Official Title: Adaptation and Pilot Testing of a Mindfulness-Based Insomnia and Symptom Management Intervention for Women With Breast Cancer Receiving Treatment in Rural Medically Underserved Areas

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Consent to Participate in a Research Study
ADULT
Adaptation and Pilot Testing of a Mindfulness-Based Insomnia and Symptom Management Intervention for Women with Breast Cancer (Nite2Day) Receiving Treatment in Rural Medically Underserved Areas (Phase II)

KEY INFORMATION SUMMARY
People with breast cancer often experience multiple difficult symptoms, for example insomnia, fatigue, stress, and pain. This study is being done to adapt and test a mindfulness-based insomnia and symptom management intervention for women with breast cancer (*Nite2Day*).

Participants in Phase II of this study will complete six, 45-60 minute intervention sessions with a study therapist. Intervention sessions will be conducted remotely via conference (i.e., Zoom) or telephone. During these sessions, participants will learn mindfulness and cognitive-behavioral strategies to cope with nighttime sleep disturbances and daytime symptoms of fatigue, stress, and pain. Participants will be asked to complete three, brief (15-20 minute) surveys that will ask questions about their background, cancer diagnosis and treatments, cancer symptoms, and experience with the intervention. Participants will be compensated for completing all intervention sessions and surveys. Total study duration is about 12 weeks.

The greatest risk of this study is loss of confidentiality. Benefits from participating might include learning skills to reduce nighttime sleep disturbances and daytime symptoms of fatigue, stress, and pain. 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, continue to read below.

You are being asked to take part in this research study because you have been diagnosed with breast cancer. Research studies are voluntary. You do not have to agree to be in this study. Please read this consent form carefully and take your time making your decision. The study team will discuss the study with you. Please ask about 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 and will be reviewed with you by the study team.

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

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Hannah Fisher, PhD will conduct the study. The study is funded by a developmental grant from the Duke Cancer Institute as part of the P30 Cancer Center Support Grant (NIH CA014236) from the National Cancer Institute. Portions of Dr. Fisher's research team's salaries will be paid by this grant.

Who will be my doctor on this study?
If you decide to participate, your regular healthcare provider and team will not change during the time that you are in the study. Dr. Fisher and the study team will be in contact with your healthcare providers as needed during the course of the study. Study sessions will be led by Dr. Fisher or by another mental health professional.

Why is this study being done?
The purpose of this study is to adapt and test a mindfulness-based insomnia and symptom management intervention for women with breast cancer (*Nite2Day*). In this phase of the study (Phase II), we are evaluating the feasibility, acceptability, and preliminary impact of the *Nite2Day* intervention in women with breast cancer receiving treatment in rural, medically underserved areas.

How many people will take part in this study?
In this phase, up to 15 women with breast cancer will take part in this study from the Duke Cancer Network.

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 then participate in six, 45-60 minute intervention sessions with a study therapist. All sessions will be done remotely via videoconference (i.e., Zoom), either with a device (e.g., iPad tablet) we provide to you or on your own personal smartphone, tablet, or computer. You will be asked to complete daily sleep diaries throughout the intervention. 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 *Nite2Day* 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

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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. You will also be provide with ear plugs and a sleep eye mask to use throughout the study; these materials will be yours to keep after the study is complete. The *Nite2Day* sessions will be audio recorded and reviewed by Dr. Fisher and her research team to help develop and refine the intervention. These audio recordings will be deleted when the study is complete.

You will be asked to complete 3 surveys. They will each take about 15-20 minutes and include questions about you and your background, your cancer diagnosis and treatments, and your cancer symptoms (e.g., insomnia, fatigue, stress, pain). We will also ask you to give us feedback on the *Nite2Day* sessions and intervention content; we will use your feedback to make the *Nite2Day* intervention better for other patients with cancer 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 7-8 weeks later and the final survey is about 11-12 weeks after the start of the study.

While you are enrolled, the study team will collect limited information from your medical record. This information will be about your health status, cancer diagnosis, your cancer and symptom treatments, and any sleep, pain, or psychiatric medication prescriptions (if applicable).

Will I be given research results that may affect my medical care?
We do not anticipate any research results that would affect your medical care.

How long will I be in this study?
You will be in the study for approximately 12 weeks. You can stop participating at any time without penalty. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

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 guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable.

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You may refuse to answer any of the questions. Discussing stressors associated with your symptoms may be upsetting. You have the option of not discussing concerns you find upsetting.

