UNIVERSITY OF ROCHESTER MEDICAL CENTER

WILMOT CANCER INSTITUTE

Development of a Personalized Discussion Prioritization Tool for Older Adults Considering Adjuvant Chemotherapy for Breast Cancer

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Study Principal Investigator:

Allison Magnuson, DO
James P Wilmot Cancer Center
601 Elmwood Ave, Box 704
Rochester, NY 14642
Phone: (585) 275-7246/ Fax: 273-1042
Email: Allison_Magnuson@URMC.Rochester.edu

Study Sub-Investigator:

Supriya G. Mohile, MD, MS
Division of Hematology/Oncology
University of Rochester Medical Center
James P Wilmot Cancer Center
601 Elmwood Ave, Box 704
Rochester, NY 14642
Email: Supriya_Mohile@URMC.rochester.edu

Mina S. Sedrak, MD, MS
City of Hope National Medical Center
1500 E. Duarte Road
Duarte, CA 91010
Email: Msedrak@coh.org

Jessica Gooch, MD
University of Rochester Medical Center
Department of Surgery
601 Elmwood Avenue, Box SURG
Rochester, NY 14642
Email: Jessica_Gooch@URMC.Rochester.edu

Study Personnel:

Terri Lloyd
James P Wilmot Cancer Center
601 Elmwood Ave, Box 704
Rochester, NY 14642
Phone: (585) 276-5652/ Fax: (585) 273-1042
Email: Terri1_Lloyd@URMC.Rochester.edu

Jessica Bauer
James P Wilmot Cancer Center
601 Elmwood Ave, Box 704
Rochester, NY 14642
Phone: (585) 276-6562/ Fax: (585) 273-1042
Email: JessicaC_Bauer@URMC.Rochester.edu

Chandrika Sanapala
James P Wilmot Cancer Center
601 Elmwood Ave, Box 704
Rochester, NY 14642
Phone: (585) 275-4391/ Fax: (585) 273-1042
Email: Chandrika_Sanapala@URMC.Rochester.edu

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1. PURPOSE OF STUDY

1.1. Overall Goal:

We have developed a Discussion Prioritization Tool (DPT) for older adults considering adjuvant chemotherapy. The DPT utilizes Conjoint Analysis (CA) methodology and the objective of the current study is to assess usability of this DPT in our target population, older adults with breast cancer and to adapt the tool to optimize usability for our target population.

1.2. Study objectives and Hypothesis:

1.2.1. Primary objective:

To evaluate the usability of the DPT in ten older adults considering adjuvant chemotherapy or has made a decision about receiving adjuvant chemotherapy for breast cancer within the past 12 months.

1.2.2. Secondary objective:

To adapt the DPT using “talk aloud” method to optimize usability for our target population.

1.2.3. Hypothesis:

The DPT tool will demonstrate adequate usability in older adults considering adjuvant chemotherapy or has made a decision about receiving adjuvant chemotherapy for breast cancer within the past 12 months.

1.2.4 Usability and feasibility metrics:

The usability and feasibility of the DPT will be evaluated based on the following:
Primary Usability Assessment Measures: System Usability Scale (SUS) (score on 10-item scale, total score ranging 0-100; higher score corresponds to greater usability). We will deem the tool usable if our mean SUS score among the 10 patients enrolled is >68.

Secondary Usability Assessment Measures:

a) Recruitment rates (percentage of patients who are approached and agree to enroll)
b) Talk Aloud Method (recordings of patients feedback while using the DPT)

2. BACKGROUND AND RATIONALE

2.1 Breast Cancer is a disease of aging. Among other elements, age is a crucial risk factor in developing cancers. In breast cancer specifically, incidence has been shown to rise with age, resulting in the majority of deaths related to breast cancer occurring in women aged 65 years and older [1]. In 2016, it was found that the prevalence of breast cancer among women aged 65 and over was 436.9 per 100,000 per year [2]. In patients with breast cancer, many are considered for adjuvant systemic therapy (e.g. chemotherapy). This is particularly relevant for older adults with higher risk breast cancer subtypes. For example, nearly 15% of older patients have triple negative breast cancers, which represent the most aggressive breast cancers with the majority of recurrences occurring within the first several years after treatment [1].

2.2 Patient goals and preferences are an important component in developing treatment plans for localized breast cancer. Providing patient-centered care that incorporates patient goals and values in the oncology treatment decision making process is important [1]. When it comes to healthcare decisions, each patient has their own individual goals, beliefs, preferences, life experiences and values that influence their treatment preferences [1]. Identifying what is important to patients with breast cancer can ultimately tailor conversations for each patient when discussing cancer treatment options. In addition, evaluating the patient's overall health and potential risks and benefits of various treatment option is also critical, particularly for older adults. The geriatric assessment (GA) is a validated tool to assess the overall health status of older adults and is superior to other measures of "fitness" in oncology (e.g. performance status assessment) [3]. The GA is a multidimensional tool that assesses domains relevant for older adults, including comorbidities, psychological status, functional status, physical performance, cognition, nutritional status, social support and polypharmacy and is recommended by national guidelines in the care of older adults with cancer [3]. Awareness of potential deficits or vulnerabilities in these areas (through the completion of the GA) could ultimately assist in decision making or can be used to identify patients who would benefit from interventions that would improve their health for treatment [3].

