Effects of Bright Light on Co-occurring Cancer-related Symptoms in Breast Cancer Survivors

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Informed Consent

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INFORMED CONSENT DOCUMENT

Project Title: **Effects of bright light on co-occurring cancer-related symptoms in cancer survivors: A personalized intervention**

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Sponsor: National Institute of Health

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. The purpose of this research study is to learn about how light therapy affects your post-treatment symptoms and well-being. The researchers also want to learn about how easy or difficult it is for you to use light therapy at home. The study activities include a 2-week home-based light therapy, 3-overnight in-laboratory sleep study, temperature monitoring, and surveys.

We invite you to participate in this research study because you are an adult and had completed treatments of cancer.

This study is not designed to diagnose any sleep disorder. The light therapy device is considered investigational, which means that it has not been approved by the U.S. Food and Drug Administration.

WHAT WILL HAPPEN DURING THIS STUDY?

- On the first visit for screening, you will be asked to answer several surveys. They are asking about your demographic information, health status, and post-treatment symptoms. You may skip any questions that make your feel uncomfortable. You will also be asked to give us some information about your health and medications that you are taking. It may take 30-40 minutes to complete. After this, you may or may not be asked to participate further.

- After the screening, you will be randomized to either a blue-green light group or a red light group. Randomized means you will be assigned by chance (like flipping a coin) to one of the two groups, with an equal chance of being assigned to either group.

- You will be asked to give us your telephone number and address so that you can be contacted to arrange the future study activities. We will keep your contact information confidential. Your

contact information is only used for the study purpose. Only qualified research staff can access the information. Your contact information will be destroyed once the study has been completed.

No matter what group you are assigned, the study activities will last for about 3 weeks. You will make 3 overnight visits to a sleep laboratory. Each visit will last 12-14 hours. Also, we will call you periodically while you are in the study to remind you about study activities and to answer any questions you might have.

- The first overnight stay at a sleep laboratory: You will report to the sleep laboratory between 7:00-8:00 pm on a convenient weekday. Once you are in bed, a research staff will apply electrodes to your scalp, forehead, and chin and connect them to a sleep monitoring device. You will be asked to wear the electrodes throughout the night. The electrodes will be removed within 30 minutes of waking the next morning. The visit will last 12-14 hours.

  You are encouraged to bring your personal items and maintain your bedtime ritual during your stay in the sleep laboratory. Snacks will be available for you throughout your stay. Breakfast will be provided in the morning.

- The second overnight stay at a sleep laboratory: You will report to the sleep laboratory between 7:00-8:00 pm on a convenient weekday within a week of your first visit to the sleep laboratory. You will be asked to answer a booklet of questionnaires related to your symptoms and well-being. After that, you will be instructed to answer a list of computer-based questions via iPad Air. It may take 60-90 minutes to complete the questionnaires. You are free to skip any questions that you would prefer not to answer.

  Before going to bed, you will be instructed to self-insert a rectal probe that monitors your body temperature. After that, a research staff will apply electrodes to your scalp, forehead, and chin and connect them to a sleep monitoring device. You will be asked to wear the electrodes and the rectal probe throughout the night. The electrodes and the rectal probe will be removed within 30 minutes of waking the next morning.

  You will be asked to refrain from consuming alcohol, using tobacco, and taking sleep medication during the 12-hour period before checking in to the sleep laboratory and throughout the laboratory stay. You are encouraged to bring your personal items and maintain your bedtime ritual during your stay in the sleep laboratory. Snacks will be available for you throughout your stay. Breakfast will be provided in the morning. You are free to leave after 7-8 am the next morning. The visit will last 12-14 hours.

  You will be provided with a diary "*my daily log"* and maintain the daily diary activity, starting on that day and throughout the entire study period. You will be asked to record sleep/wake times and naptimes throughout the day. You will also be asked to answer 3 questions regarding your overnight sleep each morning and 2 questions regarding your overall fatigue each night before going to bed. It will take you about 2 to 5 minutes every time. You are free to skip any questions that you would prefer not to answer.

- Before returning home from the sleep laboratory, you will be given a cap with a light in the visor and an alarm watch. You will be instructed to wear the cap with the light on for 30 minutes either within 30 minutes of waking or between 7-8 pm for 14 days. The alarm watch will be set for the time to use the light visor cap. You will be asked to record the time the light treatment starts and ends on a daily basis.

  On 2 selected days during this 14-day period, you will also be asked to wear a light-weight meter just below the neck while you are awake.

  You will receive a daily phone call from a research staff for the first 3 days and then weekly phone calls for the rest of the study to answer questions.

- The third overnight stay at a sleep laboratory: You will report to the sleep laboratory between 7:00-8:00 pm the evening following the 14-days of light intervention. You will be asked to answer the same booklet of questionnaires and the computer-based questions that you completed before. It may take 60-90 minutes to complete the questionnaires. You are free to skip any questions that you would prefer not to answer.

  Before going to bed, you will be instructed to self-insert a rectal probe that monitors your body temperature. After that, a research staff will apply electrodes to your scalp, forehead, and chin and connect them to a sleep monitoring device. You will be asked to wear the electrodes and the rectal probe throughout the night. The electrodes and the rectal probe will be removed within 30 minutes of waking the next morning.

  You will be asked to refrain from consuming alcohol, using tobacco, and taking sleep medication during the 12-hour period before checking in to the sleep laboratory and throughout the laboratory stay. You are encouraged to bring your personal items and maintain your bedtime ritual during your stay in the sleep laboratory. Snacks will be available for you throughout your stay. Breakfast will be provided in the morning. You are free to leave after 7-8 am the next morning. The visit will last 12-14 hours.