The *Nite2Day* 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 the behavioral therapies are introduced, and improve over time, typically resolving by the end of treatment.

If you are provided with a device (i.e., iPad tablet) to complete the intervention sessions and/or surveys, you should not use this for personal use (like Internet searching, texting, emailing, phone calls, storing personal contacts, downloading mobile apps). If you were to use it for non-study related reasons, this could add your personal information onto the tablet and potentially result in it being sent to unauthorized persons. The tablet will be preset with security settings. Please do not alter these settings. When you return the tablet at the end of the study, it will be cleaned to remove any of your personal information. If the tablet is lost or stolen, please contact the study team immediately. As with all technology, we ask you to wait until you are in a safe environment, use good judgment, and follow prevailing laws. Do not perform study-related activities while you are driving.

There is some risk of loss of confidentiality due to the use of videoconferencing to conduct the *Nite2Day* intervention sessions. It is recommended that you run a current operating system (OS) on your device, review the privacy/security settings often, and restrict any unnecessary access. You may stop your participation in this study at any time.

We are not asking you to make any health decisions based on this study. You should discuss health decisions directly with your healthcare provider.

There may be risks, discomforts, or side effects that are not yet known.

Are there benefits to taking part in the study?
If you participate in this study, there may not be direct medical benefits to you. We hope that participation in this study might provide you with the opportunity to

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learn skills that can help you reduce your nighttime sleep disturbances and daytime symptoms of fatigue, stress and pain. 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. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

As part of the study, results of any study-related activities and surveys may be shared with the National Cancer Institute and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include:

- representatives and affiliates of the National Cancer Institute
- the Duke University Health System (DUHS) Institutional Review Board,
- the Duke Office of Audit, Risk and Compliance, and others as appropriate.

If any of these groups review your research record, they may also need to review your entire medical record. This information may be further disclosed by the sponsor of this study or to outside reviewers for audit purposes. If disclosed by the sponsor or outside reviewers, the information is no longer covered by federal privacy regulations.

Finally, you should understand that the study team is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

As part of this study, Dr. Fisher and her study team will ask you to complete surveys. Results of the surveys are done solely for this research study and not as part of your regular care 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

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is completed. At that time, either the research information not already in your medical record may 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 name or other personal information will not be revealed.

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 confidential. If you decide to share your 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.

The National Institutes of Health (NIH) has issued a Certificate of Confidentiality (CoC) for this study. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or lawsuit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings, like a court order.

There are some important things that you need to know about the CoC:

- It DOES NOT stop reporting required by federal, state or local laws. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others.
- It CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs, including when the Food and Drug Administration (FDA) requires it.
- It DOES NOT prevent your information from being used for other research if allowed by federal law.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers,

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medical providers or any other people not connected with the study. The CoC does not stop you from willingly releasing information about your involvement in this study. It also does not prevent you from having access to your own information.

Will it cost me anything to be in the study?
There are no costs to you for participating in this study. You and your insurance company will not be billed for your participation.

Will I be paid to be in the study?
You will receive $40 for completing each of the three surveys. If you complete all *Nite2Day* intervention sessions, you will also receive an additional $30 payment. Total compensation may be up to $150.

If you choose to withdraw from the study, you will only receive compensation for the parts of the study that you completed. To issue your payment, Duke University will need to collect your name, mailing address, and social security number for tax reporting purposes. If you do not want to provide this information, you cannot be paid but you can still take part in the research study.

What about research related injuries?
Immediate necessary medical care is available at Duke University Medical Center or your local medical center in the event that you are injured as a result of your participation in this research study. 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 at (317) 270-4933 after hours and on weekends and holidays.

What if I want to withdraw from the study?
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 the Duke Cancer Network. If you decide to withdraw, please contact Dr. Fisher in writing to

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let her know that you are withdrawing from the study (Mailing address: Hannah Fisher, PhD, 2400 Pratt Street, 7th Floor, Office #7056, Durham, NC 27705).

We will tell you about new information that may affect your health, welfare, or willingness to stay in this 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 samples or data, we will no longer be able to identify and destroy them.

The use of your data and samples may result in commercial profit. You will not be compensated for the use of your data and samples other than what is described in this consent form.

A description of this clinical trial will be available on https://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.

Whom should 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 (317) 270-4933 after hours and on weekends and holidays.

You can call the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111 if:

- You have question about your rights as a research participant
- You wish to discuss problems related to the research
- You have any concerns or suggestions related to the research
- Want to obtain information or offer input about the research

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