2.3 Information preferences vary amongst older adults with breast cancer. When deciding about treatment options, patients were shown to have three different styles such as physician based, patient based, or shared. Patients who made decisions based on their physicians, did so in fear of making the wrong choice. Other patients were satisfied making their own choices, while others relied on support from their physician to help make a shared decision about treatment [4]. Some patients elect to decline adjuvant therapy, and studies suggest a variety of reasons for this including prior family experience, not wanting to burden to others, clinical comorbidities that could increase their chance of adverse effects, and prior negative experiences [4]. Overall, there are multiple key elements that a patient considers when making decisions about treatment.

2.4. The aging process is heterogeneous and older adults of a similar chronologic age do not necessarily have similar health status. A geriatric assessment (GA) can be utilized to better understand the overall health status of an older adult. GA has been shown to be feasible in oncology[5] and also improves communication about aging-related issues between older adults with cancer and their oncologists.[6] Elements of the GA are associated with chemotherapy toxicity and other adverse outcomes such as hospitalization and early termination of chemotherapy. Recently, a risk model was developed and validated for older adults receiving adjuvant therapy for breast cancer (the Cancer and Aging Research Group-Breast Cancer [CARG-BC]) to estimate the risk of chemotherapy toxicity and other adverse events.[7] The CARG-BC includes clinical variables (e.g. cancer stage), laboratory results (e.g. liver function test), as well as GA elements (e.g. fall history) and a total sum score is calculated. The total CARG-BC score correlates with a risk of chemotherapy toxicity. Providing the results of a patients GA, their CARG-BC score, and their preferences about treatment options may facilitate a more personalized discussion about the benefits and risks of adjuvant treatment options for older adults with breast cancer.

2.5. Conjoint analysis is a method for eliciting patient preferences. Given the complexity of adjuvant chemotherapy decision making for older adults with breast cancer, enhancing support and promoting treatment discussions in the context of patient's goals and preferences is an important need. With this need in mind, our group has completed interviews with patients with cancer patients who are considering adjuvant therapy. As a result of these interviews, our group has developed a common list of attributes (variables found to be important in decision making)

that were used to create the Discussion Prioritization Tool (DPT) using Conjoint Analysis (CA) methodology. CA which is a method that can assess the relative importance that patients place on different aspects of care by asking patients to make a series of trade-offs between competing options. Attributes that were identified were quality of life, fatigue, activities of daily living, falls/balance, cognition, distress/worry, risk of treatment toxicity, risk of hospitalization, burden on support system, and outcome (recurrence risk/survival) [8].

Other decisional support tools have been developed and tested in oncology and demonstrated promising utility. For example, CONNECT, a computer-based communication aid, was developed to improve communication between patients with advanced cancer and their oncologists.[9] CONNECT included assessment of patient values, goals, and communication preferences and was tested in a 3-arm, prospective, randomized clinical trial. Patients who engaged with the CONNECT tool felt that it made treatment decisions easier to reach and helped them to be more satisfied with these decisions. Patients in the intervention arms also reported higher levels of satisfaction with communication. Other decision aids have also shown potential benefit, but the majority of these focused on patients with advanced cancer[10-13] or were not specific for the older adult population.[14, 15] To our knowledge, this is the first discussion prioritization tool developed for older adults with breast cancer considering adjuvant chemotherapy that incorporates GA and aging-specific preferences and relates patient preferences to validated risk tool results (the CARG-BC).

3. ADMINISTRATIVE ORGANIZATION

3.1. Research location and participating site:
The study will be conducted through the Wilmot Cancer Institute at the University of Rochester Medical Center and will enroll patients through the Comprehensive Breast Care Center (located at Pluta Cancer Center)

Dr. Mina Sedrak, of the City of Hope is a co-investigator on the protocol. However, we will not be enrolling patients from the City of Hope. Dr. Sedrak will only have access to de-identified data and will be participating in data analysis for this study.

4. STUDY DESIGN

4.1 Study Design:
This is a single arm pilot study to determine usability.

5. SUBJECT POPULATION

5.1 Subject Population:
The eligibility criteria is aimed at identifying older patients diagnosed with localized breast cancer who are being considered for adjuvant chemotherapy or has made a decision about receiving adjuvant chemotherapy for breast cancer within the past 12 months. Since our study team is developing a tool that incorporates geriatric specific factors, we will recruit patients who are aged 65 or older. The study will have no restrictions on race or gender. However due to the disease, we anticipate that most, if not all participants will be female.

5.2 Number of subjects:

Our study team expects 10 subjects to participate in the study. The majority of usability studies demonstrate that usability can be optimized in a small number of subjects (e.g. 10). We anticipate being able to enroll the targeted number of patients in <1 year duration.

5.3 Vulnerable Subjects:
Recruitment will exclude vulnerable populations such as fetuses, neonates, children, pregnant woman, prisoners, adults with decisional impairment, and institutionalized individuals.

6. INCLUSION AND EXCLUSION CRITERIA

6.1 Inclusion Criteria.

- Age ≥65
- Diagnosis of stage I-III BC
- Being considered for adjuvant chemotherapy or has made a decision about receiving adjuvant chemotherapy for breast cancer within the past 12 months.
- Able to speak and read English
- Able to participate in study procedures.

6.2 Exclusion Criteria.

- Lacking medical decision-making capacity as determined by their oncologist
- Evidence of metastatic disease

7. RECRUITMENT AND CONSENT

Subjects will be identified and enrolled at the University of Rochester Comprehensive Breast Cancer Center at Pluta Cancer Center. The clinic schedules of breast oncologists and their advanced practice providers (APPs) will be screened for eligible patients.

To ensure appropriate safety precautions when conducting in-person study procedures, the process for conducting in-person visits outlined in the Guidance for Human Subject Research will be followed.

