NCT#: NCT04867122

Title: Problem-Solving Therapy for Cancer Caregivers: A Randomized Clinical Trial in Outpatient Palliative Care

Date: 04/03/2023

[Insert greeting],

My name is **[insert name]**. I received your name and telephone number from **[name the facility that provided the information]**. I am calling you about a research study because you have been identified as a family member or friend of someone with cancer who is receiving healthcare from one of the institutions that is partnering with my team to conduct a research study**.** The purpose of this study is to learn if a new program we have created helps people like yourself solve problems they face when caring for someone with cancer.

Would you be interested in learning more about the study? Please feel free to ask questions at any time.

[If the individual states, "no"]
Thank you for your time and consideration. **[End the call]**

-OR-

[If the individual states, "yes"]

KEY INFORMATION
This is a research study conducted by Dr. Karla Washington having to do with family caregivers. You should carefully consider the information in this consent document and discuss it with the research team. You should understand why you might want to participate, or why you might not want to participate. You may choose to participate or not.

If you agree, you will be volunteering to participate in the research study. As a voluntary participant, you will be asked to spend approximately 30 minutes completing a series of survey questions online at three time points over the course of two months. You will also be asked to participate in three 45- to 60-minute phone conversations with a member of the research team, each about one week apart. All of your participation will occur remotely, meaning that you can complete the surveys and participate in the phone calls from your home. The main risks to you if you participate are frustration with scheduling calls in the midst of your many other caregiving responsibilities. You may also feel upset when describing some of your caregiving experiences.

You may benefit from volunteering because the conversations you have with the researchers may help you feel less distress or identify more positive aspects of your caregiving experience. By volunteering you may also help someone else in the future.

There is no cost to you. You will be paid up to $100 for being a volunteer participant. All of this information will be explained as we continue our conversation.

PHONE CONSENT
If you decide to take part in this study, you will be assigned to one of two groups. Your group will be determined by chance (like the flip of a coin). If you enroll in the study, a member of the

research team will run a computer program that indicates which group you will be in. The member of the research team signing you up for the study will have no control over which group you are in.

If you are assigned to the Attention Control group, you will be asked to complete a series of survey questions online. This will take around 30 minutes. You will be asked to complete the same questions online approximately four weeks and eight weeks after you enroll in the study. In addition, you will be asked to participate in three 45- to 60-minute conversations with a member of the research team, each about one week apart. You can choose whether to take part in these conversations over the phone or by using a secure, web-based video-conferencing program called Zoom. During these conversations, you will discuss a range of different topics such as how cancer centers can better support patients' families. You can share as much or as little information during these conversations as you like. Additionally, some people assigned to this group will also be asked to take part in an hour-long, audio-recorded interview during which they will be asked to discuss how members of their communities and/or social support networks (for example, their family members or friends) influence their experiences as family caregivers.

If you are assigned to the Intervention group, you will be asked to complete the same survey questions following the same schedule as group one. You will also be asked to take part in three 45- to 60-minute conversations (using the telephone or Zoom) with a member of the research team, just like the people in the first group. However, unlike the people assigned to the Attention Control group, during these calls you will learn and practice skills that might help you solve problems you encounter when caring for someone with cancer. Additionally, some people assigned to this group will also be asked to take part in an hour-long, audio-recorded interview during which we will ask questions about what it was like to learn and practice problem-solving skills or how members of their communities and/or social support networks influence their experiences as family caregivers. Only members of the research team will have access to these recordings, and they will be destroyed as soon as the analysis of the data from this study is complete.

Regardless of the group you are in, you will answer the same survey questions. The questions will ask you to provide basic demographic information such as your age and whether you live with the person with cancer whom you help. In addition, you will be asked to answer questions about your emotions and your experiences as a family caregiver.

Your private information will be shared with researchers at our participating sites at the University of Missouri, University of Pennsylvania and Washington University in St Louis. The interviews and group sessions may be completed by study teams at all three sites.

The National Cancer Institute and Barnard Trust are funding this research study.

Identifiers may be removed from your private information and used for future research or shared with others. If this occurs, we will not ask you for additional consent.

