MCC-20-16188
NCT04919993
HM20019949
3/24/2021

RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE: Cognitive Behavioral Therapy for Insomnia in Primary Brain Tumor Patients

VCU INVESTIGATOR: Ashlee Loughan, Ph.D., Assistant Professor of Neurology
Phone Number: 804-828-9815

ABOUT THIS CONSENT FORM

If any information contained within this consent form is not clear, please ask study staff to explain any information that you do not fully understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

PURPOSE OF THE STUDY

The purpose of this research study is to investigate the effect of a brief online behavioral intervention, cognitive behavioral therapy for insomnia (CBT-I), on brain tumor patients' insomnia symptoms. Specifically, we hope to better understand the potential benefits of this intervention on brain tumor patients' sleep, fatigue, mood, and chronic inflammation. This may lead to improvements in our understanding of how to enhance brain tumor patients' health, quality of life and overall functioning. You were selected as a possible participant for this study because you are receiving medical care for a primary brain tumor at the VCU Massey Cancer Center and reported having some symptoms of insomnia.

PROCEDURES

If you decide to participate in this study you will be asked to sign this consent form after you had all of your questions answered and understand what will happen to you. At the start of the study, you will be asked to complete online questionnaires related to your current sleep, fatigue, pain, health, cognition, and mood (e.g., symptoms of generalized anxiety, depression, and death-related anxiety) and complete a few tasks which examine your thinking abilities and memory. These questionnaires and tasks will take approximately 30 minutes to complete. We will mail you a wrist-worn monitor to wear for 1 week prior to beginning the program that measures your sleep and activity. In addition, we will use some of your blood sample (collected as part of your standard of care routine lab draws) to analyze levels of chronic inflammation. Please note, we will not collect any additional blood (in terms of amount or frequency) than is required to meet standards of care. The blood drawn at these visits would occur regardless of your participation status in this study.

Following this initial intake assessment, you will be asked to participate in six online sessions of group cognitive behavioral therapy for insomnia (CBT-I) over Zoom. CBT-I is a manualized, psychotherapeutic treatment commonly used to combat symptoms of insomnia is a variety of populations. Each CBT-I session will last approximately 90 minutes and will include 6-7 other participants. Session One will provide a general overview of CBT-I. Sessions Two and Three will introduce behavioral and relaxation strategies to address sleep disturbance. Sessions Four and Five will address unhelp thoughts which may contribute to sleep disturbance. Finally, Session Six will provide a summary of all of the information covered. Each week you will be asked to complete a sleep diary to track your sleep and be encouraged implement strategies covered during each group session which are designed to help improve your sleep.

Following the six weeks of CBT-I sessions, you will be asked to complete the same battery of online questionnaires and tasks again. Similar to the baseline assessment, these questionnaires will take approximately 30 minutes to complete. We will mail you a wrist-worn monitor to wear for 1 week prior to beginning the program that measures your sleep and activity. In addition, we will use some of your blood sample (collected as part of your standard of care routine lab draws) to analyze levels of chronic inflammation. As before, we will not collect any additional blood (in terms of amount or frequency) than is required to meet standards of care. The blood drawn at these visits would occur regardless of your participation status in this study. Lastly, we will ask you to complete the questionnaires only a third final time, three months following the CBT-I intervention; we will also ask you at this time to answer a few questions about your satisfaction with the program. Overall, your participation in this study will last a total of five to six months, though the CBT-I intervention itself only occur for six consecutive weeks. A maximum of 125 of participants will be enrolled in this study.

You may be (virtually) accompanied to these sessions by one, adult caregiver of your choice if you would like (though this is not required for participation). Upon the completion of the intervention, we would like to contact your caregiver via telephone to inquire about any potential benefits noted over the course of this intervention. If your caregiver would like to participate in this part of the study, please indicate below and provide the name of the caregiver and their phone number.

☐ Yes, I would like my caregiver to provide feedback about their perception of the intervention, and they have agreed for me to share their contact information with the study team.