7.1 Identification of Study Subjects, Recruitment, and Consent Procedures

Potential patients will be identified in multiple ways. First, study participants will be identified by their treating physician, the nurses that work with the physicians, and the study coordinator. The study coordinator works closely with the physicians and nurses to monitor patients and identify those patients who are being considered for adjuvant chemotherapy or has made a decision about receiving adjuvant chemotherapy for breast cancer within the past 12 months. With permission from oncology providers, we will screen for eligible patients from clinic schedules. The study coordinator contacts the physician (or their designee) and lets them know that a patient may be eligible for the study. The physician (or their designee) then confirms if the patient is a good study candidate or not and affirms that the patient has decision making capacity. If there is a question about eligibility, the principal investigator will be contacted and will meet with the patient and/or health care proxies, review the medical records, and perform an assessment of eligibility if necessary. After meeting with the physician (or their designee), the study coordinator will meet with the patient either in person or via phone, and explain the details of the study. Study staff will introduce the study to the patients and provide adequate

time to read the consent.

Our study group anticipates two different types of scenarios for the recruitment and consent process. Potential study subjects may be consented either in person or verbally during a virtual visit. Study participants will also have the ability to complete the study in person or virtually.

Potential scenarios for <u>in-person</u> consent:

1) <u>Physician/Study Investigator makes the initial contact and provides consent form, and patient signs consent with the physician on the same day:</u> After confirming with the physician (or their designee) that a patient is a potential candidate for the study, the study staff will provide a consent form to the treating physician/study investigator so he/she can provide it to the patient during an in-person clinic visit. The physician/study investigator will go over every detail of the study during the clinic visit with patient. If agrees, the patient will sign the consent form with the physician/study investigator during the same in-person visit.

2) <u>Study staff makes the initial contact and provides consent form, and patient signs consent with the study staff on the same day:</u> After confirming with the physician (or their designee) that a patient is willing to speak with the study coordinator about the study, the patient will be provided with an informed consent form by the study staff when they come in for an in-person clinic visit. The study staff will introduce the study to the patients and go over every detail of the study. If agrees, the patient will sign the consent form with the study staff during the same in-person visit with the study staff.

Potential scenarios for <u>verbal</u> consent:

1) <u>Physician/Study Investigator makes the initial contact, study staff follows up with the patient on the phone, and patient provides verbal consent on the phone:</u> After confirming with the physician (or their designee) that a patient is a potential candidate for the study, the physician/study investigator confirms with the patient that he/she is willing to speak with the study staff about the study. The study staff will then call the patient via phone. The study coordinator will use the verbal consent script as a written aid and will go over every detail of the study with the patient to recruit them for the study. Study staff will sign and date it to confirm that he/she followed the script and the patient agrees to participate in the study. Following the completion of verbal consent with the subject, the coordinator will mail or email the subject a study information sheet that summarizes what the study entails and the subject's involvement in it.

2) <u>Physician/Study Investigator makes the initial contact and provides consent form, study staff follows up with the patient on the phone, and patient provides verbal consent on the phone:</u> After confirming with the physician (or their designee) that a patient is a potential candidate for the study, the study staff will provide a consent form to the treating physician/study investigator so he/she can provide it to the patient during an in-person clinic visit. If the patient is interested but does not want to consent on the same day, the patient will bring the consent form home. The study staff will then call the patient via phone. The study coordinator will use the verbal consent script as a written aid and will go over every detail of the study with the patient to recruit them for the study. Study staff will sign and date it to confirm that he/she followed the script and the patient agrees to participate in the study. Following the completion of verbal consent with the subject, the

coordinator will mail or email the subject a study information sheet that summarizes what the study entails and the subject's involvement in it.

3) Study staff makes the initial contact and provides consent form, study staff follows up with the patient on the phone, and patient provides verbal consent on the phone: After confirming with the physician (or their designee) that a patient is willing to speak with the study coordinator about the study, the patient will be provided with an informed consent form by the study staff when they come in for an in-person clinic visit. If the patient is interested but does not want to consent on the same day, the patient will bring the consent form home. The study staff will then call the patient via phone. The study coordinator will use the verbal consent script as a written aid and will go over every detail of the study with the patient to recruit them for the study. Study staff will sign and date it to confirm that he/she followed the script and the patient agrees to participate in the study. Following the completion of verbal consent with the subject, the coordinator will mail or email the subject a study information sheet that summarizes what the study entails and the subject's involvement in it.

7.1.1. Informed Consent

Informed consent will be obtained from the patient by the study investigators or coordinators. Consent documents will be signed by the patient and maintained in the patient record with copies provided to the patient. For verbal consent, documents will be maintained in the patient record with copies provided to the patient. Justification for waiver of documentation of written consent: If the patient cannot meet in person with the study coordinator to sign the informed consent, the study coordinator will verbally consent the subject. The study coordinator will use the verbal consent script, then sign and date it to confirm that s/he followed the script and the subject agreed to participate in the study. Following the completion of verbal consent with the subject, the coordinator will mail or email the subject a study information sheet that summarizes what the study entails and the subject's involvement in it.

Alteration of HIPAA Authorization:
We are requesting an altering of HIPAA authorization. We will provide an information sheet to patients who provided verbal consent. Verbal consent will allow for reduction of in-person visits, thus maximizing the safety of both patients and study staff. Nonetheless, when possible and if we are able to coordinate study and clinic visits, we will obtain written informed consent.

