Cover Page for ICF

Official Title:	Efficacy of Nurse-Delivered Brief Behavioral Treatment to Self-Manage Insomnia in Cancer Survivors
NCT number:	NCT03810365
Document Type:	Study Informed Consent Form IRB Renewal 9/26/2023
Date of the Document:	9-26-2023

Permission to Take Part in a Human Research Study

University at Buffalo
The State University of New York
University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federalwide Assurance ID#: FWA00008824

Adult Consent to Participate in a Research Study

Title of research study: Efficacy of Nurse-Delivered Brief Behavioral Treatment to Self-Manage Insomnia in Cancer Survivors

Version Date: 09/15/2022

Investigator: Grace Dean, PhD, RN

Key Information: The following is a short summary of this study to help you decide whether to be a part of this study. More detailed information is listed later on in this form.

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

You are being invited to take part in a research study that examines the way that individual sleep education versus healthy eating education affects insomnia in cancer survivors.

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?

Insomnia is a common complaint in cancer survivors. The most effective nontoxic treatment for primary insomnia is cognitive behavioral therapy, but we do not know the correct dose or best delivery method for cancer survivors. The results of this study should help to further our understanding of how to best provide therapy to improve sleep and quality of life in cancer survivors with insomnia.

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

We expect that you will be in this research study for approximately 13 months.

You will be asked to complete a packet of self-report questionnaires 4 times throughout the study at baseline, 1 month, 3 month and 12 month time intervals, complete 1 week sleep diaries and wear a wristwatch (actigraph) at baseline and 6 other weeks during the study. Additionally, you will be asked to attend an individual education session for either sleep or healthy eating education and participate in 2 follow-up phone calls. Following the 1 month data collection, the interventionist will contact you to provide feedback on sleep diary data. At 6-months and 9-months, you will receive a brief email from us as a safety check and answer 3 questions about your sleep.

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

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

A reasonable foreseeable risk is excessive daytime sleepiness early in the study from having night-time sleep curtailed as part of the intervention. Daily sleep diaries provide daily daytime sleepiness measures and the PI and Study Coordinator will monitor for this risk. The known risks associated with this study include the possibility that you might become upset thinking about some of the questions or topics in this study. If this occurs, you should notify the research assistant and you will be provided with an appropriate referral for assistance. The skin on your wrist may become irritated by wearing the actigraph. If this occurs, we will advise you to remove the actigraph, apply a thin layer of Eucerin lotion to the affected area and wear the actigraph on the opposite wrist. Any significant new findings developed during the course of this research that uncover new risks, which may affect your willingness to continue participation, will be provided to you in writing.
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 in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include learning new techniques for improving sleep and/or healthy lifestyle modifications, and the opportunity to verbally share thoughts and feeling related to the research with others who are in a similar situation. The study may also help researchers to improve future services for those who are faced with sleep problems.

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

Participation in research is completely voluntary. You may choose not to enroll in this study. Instead of being in this research study, your choices may include: a referral to a sleep center for further evaluation and treatment for your insomnia. At a sleep center you may be referred to a psychologist or nurse practitioner for cognitive behavioral therapy or you may be prescribed medications for your insomnia. The important risks and possible benefits of these alternatives include: medications may have side effects, but both therapies may be helpful in improving your sleep.

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 (716)-829-3235. You may also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu

This research has been reviewed and approved by an Institutional Review Board ("IRB"). An IRB is a committee that provides ethical and regulatory oversight of research that involves human subjects. You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu if:

- You have questions about your rights as a participant in this research
- 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 want to get information or provide input about this research.

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How many people will be studied?

We expect about 158 people in this research study.

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

If you agree to be a part of this study, you will wear an overnight portable device to screen for a condition called sleep apnea. If you have sleep apnea, we will provide you with 2 copies of the report for you and to follow up with your healthcare provider about next steps. If you do not have sleep apnea, you will then be asked to complete a packet of self-report questionnaires to assess sleep patterns and overall quality of life. Filling out the questionnaires should take about 60 minutes. You are free not to answer any questions you do not wish to answer. You will then be asked to wear a device that looks like a wristwatch (actigraph) that records your wrist movement and light exposure continuously for 7-days. You will then be asked to complete a 7-day sleep diary. After the baseline data is completed, you will be asked if you are willing to be randomized, like flipping a coin, to be scheduled for a sleep or healthy eating education session. Following the approximately 45-minute education, you will be asked to complete the sleep diary weekly for 2-weeks to assess the effect of the education. One and two weeks after the education, you will receive a 20 to 30 minute telephone call to discuss your progress with applying the educational content. One-month, 3-months and 12-months after the education, you will be asked to wear the actigraph for 7-days, complete a sleep diary for 7-days and complete the self-report questionnaire packet. Following the 1 month data collection, the interventionist will contact you to provide feedback on sleep diary data. At 6-months and 9-months, you will receive a brief email from us as a safety check and answer 3 questions about your sleep. If you are excessively sleepy, we will provide recommendations to you to reduce sleepiness. At 12-months, we will also ask you to complete an evaluation questionnaire. You may withdraw from the study at any time. Just let Dr. Grace Dean know that you no longer wish to continue with the study. Withdrawing would have no foreseeable negative effects.

The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor 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: use an overnight device to screen for sleep apnea, answer a variety of questionnaires about your sleep and quality of life, complete sleep diaries, attend one education session, participate in two telephone calls and wear a wrist actigraph.

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

You can leave the research at any time and it will not be held against you. If you decide to leave the research, contact the investigator so that the investigator can remove you from scheduled data collection and procedures. If you stop being in the research, already collected data may not be removed from the study database. You will 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. If you choose to not participate in some portion of the intervention or telephone calls, we would still be interested in obtaining follow up data collection. Withdrawing would have no foreseeable negative effects.

