MCC-22-19366
Forgotten Voices: Addressing Unmet Needs in Brain Tumor Caregivers (AIM 2)
NCT05590273
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RESEARCH SUBJECT INFORMATION AND CONSENT FORM

VCU IRB PROTOCOL NUMBER: HM20024428

STUDY TITLE: Forgotten Voices: Addressing Unmet Needs in Brain Tumor Caregivers

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ABOUT THIS CONSENT FORM

You are being invited to participate in a research study. **It is important that you carefully think about whether being in this study is right for you and your situation**. This consent form is meant to assist you in thinking about whether or not you want to be in this study. **Please ask the investigator or the study team to explain any information in this consent document that is not clear to you.** You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision. Your participation is voluntary. You may decide not to participate in this study. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

AN OVERVIEW OF THE STUDY AND KEY INFORMATION

Why is this study being done?

The purpose of this study is to see if a therapy approach called Managing Cancer and Living Meaningfully (abbreviated as CALM), which has previously shown to be helpful for patients with cancer, will be helpful for caregivers of patients with brain cancer. CALM was designed to help people with cancer and their loved ones manage the problems associated with their disease, yet research has not yet evaluated caregivers' participation in CALM. Specifically, we hope to better understand the potential benefits of this intervention and learn how to best adapt the intervention to fit the needs of caregivers. This may lead to improvements in our understanding of psychological well-being and quality of life of caregivers.

You were selected as a possible participant for this study because your loved one (patient with brain cancer) enrolled in the DoD CA200896 (IRB HM20022755; MCC-21-18040) trial of CALM therapy in brain cancer and has requested their caregiver join them in their CALM therapy sessions. You may participate in the CALM intervention without participating in this research study. All procedures used in this study are experimental.

What Will Happen if I Participate in The Study?

If you decide to participate in this research study, you will be asked to sign this consent form after you have had all your questions answered and understand what you will be asked to do. This study will enroll participants who serve as caregivers for patients diagnosed with brain cancer and participate in the CALM intervention as part of the DoD CA200896 (IRB

HM20022755; MCC-21-18040) trial. If you meet all study eligibility, you will be asked to do the following things:

1. Complete ~15-20-minute online surveys before the CALM intervention program (baseline) and immediately after the program (3 months). Questions will ask about your demographics, caregiving responsibilities, mood, existential distress, spirituality, quality of social relationships, and quality of life.

2. Meet with a study clinician and your loved one about every other week, 3-6 times for therapy sessions via Zoom, lasting 50-60 minutes each. Sessions are led by trained clinicians under the supervision of Dr. Loughan. These sessions will be video recorded to ensure all participants receive the same care. You may choose to opt out of recording your sessions at the bottom of this consent.

3. Complete ~5-minute online surveys after each session on your satisfaction with the program.

4. Complete an exit interview by telephone within 1 month (4-month timepoint) after the 6-session intervention. This exit interview will last approximately 15-30 minutes.

Your participation in this study will last up to 4 months. Approximately 6 caregivers will participate in this study.

What alternative treatments or procedures are available?
Participation in this study does not impact your ability to receive treatment from the team. If you do not participate, you are still able to join your loved one in their CALM sessions. You may also receive usual care, including referrals to community providers. The study team will discuss these options with you.

What are the risks and benefits of participating?
Research studies often involve some risks. However, the risks of this study are minimal. Sometimes answering questions about your psychological and emotional health can cause people to become upset. Some of the questions may be difficult while others may be easy for you. You do not have to answer any questions that make you upset. If you become upset, the study team will provide your resources for support.

As with any study, there is a potential risk of compromising confidentiality. However, this is unlikely, as your personal information will be kept private and any information you provide will be stored in a secure manner. Results from this study may be published but individual participants will not be identified in the publications.

You may notice improvement in your mood, which can affect your quality of life and relationships. There is evidence to suggest the CALM program has benefits for patients. However, there have not been research studies for CALM in caregivers. Therefore, there is a possibility you may not get any direct benefit from this study, but the information we learn from people in this study may help us design better programs for caregivers of brain cancer patients

WHAT ARE THE COSTS?
There are no financial costs for participating in this study. However, study participation will involve spending time meeting with the researchers, completing online surveys, and attending the CALM intervention sessions.