The study cannot be conducted without the use of protected health information (PHI) as we have to link patient reported data with medical history collected on electronic medical record. We have adequate plans to protect the PHI from improper use and disclosure. We will destroy identifiers after completion of the study for 7 years. We will not reuse or disclose the PHI to another person or entity other than the study investigators. The waiver will not adversely affect the privacy rights of the individual and the research cannot be practicably done without access to the use of the PHI.

7.1.2. Human Subject Protection

The University of Rochester Research Subject Review Board Investigator Guidance policy

will be used to ensure that ethical standards for human subjects are upheld.

7.1.3. Participation

Regulations at the state, federal, and institutional level will be adhered to in regards to informed consent. Study participation is completely voluntary. After consenting, participants may withdraw from the study at any time for any reason, and they may do so without any repercussions. Participants may also be withdrawn by study personnel if it is determined that it is not favorable for the patient. All information regarding consent and withdrawal will be kept confidential.

7.1.4. Duration

Participation in the study will last approximately 60-90 minutes during a one time in-person or virtual visit. If needed, our study team may follow up with the participant for further information for up to 2 months after the initial completion of the study procedures. After the study is completed, participant data will be maintained for 7 years at URMC and will be kept in a password-protected database.

7.1.5 Subject Capacity

We will ensure through the patient's primary oncologists that the patient has capacity to consent and participate in the study by confirming the patient's medical decision-making capacity with the oncologist.

7.1.6 Subject/Representative Comprehension

The study subject's capacity to participate in the study will be confirmed by their primary oncologist prior to approaching the patient to discuss the study. During the consent process, the subject must be able understand and report the purpose of the study, its procedures, risks, and benefits in order to demonstrate full comprehension of the study.

8. REGISTRATION

If a patient meets eligibility criteria and has provided informed consent, the study personnel will enter the following information into the OnCore Database:

8.1. Registration Information

- **8.1.1** Site
- **8.1.2** Most recent IRB approval date
- **8.1.3** Name of person registering study participant
- **8.1.4** Eligibility verification

8.1.5 Verification that consent form has been signed and date signed. If verbal consent obtained, verification that verbal consent form has been signed and dated by the consenting individual.
8.1.6 Treatment facility (Pluta)
8.1.7 Participant's identification
8.1.7.a First and last names
8.1.7.b Birth date (MM/DD/STREAM)
8.1.7.c Gender
8.1.7.d Race
8.1.7.e Five-digit zip code
8.1.7.f Medical Record Number
8.1.7.g Ethnicity
8.1.7.h Patient's preferred and alternate phone numbers (and email address if patients consent to be contacted via email)
8.1.7.i Date of baseline visit

9.0. DISCUSSION PRIORITIZATION TOOL

The proposed tool consists of three components:
1) A survey tool consisting of demographic questions and selected patient-reported Geriatric Assessment measures;
2) Selected coordinator-administered geriatric assessment measures; and
3) The Conjoint analysis to elicit patient preferences, (see Figure 1 for depiction of conjoint analysis question).

9.1 Demographic measures (see table 1.a)
9.2 Patient-reported GA measures (see table 1.b)
9.3 Coordinator-administered GA measures (see table 1.c)
9.4Conjoint Analysis

There are two main components of a conjoint analysis i.e., attributes (characteristics or factors that influence decision-making) and levels (degree of the characteristics). These attributes are categorized into 3 separate groups: benefits of treatment, potential risks of treatment, and quality of life during treatment. Scenarios are then drawn up for each of the attributes and levels (Figure 1). Patients will be presented with scenarios and asked to select one that is consistent with their preferences. This process then repeats until all attributes are evaluated. At completion, a summary containing a ranking of factors will be provided to the oncologists. A summary with patient concerns (i.e., factors that are important to them) and question prompt list will be provided to patients.

Table 1 outlines the attributes that are included in the conjoint analysis. Attributes are organized by Meta-Attributes (global descriptors of how attributes are organized). The software presents one attribute in each of the 4 meta-attributes for each hypothetical scenario (see figure 1 for layout of how met-attributes are presented; see table 1 for attributes in each meta-attribute).

Table 1: List of Meta-Attributes and Attributes included in the conjoint analysis.

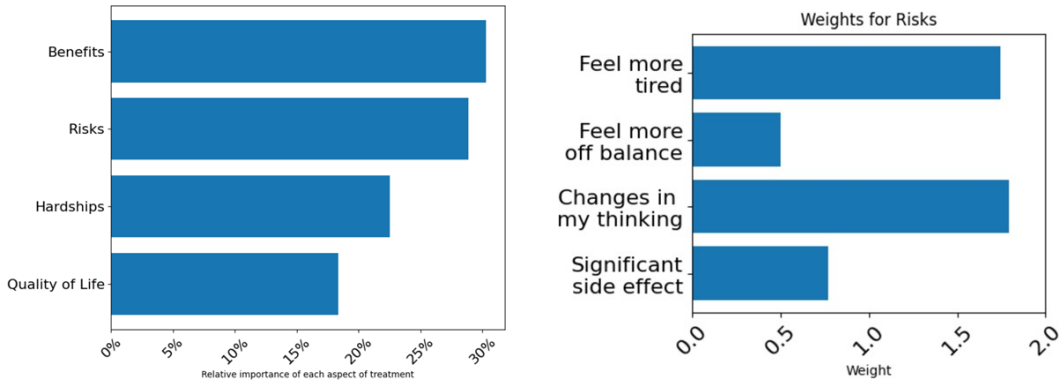
Meta-Attribute	Attribute
Benefit of Therapy	Recurrence Risk
	Survival
	Worry/distress
Side Effects of Therapy	Fatigue
	Falls/Balance
	Cognition
	Risk of treatment Toxicity
Hardship	Risk of hospitalization
	Burden on support system
Quality of life	Relatively unchanged
	Significantly worse than it is right now

Figure 1 below is a representation of how the conjoint scenarios are displayed. This is an iterative process, whereby participants select one hypothetical scenario from the first set of options. They subsequently are presented with a second set of options and are asked to again select a preferred hypothetical scenario. Figure 1 is an image of how the scenarios appear to participants when using the online tool.

