Memorial Sloan Kettering Cancer Center
IRB Number: 21-161 A(6)
Approval date: 23-Aug-2022

Verbal Informed Consent for Clinical Research

Study title for participants: A Study of Attention and Memory Processes in Breast Cancer Survivors

Official study title for internet search on http://www.ClinicalTrials.gov: Neural and Cognitive Mechanisms of Attention and Memory Deficits in Cancer Survivors

Subtitle: Breast Cancer Survivor Consent

Lead Researcher: James Root, PhD (646-888-0035)

Directions for the consenting professional:
- You can attempt to contact the potential participant **only 3 times**.
- Do not leave a voicemail message unless you have received IRB approval to do so.

Introduction

Hello, may I speak with (potential participant's name)?

If NO:
- **Do not** leave your name or number to call back. Say that you will call back another time and ask for a good time to reach the potential participant.

If YES:
- Continue with discussion.

My name is (consenting professional), and I am calling from the Department of Psychiatry at Memorial Sloan Kettering Cancer Center. I am contacting you about our research study, Neural and Cognitive Mechanisms of Attention and Memory Deficits in Cancer Survivors. We are asking you to take part in this study because you are at least 50 years old and no older than 70 years old, you have a history of breast cancer, and you received treatment for your cancer at least 1 year ago.

Would this be a good time to speak with you about this study? Our conversation will take about 15 minutes.

If NO:
- Ask when a better time might be to call and record his/her availability.
- If the potential participant is not interested in hearing more: Thank the potential participant for his/her time and end the call.

If YES:
- Continue with discussion.

Overview of the Consent Discussion

During this call, I will explain the study and its risks and benefits, and we will discuss any questions you have. After that, I will ask if you would like to take part in the study. It is important to know that a research study is completely voluntary. You can choose whether to take part, and you can change your mind at any time. Please take your time to make your decision. If you have questions at any time, please feel free to ask me for more information.

Study Information

The purpose of this study is to *observe* the attention and memory processes in breast cancer survivors. Both cancer survivors and healthy volunteers (who are the same age as the cancer survivors) will participate in this study so we can compare the results of testing on each group of participants.

Cancer survivors often have cognitive (mental) changes after cancer treatment, including problems with processing information (impaired thinking), memory, and attention. These changes are often referred to as cancer-related cognitive dysfunction (CRCD), and they may affect cancer survivors' quality of life. Cancer survivors and others may think these problems are because of a breakdown in memory (memory decay) that happens during the course of cancer treatment. However, recent studies have suggested that forgetfulness and other cognitive changes in cancer survivors may be because of attention difficulties that prevent cancer survivors from successfully learning new information.

During this study, we will use electroencephalography (EEG) to test attention problems (deficits) in cancer survivors and see if these deficits affect survivors' ability to learn new information. We will also look at whether cancer survivors are able to detect their own attention deficits and errors while they are participating in the learning process. In addition to using EEG, this study will use traditional neurocognitive tests that include tests of attention, learning, memory, the ability to process information, and processing speed.

This study does not involve any treatment.

If you decide to take part in this study you will complete questionnaires, traditional neurocognitive tests, and participate in an attention and memory assessment (evaluation) using an EEG test. You will complete these tests and questionnaires at a single 2.5 – 3 hour visit. After this visit, your participation in the study will be complete.

You will not receive the results of this research study.

About 60 people will take part in this study at Memorial Sloan Kettering Cancer Center.

Do you have any questions about this study so far?

Risks and Benefits

There are both risks and benefits to taking part in this study. If you choose to take part in this study, there is a risk that:

- You may lose time at work, school, or at home, and you may spend more time than usual in the hospital or doctor's office
- You may be asked sensitive or private questions that you do not usually discuss

There are no physical risks involved in participating in this study. You may feel uncomfortable, stressed, or upset when you are filling out the questionnaires. You do not have to answer any questions that cause you to feel uncomfortable, stressed, or upset. If you become very upset while you are taking part in this study, we can give you a list of counseling resources that might be helpful. You may ask the study team (lead researcher and research staff) any questions you may have about risks.