There are risks to taking part in any research study. There may be problems caused by the study that we do not know about yet. You may experience some frustration with scheduling telephone or Zoom calls in the midst of your many other caregiving responsibilities. You may also feel upset when describing some of your caregiving experiences. One of the questionnaires collects information about self-harm. All people completing the questionnaire will be given the contact information for the national suicide hotline. In addition, while we will do our best to make sure that your personal information from this study is kept confidential, there is the possibility of a confidentiality breach. Please do not hesitate to discuss any concerns with a member of our research team. If we learn about new important risks, we will tell you. We will also tell you about any new information we learn that may affect your decision to continue taking part in the study.

You will not have any costs for being in this research study. You will, however, remain financially responsible for costs associated with your Internet, telephone, or cellular data plan, regardless of the group you are in. So, for example, if you use a personal computer connected to the Internet to take part in a problem-solving session, you will be financially responsible for whatever it costs to use the Internet, but using the Zoom program will not cost extra.

In return for your time and effort, and to cover any expenses you incur as part of your study participation, you will be paid up to $100 total. $25 will be received after you complete the first series of survey questions, and $75 will be received after you participate in the conversations with the researcher and complete the final series of survey questions. You will be asked to provide your social security number (SSN) to be paid. If your social security number is obtained for payment purposes only, it will not be retained for research purposes. You will also need to provide an address where your check can be mailed.

We will keep the information you provide confidential by labeling information you provide with a code we will assign when you enroll in the study. This information will be stored on a highly restricted server at Washington University. Your name and contact information will be kept separate from your answers to the study questions and any information you provide during interviews. Information contained in your study records that could be used to identify you will not be shared with anyone who is not part of the research team without your specific permission except as required by law. Any report or article that we write will not include information that can directly identify you. However, federal regulatory agencies, Washington University, University of Missouri and University of Pennsylvania, including the Washington University Institutional Review Board (a committee that reviews and approves research studies) and the Human Research Protection Office may inspect and copy records pertaining to this research activity.

The Siteman Cancer Center at Washington University School of Medicine and Barnes-Jewish Hospital are supported by funding from the National Cancer Institute (NCI). To meet NCI requirements, identifiable information about you relating to your participation in this study (including your social security number) may be stored in a secure database at the Siteman Cancer Center. This database may be reviewed by Siteman Cancer Center personnel. All information

will be securely and confidentially maintained.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others*;*
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

Your participation in this study is completely voluntary. You may choose not to take part at all. If you decide to participate in the study, you may stop participating at any time. Any data that was collected as part of this study will remain as part of the study records and cannot be removed. If you decide not to take part in the study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

Some of the information we collect as part of this study is considered Protected Health Information (PHI) that identifies you. Your health information is protected by law under HIPAA (the Health Insurance Portability and Accountability Act). Because of this law, you will need to give the research team permission to use and share your protected health information for this research.

When possible, the research team will make sure information cannot be linked to you. Once information doesn't identify you, it may be used and shared for other purposes not discussed.

The information collected today during the phone consent may be seen by people making sure the research is being done right. This may be people at Washington University, people from the federal Office for Human Research Protections, the National Cancer Institute, and the Siteman Cancer Center Clinical Trials Office.

- If you agree, you are giving permission for us to use of your PHI for this research, and your permission will not expire.

- If you do not agree to allow us to use your PHI it will not affect your treatment or the care given by your health provider, insurance payments or enrollment in any health plans, or any benefits to which you are entitled. However, it will not be possible for you to take part in this study.

- Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

- If you change your mind and do not want the research team use or share your information, you will need to provide a written letter to the research team cancelling your permission. Please contact the Human Research Protection Office for more information on how to revoke your authorization or contact the research team to request the withdrawal letter. If you do this, the research team may only use and share information already collected for the study. You will not be allowed to continue to participate in the study.

- If you have questions or concerns about your privacy and the use of your protected health information, please contact the Washington University Privacy Officer at 866-747-4975.

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Dr. Washington at (314) 285 0905. If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 1-(800)-438-0445 or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.