Figure 1:

When participants have completed the exercise, the tool provides output ranking of the meta-attributes and three attributes (benefit of therapy, side effects of therapy, hardship). Figure 2 is an example image of how the output of patient preferences can appear for the meta-attribute and side effects of therapy.

Figure 2: Conjoint analysis output example of meta-attribute and attribute ranking.



As described below in study procedures, results of the conjoint analysis as well as geriatric assessment results are provided to participants. For oncologists, the results provided include the conjoint analysis output, geriatric assessment results, and CARG-BC score.

10. STUDY PROCEDURES

10.1 Methods and Procedures:

We will screen and consent eligible patients of treating physicians at University of Rochester Comprehensive Breast Cancer Center at Pluta Cancer Center.

Consented study subjects will have the option of giving permission for use of their email address in order to send a link to their virtual visit (if subject is not completing the tool in person) or to receive the output from the tool via email.

Participants will complete GA measures (Table 1) and the DPT during a single 30-60 minute study visit either in-person or via virtual visit. In lieu of a post-study interview, our team will utilize the Talk Aloud method with participants while they complete the study assessments and ask the subject follow-up questions after completion of study assessments and the DPT. The Talk Aloud method is designed to identify points of patterns of cognitive thinking, decision making, and problems related to function and language that occur while the participant is engaging with the DPT. Participants will have the option of completing the study during an in-person or virtual visit – this approach is being taken due to COVID precautions to enhance social distancing where able. Slight variations in procedures will be implemented to accommodate an in-person study visit or a virtual study visit. Both scenarios will include the same procedures of completing the GA and the DPT using the Talk Aloud method.

Results that are generated from the Discussion Prioritization Tool will be emailed to the study subject as well as their oncologist. Obtaining permission to send results via email is included during the in-person and verbal consent process.

As for study subjects who complete the DPT virtually, their results will be emailed and screen shared with them via Zoom in order to help them respond to the post study follow-up questions.

10.1.2 In-Person visit:

The study coordinator will familiarize eligible patients to the study by using the following script when approaching for consent.

Coordinator Recruitment Script: The goal of this study is to design a tool that helps patients and oncologists have more personalized discussions about the treatment options for breast cancer. Our hope is that this tool will help make you and your oncologist aware of factors that are important to you when discussing the different treatment options. This tool is not intended to make any decisions for you or to replace discussions that you have with your oncologist regarding your treatment. The online tool will ask questions about your overall health and also will present hypothetical situations about different treatment options. The different treatment options presented are not specific for you or your breast cancer, and are only meant to better understand how you consider the different characteristics between the options.

Once informed consent is obtained in person, patients will meet with a study coordinator either during the same visit or at another time and place based on the patient's preference. When the coordinator meets with the study participant, they will be provided with a tablet to complete the baseline GA measures (table 1).

The following measures are administered to the patient by the study coordinator.

1. Blessed cognitive test
2. Nutritional assessment

The following GA measures are self-reported by the patient:

1. Demographics
2. IADL
3. Falls history
4. OARS physical health
5. Comorbidity
6. Polypharmacy
7. GDS
8. GAD-7
9. OARS social functioning

Measures administered by the study coordinator will be completed first, then followed by the patient reported measures which will be completed as a component of the tool.

After completing the baseline GA measures, participants will then complete the DPT on the tablet provided by the study staff. Patients will be presented with several scenarios at once (similar to figure 1 above) and asked to select one that is consistent with their preferences. This process will repeat until all attributes are evaluated in the tool. While the subject is completing the DPT, they will be audio recorded in order to collect data for the Talk Aloud method.

After completing the GA and DPT, the summary of the results will be sent to the study email at GeriOncConjointTool@URMC.Rochester.edu. Once the results are emailed, the study coordinator will then show the participant their results on the IPad and will evaluate the patient's impression while they look over their results. We will ask participants to continue with the talk aloud method as they are reviewing the results provided by the conjoint analysis.

The summary of the results that contain a ranking of factors will be provided to the patient's oncologist and the participant will also be provided with their results either in the form of an email sent to their personal email address or in the form of a hard copy print out.

Once results have been provided to the patient, the study patient will then complete a quantitative measure (SUS) evaluating the usability of the tool (Table 2).

The SUS will be administered verbally and the coordinator will have the questions visually available on the IPad for the patient as we go over the questions with them. The study coordinator will record the patient's responses on a hard copy of the SUS form.

Lastly, we will ask additional questions to assess the usability of the tool at the end of the study.

1. Do you have any feedback about the tool?
2. What is your impression of the results in terms of format and understanding?
3. Do you feel that the results accurately reflect your preferences?

10.1.3 Virtual Visit:

The study coordinator will familiarize eligible patients to the study by using the following script when approaching for consent.

Coordinator Recruitment Script: The goal of this study is to design a tool that helps patients and oncologists have more personalized discussions about the treatment options for breast cancer. Our hope is that this tool will help make you and your oncologist aware of factors that are important to you when discussing the different treatment options. This tool is not intended to make any decisions for you or to replace discussions that you have with your oncologist regarding your treatment. The online tool will ask questions about your overall health and also will present hypothetical situations about different treatment options. The different treatment options presented are not specific for you or your breast cancer, and are only meant to better understand how you consider the different characteristics between the options.

