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

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Study Procedures

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Recruitment

1) The tumor registry at the Sparrow Hospital will be utilized for the study recruitment. The tumor registry will provide the principal investigator with a list of names and contact information (address, phone number, and/or email) of those individuals who may be eligible for the study. An invitation letter and the study flyers will be mailed to the potential candidates. Up to 2 follow-up reminders will be mailed 2-3 and 4-5 weeks after the initial mail. Those who are interested in participation can either call or email the principal investigator. The initial phone conversation will start with the principal investigator or a research assistant introducing herself/himself. Only when the person agrees, the principal investigator or a research assistant will briefly discuss the study and then schedule the visit for recruitment/consent.

2) ResearchMatch.org will be utilized as a recruitment tool for this study. Recruitment message from ResearchMatch will be sent to the matched volunteers. The individuals can then let the ResearchMatch team know whether they are interested or not. The ResearchMatch team will then release the contact information of those who have expressed their interest to the principal investigator. The initial phone conversation will start with the principal investigator or a research assistant introducing herself/himself. Only when the person agrees, the principal investigator or a research assistant will briefly discuss the study with the persons and then schedule the visit for consent.

3) Recruitment materials (flyers) will be placed at public areas (e.g. college of nursing building etc.) and at the clinics (e.g. waiting area). Those who are interested in participation can either call or email the principal investigator. The initial phone conversation will start with the principal investigator or a research assistant introducing herself/himself. Only when the person agrees, the principal investigator or a research assistant will briefly discuss the study with the persons and then schedule the visit for recruitment/consent.

Procedures

If the candidate agrees to be approached, the investigator/research assistant will contact the candidate over the telephone. The topic and the purposes of the study will be introduced. If the candidate is interested, the investigator/research assistant will schedule the visit for recruitment/consent. (Script is followed)

The recruitment/consent visit will be either on the day of the individual's convenience. The investigator/research assistant will provide explanation of the screening, the study procedures involved, the time commitment, and the purpose of written consent. Also, the candidates will be told that phone calls will be made during the study period. Potential subjects will be instructed to read the consent forms carefully. Any questions will be answered before signing. Before written consent is obtained, no personal information will be revealed or recorded. (Pink folder)

After giving informed consent, candidates will first complete the demographic information and 4 self-administered screening tools including the Horne-Ostberg Morningness-Eveningness Questionnaire (MEQ), the International Statistical Classification of Diseases and Related Health Problems (10th revision) (ICD-10) criteria for cancer-related fatigue, Pittsburgh Sleep Quality Index (PSQI), and the Center for Epidemiological Studies Depression Scale (CES-D). A research staff will instruct the participant and administer the Montreal Cognitive Assessment (MoCA) with paper and pencil. After that, candidates will then be individually screened/interviewed for the exclusion criteria (scoring criteria provided). Those who met the study criteria will be scheduled of the study activities (Blue folder).

Participants will be enrolled in the study for approximately 3 weeks. Each participant will make 3 overnight visits to the sleep laboratory. The research protocol consists of a pre-study adaptation night, baseline data collection, 14-day treatment phase, and post-treatment data collection. Night-time Sleep patterns and overnight core body temperature will be monitored in a sleep laboratory before and after the bright light intervention.

	Pre-Study	**Baseline**		**Treatment**	**Post-Treatment**	
Study Day	**(prior baseline)**	**D1**	**D2**	**(14 consecutive days)**	**D1**	**D2**
Bright light protocol				**X** (daily)		
Polysomnography (overnight only)	**Adaptation night**	**X**	**End**		**X**	**End**
Core body temperature (overnight only)	**Adaptation night**	**X**	**End**		**X**	**End**
Self-reported measurement* *& cognition assessment*		**X**			**X**	
Daily log		**X**	**X**	**X** (daily)	**X**	**X**

Pre-study adaptation night: To facilitate adaptation to sleep study procedures and a new sleep environment, the participants will report to the sleep laboratory around 8 pm on a convenient weekday. After checking in to the sleep laboratory, the research staff will provide instruction for daily log. A study schedule will be provided to the study participant (completed by a research stuff). The sleep lab stuff will give a tour to sleep lab. Before going to bed, the person will then be connected to the polysomnography (PSG) recording and undergo continuous PSG for one night. The recorded PSG data during the adaptation night will not be analyzed as per standard sleep research methodology.