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

A reasonable foreseeable risk is excessive daytime sleepiness early in the study from having night-time sleep curtailed as part of the intervention. Daily sleep diaries provide daily daytime sleepiness measures and the PI and Study Coordinator will monitor for this risk. The known risks associated with

this study include the possibility that you might become upset thinking about some of the questions or topics in this study. If this occurs, you should notify the research assistant and you will be provided with an appropriate referral for assistance. The skin on your wrist may become irritated by wearing the actigraph. If this occurs, we will advise you to remove the actigraph, apply a thin layer of Eurcerin lotion to the affected area and wear the actigraph on the opposite wrist. Any significant new findings developed during the course of this research that uncover new risks, which may affect your willingness to continue participation, will be provided to you in writing.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB, the National Institutes of Nursing Research and other representatives of this organization.

The sponsor, monitors, auditors, the IRB, will be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential. Your information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

Federal law provides additional protections of your medical records and related health information. These are described in the HIPAA section of this document.

Can I be removed from the research without my OK?

The principal investigator of the study can remove you from the research study without your approval. Possible reasons for removal include a positive screening for sleep apnea. If you screen positive for sleep apnea you will be referred out from the study. The investigator will provide a referral letter to you and your primary doctor (as needed), to inform about the results from the apnea test. You may come back to the study after your sleep apnea is successfully treated if your insomnia persists. Participants will be withdrawn from the research without their consent if they are unable to complete their responsibilities listed on the consent form or if they falsify responses.

What else do I need to know?

Who is paying for this research?

This research is being funded by the National Institute for Nursing Research (NINR). This research involves no more than minimal risk.

Will I get paid for my participation in this research?

If you agree to take part in this research study, we will pay you a total of $75.00 for your time and effort. You will receive $25 for completing baseline questionnaires and the time 1 educational intervention, $25 for completing questionnaires again at one-month and 12-months after the education.

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HIPAA: Authorization for the Use and Disclosure of Identifiable Health Information for Research Purposes

This section describes information about you and about your health that will be obtained by the researchers when you participate in the research study. By signing this form you are agreeing to permit the researchers and/or other parties (described in detail below) to have access to this information and to use or disclose it for the purposes of the research described in this document. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

A. What individually identifiable health information will be collected about you as part of this research study?

__√__ Information from your full medical records: including cancer type, treatment specifications and co-morbidities**.**

___√__ New Health Information created from study related tests, procedures, visits, and/or questionnaires as described in this consent form.

B. Who is authorized to create or provide this information for research use?

_____ KALEIDA Health, Buffalo NY
_____ ECMC Healthcare Network, Buffalo NY
_____ UBMD Clinical Practice Plan(s) (identify):_____
_____ University at Buffalo School of Dental Medicine
_____ Principal Investigator or designee
___√___ Other(s) (identify): Roswell Park Comprehensive Cancer Center_____

C. Who is authorized to receive the information from the information providers identified in (B)?

__√__ Principal Investigator or designee
_____ Other(s) (identify):_____

D. With whom may your protected health information be shared?

Your health information may be shared with others outside of the research group for purposes directly related to the conduct of this research study or as required by law, including but not limited to:

__√__ Clinical staff not involved in this research study who may become involved in your care if it is potentially relevant to your treatment
__√__ The sponsor of this research study, the National Institute for Nursing Research.
__√__ The organization(s) responsible for administering this research, Research Foundation of SUNY, UB Foundation Services, Inc.

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Your information may also be shared with individuals or entities responsible for general administration, oversight and compliance of research activities. Examples of this include the institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring Boards, an Institutional Review Board, The Research Foundation of the State University of New York, University at Buffalo Foundation Services, and accrediting bodies, or with certain government oversight agencies that have authority over the research including the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your information may also be shared with other entities as permitted or required by law. All reasonable efforts will be used to protect the confidentiality of your individually identifiable health information that may be shared with others as described above.

Although safeguards are in place to prevent accidental disclosure of your information beyond the purposes described above, the information disclosed through this authorization is no longer protected by HIPAA. There is the potential for this information to be re-disclosed by the recipient(s). After such a disclosure, the information may no longer be protected by the terms of this authorization against further re-disclosure.

E. How long are the information providers listed in (B) authorized to provide your information for this research project?

___√__ This authorization will expire at the end of the research study. After that time, this authorization may not be used to acquire additional information about you.

F. What are your rights after signing this authorization?

You have the right to revoke this authorization at any time. If you withdraw your authorization, no additional efforts to collect individually identifiable health information about you will be made. You should know, however, that protected health information acquired using this authorization prior to its withdrawal may continue to be used to the extent that the investigator(s) have already relied on your permission to conduct the research. If you chose to withdraw this authorization, you must do so in writing to the following individual(s): Grace E. Dean, PhD, RN. University at Buffalo, School of Nursing, 3435 Main Street, 301D Wende Hall, Buffalo, NY 14214-8013.

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your individually identifiable health information.

G. What will happen if you decide not to sign this authorization?

Refusing to sign this authorization will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign this authorization, you will not be able to participate in the research study.

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Certification

I have read and I believe I understand this informed consent document. I believe I understand the purpose of the research and what I will be asked to do. I have been given the opportunity to ask questions and they have been answered satisfactorily. _____(Verbal approval)

I understand that I may stop my participation in this research study at any time and that I can refuse to answer any question(s)._____(Verbal Approval)

I understand that my identifying information will remain confidential, that all data associated with my participation will be stripped of identifiers, and that I will not be identified in reports on this research._____(Verbal approval)

Certification of Verbal Consent

I hereby give my informed and free consent to be a participant in this study: _____(date)_

I do not agree to participate in this study:_____