Once informed consent is obtained verbally, patients will provide the study coordinator with their email address so that the study team will have the ability to email and provide a link to the GA measures as well as a link enter a Zoom meeting to complete the study procedures. The study coordinator will organize a day and time that works best for the subject to complete the tool.

The following measures are administered to the patient by the study coordinator.

1. Blessed cognitive test
2. Nutritional assessment

The following GA measures are self-reported by the patient:

1. Demographics
2. IADL
3. Falls history
4. OARS physical health
5. Comorbidity
6. Polypharmacy

7. GDS
8. GAD-7
9. OARS social functioning

Measures administered by the study coordinator will be completed first, then followed by the patient reported measures which will be completed as a component of the tool.

Following the baseline GA measures, participants will then complete the DPT during a study visit with the coordinator that is conducted through telehealth platform (e.g. University of Rochester Zoom platform). The link to the DPT will be emailed to the patient so they can open and complete it during the study visit Zoom meeting.

When completing the DPT, patients will be presented with several scenarios at once (similar to figure 1 above) and asked to select one that is consistent with their preferences. This process will repeat until all attributes are evaluated in the tool. Participants will use the talk aloud method while completing the DPT. Feedback given through the Talk Aloud method will be recorded using the secure Zoom record feature during the study visit.

After completing the GA and DPT, the summary of the results will be sent to the study email at GeriOncConjointTool@URMC.Rochester.edu. Once the results are emailed, the study coordinator will then share the results with the participant by using the screen-share feature on Zoom. The study coordinator will evaluate the patient's impression while they look over their results. We will ask participants to continue with the talk aloud method as they are reviewing the results provided by the conjoint analysis.

The summary of the results that contain a ranking of factors will be provided to the patient's oncologist and the participant will also be provided with their results either in the form of an email sent to their personal email address or in the form of a hard copy print out.

Once results have been provided to the patient, the study patient will then complete a quantitative measure (SUS) evaluating the usability of the tool (Table 2).

The SUS will be administered to the patient verbally while displaying the questions by using the screen-share feature on Zoom while we go over the questions with them. The study coordinator will record the patient's responses on a hard copy of the SUS form.

Lastly, we will ask additional questions to assess the usability of the tool at the end of the study.

4. Do you have any feedback about the tool?
5. What is your impression of the results in terms of format and understanding?
6. Do you feel that the results accurately reflect your preferences?

11. AUDIO/VIDEO RECORDINGS

11.1 In Person: Audio Recordings
Audio recordings will be used during in-person study visits in order to collect Talk Aloud data while the study subject completes the conjoint decision-making tool. A secure, handheld recorder will be used to record the subject's feedback. All audio recordings will be uploaded and stored by the research coordinator in a password protected file in Box.

11.2 Virtual: Video Recordings
Video recordings will be used during virtual study visits in order to collect Talk Aloud data while the study subject completes the conjoint decision-making tool. Video recordings will be

made during a secure virtual visit by using the record function on Zoom to record the subject's feedback. All video recordings will be uploaded and stored by the research coordinator in a password protected file in Box.

12. RISKS/BENEFITS TO SUBJECTS

12.1 Potential Risk.
This is a minimal risk study. However, a participant may experience psychological stress while participating in the study. While this is unlikely to provoke significant problems, the PI (Dr. Magnuson) will be available for evaluation and referral to appropriate behavioral care if needed. Risks to privacy using telehealth and telecommunications are also potential concern. We recognize that while encryption of videoconferencing makes breeches of private information unlikely, not all risks to privacy can be completely eliminated. We will inform all participants using the telehealth equipment of this.

12.2 Protection Against Risks.
There is the risk of loss of confidentiality but this is minimal due to safeguards in place. All of the participant's information will be kept password protected and encrypted with access restricted to the Principal Investigator and designated senior staff.

12.3 Potential Benefits to the Subjects.

There may be no direct benefits to participating in this study. However, the study may help to assist older patients when making decisions about treatment options.

12.4 Alternatives to Participation.
Taking part in this study is voluntary. Participants are free not to take part or to withdraw at any time, for whatever reason without consequence.

13. COSTS FOR PARTICIPATION

There will not be any cost incurred to the participants during this study. Materials to complete the study procedures, such as an IPad, will be provided by the study team. These will be returned to the study team upon completion of the procedures.

14. PAYMENT FOR PARTICIPATION

Subjects will be given a $30 gift card at the time of completion for their participation in the study to compensate for the time spent on study procedures.

15. DATA / SAMPLE STORAGE FOR FUTURE USE

15.1. All hardcopy research records will be stored onsite in the URMC, in locked research files at the WCI. The Cancer Center is secured with electronic key cards. Offices within the Cancer Center are again secured by key and data is kept in locked file cabinets. Electronic research records are stored on the URMC's password secured and firewall protected networks. These are the same methods of security used for patient medical records. All study data will be kept for a period of 7 years after the study and all reports and publications are complete.

15.3. All data collected for the current study will be used in post hoc analyses as appropriate. Data will not be used for future studies without prior consent of the patient. The patient's individual research record will not be shared with their treating physician, unless they provide consent or the patient's treating physician is a study physician, in which case they will have access to study data as a study co-investigator. Overall study results will be presented to participants, faculty and staff at the URMC after completion of the study. Study results will be presented at professional meetings and published.

