CONSENT FORM

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

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This consent form describes a research study, what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully.

The study staff will explain this study to you. Please ask questions about anything that is not clear before you agree to participate or at any time. You may take this consent form home to think about and discuss with family or friends.

Key Information

- Being in this research study is voluntary – it is your choice.
- You are being asked to take part in this study because you are aged 65 or older and have a diagnosis of early stage breast cancer and are considering adjuvant chemotherapy (i.e. chemotherapy that is given after surgery) or has made a decision about receiving adjuvant chemotherapy for breast cancer within the past 12 months.
- The purpose of this study is to evaluate the feasibility and usability of a communication tool, administered through a tablet, laptop, or computer, for its ability to aid communication about treatment decision-making. We would like to gather feedback from individuals like yourself to improve and adapt the communication tool.
- Your participation in this study will last approximately 60-90 minutes during one study visit.
- Procedures will include assessments, questionnaires, completing the tool and follow-up questions to assess your experience in the study.
- There are risks from participating.
    - The most common and serious risk is loss of confidentiality. See the "Risks of Participation" section in this consent form for more information. You should discuss these risks in detail with the study team.

Introduction

You are being asked to take part in this study because you are aged 65 or older, have a diagnosis of localized breast cancer and are considering adjuvant chemotherapy or has made a decision about receiving adjuvant chemotherapy for breast cancer within the past 12 months. This form describes the known possible risks and benefits of the study. You are completely free to choose whether or not to participate in this study.

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 area of important need. With this need in mind, our group has created a tool using 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.

This study is being conducted by Dr. Allison Magnuson from the University of Rochester's Geriatric Oncology Program.

Purpose of Study

The purpose of this study is to assess the usability of a communication tool, administered through a tablet, laptop, or computer, for its ability to aid in treatment decision-making. We would like to gather feedback from individuals like yourself to improve and adapt the communication tool.

Description of Study Procedures

If you decide to take part in this study, you will be asked to…

- Complete questionnaires asking questions about your demographics, functional status, comorbidities, mood, social support, and nutritional status. These questions will take you approximately 15-20 minutes to complete.
- We will perform a measure of your cognition. We will ask you some questions to evaluate your orientation, memory, concentration, and language.
- Use the Discussion Prioritization Tool to answer questions about your treatment preferences while being audio/video recorded for feedback about your experience using the tool.
- Results generated from the Discussion Prioritization Tool will be emailed to you and your oncologist.
- After you have completed the tool, you will complete a questionnaire and three interview questions about the usability of the tool.

Information about your study participation and study results may be included in your electronic health record. If you have concerns about this or to obtain more detail, you should discuss this with the study team.

Number of Subjects

Approximately 10 subjects will take part in this study.

Duration of the Study

Your 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 you for further information for up to 2 months after the initial completion of the study procedures. After the study is completed, your data will be maintained for 7 years at URMC and will be kept in a password-protected database.

Risks of Participation

This is a minimal risk study. However, you 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.

There are also potential risks to privacy using telehealth and telecommunications. We recognize that while encryption of videoconferencing makes breeches of private information unlikely, not all risks to privacy can be completely eliminated.

There is a risk for loss of confidentiality and privacy because we will collect medical and personal data from you and your medical record. Protected health data and personal data will be kept as confidential as it can be but complete confidentiality cannot be guaranteed.

The study team may be notified if you receive other health care services at URMC or its Affiliates (e.g., visit to the emergency room). In addition, the following individuals may know you participated in research and may see results of testing conducted for this study:

- Staff at the University of Rochester Medical Center and its Affiliates (e.g., Strong Memorial Hospital, Highland Hospital, URMC primary care, specialist physician offices) who have a reason to access your electronic health record.
- Health care providers who are involved in your care at a facility that is not part of the University of Rochester Medical Center and its Affiliates and who have reason to access your electronic health record.
- Individuals who request a copy of information from your health record for activities such as treatment or payment (e.g., medical insurance companies, worker's compensation).

