Memorial Sloan Kettering Cancer Center
IRB Number: 22-248 A(6)
Approval date: 08-Aug-2024

Verbal Informed Consent for Clinical Research

Study title for participants: A Study of Counseling Support for Cancer Survivors Ages 65+

Official study title for internet search on http://www.ClinicalTrials.gov: Brief Behavioral Activation for the Treatment of Depression in Older Adult Cancer Survivors

Subtitle: Randomized Participant Consent

Lead Researcher: Rebecca Saracino, PhD (646-888-0263)

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, A Study of Counseling Support for Cancer Survivors Ages 65+. We are asking you to take part in this study because you have a history of cancer, are at least 65 years old with symptoms of depression, and you completed active cancer treatment.

Would this be a good time to speak with you about this study? Our conversation will take about 15-20 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:

- [OPTION 1 (if study information sheet was provided):] Do you have the hard copy of the study information sheet available to use as a guide to our discussion?
- [OPTION 2 (if study information sheet was not provided ahead of time):] After our conversation, we will mail you a study information sheet that includes key information about this study.

Study Information

The purpose of this study is to find out if a psychotherapy method called behavioral activation (BA) can be successfully delivered by telephone or videoconference (remotely) and can effectively treat depression in older cancer survivors. BA is a therapeutic technique that guides people to set goals and engage in enjoyable or rewarding activities as a way of changing behavior and reducing symptoms of depression.

BA has been shown to be effective in treating depression, including in older adults but, because older adult cancer survivors (OACS) often have difficulty with mobility or face other challenges in traveling to receive face-to-face treatment, the study researchers want to find out if BA can be delivered remotely instead. This study will compare remote delivery of BA with remote delivery of supportive psychotherapy (SP), a standard psychotherapeutic intervention that has been shown to be an effective form of treatment for depression in OACS.

People who are not in a study are usually treated with standard counseling or psychotherapy, which may be done in person or remotely, and they may receive medication.

If you decide to take part in this study, we will gather information from your medical records, including information about your cancer history and treatment, as well as your current health conditions, medications, and any care you are receiving.

You will be asked to complete 3 sets of questionnaires. These questionnaires will ask about your illness, quality of life, depression, and anxiety, and they will take up to 30 minutes to complete.

The questionnaires may be completed in one of 3 ways. You will choose the option you prefer when the study team contacts you to complete the first set of questionnaires.

- [OPTION 1 (over the phone):] Study questionnaires will be sent to your home by mail or secure email and you will follow along as someone from the study team reviews the questionnaires with you. A member of the study team will record your responses, so you don’t have to write down your answers.
- [OPTION 2 (over email):] A member of the study team will send you an email with a secure online link to the study questionnaires. You will click on the link to complete the questionnaires.

- [OPTION 3 (on paper):] A member of the study team will mail you paper copies of the questionnaires that you can complete on your own. The package will include a return label that you can use to mail the completed forms back to the study team.

After you complete the first set of questionnaires, a computer will assign you by chance, like flipping a coin, to have remote BA or SP. This process is called randomization, and it is done by chance because no one knows if one treatment is better or worse than the other. You have a 1 in 2 chance of being randomized to either treatment.

After you are randomized to receive BA or SP, you will have a total of 10 therapy sessions over 10 weeks with a licensed mental health counselor who has been trained to provide remote BA or SP. You will participate in these sessions remotely, using your choice of telephone or videoconference. Each session will take about 30-50 minutes and will be audio-recorded. Recordings of your sessions will be reviewed by the study team so that they can provide the counselor with feedback about the interactions that occurred during your sessions. We may use information in these recordings for educational and/or training purposes. Audio recording clips or direct quotes from your sessions may be used in academic and educational presentations and/or publications. However, your name and any other identifying information will not be used. If you elect to discontinue sessions at any time, you will be invited to remain on study and complete questionnaires only.

If you are randomized to BA sessions, you will be asked to complete Daily Monitoring Forms to track your daily activities. You will be asked to send de-identified photos of these completed forms, if possible, to the research team once each week prior to Sessions 2-10. These forms will be shared with the mental health counseling conducting your sessions so that they may provide personalized feedback. Participants randomized to SP sessions will not complete Daily Monitoring Forms.

Within 2 weeks after your last session of BA or SP, you will complete a second set of questionnaires that will ask about your quality of life, depression, and anxiety, and, if you are randomized to receive BA, about your satisfaction with your BA sessions. About 2 months after your last session of BA or SP, you will complete a final set of questionnaires that will ask about your quality of life, depression, and anxiety. It will take up to 30 minutes to complete each set of questionnaires.
After you've completed the third set of questionnaires, your participation in the study will end.

About 90 people will take part in this study at Memorial Sloan Kettering Cancer Center (MSK).

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 become uncomfortable during the sessions, but these feelings are likely to be temporary. If you do become uncomfortable, please tell someone on the study team, and one of the study doctors will provide support to you. The study team includes licensed mental health professionals. In addition, you may feel uncomfortable, stressed, or upset while you are completing the questionnaires. You may ask the study team any questions you may have about the risks of participating in this study.

Taking part in this study may or may not benefit you, but what we learn from this research may help other OACS in the future.

Alternatives to Participation

If you decide not to take part in this study, you may choose to have the usual approach to treatment for depression, or you may choose to take part in a different research study if one is available. You may also choose not to be treated for depression.

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 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 therapy (BA or SP). You and/or your health plan/insurance company will have to pay for all the other costs of your survivorship care while you are participating in this study.

You will receive $60 for completing 3 sets of questionnaires and 10 BA or SP sessions.

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 treatment 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, Dr. Rebecca Saracino, at 646-888-0263. 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)		