Memorial Sloan Kettering Cancer Center
IRB Number: 22-223 A(5)
Approval date: 02-Jan-2024

Verbal Informed Consent for Clinical Research

Study title for participants: A Study of Cognitive Health in Survivors of Prostate Cancer

Official study title for internet search on http://www.ClinicalTrials.gov: Prostate Cancer Survivorship and Cognitive Health (PRO-HEALTH)

Lead Researcher: Kevin Liou, MD (646-608-8558)

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 Medicine at Memorial Sloan Kettering Cancer Center. I am contacting you about our research study, Prostate Cancer Survivorship and Cognitive Health (PRO-HEALTH). We are asking you to take part in this study because you completed treatment for prostate cancer within the last 10 years and you receive follow-up care at MSK.

Would this be a good time to speak with you about this study? Our conversation will take about 20-30 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. Whatever choice you make, your medical care will not be affected. Please take your time to make your decision. If you have questions at any time, please feel free to ask me for more information.

Before continuing:

- Do you have the hard copy of the introduction letter available to use as a guide to our discussion?

Study Information

The purpose of this study is to learn about changes in the mental (cognitive) function of prostate cancer survivors following cancer treatment, including problems with processing information (impaired thinking), memory, and attention. These changes are known as cancer-related cognitive dysfunction (CRCD). Specifically, we want to learn about the relationship between peoples' experiences of CRCD and other conditions they may have (co-morbid factors), including anxiety, depression, and insomnia. We will also find out how additional things may contribute to CRCD, including social factors, the characteristics of participants' prostate cancer, and the type of cancer treatment or other medications they received. The study researchers think that learning about the combined factors that contribute to CRCD in prostate cancer survivors may help in the development of better treatments for this condition in the future.

If you decide to take part in this study you will complete a questionnaire that asks questions about your health, cognitive function, general daily functioning, and quality of life. The questionnaire will take around 25-50 minutes to complete; you may complete it on paper, online using a secure web link, or over the phone with a member of the study team. The study team will also review your medical record to get additional information about your health and your cancer treatment.

All study participants will complete the questionnaire. You may also choose to undergo optional neurocognitive testing, which I will tell you about in a moment.

After you complete the questionnaire (or optional neurocognitive testing, if you choose to participate), your participation in the study will end.

You will not receive the results of this research study.

About 200 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 be asked sensitive or private questions that you do not usually discuss. If you get upset while answering these questions, we will assist you in finding a medical professional to talk. You may ask the study team (lead researcher and research staff) any questions you may have about risks.

Because no form of treatment will be provided as part of the study, you will not receive any health benefit from participating in the study. What we learn from the study may help other people in the future.

Alternatives to Participation

If you decide not to take part in this study, you may choose to continue regular follow-up with your doctor. People with concerns about CRCD may undergo testing of their mental functions (neurocognitive testing) and may be treated with medications, lifestyle changes, or cognitive rehabilitation (treatments to improve cognitive function). You may also 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.

Conflict of Interest

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

Costs of Participation

You will not have to pay for the study questionnaires or, if you choose to participate, for the optional neurocognitive testing. You and/or your health plan/insurance company will have to pay for all the costs of caring for your condition while you are participating in this study.

You will receive a $20 gift card for completing the questionnaire. If you complete the optional neurocognitive testing, you will receive an additional $20 gift card, for a total of up to $40.

Optional Studies

This part of the consent describes an optional study that you can choose to take part in. You will not get health benefits from this study. The doctors leading this research hope that the results of this study will help other prostate cancer survivors in the future.

The results of this study will not be added to your medical records, and you will not be informed of the test results.

You will not be billed for this optional study. You can still take part in the main study even if you do not participate in the optional study. If you sign up for but cannot complete the optional study for any reason, you can still take part in the main study.

Optional neurocognitive study

If you choose to take part in this study, you will undergo neurocognitive function testing. Neurocognitive function is related to a person's ability to think and reason, and this kind of testing is commonly used to measure these abilities. We are doing this optional study to learn about the relationship between the results of these tests and participants' co-morbid conditions. The study researchers think that what we learn may help in the development of better treatments for CRCD in the future.

You will be asked to complete verbal tests over the phone or Zoom, as well as a computer-based test at home. These tests measure attention, learning, memory, the ability to process information, and processing speed. These tests will take about 30 to 60 minutes to complete.

This neurocognitive function testing will be used only for research and not to guide your medical care.

