Memorial Sloan Kettering Cancer Center
IRB Number: 20-241
Approval date: 12-Jun-2020

Verbal Informed Consent for Clinical Research

Study title for participants: Communication Training for Cancer Patients, Their Caregivers, and Their Doctors

Official study title for internet search on http://www.ClinicalTrials.gov: Values and Options in Cancer Care 2.0 (VOICE 2.0): Building on Lessons Learned to Improve Communication and Illness Understanding in Cancer Patients and Their Caregivers

Subtitle: Patient Consent

Lead Researcher: Kelly Trevino, PhD (646-888-0026)

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 and Behavioral Sciences at Memorial Sloan Kettering Cancer Center (MSK). I am contacting you about our research study, Values and Options in Cancer Care 2.0 (VOICE 2.0): Building on Lessons Learned to Improve Communication and Illness Understanding in Cancer Patients and Their Caregivers. We are asking you to take part in this study because you have hematologic, gastrointestinal, genitourinary, gynecologic, or lung cancer. We received your information from your cancer doctor (your oncologist), who is taking part in this study. Your caregiver will also take part in this study. Your caregiver may be a family member, a partner/spouse, or a friend who supports you while you are receiving cancer care.

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

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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.

Study Information

The purpose of this study is to develop and test a new communication intervention, "Values and Options in Cancer Care 2.0" (VOICE 2.0), which involves oncologist training, patient and caregiver coaching, and caregiver support.

The VOICE 2.0 intervention was developed by members of the study team to improve communication among oncologists, patients with cancer, and caregivers. Researchers have found that clear communication about the patient's disease can help with the planning of that patient's future care and improve the well-being of both the patient and his or her caregiver. The long-term goals of developing and testing VOICE 2.0 include improving the care and respecting the wishes of cancer patients, and helping those patients and their caregivers have an improved quality of life during their experience with cancer.

The main goals of this study include:

- Seeing if VOICE 2.0 is practical and works well for the patients, doctors, and caregivers who participate in the intervention
- Looking at the effects of VOICE 2.0 on patients' and caregivers' communication with the doctor, psychological distress, and sense of meaning/purpose

If you are interested in participating in this study, you and your caregiver will complete a set of screening questions before consenting that will help to determine if you will move forward to the main part of this study.

If you decide to take part in this study, you will have an in-person or phone interview with a member of the study team. The member of the study team will collect your demographic information (for example, your age and gender) and ask you questions about your understanding of your disease and treatment, interactions with your doctor and caregiver, communication style, stress level, and feelings of meaning/purpose. The interview will take about 45 minutes.

You will participate in one coaching session with a social worker from the study team, also called an interventionist. This session will take place over video conference. You will be together with your caregiver for this session. During the session, the interventionist will review with you and your caregiver a Question Prompt List (QPL), which will take about 1 hour. The QPL contains example questions you can ask your cancer doctor about your diagnosis, course of disease, treatments, symptom management, transitions in care, self-care, family needs, and life goals.

Following the coaching session, you and your caregiver will participate in 3 additional sessions by video conference or over the phone with the interventionist. These calls will take place every other week over a 6-week period. You and your caregiver will discuss if and how you are using the questions provided during your coaching session.

You will have a second in-person or phone interview with a member of the study team within 2 weeks of your last follow-up session. You will discuss any changes since the first interview. The second interview will take about 55 minutes.

After the second interview, your participation in the study will end. Your participation in the study will last about 7-10 weeks.

Your interviews, coaching session, and follow-up sessions will be audio-recorded.

The doctors who take part in this study will complete questionnaires and participate in an online training and interview. In addition, your caregiver will participate in 3 support sessions with the interventionist.

You will not receive the results of this research study.

About 14 patients, 14 caregivers, and 7 oncologists will take part in this study at 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 you may be asked sensitive or private questions that you do not usually discuss. You may feel uncomfortable, stressed, or upset while you are completing the interviews or coaching sessions. 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.

Taking part in this study may or may not improve your communication with your doctor or caregiver. However, what we learn from this research may help us develop an effective communication intervention to improve communication among cancer patients, caregivers, and doctors.

Alternatives to Participation

Patients who are not participating in a research study usually ask a doctor, other members of the medical team, or a mental health provider for advice and recommendations about ways to manage difficult communication with doctors about cancer. 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 end your participation, your caregiver's participation will also end. Also, if your caregiver or doctor stops participating in the study, your participation in the study will end as well.

If you decide to stop, let the interventionist or 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 study team 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

The study is sponsored by MSK. The study is 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 cancer while you are participating in this study.

You will receive $15 after completing the first interview and $15 after completing the second interview, for a total payment of $30. This compensation will be provided through cash, money order, or gift card. The form of payment you receive will depend on whether it will be provided to you in person, by postal mail, or by email.

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. 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'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.

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, Kelly Trevino, PhD at 646-888-0026. 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)		