Memorial Sloan Kettering Cancer Center
IRB Number: 14-102 A(19)
Approval date: 07-Apr-2021

Verbal Informed Consent for Clinical Research
Part 3, Parent

Study title for participants: Development of Psychotherapeutic Interventions for Parents Who Lost a Child (Parent)

Official study title for internet search on http://www.ClinicalTrials.gov:
Development of Psychotherapeutic Interventions for Parents Who Lost a Child

Lead Researcher: Wendy Lichtenthal, Ph. D

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 & Behavioral Sciences at Memorial Sloan Kettering Cancer Center. I am contacting you about our research study, *Development of Psychotherapeutic Interventions for Parents Who Lost a Child*. We are asking you to take part in this study because you are a parent who has lost a child.

Would this be a good time to speak with you about this study? Our conversation will take about 10-15 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.

Before continuing:

- Do you have the hard copy of the study information sheet available to use as a guide to our discussion?

Study Information

The purpose of this study is to compare two types of counseling programs for parents who have lost a child.

If you decide to take part in this study, you will receive a counseling program through video conferencing. One of the types of counseling programs you may receive is called "Meaning-Centered Grief Therapy." Sessions will focus on finding a sense of meaning or purpose in your life after your loss. You will be encouraged to reflect on questions between sessions and if possible, to write down your responses. You will have the option of completing a larger project on your own based on the themes that will be discussed.

The other type of counseling program you may receive is supportive counseling. Supportive counseling is intended to help you cope with your loss by giving you a place to express your feelings and get support during the sessions.

The type of counseling program you receive will be determined at random. For both types of counseling programs, there will be a total of 16 weekly counseling sessions, and each session will last about 60-90 minutes.

You will be asked to participate in sessions conducted using video conferencing. Video conferencing allows people to see and hear each other using the Internet through a computer. This way, you will have the opportunity to connect with the study therapist wherever you have computer access in New York or New Jersey, the Internet, and privacy. Instructions on how to log into these sessions will be provided to you ahead of time. If you do not have access to a computer or internet, we will loan you one whenever this is possible.

All counseling sessions will be audio and/or video recorded with your permission, and we may transcribe or use audio/video clips of some of these recordings for academic, educational, or training purposes and/or for publications and presentations. Recording sessions will help us make sure that the counseling program is being carried out as planned. Each recording will be stored with a code number to protect your confidentiality. You may ask to stop the video recording at any time, and this request will not affect your participation in the study or any of your medical care. Audio recording of sessions is required. Video recording of sessions is optional. You can choose not to allow video recording and still participate.

If you are randomized to receive Meaning-Centered Grief Therapy, at the end of all of the sessions, we will ask you to complete an interview to provide feedback on your overall experience with the program, as well as how we can improve the program. This interview will be audio and/or video recorded with your permission, and we may transcribe or use audio/video clips of some of these recordings for academic, educational, or training purposes and/or for publications and presentations.

We audio record the interviews so that we can get accurate information on what you liked and disliked about the program. The research team will transcribe the recording without your name or any other identifying information. The video recording is optional and you may still take part in the study if you do not wish to be video recorded. Part of the video recording may be used as a testimonial to share with other parents so they will have a better understanding of how it feels to be part of these sessions. The video recording may also be used in presentations and/or study recruitment materials. These videos will be uploaded to a secure internet platform that uses a password. Only those with the password will be able to access the videos. If individuals who are not involved in this research study obtain the link to the video and the password, it may be possible for

them to view the videos.

All participants will be asked to complete a set of questionnaires at four different time points. Questionnaires will take about 75-90 minutes to complete. These assessments will be completed using a secure website. Your name will not be used. You will be assigned a random number, which will identify your responses. If you do not wish to complete questionnaires online, we can arrange for you to complete them by mail, phone, or email. Information from your questionnaires might be shared with study therapists in an effort to increase the quality of the counseling. You will also be asked to complete questionnaires over the phone at 3 different time points. These questionnaires will take about 10 minutes each. Once you complete the sessions and the last set of questionnaires, your participation in this study will be done. The research team would only contact you to clarify any answers you have provided. While participating in this study, you can seek out any other form or forms of support you think might be helpful. We will ask about new services you are receiving in the study questionnaires. Content from your responses to these questionnaires may also be used for academic, educational, or training purposes and/or for publications and presentations.

We will also ask you to fill out a brief questionnaire prior to each weekly session as well as a weekly session rating after each session. These will take about 3-5 minutes each.

In addition, we would like to collect some emergency contact information from you. We ask that you provide us with the names and contact information of one or two individuals you designate as emergency contacts. These emergency contacts may only be contacted if we are worried about your well-being. We also ask that you provide the contact information of your local hospital to call an ambulance in the event of an emergency as well as contact information for any treating primary care physicians or mental health providers if applicable.

You will participate in the study for a total of about 7-8 months, including all sessions and follow up questionnaires.

