PRINCIPAL INVESTIGATOR: Terri Armstrong, PhD, ANP-BC

STUDY TITLE: Managing Cancer and Living Meaningfully (CALM) Therapy in Individuals Diagnosed with a Primary Central Nervous System Tumor

STUDY SITE: NIH Clinical Center

Cohort: Affected patient

Consent Version: 05/06/2022

WHO DO YOU CONTACT ABOUT THIS STUDY?

Principal Investigator: Terri Armstrong, PhD, ANP-BC
240-760-6003
Email: terri.armstrong@nih.gov

KEY INFORMATION ABOUT THIS RESEARCH

This consent form describes a research study and is designed to help you decide if you would like to be a part of the research study.

You are being asked to take part in a research study at the National Institutes of Health (NIH). This section provides the information we believe is most helpful and important to you in making your decision about participating in this study. Additional information that may help you decide can be found in other sections of the document. Taking part in research at the NIH is your choice.

You are being asked to take part in this study because you are an English-speaking adult, who has been diagnosed with a primary central nervous system tumor (PCNST) and who is participating in our Natural History Study.

The purpose of this research study is to understand if the therapy intervention, referred to as Managing Cancer and Living Meaningfully (CALM) can help people with PCNST suffering from distress. By distress, we refer generally to negative feelings such as being angry, afraid, sad, or anxious.

CALM therapy was developed to promote well-being in people with cancers (other than brain and spine cancers) that cannot be cured and has reported positive effects.

Often, a person in distress may be advised to seek mental health counseling. The goal of CALM therapy is to provide a supportive and reflective space for you to process your distress.

If you decide to join this study, here are some of the most important things that you should know that will happen:

- You will be asked to fill out questionnaires addressing your well-being before CALM therapy and approximately 3 and 6 months after therapy.

- You will be assigned to a CALM therapist and have 3-6 individual therapy sessions, each approximately 45-60 minutes in length, delivered over 6 months. If your therapist thinks it is necessary, you may have additional sessions during the six month period.
- After the 3rd session, we may interview you and ask how it feels to be in CALM therapy.
- We would like your family member (e.g., spouse, adult son/daughter, or other persons close to you) to participate in at least one CALM session with you. However, your family member does not have to participate.
- You do not need to come to the NIH Clinical Center for this study. All interactions will be done remotely by smartphone, computer, or tablet. Sessions will be audio recorded for quality assurance purposes. You can request that the session not be recorded and still be able to participate in the study. Depending on your plan, you may have to pay extra to your internet or data plan provider for access to the study software.
- Your participation on the study will last for approximately 6 months.

There are potential risks in therapy. Earlier studies with CALM have produced no negative feedback from participants about their experiences of CALM. There are also risks to the potential exposure of your information and your potential discomfort with some of the questions we might ask. You will not be required to answer questions that make you uncomfortable and measures are in place to safeguard your data.

This study may benefit you by reducing distress and making you feel better. Results from our research may help others in the future.

We do not think there are serious risks or discomforts associated with participation in this study.

You are free to stop participating in the trial at any time. If you decide to stop, the study researcher may ask you a few questions before stopping to assure that you withdraw from the study safely.

The remaining document will now describe the research study in more detail. This information should be considered before you make your choice. Members of the study team will talk with you about the information in this document. Some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research interventions in which they would want to participate. Take the time you need to ask any questions and discuss this study with NIH staff, and with your family, friends, and personal health care providers.

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

You may choose not to take part in this study for any reason. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. In either case, you will not lose any benefits to which you are otherwise entitled. However, to be seen at the NIH, you must be taking part in a study or are being considered for a study. If you do choose to leave the study, please inform your study team to ensure a safe withdrawal from the research.

WHY IS THIS STUDY BEING DONE?

This is a research study. The purpose of this research study is to find out if the managing Cancer and Living Meaningfully (CALM) therapy can help people with PCNST suffering from distress. By distress, we mean negative feelings such as being angry, afraid, sad, or anxious.

