Official Title	A Crossover Randomized Controlled Trial to Investigate the Acceptability and Efficacy of Cecebot, a Conversational Agent for Insomnia After Breast Cancer
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INFORMATION ABOUT A UNIVERSITY OF WASHINGTON RESEARCH STUDY

Studying a Chatbot to Help with Sleep after Breast Cancer Treatment (Cecebot)

What is this study about?

Our research team is doing this study to see how useful and helpful an insomnia program is for women who have finished breast cancer treatment and are having trouble sleeping. This program is a chatbot that gives advice and information over text message. Please read this form carefully. It gives information to help you decide whether to be in the study. Joining the study is voluntary. Feel free to take your time and ask any questions you may have about the study.

What will you be asked to do?

If you decide to join this study, we will ask you to complete 3 remote study visits over 3 months. Participating in this study is completely remote. There are no in-person study visits. Each study visit is expected to take 1 – 1.5 hours to complete depending on the visit. The visits will take place on video or audio call.

For the first visit, we will ask you to complete a survey that will ask questions about your past and current health, including cancer history, current sleep, and mental health, among other questions. You can refuse to answer any question at any time. We expect these surveys to take about an hour to complete. Once you are done with the surveys, you will be assigned to either 1) begin a 6-week insomnia program ("Sleep Program First" group) or 2) wait 6 weeks and then begin the 6-week insomnia program ("Wait First" group). This assignment is random, like flipping a coin. If you are assigned to the insomnia program at this visit, we will give you further instructions about how to start.

The second visit will happen about 6 weeks into the study. We will ask you to do another survey similar to the first visit. If you are in the "Sleep Program First" group we will give you instructions on ending the program. If you were assigned to the "Wait First" group, we will give you instructions on starting the program. The third and final visit will happen about 12 weeks into the study and will include another survey similar to the first and second visits. If you were assigned to the "Wait First" group we will give you instructions on ending the program.

The insomnia program is delivered by a chatbot named "Cecebot". Cecebot will contact you through standard text messaging to your phone number. This is also called short messaging service or "SMS" texting. During the 6-week program, Cecebot will be in touch at least once a day to ask you to share information about your sleep and activities from the previous day. This information will help Cecebot give personal suggestions for how to help improve your sleep. Many days, Cecebot will be in touch more than once to share tips and sleep guidance in short conversations designed to take no more than 10 minutes. Cecebot will also share audio to help relax and other tools. Cecebot is automated and conversations with Cecebot will not be monitored by a human.

During the 6-weeks you are completing the program, we will ask you to wear a FitBit activity tracker. Cecebot is paired with a FitBit, and the data being collected through your FitBit will be shared with Cecebot so she can make personal suggestions, send occasional reminders and motivational messages related to physical activity and give you a summary of your information. The FitBit will be provided at no cost. We will provide materials to return the FitBit at no cost when you are done with Cecebot.

Information about Study Visits

Study Visits	"Sleep Program First" Group	"Wait First" Group
Baseline (study start)		
Complete surveys and meet with research team (videocall)	X	X
Random assignment to either start the sleep program right away, or wait 6 weeks to start the sleep program.	X	X
Begin sleep program	X	
Week 6 (1.5 months)		
Complete surveys and meet with research team (videocall)	X	X
Finish sleep program	X	
Begin sleep program		X
Week 12 (3 months)		
Complete surveys and meet with research team (videocall)	X	X
Finish sleep program		X

Why might you want, or not want, to participate?

There are some possible risks related to doing this study. We expect all risks to be mild if they happen. The risks we believe could occur are listed in the table below. Each row has a different possible risk and has information about that risk.

