MCC-20-16440
HM20020308
11/19/2020
NCT04646213

RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM (CAREGIVER)

STUDY TITLE: Managing Cancer and Living Meaningfully (CALM) in Primary Brain Tumor Patients

VCU INVESTIGATOR: Ashlee Loughan, PhD, Neuropsychologist, Assistant Professor of Neurology, Division of Neuro-oncology, 804-828-9815

SPONSOR: American Cancer Society Institutional Research Grant

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 staff 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 research study is to find out if a psychotherapy developed for cancer patients, called CALM, will be feasible and acceptable in adult patients with brain tumors and their caregivers. We think that CALM may help to reduce cancer-related distress in brain tumor patients and their caregivers because it was found to do so in other cancer patients. We want to learn if CALM reduces distress and improves quality of life. We also want to learn what aspects of CALM may be helpful, if any, and how we might improve upon this psychotherapy in the future. This study will allow us to learn more about CALM for patients with brain tumors.

The results of this study will help us develop more services for brain tumor patients and their loved ones.

What will happen if I participate?

In this study, you will be asked to do the following things:

1. Take surveys and answer questions about your mood, anxiety, and feelings about your loved-one's diagnosis and prognosis. These surveys will be emailed to you at 1-week before your loved one participates in the CALM intervention, immediately following the intervention (3-month timepoint), and 3-months after the intervention (6 month timepoint).
2. If interested, caregivers are welcome to participate in the CALM intervention with their loved ones – though this is not required to participate in the study. The frequency of visits is flexible and will be determined based on your and your loved-one's preferences and needs.

Your participation in this study will last up to 6 months. Approximately 24 individuals will participate in this study.

What alternative treatments or procedures are available?

If you decide not to enter this study, your loved-one can still participate. They can also receive the usual care that they would receive even if you (or they) were not in the study. This includes medical treatment for their brain tumor and/or referrals to neuropsychology or social work services. The study staff will discuss these options with you.

What are the risks and benefits of participating?

There are both risks and benefits of participating in research studies. We want you to know about a few key risks right now. We will give you more information in the "WHAT RISKS AND DISCOMFORTS CAN I EXPECT FROM BEING IN THE STUDY?" section.

Risks and Discomforts	Benefits to You and Others
• Participation in research might involve some loss of privacy. There is a small risk that someone outside the research study could see and misuse information about you. • The study questionnaires ask questions that are sensitive, personal, and upsetting in nature and may make you feel uncomfortable.	There is some evidence that CALM is effective in reducing cancer-related distress for patients. However, it is unlikely that it will work with everyone, and we cannot promise that it will help your loved one. This study may help the investigators learn things that may help other people in the future.

Now that you have a general overview of the study, we want to provide the details about what your participation involves. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask the study staff.

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 of your questions answered and understand what will happen to you.

If you choose to consent to this study, you will spend approximately 30-minutes filling out online questionnaires about your mood, feelings towards your loved one's diagnosis, and other mental health symptoms 1-week prior to your loved one starting the intervention.

Immediately following the intervention (3-month timepoint), you will be asked to complete the same series of psychological measures and again at 3-months post-intervention (6-month timepoint). Your answers will have no bearing on you or your loved one's clinical care or your future research opportunities.

WHAT RISKS AND DISCOMFORTS COULD I EXPERIENCE FROM BEING IN THE STUDY?

Non-Physical Risks
Participation in research might involve some loss of privacy. There is a small risk that someone outside the research study could see and misuse information about you.

Questionnaires may contain questions that are sensitive, personal, and upsetting in nature. You may refuse to answer any question that makes you feel uncomfortable.

You may learn things about yourself that you did not know before and that could affect how you think about yourself.

CAN I STOP BEING IN THE STUDY?
You can stop being in 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 or VCU Health. Tell the study staff 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
- you're 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?

If you choose to participate in this study, you will be assigned a study ID number, which will be used on all questionnaires. You will be asked to provide your email address in order to receive follow-up surveys. Our online data collection system, RedCap, allows the designation of fields as identifiers. The email field will be tagged as an identifier. RedCap allows you to export data without identifiers attached. Also, RedCap enables you to restrict who has access to identifiers. Once data collection is complete, data will be exported from RedCap without identifiers. No user other than the primary researchers will have access to identifiers. The data are being collected only for research purposes. When data collection is finished, ID numbers will identify your data, not emails. Access to all data will be limited to study personnel and access to identifying information will be limited to only the primary researcher.

This research involves the transmission of data over the internet. Although every reasonable effort has been taken to ensure the effective use of available technology, confidentiality during the actual Internet communication procedure cannot be guaranteed.

We will not tell anyone the answers you give us; however, information from the study may be looked at or copied for research or legal purposes by Virginia Commonwealth University's Health System.

What we find from this study may be presented at meetings or published in papers, but your name will not ever be used in these presentations or papers.

Should you qualify and express interest to participate in the study, 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.

If you tell us that you may hurt yourself or someone else, the law says that we must let people in authority know. 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 might be removed from the information you provide in this study, and after that removal, the information could be used for other research studies by this study team or another researcher without asking you 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.

Participant name printed: _____

Participant signature:_____

Date: _____

STATEMENT OF CONSENT

I have been provided with an opportunity to read this consent form carefully. All of the questions that I wish to raise concerning this study have been answered. By signing this consent form, I have not waived any of the legal rights or benefits to which I otherwise would be entitled. My signature indicates that I freely consent to participate in this research study. I will receive a copy of the consent form for my records.

Signature Block for Enrolling Adult Participants	
_____ Adult Participant Name (Printed)	
_____ Adult Participant's Signature	_____ Date
_____ Name of Person Conducting Consent Discussion (Printed)	
_____ Signature of Person Conducting Consent Discussion	_____ Date
_____ Principal Investigator Signature (if different from above)	_____ Date