CONSENT FORM

Mitigating Cancer-Related Cognitive Impairment in Older Adults with Breast Cancer Receiving Chemotherapy: Memory and Attention Adaptation Training-Geriatrics (MAAT-G)

Phase II: A randomized pilot study

Principal Investigator: Allison Magnuson, DO
University of Rochester Medical Center
James P. Wilmot Cancer Center
601 Elmwood Avenue, Box 704
Rochester, NY 14642

UR Medicine Noyes Health
Myers Cancer Center
111 Clara Barton St.
Dansville, NY 14437

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 and ask questions about anything that is not clear before you agree to participate. 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 age 65 or older and are receiving cancer treatment.
- The purpose of this study is to test the ability of MAAT-G to maintain or improve cognition compared to active control.
- Your participation in this study will last for up to 5 months after the initial visit
- Procedures will include background assessments, workshops, workbooks, and interviews. Some of these procedures may be optional.
- There are risks from participating.
    - The most common risk is becoming tired.
    - One of the most serious risks is loss of privacy. See the "Risks of Participation" section in this consent form for more information. You should discuss these risks in detail with the study team.
- You might or might not benefit from being in this research study.

Purpose of Study

You have been asked to participate in this research study because you are age 65 or older and are receiving cancer treatment. The purpose of this study is to test the ability of MAAT-G to maintain or improve cognition compared to active control. Your participation in this study is expected to last up to 5 months after the initial visit.

Background:

One common side effect of cancer treatment is cognitive impairments, such as memory loss or difficulty concentrating. Older adults, especially those with pre-existing cognitive difficulties, are at increased risk for developing progressive cognitive impairment with cancer treatment. There is no standard approach in oncology practice to reduce this risk. We have adapted an existing program, called Memory and Attention Adaptation Training (MAAT) for older adults, and the goal of this project is to test the ability of MAAT-G to maintain or improve cognition compared to active control.

In phase I of this study, all subjects received the MAAT-G intervention, which includes workshops with a psychology fellow training in delivering the MAAT-G program. All subjects also had an assessment at baseline and at the end of the program.

Phase I allowed the study team the opportunity to understand how to tailor the MAAT- G intervention further. The information collected in Phase I was used to standardize the MAAT-G intervention for Phase II of this study.

Description of Study Procedures

Before you begin the study:

You will review this document and we will answer any questions you have. If you decide to participate, you will sign this document.

If you decide to take part in this study, you will be randomly assigned (by chance, like the flip of a coin) to one of the two possible groups:

- Group 1 – Supportive Therapy (time and attention control)
- Group 2 – MAAT-G intervention

You will be asked to do a number of things, listed below.

Baseline Assessment:

At your first visit, you will be asked to complete a number of questionnaires. Some questions require a trained research coordinator to administer them; the coordinator will set up a telephone or televideo meeting to complete those questionnaires with you. Other questions you will complete on your own and then you will mail back to the study team. If you have a hard time completing any of the questions or tasks, a member of the research team will set up a telephone or televideo meeting to help you.
You will also be asked to complete a cognitive assessment. The research coordinator

will collect your email address and send you a web-based link. You will complete the cognitive assessment on your own. If you have a hard time completing it or have any questions, the research coordinator will help you.
The questionnaire asks about the following items:

Demographic Interview – about 5 minutes to complete:
You will be asked to provide the following information:

- Age
- Gender
- Marital Status
- Employment status
- Language Preference
- Race/Ethnicity
- Education
- Household composition (how many people live in your household, how they are related to you and so on)

Evaluations – about 15 minutes to complete:

- Functional Status: such as questions like ability to use the telephone, walk, go shopping, prepare your own meals, do housework, take your own medications, handle your own money
- Questions about anxiety and depression symptoms
- Questions about your quality of life

Cognitive Assessment: about 60 minutes to complete
The cognitive assessment includes the following items:

- An assessment of verbal fluency
- An assessment of short term visual/spatial memory
- An assessment of verbal learning and short-term memory
- An assessment of processing speed and attention
- An assessment of reading, spelling, and arithmetic

You are receiving or will receive cancer treatment, which has been prescribed by your doctor. This treatment is not considered part of this research study. We will record the doses of the cancer treatment and whether you require hospitalization or a change in the planned treatment and supportive care medications.

Intervention:
After the baseline assessment, you will be assigned at random (by chance using a computer) to one of the two study groups for the ten-week study period:

- Group 1: Group 1 will engage in Supportive Therapy (ST) which utilizes reflective listening to help deepen awareness of participants' emotional experience. This will consist of 10 weekly sessions with a trained clinician via video-conferencing and with the use of an ST manual. For participants that are randomized to the ST

group, after the completion of all the study procedures and time points, ST participants will be allowed to receive the MAAT-G program if they are interested.

- Group 2: Group 2 will receive the MAAT-G program, which involves ten sessions with a trained clinician via video-conferencing and a workbook with cognitive exercises to practice at home.

Workshops:
You will be asked to attend 10 workshop sessions lasting approximately 30-45 minutes each. Each workshop will be led by a trained clinician, such as a psychologist, psychology post-doctoral fellow, psychology intern, or research nurse. These will be delivered through a videoconferencing program called Zoom so that you can participate with the session using a tablet, provided by the study, while at home. These sessions will occur approximately once a week. Every attempt will be made to schedule these sessions at your convenience.