All research study therapists are either MSK mental health clinicians or non-MSK employed mental health clinicians contracted to work on specific research studies. We use the services of non-MSK mental health clinicians as study therapists so that we can best accommodate your schedule and availability to attend these counseling sessions. All clinicians, whether employed by MSK or hired per research study, have at minimum a Master's degree and are qualified and experienced mental health clinicians trained in the counseling program you will receive.

You will not receive the results of this research study.

About 66 people will take part in this study at Memorial Sloan Kettering Cancer Center.

Do you have any questions about this study so far?

To verify that you qualify to participate, we need to ask you a few questions to about your emotional well-being, your feelings about your loss, and your distress. Would you be willing to complete a brief 5-minute survey?

If NO:

- Thank the potential participant for his/her time and end the call.

If YES:

- Administer PG-13 and eligibility questions.

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If ELIGIBLE:

- Thank you for answering these questions. You are eligible to take part in the study, which I will now tell you more about.

If INELIGIBLE:

- Thank you for answering these questions. It looks like you do not qualify for this study. This study is enrolling parents who may have more difficulty with dealing with the loss of their child. If you feel that you need additional support, I would be happy to refer you to the Counseling Center here should you wish to make an appointment. Would you like a referral?

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 upset by the discussions or by some of the questions we will ask you. The research staff includes well-trained mental health professionals. You may contact them before, during, or after you complete the questionnaires for assistance or to provide referrals as needed. If you become very upset because of taking part in this study, you will also be offered a referral for care by the MSK Psychiatry staff. You will be billed for these additional services. You may ask the study team (lead researcher and research staff) any questions you may have about risks.

Taking part in this study may not benefit you directly, but what we learn from this research may help us learn more about a counseling program for parents who are coping with the loss of their child. You may benefit from knowing that your participation could help other parents in the future. In addition, by taking part in this study, you will be offered 16 60-90 minute weekly sessions of either Meaning-Centered Grief Therapy or supportive counseling free of charge. These counseling programs could help reduce emotional difficulties you may be experiencing.

Alternatives to Participation

If you decide not to take part in this study, we can refer you to other services at our counseling center, 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 the National Cancer Institute.
No conflicts of interest have been identified for either the institution or the investigator(s) in this study

Costs of Participation

There are no costs to taking part in this study. Research studies sometimes provide monetary compensation for time spent on the study and/or expenses associated with travel. You will receive $50 in the form of a money order mailed to you after you complete the last questionnaire as a thank you for your time and participation.

In case of injury from study related procedures, for example becoming upset, you will get treatment by being offered a referral for care by the MSK Counseling Center, but you and/or your health plan will be charged for this treatment. Additionally, if you decide to seek private consultations, either in addition to or instead of this study, you will be billed for these services. You do not lose any of your legal rights to seek payment by verbally consenting to participate on 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.

Your participation will be confidential. However, there are two exceptions to this strict confidentiality policy. 1) If we learn that you are seriously suicidal and may pose a significant and acute risk of self-harm or harm to others, we will inform an MSKCC licensed psychiatrist or psychologist or your primary care doctor. This will be done so that timely and appropriate psychiatric assessment and care can be provided by the MSK Psychiatry Service or local providers when geographically appropriate. 2) Since only one parent may participate in this study, if applicable, the non-participating parent may be informed of the participating parent's enrollment to the study. This will only occur if both parents from the same household are interested in participating. However, no other study information or data will be shared with the non-participating parent.

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. 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.

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.

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, Wendy Lichtenthal, PhD at 646-888-4812. 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.

We have a couple of things we need to clarify and ask before we move on to the final step of this consent.

As previously mentioned, the counseling sessions and exit interview will be audio taped in order to make sure the treatment programs are all run in the same way.

Please indicate you understand that you will be audio recorded as part of this study.

☐ *Yes, I understand I will be audio recorded as part of this study.*

If NO:

- If patient says that they do not agree to be audio recorded, thank them for their time. Remind them that as part of this study, all sessions and exit interviews for all those participating are audio recorded for quality assurance. Please inform the study coordinator and the PI immediately so that they can address the issue further if necessary.

The sessions may be video recorded. Videos may be used for academic, educational, or training purposes. If you do not agree, your sessions will not be videotaped. However, you can still participate in the study.

Please indicate if you agree to be video recorded during the sessions.

☐ *Yes, I agree to be video recorded during the sessions.*

☐ *No, I do not wish to be video recorded during the sessions but still wish to participate*.

Additionally, the exit interview may be video recorded. This video will be used for academic, educational, and/or training purposes, as well as study recruitment. If you do not agree, the interview will not be videotaped, but you can still participate in the study.

Do we have your permission to video record your interview?

☐ *Yes, I agree to be video recorded for the exit interview.*

☐ *No, I do not wish to be video recorded for the exit interview but wish to participate.*

You may be invited to complete an optional project during your participation. We are asking for your permission to save materials related to this project on our secure shared drive for research and training purposes. You are under no obligation to agree to this, and you may still participate in the study even if you do not give permission for us to save these materials.

Do we have your permission to save materials related to this optional project?

☐ *Yes, I agree to my materials being saved for this optional project.*

☐ *No, I do not agree to my materials being saved for this optional project.*

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)		