Official Title:

Mindfulness and Cognitive Behavioral Therapy for Sleep in Cancer

NCT: NCT04736056

IRB Document Date: February 1, 2023

Duke University Health System

Consent to Participate in a Research Study
ADULT
Mindfulness and Cognitive-Behavioral Therapy for Sleep in Cancer – Phase II (Single-Arm Pilot)

CONCISE SUMMARY

The purpose of this research study is to develop and test an adapted version of Mindfulness-Based Therapy for Insomnia for patients with hematologic cancer who have undergone inpatient treatment. In this phase of the study, participants will complete six, 60- to 75-minute intervention sessions with a study therapist. During these sessions, participants will learn mindfulness and cognitive-behavioral strategies to cope with nighttime symptoms of insomnia and daytime symptoms of fatigue, pain, and stress. Participants will be asked to complete three surveys that will take approximately 30-40 minutes and will ask questions about your cancer, your symptoms, and your experience with the intervention. Total study duration is about 11 weeks.

The greatest risk of this study is loss of confidentiality. Benefits from participating in this study might include obtaining skills to reduce your nighttime sleep disturbances and daytime symptoms of fatigue, pain, and/or stress. Information learned from this study may also benefit other patients with cancer in the future.

If you are interested in learning more about this study, please continue to read below.

INTRODUCTION

You are being asked to take part in this research study because you have undergone inpatient treatment for a hematologic cancer. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

Hannah. M. Fisher, PhD will conduct this study and it is funded by the National Cancer Institute (NCI). The sponsor of this study, the NCI, will pay Duke University to perform this research, and these funds will reimburse all of Dr. Fisher's salary.

WHO WILL BE MY DOCTOR ON THIS STUDY?

If you decide to participate, Dr. Hannah Fisher, will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

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WHY IS THIS STUDY BEING DONE?

The purpose of this study is to develop and test an adapted version of Mindfulness-Based Therapy for Insomnia ("Mindful Night-to-Day") that will help patients with hematologic cancer cope with nighttime sleep disturbance and daytime symptoms (fatigue, pain, and/or stress) that are common after discharge from inpatient treatment. In this phase of the study (Phase II), we are testing the feasibility, acceptability, and preliminary efficacy of the Mindful Night-to-Day intervention.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

A maximum of approximately 38 hematologic cancer patients will take part in this study at Duke.

WHAT IS INVOLVED IN THE STUDY?

If you agree to be in this study, you will be asked to sign and date this consent form.

You will be asked to complete six, 60- to 75-minute intervention sessions with a study therapist. All sessions will be done in-person or remotely via videoconference (i.e., Zoom) either with a smartphone we provide to you or on your own personal smartphone or computer. You will be asked to complete daily sleep diaries before each session, and at the beginning of each session you will be asked several questions about any recent cancer treatments, use of sleep and/or pain medication, and coping skill use. The Mindful Night-to-Day sessions will teach you mindfulness and behavioral coping strategies to help you self-manage your nighttime sleep disturbance and daytime symptoms of fatigue, pain, and/or stress. You will be provided with an mp3 player. This device will be yours to keep, and will include recordings of learned mindfulness meditations and relaxation techniques. You will be asked to listen to these recordings throughout the study. The sessions will be audio recorded and reviewed by Dr. Fisher and the study team to help develop and refine the intervention. These audio recordings will be deleted when the study is completed.

You will be asked to complete 3 surveys. They will each take about 30-40 minutes and include questions about you and your background, your cancer symptoms (e.g., insomnia, fatigue, pain), and your emotions. We will also ask you to give us feedback on the sessions and intervention content; we will use your feedback to make the Mindful Night-to-Day intervention better for other patients who receive it in the future. You can skip any questions that make you uncomfortable or that you do not wish to answer. The first survey is completed at the start of the study. The second survey is about 7 weeks later and the final survey is about 11 weeks after the start of the study.

