Permission to Take Part in a Human Research Study

MedStar Health Research Institute/Georgetown University Medical Center

Location: MedStar Washington Hospital Center, MedStar Health Research Institute, Georgetown University Lombardi Comprehensive Cancer Center

Key Information: You are being asked to take part in a research study about insomnia among breast cancer survivors. This page will give you key information to help you decide whether or not you want to participate in this study. More detailed information can be found on the next pages. Ask the research team questions during the consent process and use the contact information on this form to ask questions later.

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you are a female breast cancer survivor over age 18 and are experiencing sleep disruption.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

In-person insomnia treatments can be expensive, and it may be difficult to find trained providers. Online programs suffer from high dropout. We want to improve delivery of Cognitive Behavioral Therapy for Insomnia and make it more accessible to breast cancer survivors.

How long will the research last and what will I need to do?

We expect that you will be in this research study for six weeks. You will be asked to interact with the smart speaker or website program daily and to answer questions about your sleep patterns.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way being in this study could be bad for me?

Although minimal, there may be psychological and privacy risks to this study. Psychological risks may be present due to embarrassment or discomfort with detailed behavioral and sleep questions. Additionally, privacy risks may occur if participant data and privacy is inadvertently breached in some way. All research study has some risk, and the research team does its best to minimize the potential of risks

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More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me any way?

We cannot promise any benefits to you or others from your taking part in this research but following the program recommendations may improve your trouble with sleeping.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate.

If you choose not to participate in this research study but want help with your sleep disruption, you could participate in an online cognitive behavioral therapy for insomnia program or see a trained provider.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 202-893-2430 or via email at Hannah.Arem@MedStar.net

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (202) 687-1506 or irboard@georgetown.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 76 people here will be in this research study.

What happens if I say yes, I want to be in this research?

By agreeing to participate in this study, participants can expect to be randomly assigned to either the smart speaker arm or the website-based arm. Those assigned to the smart speaker arm will receive an Amazon Echo Dot pre-loaded with the sleep helper skill. Participants will enroll by either giving spoken to voice prompts or entering information through a phone application. All participants will receive written instructions on how to enroll, and researchers from MedStar Health will confirm via email or phone that participants were able to enroll in and initiate the program. Smart speaker participants will receive written materials instructing them to complete daily modules in the morning and at night, in addition to receiving materials on how to adjust security settings to ensure privacy and maximal security. Website users will be instructed to set up a personalized account to access study information and complete baseline information for tailoring. Demographic information (e.g., age, education, income), medical history (e.g., comorbidities), and lifestyle habits (e.g., physical activity, diet) will be collected. Additionally, information on insomnia, fatigue, depression, pain, and other factors that affect sleep will be collected via online survey. The intervention will be delivered entirely remotely. At the end of the study we will ask you to fill out online questionnaires about how your symptoms have changed and will ask for feedback on the program.

From baseline to follow-up, the length of the study will be approximately 6 weeks.

The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the research team will choose what treatment you get. You will have an equal chance of being given each treatment.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to:

- If you are assigned to the smart speaker group – you will be asked to verbally interact with the Sleep Helper program twice daily to answer questions about your day and your sleep patterns for six weeks.
- If you are assigned to the website group, will receive access to a website with information about insomnia symptoms and strategies to improve sleep and you will be asked to login to the website to receive sleep recommendations.
- Both groups will be asked to fill out online forms at baseline and end of study about demographics, health, and physical symptoms.

What happens if I say yes, but I change my mind later?

You may refuse to participate, or you may discontinue your participation at any time without penalty or loss of benefits to which you would otherwise be entitled.

If you decide to leave the research, please contact the research team so that they can document your reason for leaving the study. We ask that all participants complete the questionnaires about sleep patterns at the end of the six weeks, regardless of whether they performed recommended study activity or whether there was a change in sleep patterns. It is important for understanding the impact of the program to understand the full range of outcomes and preferences for the program.

If you stop being in the research, already collected data may not be removed from the study database. You may be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

Is there any way being in this study could be bad for me? (Detailed Risks)

Although minimal, there may be psychological and privacy risks to this study. Psychological risks may be present due to embarrassment or discomfort with detailed behavioral and sleep questions. Additionally, privacy risks may occur if participant data and privacy is inadvertently breached in some way. All research study has some risk, and the research team does its best to minimize the potential of risks.

The risks and discomforts associated with participation in this study are not expected to be greater than those ordinarily encountered in daily life or during the performance or routine physical or psychological examinations or tests.

There are no costs for participating in this research.

Policy/Procedures or Research Related Injuries

If you think you have been injured as a result of taking part in this research study, tell the person in charge of this research study as soon as possible. The research investigator's name and phone number are listed in this consent form under "Who can I talk to".

The Policy and Procedure for the Sponsor Media Rez **are as follows:**
We will make every effort to prevent study-related injuries and illnesses. Media Rez will not pay for care necessitated by a research related injury.

The Policy and Procedure for MedStar Health Research Institute are as follows:
We will make every effort to prevent study-related injuries and illnesses. If you are injured or become ill while you are in the study and the illness or injury is due to your participation in this study, you will receive necessary medical care. The costs of this care will be charged to you or your third-party payor (e.g., your health insurer) in the usual manner and consistent with applicable laws. No funds have been set aside by MedStar Health Research Institute, or their affiliates, to repay you or compensate you for a study related injury or illness. You do not give up your legal rights by signing this form.

The National Cancer Institute provides an online resource to help people participating in cancer clinical trials understand which services their insurance company is required by law to pay. This can be found at the website below or can be provided by the study team:

www.cancer.gov or
1-800-4-CANCER (1-800-422-6237)

What happens to the information collected for the research?

Efforts will be made to protect your medical records and other personal information to the extent allowed by law. However, we cannot guarantee absolute confidentiality. Only trained study staff who need access to data for research purposes related to this project will have access to the data. The study team will hold data in compliance with regulatory and institutional requirements for the protection of confidentiality of participants.

You will not be identified in any reports or publications resulting from this study. In addition to the researchers and research institution(s) conducting this study, organizations that may request to inspect and/or copy your research records for quality assurance data analysis and other research related and operational or administrative purposes, include groups such as:

National Cancer Institute, MedStar Health Research Institute, MedStar Health Research Institute-Georgetown University Institutional Review Board (IRB), federal research oversight agencies.

Please note that administrative personnel involved in processing your payment for participation will be aware of your identity.

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

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.

Can I be removed from the research without my OK?

You will not be removed from the research study once you are enrolled.

What else do I need to know?

The research is being sponsored by the National Cancer Institute and was awarded to a small business called Media Rez, led by Mr. Daniel Greenberg. MedStar Health Research Institute is being paid by Media Rez to conduct this study with Dr. Hannah Arem as the principal investigator.

If you agree to take part in this research study, we will pay you a $75 gift card at the completion of the end of study forms for your time and effort. Both study arms will receive an Amazon Alexa device at study completion. An individual responsible for the conduct of this research study, Daniel Greenberg, has a financial interest in this research study.