You may either choose to participate in this optional study or decline. Your medical care will not be affected, no matter what you decide to do.

Optional Text Communication

Some people may prefer to communicate using text messages, instead of phone calls or emails. Therefore, in this section, we ask you to agree to allow a service provider, Mosio, to send you text messages on your mobile phone/device, communicating with you to:

- Remind about surveys, appointments, or other study activities.
- Get updates on how you are doing with the study.
- Address your questions or concerns during the study.

In order to make this service work:

1. A member of the study staff will ask you for your mobile telephone number. You will need to provide a mobile number that is used only by you.
2. The study team will enter your mobile telephone number and your subject identification (ID) number
onto a secure web site.
3. You will be sent text messages to support you throughout the study.
4. You will be able to reply to text messages to communicate with the study team.

Please notify study staff right away if you change your mobile phone number. This will prevent your information from being sent to the wrong person.

What is the general content of these text messages?

Examples of study messages might be: “Hello! This is a friendly reminder to complete your survey.” The content of the messages will not identify you personally, or the disease area (on which the study is focused), or your medical history.

Do I have to pay for the service?

You will not incur any additional charges for this service, over and above what you would normally be charged by your mobile network provider for sending and receiving any text messages, or transmitting/receiving data.

Who will be able to see my mobile phone number or personal information?

The secure, restricted web site associated with the service will contain your subject ID, your mobile phone number, and any messages that you respond with will also be stored in the system. This information might be seen by:

• The study doctor and his/her team: in order to enroll you in, and manage your study activities
• Mosio and its service representatives: in order to provide the text messaging service

Mosio and its service representatives will not share your contact details with other third parties unless required by law. They will not contact you except for sending the messages.

When you are no longer in the study, Mosio will stop sending you text messages (except for unusual circumstances such as an emergency).

At any point, if you reply to a message with STOP, you will no longer receive messages from the system. Study staff are also able to help you “opt out” of the messaging service through the system.

If you provide this consent and if there are changes to the information provided above, you will be informed of the new information in writing and you will be asked again to consent in writing for the new uses.

Will Mosio be able to guarantee that I receive all the messages?
Mosio will send all messages to your mobile phone number. However, they cannot guarantee that the mobile phone service provider will deliver the message to your mobile phone, or prevent disruptions in message delivery. While the messaging service is aimed at supporting you throughout the study, it remains your responsibility to understand and follow the study requirements. This text messaging service is only thought to help you to comply with all study requirements you have already consented to.

What if I have questions about the text messaging service?
If you wish to make any inquiries or complaints once your service is active, please contact the study team and they will inform Mosio. You can ask questions about the service at any time. You can call the study doctor or study staff at any time if you have any concerns or complaints. You should call the study doctor or study staff if you have questions about the research study.

How will my contact information be used and disclosed?

Study Information, your subject ID number, and other information collected as part of this text messaging service will be stored in our secure electronic trial systems.

These systems may be managed and monitored by companies who work with Mosio.

You do not have to use this text messaging service to participate in this study. If you choose not to use this text messaging service, you will not receive text notifications, and the study team will communicate with you by phone and/or email instead. You are free at any time to limit Mosio’s use and sharing of your contact information, without penalty or other consequence. However, you will not be allowed to take part, or continue to take part in this text notification messaging, if at any time you choose to limit or cancel Mosio’s use and sharing of your contact information for this service.

Your authorization (permission) to use and disclose (share) your contact information will expire when you complete the trial, unless you revoke (cancel or withdraw) it sooner. The use and sharing of your/your information will only be used for the purposes described in this Informed Consent Form

Please check Yes or No. Your medical care will not be affected, no matter what you decide to do.

I agree to participate in the text messaging service:

❑ Yes ❑ No

This is the end of the section about the Optional 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 may 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 it 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

The study doctors have a Certificate of Confidentiality from the National Institutes of Health for this study. This gives MSK an additional way to protect sensitive information that identifies you in your records if it is requested as part of a legal proceeding. However, MSK may still be required to share some of your medical information if required by law.

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.

If you agree to take part in this study, you give us permission to share your protected health information. If you do not agree to let us share your information, you will not be able to take part in this study. However, it will not affect your ongoing medical care or healthcare coverage.

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, Kevin Liou, MD at 646-608-8558. 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:
- Do you voluntarily agree to participate in the optional neurocognitive testing?

Participant response: ❑ Yes ❑ No

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)		