If you do not have internet access at home, the tablet will be equipped with a data package for your use for the purposes of the study. If the tablet is lost, stolen, or broken during the course of the study, you will be provided with another one. At completion of the study, the study coordinator will collect the tablet from you. If you have any questions or problems with the use of the tablet during the study, please contact the study coordinator at 585-275-8273.

Subject Workbook:
You will be asked to engage in practicing the techniques learned in each session in between workshops. These activities are outlined in a subject workbook which you will receive when participating in the study.

Audio/Visual Recording:
With your permission, workshop sessions will be audio recorded. The recordings will be used to monitor the fidelity of the intervention delivery and improve the workshop content. They will not be shared with anyone other than the research team. Recordings will be transcribed and kept for a maximum of one year and subsequently destroyed.

Your decision not to allow your workshop sessions to be recorded will not affect your ability to participate in this study.

If you agree to have your workshop sessions' audio recorded, you can change your mind at any time. If you change your mind, please notify Dr. Magnuson and her research team that you would like to withdraw permission to have your sessions recorded.

I give permission for my workshop sessions to be recorded:

☐ Yes ☐ No Initials: _____

Follow-up Assessment:
You will be asked to have a follow-up assessment. You will be asked to complete a second set of assessments almost identical to those at baseline. This will include the following:

- Functional Status: such as questions like your ability to use the telephone, walk, go shopping, prepare your own meals, do housework, take your own medications, handle your own money
- Questions about anxiety and depression symptoms
- Questions about the usability of the intervention
- Questions about your quality of life
- A cognitive assessment measuring verbal learning and fluency, visual/spatial memory, short-term memory, attention, processing speed, reading, spelling, and arithmetic

Interview:

- At the end of the program, we would also like to interview you, along with your caregiver if they participated, to explore your experience with MAAT-G or ST and your perception of how MAAT-G or ST altered cancer-related cognitive dysfunction symptoms and functional independence. The interview will be administered over the phone or Zoom televideoconferencing application and will be audio recorded. The recording will not be shared with anyone other than the research team. Recordings will be transcribed and kept for a maximum of one year and subsequently destroyed.

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
Phase II of the study will enroll 85 subjects. At least 35 subjects will be assigned to the MAAT-G intervention group.

Risks of Participation
Participation in this study involves the following possible risks:

Questionnaires and Other Evaluations:
You may become tired from the amount of time needed to fill out the questionnaires and carry out the other evaluations. The questionnaire will focus on life issues that could cause you to become emotionally upset. If this occurs, you will be referred to your physician to determine how best to handle the concerns and issues. Support

and counseling will be available from the study principal investigator, social workers and psychologists as needed.

Potential Loss of Confidentiality:
The risk associated with this study also includes loss of privacy and confidentiality because we will collect data from your medical record. Protected health data will be kept as confidential as it can be but complete confidentiality cannot be assured.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this website at any time.

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 or might not receive any benefit from participating in this study.

Alternatives to Participation
Your alternative is to choose not to participate in this study. Choosing not to participate will not affect your ability to receive care at the University of Rochester Medical Center.

Costs
Some of the tests/procedures/exams you will receive are standard care. These include cancer treatment and cancer care as recommended by the study doctor. You and/or your insurance company will be responsible for paying for any tests/procedures/exams that are done as part of your standard care. You are encouraged to discuss your coverage with your insurance provider.

Payments
There will be compensation of one $30 gift card for each visit, including the baseline and follow-up assessment battery, as well as each workshop session. You will not be

paid for visits that you do not complete.

Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes

The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we will use a unique study ID that is assigned when you are registered to the study and only share information with the parties identified below. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor.

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, including records of external providers that are available via your electronic health record at URMC & Affiliates
- Results of medical tests

Who may use and give out information about you?

- 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
- The National Cancer Institute (NCI) of the United States
- A Data and Safety Monitoring Committee (DSMC), an independent group of experts will be reviewing the data from this research throughout the study.

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 correctly

If the results of this study are made public, information that identifies you will not be used.

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?
Yes. 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.

May I withdraw from the study?
Yes. 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.

Voluntary 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.

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.

New Study Information

If we discover any new information that might make you change your mind about continuing in the study, we will let you know.

Sponsor Support

The Department of Medicine at the University of Rochester is paying for this study.

Return of Research Results

In general, we will not give you any individual results from your participation in the study. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

Certificate of Confidentiality

To help us further protect your privacy, the investigators have a Certificate of Confidentiality

from the Department of Health and Human Services (DHHS).

With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose or use research information, documents, or samples that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, other proceedings, or be used as evidence. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes, or to other government agencies related to communicable diseases.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your consent to receive research information, then the investigator may not use the Certificate to withhold that information. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others. Include the following only if applicable: The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect, or serious harm to the subject or others.

Contact Persons

For more information concerning this research or if you feel that your participation has resulted in any research related injury, emotional or physical discomfort, please contact**:** **Allison Magnuson, DO** at 585-275-5863 (24 hours).

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 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.

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.

_____
Subject Name (Printed by Subject)

_____
Signature of Subject Date

OR

_____
Legally Authorized Representative Name (Printed)

_____
Legally Authorized Representative Signature Date

_____
Legally Authorized Representative's Relationship to Subject

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.

_____
Name (Print)

_____ _____
Signature of Person Obtaining Consent Date