online informed consent will be obtained from all participants prior to participating in any phase of the study, and will include the contact information of the local and overseeing PIs and study coordinator that the individual may contact at any point with questions or concerns.

11. Potential Benefits of the Proposed Research to Human Subjects and Others

This study has an excellent risk/benefit ratio. On a broader scale, participation will contribute to our understanding of quality of continuing care for breast cancer survivors, and the findings from this study will inform the full-scale evaluation of an intervention to improve the quality of cancer survivorship care. For these reasons, we believe the anticipated benefits to society outweigh the small potential risk to individual participants. The study also has the potential to increase the quality of continuing care for breast cancer patients directly. If proven effective, the *ConnectedCancerCare* tool can be translated into clinical practice to fulfill a critical need: it can help support patients through their transition from treatment to survivorship, while promoting team-based care between the oncologist and primary care providers who care for them.

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