CONSENT FORM

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

Phase I

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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 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 see if an adapted program for improving cancer-related problems in memory is doable for older cancer survivors and if it helps reduce loss of independence and cancer-related cognitive impairment
- Your participation in this study will last for up to 8 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 received cancer treatment. The purpose of this study is to see if an adapted program for improving cancer-related problems in memory is doable for older cancer survivors with mild cognitive impairment and if it helps reduce loss of independence and cancer-related cognitive impairment. Your participation in this study is expected to last up to 8 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 whether the adapted MAAT program (called MAAT-Geriatrics[G]) is doable for older cancer survivors with mild cognitive impairment.

In phase I of this study, all subjects will receive the MAAT-G intervention, which includes workshops with a clinician trained in delivering the MAAT-G program. All subjects will also have an assessment at baseline and at the end of the program.

Phase I will allow the study team the opportunity to understand how to tailor the MAAT-G intervention further. The information collected in Phase I will be used to standardize the MAAT-G intervention for future studies of MAAT-G in older cancer survivors.

Phase I subjects will not be considered for subsequent phases. This consent form is for Phase I only.

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.

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 tele-video 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 tele-video meeting to help you.

You will also be asked to complete a cognitive assessment. 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 have received 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 that you previously received and any supportive care medications.

Intervention:

After the baseline assessment, you will receive the MAAT-G program, which involves ten sessions with a trained clinician 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. These will be delivered through a videoconferencing program called Zoom so that you can participate with the session using a tablet 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 gather feedback about the program and how we could better improve it. The interview will be administered over the phone 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 I of the study will enroll 39 subjects who will be assigned to the 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 $30 for each visit, including the baseline and follow-up assessment battery, as well as each MAAT-G workshop session. For this study, we use a subject payment system called Advarra Participant Payments. The system allows three ways to provide payment. You can choose: a reloadable debit card; direct deposit; or mailed paper checks. The study team will help you create a "subject profile" in the system. In order to provide payment, you will need to enter your name and date of birth into your subject profile. Depending on which payment method you choose, you may also need to enter your email address and banking information. If you already have an Advarra account (because you are in another study that uses the system), your existing profile will be used to provide payment. See the "Information Sheet for Advarra Participant Payments" for additional information. You will not be paid for visits that you do not complete.

Payments received for participation in research is considered taxable income. If you receive $600.00 or more in any one calendar year from UR or its affiliates, the University is required to report this information to the Internal Revenue Service (IRS) in a 1099 (Miscellaneous Income) form. You will be sent a copy of this form and a copy will be sent to the IRS. Depending on the amount you are paid, you may be asked to submit a W-9 form, which includes your Social Security Number.

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.

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 and Title (Print)

_____ _____
Signature of Person Obtaining Consent Date