Caregiver Name: _____

Phone Number: _____

ALTERNATIVE

If you decide not to participate this study, you can receive the usual care that you would receive even if you were not in the study. The study staff will discuss these options with you. You do not have to participate in this study to be treated for insomnia or sleep disturbance. Cognitive Behavioral Therapy for Insomnia (CBT-I) is an evidence-based treatment offered by various trained licensed psychologists. Patients may receive referrals for such therapists upon request. At this time, there are no other known local providers with a specific background in neuro-oncology who deliver CBT-I; nevertheless, patients may still find an alternative delivery of CBT-I to be effective. If the patient would like to receive pharmacological treatment for insomnia, he or she may consult with their physician(s) about prescription (e.g., Ambien) and/or over-the counter (e.g., melatonin) medications.

BENEFITS

There is some evidence that CBT-I is effective in reducing insomnia symptoms and improving sleep quality. However, it is unlikely that CBT-I will work for everyone, and we cannot promise that it will help you. Nevertheless, this study may help the investigators learn about the effect of CBT-I among patients with a primary brain tumor.

RISKS AND DISCOMFORTS

Research studies often involve some risks. There is a chance that your sleep may not get better or may become worse while you are in this study. In addition, sometimes answering questions about your emotional health, or participating in group tasks/activities related to their health can

cause some people to become upset. You do not have to answer any questions or complete any tasks that make you upset or are too difficult to complete. If you become upset, study staff will give you names of counselors to contact so you can get help dealing with these issues. You may experience skin irritation while wearing the activity monitor on your wrist; however, you are free to remove the monitor at any time.

The greatest risk to you is the loss of confidentiality. We will do our best to makes sure that your personal information will be kept private. The chance that this information will be given to someone else is very small. Of course, our research team cannot prevent other participants in the group therapy from disclosing information they hear during group sessions; however, we will try to prevent a loss of confidentiality by using first names only in group and by telling participants that group sessions should remain private (i.e., information disclosed will not be repeated outside of the group). The researchers will let you know about any significant new findings (such as additional risks or discomforts) that might make you change your mind about participating in the study.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

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.

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
- administrative reasons require your withdrawal

USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

Authority to Request Protected Health Information

The following people and/or groups may request my Protected Health Information:

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

Authority to Release Protected Health Information

The VCU Medical Center (VCUMC) may release the information identified in this authorization from my medical records and provide this information to:

- Health Care Providers at the VCUMC
- Research Collaborators
- Data Coordinators
- Others as Required by Law
- Principal Investigator and Research Staff
- Government/Health Agencies
- Institutional Review Boards

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

Type of Information that may be Released
The following types of information may be used for the conduct of this research:

☐ Complete health record	☒ Diagnosis & treatment codes	☐ Discharge summary
☐ History and physical exam	☐ Consultation reports	☒ Progress notes
☒ Laboratory test results	☐ X-ray reports	☐ X-ray films/images
☐ Photographs, videotapes	☐ Complete billing record	☐ Itemized bill
☐ Information about drug or alcohol abuse	☐ Information about psychiatric care	☐ Information about Hepatitis B or C tests
☐ Information about sexually transmitted diseases	☐ Other:	

Uses of Your Protected Health Information
Your health information as shown above will be used for the following reasons:
☐ To determine if you meet the requirements to be a participant in this study
☒ To be able to conduct the study
☐ For safety monitoring
☐ For regulatory issues
☐ Other (specify):

Expiration of This Authorization
☒ 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.
☐ This research study involves the use of a Data or Tissue Repository (bank) and will never expire.
☐ Other (specify):

Right to Revoke Authorization and Re-disclosure
You may change your mind and revoke (take back) this Authorization 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.

CONFIDENALITY
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 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 you tell us that you may hurt yourself or someone else, the law says that we must let people in authority know.

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.

QUESTIONS

If you have any questions, complaints, or concerns about your participation in this research, please contact:

Ashlee Loughan, Ph.D.
Principal Investigator

Address: McGlothlin Medical Education Center
1201 East Marshal St, Room 12-213
BOX 980070
Richmond VA 23298

Telephone: (804) 828-9815

The research / study staff named above is the best person to call for questions about your participation. If you have general questions about your rights as a participant in this or 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
(804) 827-2157; https://research.vcu.edu/human_research/volunteers.htm

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.

_____	
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