15.4. The study coordinator will assign a numerical study ID to each participant once they have signed the consent form (chronologically based on the data they signed consent i.e., 001, 002, 003…). All study forms and questionnaires will use this number and the participant's first, middle, and last initials as identifiers, to ensure data integrity. Other identifying information will not exist on these forms. A complete list of study participants with study ID, name, and contact information will be maintained separately. This linkage information will only be accessible to the study coordinator, study investigators, and the individuals responsible for maintaining the database.

15.5. Additionally, data on the socio-demographics, clinical, and cancer and treatment characteristics will be collected and managed by the research teams at URMC using secure REDCap electronic data capture tools hosted at URMC. We will also evaluate the medical records for clinical characteristics and outcomes, and utilize REDCap to collect and manage this information.

16. DATA AND SAFETY MONITORING PLAN

Only adverse events (AEs) related to the study intervention or procedures will be reported. In other words, AEs related to cancer treatment will not be reported.

16.1. Adverse Event Reporting Requirements

16.1.1. Adverse events will be reported using the URCC Adverse Event form and/or as required by the Cancer Center Clinical Trials Office.

Adverse events will only be recorded for the time that the study subject is taking part in study procedures during their one time visit with the study coordinator.

16.1.2. Adverse events will be reported in accordance with the following guidelines:

	Grade 1	Grade 2			Grade 3				Grade 4		Grade 5	
		Unexpected		Expected	Unexpected		Expected		Unexpected	Expected	Unexpected	Expected
	Unexpected and Expected	with hospitalization	without hospital-ization		with hospitalization	without hospitalization	with hospitalization	without hospitalization				
Unrelated	Not	Not	Not	Not	Not	Not	Not	Not	10	Not	10	10
Unlikely	Required	Required	Required	Required	Required	Required	Required	Required	Calendar Days	Required	Calendar Days	Calendar Days
Possible	Not	10 Calendar Days	Not	Not	10 Calendar Days	10 Calendar Days	Not	Not	24-Hour;	10 Calendar Days	24-Hour;	10 Calendar Days
Probable	Required		Required	Required			Required	Required	5 Calendar		5 Calendar	
Definite									Days		Days	
Hospitalization is defined as initial hospitalization or prolongation of hospitalization for ≥ 24 hours, due to adverse event.												

16.1.3. Adverse event reports will be submitted in one of the following ways:

(1) By email: (pdf)

(2) By mail:

(3) By fax:

16.1.4. An unexpected adverse event is defined as any adverse experience, the specificity or severity of which is not consistent with the risk information. This is a minimal risk study as detailed above.

16.1.5. A serious event refers to any event in which the outcome results in any of the following: death, a life-threatening adverse experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability, incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. We anticipate that any serious events will be related to standard of care cancer treatments and not due to the intervention. We will not collect adverse events related to cancer treatments.

16.1.6. Adverse events will be reported in accordance with institutional policies (University of Rochester, Research Subject Review Board, local IRB, URCC CCOP, CTO, and DSMB) as per their requirements.

16.2. Data Safety Monitoring

16.2.1. All adverse events requiring reporting will be submitted to the current Project Coordinator as described in Section 11.1. Serious adverse event reports will be forwarded to the study chair and the Data Safety and Monitoring Committee (DSMC). Adverse events are entered into a protocol-specific spreadsheet.

16.2.2. Adverse event rates are monitored utilizing the spreadsheet. If a serious adverse event is reported frequently, the study chair will conduct a detailed review. The DSMC Committee Chair will be notified and will determine if further action is required.

16.2.3. The Data Safety Monitoring Committee (DSMC) will review study progress and cumulative reports of adverse events every year and as needed. An overall assessment of accrual and adverse events will enable the committee members to assess whether significant benefits or risks are occurring that would warrant study closure.

17. DATA ANALYSIS PLAN

Sawtooth software will be utilized for the conjoint analyses to determine prioritization of participant preferences [16, 17].

Usability testing is the evaluation of a program through the analysis of typical end user interactions, with iterative modifications [18]. The majority of usability problems can be identified in a small set of subjects (e.g. 8-10) [18].

Quantitative Analysis: The SUS ranges 0-100; a score >68 is above average [19]. Our goal will be to achieve a mean SUS score >68 amongst the 10 patients enrolled.

Qualitative Analysis: Audio-recordings capturing the “talk aloud” feedback will be transcribed and a Process Coding framework will be utilized to analyze the transcripts. Responses to the three feedback questions will also be transcribed and a Content Analysis framework will be utilized to analyze responses. Together, this qualitative data will be evaluated for themes to optimize usability of the tool for a planned subsequent RCT to evaluate the effect of the DPT on content of conversations between patients and their oncologists.

18. REFERENCES

1. Jolly, T.A., et al., *Adjuvant Treatment for Older Women with Invasive Breast Cancer.* Womens Health, 2016. **12**(1): p. 129-146.

2. Varghese, F. and J. Wong, *Breast Cancer in the Elderly.* Surg Clin North Am, 2018. **98**(4): p. 819-833.

3. Rodin, M.B. and S.G. Mohile, *A Practical Approach to Geriatric Assessment in Oncology.* Journal of Clinical Oncology, 2007. **25**(14): p. 1936-1944.