- Before returning home, you will return the diary. Within 3 days, you will be asked to answer a few questions about your experience, issues/difficulties encountered during the study, and burden for study activities. You are free to skip any questions that you would prefer not to answer. This visit may take 20-30 minutes.

- During the study, your conversation with the research staff may or may not be recorded. You will be asked before being recorded. The audio recording will start after the introduction; your name will not be revealed in the recording. The audio record will be labeled by the date and the research staff's pseudo name. The audio record is for quality assurance and training only. The audio record will be deleted after research staff's self-analysis is completed.

- Your data may be used to develop investigational test, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration

If you are lost for follow-up during the study, we will make 3-5 attempts to contact you by phone.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 34 people will take part in this study conducted by investigators at Michigan State University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for about 3 weeks:

- The screening may take 30-40 minutes.
- The 1st sleep laboratory visit: the visit will last 12-14 hours.
- The 2nd sleep laboratory visit: the visit will last 12-14 hours.
- After the 2nd sleep laboratory visit: You will receive 30-minutes of light therapy at home by wearing a cap with lights in the visor for 14 consecutive days.
- The 3rd sleep laboratory visit: the visit will last 12-14 hours.
- Study exit: This visit may take 20-30 minutes.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

- Physical health risks (e.g. glare, eyestrain, headaches, nausea). You may find that bright light causes some mild visual discomfort including glare, eyestrain, headaches or nausea. In addition, although it is less likely, light toxicity or damage to the retina may occur and may lead to cataracts and other eye diseases such as age-related macular degeneration. It is also possible that you may experience insomnia (e.g. trouble falling asleep) as a response to light.

- Emotional health risk (e.g. feeling distressed, tired, or frustrated). You may feel stressed staying in an unfamiliar environment (sleep laboratory) overnight. You may be distressed by core body temperature measure using a rectal thermistor. In addition, you may become tired or upset when reflecting on feelings or thoughts about your symptom or illness experiences. You may become frustrated if you are unable to finish the research activities because of fatigue or other reasons.

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because the findings of this study will promote the development of an alternative therapy for managing post-treatment symptoms commonly experienced by survivors of cancer.

WHAT OTHER TREATEMENT OPTIONS ARE THERE?

Instead of being in this study, you can choose not to participate.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.
You and/or your medical/hospital insurance provider will remain responsible for your regular medical care expenses.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study.

Whether or not you will continue your participation after the screening, as a token of our appreciation, you will receive a free cook book after the completion of the screening.

You could receive up to $200 if you complete all study activities. You will receive a $100 for completing the 1st and the 2nd visits at the sleep laboratory. You will receive another $100 for completing all the remaining study activities. Cash will be given upon the completion of the specified research activity.

WHO IS FUNDING THIS STUDY?

National Institute of Health is funding this research study. This means that Michigan State University is receiving payments from National Institute of Health to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from National Institute of Health for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

If you are injured as a result of your participation in this research project, Michigan State University will assist you in obtaining emergency care, if necessary, for your research related injuries. If you have commercial insurance for medical care, your insurance carrier will be billed in the ordinary manner. As with any medical insurance, any costs that are not covered or in excess of what are paid by your insurance, including deductibles, will be your responsibility. The University's policy is not to provide financial compensation for lost wages, disability, pain or discomfort, unless required by law to do so.

This does not mean that you are giving up any legal rights you may have. You may contact Horng-Shiuann Wu at 517-884-4643 with any questions or to report an injury.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives, (including the Office for Human Research Protections) to complete federal or state responsibilities
- National Institute of Health
- The U.S. Food and Drug Administration
- Hospital or University representatives, to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and be available to your health care providers who are not part of the research team.
- Michigan State University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and Human Research Protection Program. The Institutional Review Board has reviewed this study for the protection of research participants and approved that aspect of this study.

To help protect your confidentiality, we will assign a three-digit code number to the information collected about you during this study. Confidentiality will be maintained using coded data materials. A three-digit number, starting at 101, will be given in a sequence based on the time of enrollment. All the information in paper and electronic format will be coded with a three-digit number without your name attached. The electronic data collected via iPads will be password protected and only accessible to the investigator and designated study personnel. All the completed study materials will be stored in a locked cabinet at the PI's project office. Only the investigator and designated study personnel will have access to your data. Information that identifies you personally will not be released without your written permission. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

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.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others*;*
- you give permission to disclose your information, including as described in this consent form; or

- it is used for other scientific research allowed by federal law.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

Your information collected as part of the research will not be used or distributed for future research studies. Your research information will be kept for 7 years from the date of study closure.

Are there additional protections for my research information?

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form.

Although you will not have direct access to your medical records while the study is being done, you will be given access to your medical records held by your health care provider.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have concerns or questions about this study, such as scientific issues, how to do any part of it, or to report an injury, please contact: Horng-Shiuann Wu, 1355 Bogue Street, Room #C347, East Lansing, MI 48824, wuhorngs@msu.edu, telephone: 517-884-4643).

If you have questions or concerns about your role and rights as a research participant, would like to obtain information or offer input, or would like to register a complaint about this study, you may contact, anonymously if you wish, the Michigan State University's Human Research Protection Program at 517-355-2180, Fax 517-432-4503, or e-mail irb@msu.edu or regular mail at 4000 Collins Rd, Suite 136, Lansing, MI 48910.

If you have questions or complaints regarding your research activity at Sparrow Health System, please contact the SCRI Office at SCRI@sparrow.org or 517-364-5760.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed copy of this form.

Your signature below means that you voluntarily agree to participate in this research study.

_____ _____

(Signature of Participant) (Date)

_____

(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that he or she understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____

(Signature of Person who Obtained Consent) (Date)

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(Name of Person who Obtained Consent - printed)