CALM therapy was developed to promote well-being in people with cancer (other than brain cancer) that cannot be cured. People who participated in CALM had positive experiences. We want to find out if PCNST patients have a positive response and whether CALM can be delivered remotely rather than in person.

We are asking you to join this research study because you are an English-speaking adult who has been diagnosed with a brain tumor and is participating in our Natural History Study.

WHAT WILL HAPPEN DURING THE STUDY?

If you decide to take part in this study, you will be asked to fill out questionnaires and participate in the CALM therapy sessions. You do not need to come to the NIH Clinical Center for this study. All interactions will be done remotely by smartphone, computer, or tablet. Sessions will be audio recorded for quality assurance purposes. You can request that the session not be recorded and still be able to participate in the study. The recordings will be securely collected and stored.

Initial Evaluation

During your initial evaluation, you will be asked to electronically fill out questionnaires, which are estimated together to take approximately 40-60 minutes to complete. If you already completed 2 of these questionnaires during the past 2 months while on the Natural History study, you do not need to complete them again.

These questionnaires will ask you about physical and emotional symptoms that have bothered you, depression, how distressed you feel about death and dying, how you feel in close relationships with others, and general well-being.

Individual Therapy Sessions

You will be assigned to a CALM therapist and have 3-6 individual therapy sessions, each approximately 45-60 minutes in length, delivered over 6 months.

CALM includes 4 related parts that will be discussed during sessions:

- Symptom management and communication with health care providers
- Changes in self and relations with close others
- Sense of meaning and purpose
- The future and mortality

We would like your family member (e.g., spouse, adult son/daughter, or other persons close to you) to participate in at least one CALM session with you. We will ask your family member questions about the overall experience in the CALM intervention. However, your family member is not required to participate.

Interview with Staff

After the 3rd CALM therapy session, you may or may not be asked to participate in an interview. A member of the study team will ask you questions about the CALM intervention. This qualitative interview will last approximately 15-20 minutes; your family member may participate in this interview.

Follow-Up Questionnaires

After approximately 3 and 6 months, we will ask you to complete questionnaires addressing your well-being and your participation in this study. If you already completed 2 of these questionnaires around this time on the Natural History study, you do not need to complete them again.

If your CALM therapist thinks it is necessary, you may have additional sessions within the 6 months of your participation.

HOW LONG WILL THE STUDY TAKE?

Your participation on the study will last for approximately six months.

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

We plan to have approximately 100 people participate in this study at the NIH.

WHAT ARE THE RISKS AND DISCOMFORTS OF BEING IN THE STUDY?

Potential risks to psychotherapy

CALM is a type of psychotherapy. There are potential risks to psychotherapy. You may initially feel worse as the therapy progresses. In rare cases, psychotherapy may even trigger some people to have thoughts about wanting to hurt themselves or end their lives. You will be asked to provide names and phone numbers for a good primary contact (living in the home or outside) and health care provider. We will confirm your location, create a brief safety plan (identify coping strategies, provide professional emergency contacts) to minimize risk of harm, and contact your primary contact and health care provider to ensure they are aware of the situation so that appropriate medical attention can be provided.

Risks of questionnaires

You may feel uncomfortable answering questions about your health and well-being. Please, only answer questions that you are comfortable with.

Risks of interviews

Some of the questions the interviewer will ask may be upsetting or make you feel uncomfortable. You do not have to answer any questions you do not want to answer, and you can stop at any time.

Also See “Invasion of Privacy/Breach in Confidentiality” below.

INVASION OF PRIVACY/BREACH IN CONFIDENTIALITY

Because this study involves collecting personal, identifiable information about you, there is a possibility that people who are not supposed to see this information might somehow gain access to it. We will take precautions to prevent this, but we cannot ever be certain that it won’t happen. To minimize this chance, we will assign you a study number instead of labeling the information

we collect from you with your name [or medical record number]. All of the information we collect will be stored in a secure manner, such as in a locked cabinets or password protected computer files.

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

You might not benefit from being in this study. CALM may make you feel better.

Are there any potential benefits to others that might result from the study?

Brain cancer patients may benefit from this study through the knowledge gained from your participation.

WHAT OTHER OPTIONS ARE THERE FOR YOU?

Before you decide whether or not to be in this study, we will discuss other options that are available to you. Instead of being in this study, you could choose not to participate. While enrolled in this study, you will remain under the care of your physician and another protocol of the National Institutes of Health.

DISCUSSION OF FINDINGS

New information about the study

If we find out any new information that may affect your choice to participate in this study, we will get in touch with you to explain what we have learned. This may be information we have learned while doing this study here at the NIH or information we have learned from other scientists doing similar research in other places.

Return of research results

We do not plan to return your individualized study results to you.

EARLY WITHDRAWAL FROM THE STUDY

Your doctor may decide to stop your participation for the following reasons:

- if you do not follow the study rules
- if the study is stopped for any reason

In this case, you will be informed of the reason why your participation in the study is being stopped.

You can stop taking part in the study at any time. However, if you decide to stop taking part in the study, we would like you to talk to the study doctor and your regular doctor first.

If you decide at any time to withdraw your consent to participate in the study, we will not collect any additional medical information about you. However, according to FDA guidelines, information collected on you up to that point may still be provided to designated representatives.

STORAGE, SHARING AND FUTURE RESEARCH USING YOUR DATA

Will your data be saved for use in other research studies?

As part of this study, we are obtaining data from you. We will remove all the identifiers, such as your name, date of birth, address, or medical record number and label your data with a code so that you cannot easily be identified. However, the code will be linked through a key to

information that can identify you. We plan to store and use these data for studies other than the ones described in this consent form that are going on right now, as well as studies that may be conducted in the future. These studies may provide additional information that will be helpful in understanding primary central nervous system tumors, or other diseases or conditions. This could include studies to develop other research tests, treatments, drugs, or devices, that may lead to the development of a commercial product by the NIH and/or its research or commercial partners. There are no plans to provide financial compensation to you if this happens. Also, it is unlikely that we will learn anything from these studies that may directly benefit you.

I give permission for my coded data to be stored and used for future research as described above.

_____ Yes _____ No

Initials Initials

Will your data be shared for use in other research studies?

We may share your coded data with other researchers. If we do, while we will maintain the code key, we will not share it, so the other researchers will not be able to identify you. They may be doing research in areas that are similar to this study or in other unrelated areas. These researchers may be at NIH, other research centers and institutions, or commercial entities.

I give permission for my coded data to be shared with other researchers and used by these researchers for future research as described above.

_____ Yes _____ No

Initials Initials

If you change your mind and do not want us to store and use your data for future research, you should contact the research team member identified at the top of this document. We will do our best to comply with your request but cannot guarantee that we will always be able to destroy your data. For example, if some research with your data has already been completed, the information from that research may still be used. Also, for example, if the data have been shared already with other researchers, it might not be possible to withdraw them.

In addition to the planned use and sharing described above, we might remove all identifiers and codes from your data and use or share them with other researchers for future research at the NIH or other places. When we or the other researchers access your anonymized data, there will be no way to link the data back to you. We will not contact you to ask your permission or otherwise inform you before we do this. We might do this even if you answered "no" to the above questions. If we do this, we would not be able to remove your data to prevent their use in future research studies, even if you asked, because we will not be able to tell which are your data.

NIH policies require that your clinical and other study data be placed in an internal NIH database that is accessible to other NIH researchers for future research. Usually, these researchers will not have access to any of your identifiers, such as your name, date of birth, address, or medical record number; and your data will be labeled with only a code. We cannot offer you a choice of whether your data to be placed in this database or not. If you do not wish to have your data placed in this database, you should not enroll in this study.

How long will your data be stored by the NIH?

Your data may be stored by the NIH until they are no longer of scientific value or if you withdraw consent for their continued use, at which time they will be destroyed. Your data may be stored by the NIH indefinitely.

Risks of storage and sharing of data

When we store your data, we take precautions to protect your information from others that should not have access to it. When we share your data, we will do everything we can to protect your identity, for example, when appropriate, we remove information that can identify you. Even with the safeguards we put in place, we cannot guarantee that your identity will never become known, or someone may gain unauthorized access to your information. New methods may be created in the future that could make it possible to re-identify your data.

PAYMENT

Will you receive any type of payment for taking part in this study?

You will not receive any payment for taking part in this study.

REIMBURSEMENT

Will you receive reimbursement or direct payment by NIH as part of your participation?

This study does not offer reimbursement for participants, or payment of, hotel, travel, or meals.

COSTS

Will taking part in this research study cost you anything?

NIH does not bill health insurance companies or participants for any research or related clinical care that you receive at the NIH Clinical Center.

Depending on your plan, you may have to pay extra to your internet or data plan provider for access to the study software.

CLINICAL TRIAL REGISTRATION AND RESULTS REPORTING

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 Web site will include a summary of the results. You can search this Web site at any time.

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Some of your health information from this study will be kept in a central database for research. Your name or contact information will not be put in the database. Your information may be given out if required by law. For example, certain states require doctors to report to health boards if

they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you.

Will your medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The NIH and other government agencies, like the Food and Drug Administration (FDA), which are involved in keeping research safe for people.
- National Institutes of Health Intramural Institutional Review Board

The researchers conducting this study and the NIH follow applicable laws and policies to keep your identifying information private to the extent possible. However, there is always a chance that, despite our best efforts, your identity and/or information about your participation in this research may be inadvertently released or improperly accessed by unauthorized persons.

In most cases, the NIH will not release any identifiable information collected about you without your written permission. However, your information may be shared as described in the section of this document on sharing of data, and as further outlined in the following sections.

Further, the information collected for this study is protected by NIH under a Certificate of Confidentiality and the Privacy Act.

Certificate of Confidentiality

To help us protect your privacy, the NIH Intramural Program has received a Certificate of Confidentiality (Certificate). With this certificate, researchers may not release or use data or information about you except in certain circumstances.

NIH researchers must not share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if requested by a court.

The Certificate does not protect your information when it:

1. is disclosed to people connected with the research, for example, information may be used for auditing or program evaluation internally by the NIH; or
2. is required to be disclosed by Federal, State, or local laws, for example, when information must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA);
3. is for other research;
4. is disclosed with your consent.

The Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing below you consent to those disclosures. Other permissions for release may be made by signing NIH forms, such as the Notice and Acknowledgement of Information Practices consent.

Privacy Act

The Federal Privacy Act generally protects the confidentiality of your NIH medical information that we collect under the authority of the Public Health Service Act. In some cases, the Privacy Act protections differ from the Certificate of Confidentiality. For example, sometimes the Privacy Act allows release of information from your record without your permission, for example, if it is requested by Congress. Information may also be released for certain research purposes with due consideration and protection, to those engaged by the agency for research purposes, to certain federal and state agencies, for HIV partner notification, for infectious disease or abuse or neglect reporting, to tumor registries, for quality assessment and medical audits, or when the NIH is involved in a lawsuit. However, NIH will only release information from your medical record if it is permitted by both the Certificate of Confidentiality and the Privacy Act.

POLICY REGARDING RESEARCH-RELATED INJURIES

The NIH Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH, the NIH Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

PROBLEMS OR QUESTIONS

If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Terri Armstrong, PhD, ANP-BC, email: terri.armstrong@nih.gov, and telephone: 240-760-6003. You may also call the NIH Clinical Center Patient Representative at 301-496-2626, or the NIH Office of IRB Operations at 301-402-3713 if you have a research-related complaint or concern.

CONSENT DOCUMENT

Please keep a copy of this document in case you want to read it again.

Adult Research Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I consent to participate in this study.

Signature of Research Participant	Print Name of Research Participant	Date

Investigator:

Signature of Investigator	Print Name of Investigator	Date