Memorial Sloan Kettering Cancer Center
IRB Number: 22-019 A(8)
Approval date: 28-Jun-2024

Verbal Informed Consent for Clinical Research

Study title for participants: Meaning-Centered Psychotherapy at Home

Official study title for internet search http://www.ClinicalTrials.gov:
A Pragmatic Randomized Control Trial of Nurse-Delivered Brief Meaning Centered Psychotherapy for Homebound Palliative Care Patients

Subtitle: Randomized Participant Consent (Patient)

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 (MSK). I am contacting you about our research study, Meaning-Centered Psychotherapy at Home. We are asking you to take part in this study because you have cancer, you recently completed care with VNS Health, and you are in VNS Health's post-acute care program.

Would this be a good time to speak with you about this study? Our conversation will take about 10 minutes.

If NO:
- Ask when a better time might be to call and record the participant's availability.
- If the potential participant is not interested in hearing more: Thank the person for their 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 introductory letter was provided):] Do you have the hard copy of the study introductory letter 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 or email you a study information sheet that includes key information about this study.

Study Information

The purpose of this study is to see if a type of counseling called Meaning-Centered Psychotherapy at Home, also known as MCP-H, can effectively treat distress in homebound patients with cancer.

Meaning-Centered Psychotherapy, or MCP, is a therapy that uses discussion, listening, and counseling to improve a person's sense of hopelessness, spiritual well-being, physical and mental health, and quality of life. In previous studies in people with serious illness who experienced lengthy physical and mental suffering, this intervention was shown to enhance people's sense of meaning and spiritual well-being and decrease their symptoms of anxiety and depression.

If you decide to participate in this study, you will first complete 1 set of questionnaires that ask about your medical history, levels of distress, spiritual well-being, and quality of life, and they will take up to 30 minutes to complete.

After you complete this first set of questionnaires, a computer will assign you by chance, like flipping a coin, to a treatment group in the study. This process is called randomization, and it is done by chance because no one knows if one treatment group is better or worse than the other. You have a 1 in 2 chance of being randomized to either group. Both you and the study doctor will know which intervention you are receiving. There are two groups for this study:

- Participants in Group 1 will receive the Meaning-Centered Psychotherapy at Home (MCP-H) intervention
- Participants in Group 2 will receive a local referral for psychological care – this is referred to as "treatment as usual"

If you are randomized to receive MCP-H, you will have a total of 3 audio-recorded sessions with a nurse who is training to deliver MCP-H to people with your condition. You will participate in these sessions over 3 to 6 weeks at your home (if a session cannot be conducted in your home, the session will be offered via telephone or videoconference). Each session will take about 30 minutes. Recordings of your sessions will be reviewed by the study team so that they can provide the nurse in training with feedback about the interactions that occurred during your sessions. We may use information in these recordings for academic, educational, or training purposes and/or for publications and presentations. 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.

About 2 weeks after your last session (if randomized to MCP-H) or 6 weeks after your first set of

questionnaires (if randomized to “treatment as usual”), you will complete a second set of questionnaires that will ask about your levels of distress, spiritual well-being, and quality of life. Participants in the MCP-H group will also be asked about satisfaction with your MCP-H sessions. About 2 weeks after you’ve completed your second set of questionnaires, you will complete a final set of questionnaires that will ask about your levels of distress, spiritual well-being, and quality of life. It will take up to 30 minutes to complete each set of questionnaires.

The questionnaires you complete before and after randomization may be completed in one of 3 ways:

- [OPTION 1 (over the phone):] Study questionnaires will be sent to your home by US 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.

If you decide to participate in this study, you will choose the option you prefer when the study team contacts you to complete the first questionnaire.

After you’ve completed all 3 sets of questionnaires, then your participation in this study will end. This study will take you about 10-12 weeks to complete.

You will not receive the results of this research study.

About 90 people will take part in this study.

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 well-trained 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. Emergency contact information will be retrieved in the beginning of the study and be provided to the interventionist to use in case of emergency during the sessions. Emergency contact information may also be utilized by staff to reach you if primary contact information is unserviceable or if unresponsive after multiple attempted contacts for study related activities.

Taking part in this study may or may not benefit you, but what we learn from this research may help other cancer patients in the future. The study researchers will use the feedback you provide to make changes to the training program so that we can improve our efforts to assist nurses at VNS Health to

deliver MCP-H.

Alternatives to Participation
If you decide not to take part in this study 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) 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
There are no costs involved in 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 $25.00 for completing each set of study questionnaires ($75.00 total for completing all 3 sets of questionnaires). Your compensation will be in the form of money order or a gift card.

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 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.

VNS Health 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 Institutional Review Board (IRB)
- VNS Health 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.

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 VNS Health Institutional Review Board (IRB) at 212-609-5766.

Agreement to Participate

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

If NO:

- Thank the person for their 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)		