Because this study does not provide treatment, you will not receive any health benefit from participating in the study. What we learn from this study may help other people in the future.

Alternatives to Participation

This study does not involve treatment for any problems with attention and/or memory. If you decide not to take part in this study, you may choose to take traditional neurocognitive tests that include tests of attention, learning, memory, the ability to process information, and processing speed and receive advice from doctors about new ways of going about daily activities , or you may choose to take part in a different research study if one is available.

Ending Participation

You can decide to stop participating in this study at any time. If you decide to stop, let the study team know as soon as possible. We will not be able to withdraw information about you that has already been used or shared with others.

The study team will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study. The lead researcher may remove you from the study if it is no longer in your best interest or you do not follow the study rules.

Conflict of Interest

This study is sponsored by Memorial Sloan Kettering Cancer Center (MSK) and funded by the National Institutes of Health (NIH). There are no known investigator and/or institutional conflicts of interest for this study.

Costs of Participation

There are no costs to taking part in this study. You and/or your health plan/insurance company will have to pay for all the costs of caring for your health while you are in this study.

You will receive a payment of $40 in cash, money order, or electronic gift cards for taking part in this study.

Do you have any questions?

Privacy and Security Information

Your privacy is very important to us, so I would like to end by explaining who will have access to your information and how your information will be used.

In the future, any information that identifies you may be removed. Your data will be assigned a unique code, and the list that links the code to your name will be stored separately from your data. Your information may be used for research that has not been described in this consent form, and they may be shared with another investigator for future research. You will not be asked if you agree

to take part in future research studies.

If your information from this study is used in any reports or publications, your name and anything else that could identify you will not be used. It is possible that your de identified information from this study will be shared with other researchers outside of MSK, and may be stored in public databases related to research. All requests for data sharing will be reviewed by the study sponsor, and if individual results are included in the data, they will not contain any identifiable information about you, such as your name, address, telephone number, or Social Security number. Your privacy is very important to us and we use many safety procedures to protect your privacy. However, we cannot guarantee that no one will ever be able to use your information to identify you.

MSK must get your permission before using or sharing your protected health information for research purposes. Your protected health information includes your medical and research records, which could include HIV-related or genetic information.

The main reasons for using or sharing your information are to do the study, to check your health status, and to find out the research results. We also want to make sure the research meets legal and institutional requirements.

Your protected health information may be shared with and used by the following:

- The study's lead researcher and the research team
- People and offices that deal with research oversight, quality assurance, and/or billing, if applicable.
- MSK and the sponsor's research collaborators, business partners, subcontractors and agent(s) working to conduct the study, to monitor the study, or to analyze the study information for this study or for other research about the study.
    - Once your data is shared, it may not be as well protected as it is at MSK.
    - Your information may also be shared with federal and state agencies, and other domestic or foreign government bodies including:
        - the Office for Human Research Protections of the US Department of Health and Human Services
        - the National Cancer Institute /National Institutes of Health

If your information from this study is used in any reports or publications, your name and anything else that could identify you will not be used. Your information may be given out, if required by law. However, the researchers will do their best to make sure that any information about you that may be released will not identify you.

Contact Information

You can talk to the study team about any questions or concerns that you may have about this study. You may also contact the lead researcher, Dr. James Root at 646-888-0035. More information about this study may be available at ClinicalTrials.gov.

For questions about your rights while you are participating in this study, call the MSK Institutional Review Board (IRB) at 212-639-7592. If you have concerns, complaints, or input on research, or if you would like more information about the informed consent process, please contact the MSK Patient Representative Department at 212-639-7202.

Agreement to Participate

Based on our discussion, do you voluntarily agree to participate in this study?

If NO:

- Thank the participant for his/her time. Do not complete the below participant and consenting professional information. Add a note to the medical record/research file indicating that he/she declined to participate.

If YES:

- Continue.

Thank you so much for your time and for agreeing to participate in this study.

Participant Information	
Participant Name	
MRN/Study ID	

Consenting professional must personally sign and date		
Consenting professional's signature		**Date:**
Consenting professional's name (Print)		