4. Angarita, F.A., et al., *Patient-reported factors influencing the treatment decision-making process of older women with non-metastatic breast cancer: a systematic review of qualitative evidence.* Breast Cancer Res Treat, 2018. **171**(3): p. 545-564.
5. Hurria, A., et al., *Developing a cancer-specific geriatric assessment: a feasibility study.* Cancer, 2005. **104**(9): p. 1998-2005.
6. Mohile, S.G., et al., *Communication with older patients with cancer using geriatric assessment: a cluster-randomized clinical trial from the National Cancer Institute Community Oncology Research Program.* JAMA oncology, 2020. **6**(2): p. 196-204.
7. Magnuson, A., et al., *Development and Validation of a Risk Tool for Predicting Severe Toxicity in Older Adults Receiving Chemotherapy for Early-Stage Breast Cancer.* J Clin Oncol, 2021. **39**(6): p. 608-618.
8. Magnuson, A., Zittel, J. Gilles, M., Wittink, M., Wells, M.,. *The role of self-perception of age in decisions about adjuvant chemotherapy for older adults with cancer*. in *SIOG*. 2018.
9. Meropol, N.J., et al., *A web-based communication aid for patients with cancer: the CONNECT study.* Cancer, 2013. **119**(7): p. 1437-1445.
10. Chiew, K.S., et al., *Development and evaluation of a decision aid for patients considering first-line chemotherapy for metastatic breast cancer.* Health expectations, 2008. **11**(1): p. 35-45.
11. Smith, T.J., et al., *A pilot trial of decision aids to give truthful prognostic and treatment information to chemotherapy patients with advanced cancer.* The journal of supportive oncology, 2011. **9**(2): p. 79.
12. Sepucha, K.R., et al., *Is there a role for decision aids in advanced breast cancer?* Medical Decision Making, 2009. **29**(4): p. 475-482.
13. Oostendorp, L.J., et al., *Decision aids for second-line palliative chemotherapy: a randomised phase II multicentre trial.* BMC medical informatics and decision making, 2017. **17**(1): p. 1-14.
14. Zdenkowski, N., et al., *Single-arm longitudinal study to evaluate a decision aid for women offered neoadjuvant systemic therapy for operable breast cancer.* Journal of the National Comprehensive Cancer Network, 2018. **16**(4): p. 378-385.
15. Hawley, S.T., et al., *Improving breast cancer surgical treatment decision making: the iCanDecide randomized clinical trial.* Journal of Clinical Oncology, 2018. **36**(7): p. 659.
16. Wittink, M.N., et al., *Towards Patient-Centered Care for Depression: Conjoint Methods to Tailor Treatment Based on Preferences.* Patient, 2010. **3**(3): p. 145-157.
17. Fraenkel, L., S. Bodardus, and D.R. Wittnik, *Understanding patient preferences for the treatment of lupus nephritis with adaptive conjoint analysis.* Med Care, 2001. **39**(11): p. 1203-16.
18. Kushniruk, A., *Evaluation in the design of health information systems: application of approaches emerging from usability engineering.* Comput Biol Med, 2002. **32**(3): p. 141-9.
19. Schnall, R., H. Cho, and J. Liu, *Health Information Technology Usability Evaluation Scale (Health-ITUES) for Usability Assessment of Mobile Health Technology: Validation Study.* JMIR Mhealth Uhealth, 2018. **6**(1): p. e4.

19. Table 1. Measures.

Discussion Prioritization Tool – Measures Included	
1.a Patient Demographics	
Demographics	• Gender • Age • Health status • Race/Ethnicity • Education • Who do you live with • Describe living situation
1.b Patient Reported GA Measures	
Functional Status	• *IADL* o Instrumental Activities of Daily Living (IADL): Self-reported functional status will be assessed using the IADL subscale of the Multidimensional Functional Assessment • *Falls History* o A self-reported history of falls in the past three months will be recorded. • *OARS Physical Health* o A survey that asks about the people involved in the patient's medical and social support.
Comorbidity	• *OARS Comorbidity* o A self-report of any existing comorbidities and their effect on the patient's daily life. • *Polypharmacy* o We will record all prescription and non-prescription medications, dosage and frequencies from the medical records. Polypharmacy is defined as the use of 5 or more medications.
Psychological	• *GDS* o *A screening tool for depression* • *GAD-7* o *A screening tool for anxiety*
Social Functioning	• *OARS Medical Social Support* o A survey that asks about the people involved in the patient's medical and social support.
1.c Coordinator Administered Assessments	
Cognition	• *Mini-Cog (in person)* o An assessment consisting of memory questions and a drawing to help determine the current cognitive status of the patient. • *Blessed (virtual)* o A 6 question assessment to help determine the current cognitive status of the patient.
Nutrition	• *Nutritional Status* o Nutritional status of the patient will be determined by their current height, current weight, and weight 6mo. ago.

19.1 Table 2. System Usability Form (SUS).

System Usability Scale

Instructions: For each of the following statements, mark one box that best describes your reactions to the technology tool *today*.

	Strongly Disagree	2	3	4	Strongly Agree
1. I think that I would like to use this technology tool frequently.	☐	☐	☐	☐	☐
2. I found this technology tool unnecessarily complex.	☐	☐	☐	☐	☐
3. I thought this technology tool was easy to use.	☐	☐	☐	☐	☐
4. I think that I would need assistance to be able to use this technology tool.	☐	☐	☐	☐	☐
5. I found the various functions in this technology tool were well integrated.	☐	☐	☐	☐	☐
6. I thought there was too much inconsistency in this technology tool.	☐	☐	☐	☐	☐
7. I would imagine that most people would learn to use this technology tool very quickly.	☐	☐	☐	☐	☐
8. I found this technology tool very cumbersome/ awkward to use.	☐	☐	☐	☐	☐
9. I felt very confident using this technology tool.	☐	☐	☐	☐	☐
10. I need to learn a lot of things before I could get going with this technology tool.	☐	☐	☐	☐	☐

Please provide any comments about this technology tool: