MCC-22-19485
FearLess in Cognitively Intact Patients with Glioma
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RESEARCH SUBJECT INFORMATION AND CONSENT FORM
VCU IRB PROTOCOL NUMBER: HM20025081
MCC PROTOCOL NUMBER: MCC-22-19485

STUDY TITLE: FearLess in Cognitively Intact Patients with Glioma

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SPONSOR: Massey Cancer Center

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 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 newly developed therapy approach called FearLess. Similar therapies have been shown to be helpful with other individuals with cancer and we are examining if FearLess will be helpful for those with brain tumors. Specifically, we hope to better understand the potential benefits of this intervention to support mood and quality of life. This may lead to improvements in our understanding of how to enhance brain tumor patient's wellbeing and overall functioning. Another purpose of this study is identify future adaptations needed to FearLess.

You were selected as a possible participant for this study because you are receiving medical care for a brain tumor at the VCU Massey Cancer Center.

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 you will be asked to do. This study will enroll participants who have been diagnosed with a glioma. The total duration of your participation in this study is expected to be approximately 3-4 months. If you have been diagnosed with a glioma and choose to participate in this study, you will be asked to do the following things:

1. Complete ~30-minute online surveys before the FearLess intervention program (baseline) and immediately after the program (post-intervention; 8-12 weeks). Questions will ask about your fear of cancer recurrence, mood, and quality of life.
2. Allow researchers to access your medical records in order to collect data about your diagnosis and treatment history.
3. Meet with a study clinician weekly for a total of 8-12 sessions via Zoom, lasting 60 minutes each. Sessions are led by trained study team members under the supervision of Dr. Loughan. These sessions will be video-recorded to ensure all participants receive the same information. We'll ask all participants to only use first names. You may choose to opt out of recording your sessions at the bottom of this consent.

4. Complete ~5 minute online surveys after each session on your satisfaction with the program.
5. Complete an exit interview by telephone approximately 1 month after the 8-12 session intervention. This exit interview will last approximately 30 minutes.

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 will be able to access treatment as usual care in clinic. This includes regular neuropsychological evaluations and recommendations from Dr. Loughan. The study team will discuss these options with you. You do not have to participate in this study to be treated for any mental health or cognitive concerns related to your diagnosis and treatment.

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. If you become upset, the study team will provide your resources for support.

There is a low risk of physical injury associated with physical activity, even gentle forms such as chair yoga. For example, mild physical activity may cause sore or pulled muscles, physical discomfort (e.g. increased heart rate, shortness of breath, and/or fatigue), and/or accidental injuries such as falling. However, the gentle chair yoga taught in this intervention will be guided by trained interventionists familiar with teaching yoga-naïve individuals. The classes are designed for people of any fitness level and experience with yoga is not needed.

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.

If you are enrolling in the study alongside a caregiver, there is a risk that your relationship with that person may change because the intervention is meant to enhance communication about fear of cancer recurrence. We expect that these changes will improve your relationship; however, there is a risk that you experience negative relationship changes. If this is the case, we will discuss your options including stopping the intervention and/or referring you to couples' or family therapy.

You may notice improvement in your mood, which can affect your quality of life and relationships. However, there is a possibility you may not get any direct benefit from this study. The information we learn from people in this study may help us design better programs for brain tumor patients.

Details about what your participation involves are provided below. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, please ask the study team for help.

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 FearLess intervention sessions.

WILL I BE PAID TO PARTICIPATE IN THE STUDY?
You will be paid $25 e-gift cards upon completion of each of the following: 1) baseline questionnaires; 2) post-intervention questionnaires; 3) telephone exit interview. If you complete all scheduled study visits, you will receive a total of $75 in e-gift cards.

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 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
- you have not followed study instructions or don't respond to follow-up contacts to finish the study

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 are 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.

Massey Cancer Center is funding or supporting this study. Massey will be allowed access to research records as a part of its human subjects protection oversight activities. 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 (DHHS)

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.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will include a summary of the results and will not include any identifiable information. 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.

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.

HOW WILL MY HEALTH INFORMATION BE USED AND SHARED DURING THIS STUDY?

As part of this research study, we will ask you to share identifiable health information with us and/or permit us to access existing information from your healthcare records. This type of information is considered "Protected Health Information" that is protected by federal law.

What type of health information will be used or shared with others during this research?
The following types of information may be used for the conduct of this research:

- Your name
- Medical record number
- Birthdate
- Dates of diagnosis / treatment /evaluation
- Information from your complete health record

Who will use or share protected health information about me?
VCU and VCU Health are required by law to protect your identifiable health information.
By consenting to this study, you authorize VCU/VCU Health to use and/or share your health information for this research. The health information listed above may be used by and/or shared with the following people and groups to conduct, monitor, and oversee the research:

- Principal Investigator and Research Staff
- Institutional Review Boards
- Government/Health Agencies
- Others as Required by Law

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

When will this authorization (permission) to use my protected health information expire?
This authorization will expire when the research study is closed, or there is no need to review, analyze, and consider the data generated by the research project, whichever is later.

Statement of Privacy Rights
You may change your mind and revoke (take back) the right to use your protected health information at any time. Even if you revoke this Authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you revoke this Authorization you may no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the Principal Investigator. Should you revoke authorization, you will no longer receive FearLess therapy sessions or study-related payments.

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: McGlothlin 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: _____

Signature of Person Conducting Informed Consent_____ Date:_____

Principal Investigator Signature:_____ Date:_____