WILL I BE PAID TO PARTICIPATE IN THE STUDY?
You will be paid $20 in Amazon e-gift cards upon completion of: (1) baseline questionnaires and (2) post-CALM intervention questionnaires (after 3-6 sessions) and subsequent phone interview with study team (4 months). If you complete all components, you will receive a total of $40 in Amazon e-gift cards. If you withdraw before the end of the study, you will only receive a $20 Amazon e-gift card if you completed study visit one.

Total payments within one calendar year that exceed $600 will require the University to report these payments annually to the IRS and you. This may require you to claim the compensation you receive for participation in this study as taxable income. VCU is required by federal law to collect your social security number. Your social security number will be kept confidential and will only be used to process payment.

CAN I STOP BEING IN THE STUDY?
You can withdraw from this research study at any time. Leaving the study will not affect your (or your loved one's) medical care, employment status, or academic standing at VCU, VCU Massey Cancer Center, or VCU Health. Tell the study team if you are thinking about stopping or decide to stop.

Your participation in this study may be stopped at any time by the investigator without your consent. The reasons might include:

- the investigator thinks it necessary for your health or safety
- your loved one or yourself are found to not be eligible for the study
- you have not followed study instructions
- administrative reasons require your withdrawal

HOW WILL INFORMATION ABOUT ME BE PROTECTED?
VCU and the VCU Health System have established secure research databases and computer systems to store information and to help with monitoring and oversight of research. Your information may be kept in these databases but are only accessible to individuals working on this study or authorized individuals who have access for specific research related tasks. Identifiable information in these databases is not released outside of VCU unless stated in this consent or required by law. Although results of this research may be presented at meetings or in publications, identifiable personal information about participants will not be disclosed. Personal information about you might be shared with or copied by authorized representatives from the following organizations for the purposes of managing, monitoring, and overseeing this study:

- Representatives of VCU and the VCU Health System
- Officials of the Department of Health and Human Services

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Web site at any time.

In general, we will not give you any individual results from the study. If we find something of medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

If you disclose to us that you may cause injury to yourself or others, we are required by law to report that information to the appropriate authorities. In the case that you report active suicidal ideation and pose an imminent threat to yourself or others, 911 will be alerted to do a welfare check.

In the future, identifiers will be removed from the information you provide in this study, and after that removal, the information/samples could be used for other research studies by this study team or another researcher without asking for additional consent.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may decide to not participate in this study. Your decision not to take part will involve no penalty or loss of benefits to which you are otherwise entitled. If you do participate, you may freely withdraw from the study during active data collection. Your decision to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled. If you would like the withdraw your data, please contact one of the researchers listed below.

WHOM SHOULD I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?

If you have any questions, complaints, or concerns about your participation in this research, the investigator named below is the best person to contact:

Ashlee R. Loughan, Ph.D.
Principal Investigator
Address: McClothlin Medical Education Center
1201 East Marshall St, Room 12-213
Box 980070
Richmond, VA 23298
Telephone: (804) 828-9815

If you have any general questions about your rights as a participant in this study or in any other research, or if you wish to discuss problems, concerns or questions, to obtain information, or to offer input about research, you may contact:

Virginia Commonwealth University Office of Research
800 East Leigh Street, Suite 3000, Box 980568, Richmond, VA 23298
Telephone: 804-827-2157
Website: https://research.vcu.edu/human_research/volunteers.htm

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

I have been given the chance to read this consent form. I understand the information about this study. Questions that I wanted to ask about the study have been answered. My signature says that I am willing to participate in this study. I will receive a copy of the consent form once I have agreed to participate.

I permit the researchers to video record sessions. All recordings will be used for supervision purposes and these recording will be destroyed at the end of the study. Check Yes or No.

____Yes
____No

Participant name printed: _____

Participant signature: _____

Date: _____

_____
Name of Person Conducting Informed Consent Discussion / Witness

_____ _____
Signature of Person Conducting Informed Consent Discussion / Witness Date

_____ _____
Principal Investigator Signature (if different from above) Date