HOW LONG WILL I BE IN THIS STUDY?

You will be in the study for about 11 weeks. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled.

WHAT ARE THE RISKS OF THE STUDY?

There are no physical risks associated with this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be

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guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions. Discussing stressors associated with your symptoms may be upsetting. You also have the option of not discussing concerns you find upsetting. If you are loaned a smartphone, you should not use it for personal use (e.g., internet searching, texting, emailing, phone calls, storing personal contacts, downloading mobile apps) during the study. If you are loaned a smartphone for use during this study and you use it for non-study related reasons, this could add your personal information onto the device and potentially result in it being sent to unauthorized persons. If you are loaned a smartphone, it will be preset with security settings. Please do not alter these during the course of the study. When you return the smartphone at the end of the study, it will be cleaned to remove any of your personal information. If the smartphone is lost or stolen during the course of the study, please contact the study team immediately. Study sessions may be completed via Zoom. There is some risk of loss of confidentiality due to the use of videoconferencing (i.e. Zoom) to conduct the intervention sessions. You may stop your participation in this study at any time.

The Mindful Night-to-Day intervention involves sleep consolidation and reconditioning exercises. Although unexpected, it is possible that these sleep strategies may result in increased daytime sleepiness, and some problems with mood and/or slowed thinking during treatment; however, these effects are primarily restricted to the early stages of treatment, when behavioral therapies are introduced, and improve over time, typically resolving by the end of treatment.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you are a patient who participates in this study, there may not be direct medical benefits to you. We hope that participation in this study provides you with the opportunity to learn skills that can help you reduce your nighttime sleep disturbances and daytime symptoms of fatigue, pain, and/or stress. We also hope that the information learned from this study will benefit other patients with cancer in the future.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Study records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of Duke University Health System (DUHS). For records disclosed outside of DUHS, you will be assigned a unique code number. The key to the code will be kept in a locked file in Dr. Fisher's office located at 2400 Pratt Street, 7th Floor, Room 7061, Durham, NC 27705. All audio recordings will be stored on an encrypted laptop and will be available only to authorized study personnel as necessary to review the content of the sessions. All audio recordings will be destroyed at the end of the study.

As part of the study, the study team will report the results of your study-related questionnaires and assessments to the NCI. In addition, your records may be reviewed in order to meet federal or state

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regulations. Reviewers may include the Duke Human Subjects Research Compliance, Duke University Health System Institutional Review Board, and Duke Cancer Institute. If your research record is reviewed by this group, they may also need to review your entire medical record. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by the federal privacy regulations. Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

As part of this study, Dr. Fisher and her study team will ask you to complete brief assessments (questionnaires). The questionnaires are done solely for this research study and are not part of your regular care. Questionnaire data will not be included in your medical record.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record will be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed.

WHAT ARE THE COSTS TO YOU?
There will be no costs to you as a result of being in this study.

WHAT ABOUT COMPENSATION?
You will receive $40 for completing each of the three study assessments. Total compensation may be up to $120. If you choose to withdraw from the study, you only will receive compensation for the parts of the study that you completed.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center or your local community hospital emergency room in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury. For questions about the study or research-related injury, contact Dr. Fisher at (919) 416-3471 during regular business hours or by page at 919-206-3140.

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WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes except to keep track of your withdrawal.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke and will not affect your job status if you are a Duke employee. If you do decide to withdraw, we ask that you contact Dr. Fisher in writing and let her know that you are withdrawing from the study. Dr. Fisher's email is hannah.fisher@duke.edu and mailing address is 2400 Pratt Street, 7th Floor, Room 7061, Durham, NC 27705. You will be asked to return the smartphone, if loaned one. If you choose to withdraw from the study, your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your data, we will no longer be able to identify and destroy it.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

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

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Fisher at 919-416-3471 during regular business hours and 919-206-3140 after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at 919-668-5111.

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STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time