Benefits of Participation
You might not benefit from being in this research study. However, the study may help to assist older patients when making decisions about treatment options.

Alternatives to Participation
Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

Sponsor Support
The study is being funded through the National Institute of Health (NIH).

Costs:
There will be no costs to you to participate in this study.

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

Confidentiality of Records
The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we will keep all information you provide to us in locked filing cabinets in a locked office and electronic data will be kept in a password-protected and secure database. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor. If this does happen, we will take precautions to protect the information you have provided.

Audio and video recordings will be transcribed by a professional transcription service. Both the audio and video recordings and their transcripts will be kept for a period of 7 years after the study and all reports and publications are complete.

Results of the research may be presented at meetings or in publications, but your name will not be used.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one.

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:

- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Past and present medical records related to the study

Who may use and give out information about me?

- The study doctor and the study staff
- URMC and Affiliates

Your information may be given to:

- The Department of Health and Human Services
- The University of Rochester

Why will this information be used and/or given to others?

- To do the research
- To study the results
- To see if the research was done right

What if I decide not to give permission to use and give out my health information?

- Then you will not be able to be in this research study.

May I review or copy my information?

- Yes, but only after the research is over.

How long will this permission be valid?

- This permission will last indefinitely.

May I cancel my permission to use and disclose information?

- You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

How long will my health information be kept?

- We will keep your information for 7 years after study completion. Your information will be destroyed after.

May I withdraw from the study?

- Yes, you may withdraw from the study. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?

- No. There is a risk that your information will be given to others without your permission.

Contact Persons

For more information concerning this research or if you feel that your participation has resulted in any emotional or physical discomfort please contact: Dr. Allison Magnuson at (585) 275-5863. For questions about this study please contact the Study Coordinator, Jessica Bauer at (585) 275-6525.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

Voluntary Participation

Taking part in this study is voluntary. You are free not to participate or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefits to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

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Use of E-mail for Communication in Research

When using e-mail to communicate with you in this study, the researcher cannot guarantee, but will use reasonable means to maintain security and confidentiality of e-mail information sent and received. You and the researcher should understand the following conditions, instructions and risks of e-mail use:

Conditions for e-mail use:

a) E-mail is not appropriate for urgent or emergency situations. The researcher cannot guarantee that any particular e-mail will be read and responded to.
b) E-mail must be concise. You should schedule an appointment if the issue is too complex or sensitive to discuss via e-mail.
c) E-mail communications between you and the researcher will be filed in your research record.
d) Your messages may also be delegated to any member of the study team for response.
e) The researcher will not forward subject-identifiable e-mails outside of URMC and Affiliates without your prior written consent, except as authorized or required by law.
f) You should not use e-mail for communication regarding sensitive medical information.
g) It is your responsibility to follow up and/or schedule an appointment if warranted.

Instructions for e-mail use:

a) Avoid use of your employer's computer.
b) Put your name in the body of the e-mail.
c) Put the topic (e.g., study question) in the subject line.
d) Inform the researcher of changes in your e-mail address.
e) Take precautions to preserve the confidentiality of e-mail.
f) Contact the researcher's office via conventional communication methods (phone, fax, etc.) if you do not receive a reply within a reasonable period of time.

Risks of e-mail use:

Sending your information by e-mail has a number of risks that you should consider. These include, but are not limited to, the following:

a) E-mail can be circulated, forwarded, stored electronically and on paper, and broadcast to unintended recipients.
b) E-mail senders can easily misaddress an e-mail.
c) Backup copies of e-mail may exist even after the sender or the recipient has deleted his or her copy.
d) Employers and on-line services have a right to inspect e-mail transmitted through their systems.
e) E-mail can be intercepted, altered, forwarded, or used without authorization or detection.
f) E-mail can be used to introduce viruses into computer systems.

SIGNATURES/DATES

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

Subject Consent

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

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Subject Name (Printed by Subject)

_____ _____

Signature of Subject Date

Person Obtaining Consent

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

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Name and Title (Print)

_____ _____

Signature of Person Obtaining Consent Date