What is the possible risk?	Why might this happen?	How likely is it?	How intense would it be?
Temporary increase in daytime sleepiness	Sleep program	Medium	Mild
Emotional discomfort	Survey questions; Sleep program	Medium	Mild
Physical Fatigue, joint or muscle soreness	Physical activity related to the sleep program	• Medium, if beginning new physical activity. • Low, if adding on to existing physical activity.	Mild
Elevated heart rate and/or feeling out of breath	Physical activity related to the sleep program	• Medium, if beginning new physical activity. • Low, if adding on to existing physical activity.	Mild
Breach of confidentiality or privacy	Info hacked or stolen; Research team error	Low	Mild

We don't expect a direct benefit to you, because we don't have enough information to know if our sleep program is helpful. We hope that the results of this study help provide better future treatment for breast cancer survivors with insomnia. If you experience any of the effects listed above, or any other negative, stressful, or unwanted side effects related to being in the study, we ask that you let us know as soon as you are able. You may also contact the UW Human Subjects Division if you do not want to talk with the study team.

There are other ways to treat insomnia. If you choose not to join the research, you may seek a referral for treatment from a trained sleep expert. You may wish to discuss this option with your doctor.

How will we protect the information you provide?

We will protect your confidentiality. We will store your name and other identifiable information separate from the study data. The data you provide in surveys will be stored with a study identification number. Access to your identifying information and to the link between your study ID and your name will be limited to core members of the study team and any individuals from the UW, Fred Hutchinson Cancer Center, or other agencies that may need to audit study records. When we publish the results of this study, we will not use your name.

The information we obtain from you for this study might be used for future studies. We will remove anything that can identify you from the information we share. If we do so, the information may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

What if you want to stop being in this study, or if the researcher decides you should no longer participate?

You are free to stop participating in this study at any time. Joining the study now does not mean you are required to finish it. There is no penalty for stopping. If you would like to withdraw from this study, please contact the researcher(s) listed in this consent form. If the lead researcher (Kerryn Reding) believes continued participation will cause a safety concern for someone, they are able to withdraw that participant from the study. If you are withdrawn from the study, we will let you know. There is no penalty for withdrawal.

Other information about this study.

Being in this study is voluntary. This means that you can refuse to sign up. It also means that if you do sign up, you can decide to stop being in the study at any time without penalty.

We are receiving financial support from The Hope Foundation.

During the 12 weeks of this study, we ask that you do not seek professional help for insomnia.

You will be reimbursed $25 with an electonic gift card after completing each study visit. So if you complete all 3 visits, the total reimbursement is $75. Reimbursements are not pro-rated (that is, partial payments). Good faith efforts to complete the study visits will be fully reimbursed.

We plan to enroll 60 women with current insomnia and a history of breast cancer in this project.

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

A copy of the consent form will be emailed to you at an email address that you provide. It will be a "PDF" document. Most computers already have PDF viewer software installed (such as a Web browser, like Google Chrome), which will allow you to open, read, or print the consent form. The email we send you will include a link to PDF viewer software (such as Adobe Acrobat Reader) in case your computer doesn't already have it. If you would prefer to receive a paper copy of the consent form at no cost to you, please contact the researcher(s) listed in this consent form.

What can you do if you want more information?

Talk to the study team. We are here to help you understand the study. We are glad to answer any questions you may have, even about things that are not in this document. It is our responsibility to give you the information you need to make a decision and to give you time to think about whether or not you want to sign up.

Talk to someone else. If you want to talk about the study with someone who is not part of the study team, talk about your rights as a research subject, or to report problems or complaints about the study, contact the UW Human Subjects Division.

If you have been injured or otherwise harmed by participating in this study, contact a member of the research team at 206-459-4172 or redinglab@uw.edu.

Study Team	Julia Kristoferson Palmer (Study Coordinator) 206-459-4172 redinglab@uw.edu Principal Investigator (Head of Study)

	Kerryn Reding Kreding@uw.edu
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Subject's statement

By signing this consent form, I confirm that the study has been explained to me and I volunteer to participate in the research. I have had a chance to ask questions. If I have questions later about the research or feel I have been harmed by participating in the study, I can contact a member of the research team or the UW Human Subjects Division using the information listed above. I will receive a copy of this consent form.

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Printed name of subject Signature of subject Date