The participants will be instructed to complete the 8 self-administered instruments, including PROMIS-Sleep Disturbance, PSQI, PROMIS-Fatigue, PROMIS-depression, CES-D, EORTC

QLQ-C30, PROMIS-Physical Function, and PSS on the day of baseline data collection (blue folder). They will be asked to return the completed instruments on their next sleep lab visit.

Starting from the adaptation night and throughout the study, the participants will complete the daily log each morning and before going to bed to record sleep/wake activities, naptimes, and levels of fatigue throughout the day.

Baseline data collection: Within a week (prefer next day), the participants will return to the sleep laboratory around 7 pm. After checking in the sleep lab), the participants will complete the NIH Toolbox Cognition Battery via iPad Air (administered by the research staff).

The participants will be connected to the PSG recording before going to bed and undergo overnight PSG monitoring. The recording for the PSG analysis will start at the time of lights out and will end at the time of final awakening in the morning (when the individual is out of bed). With the assistant from a research staff, the participant will be instructed to self-insert the thermistor just before going to bed and will remove (by herself) thermistor after final awakening in the morning. Core temperature readings will be continuously monitored and recorded every 5 minutes during the all-night sleep studies. The data at 5 minute intervals starting with lights out will be used for analysis.

(sleep lab instruction provided, in pink folder) The participants will be asked to refrain from consuming alcohol, using tobacco, and taking over-the-counter sleep or allergy medication during the 12-hour period before checking in to the sleep laboratory and throughout the laboratory session. Snacks (provide to participants at each sleep lab visit) will be available and breakfasts will be provided. The participants are encouraged to bring their personal items, engage in daily activities, e.g., watching TV, reading, etc., and maintain their bedtime ritual during their stay in the sleep laboratory.

Treatment phase: The treatment phase will start on the next day after the completion of baseline data collection. A light visor cap (Physician Engineered Products, Fryeburg, ME) and individualized instruction will be provided upon checking out of the sleep laboratory. A research staff meets with the study participant before checking out. The participants will be instructed to wear the light visor cap with the light on for 30 minutes either within 30 minutes of waking or between 1900-2000 hours for 14 consecutive days. A multiple-alarm watch will be provided (optional). Alarms will be set for on and off times by a research stuff. To ensure participant comprehension and ability to perform the personalized light treatment at home, the individual will be asked to demonstrate knowledge of (by verbalizing the time of the day, frequency, and duration of prescribed light treatment) and ability to use (by demonstrating) the light visor cap.

In addition, provide instruction about light meter use. On 2 randomly selected days, one weekday and one weekend day, the subjects will wear a light meter during wake time, starting from rising in the morning and ending at bedtime in the evening. To enhance adherence to the use of the light meter, participants will receive a phone reminder the day before.

Throughout the 14-day treatment phase, the participants will continue completing the daily log each morning and before going to bed. In addition, they will be instructed to record the time of

the beginning and the end of each light treatment on the daily log. Participants will receive a daily phone call from a research staff member for the first 1-3 days and then weekly phone calls for the rest of the treatment phase.

The participants will be instructed to complete the 8 self-administered instruments, including PROMIS-Sleep Disturbance, PSQI, PROMIS-Fatigue, PROMIS-depression, CES-D, EORTC QLQ-C30, PROMIS-Physical Function, and PSS on the day of posttest data collection. They will be asked to return the completed instruments on their sleep lab visit.

Post-treatment data collection: The post-treatment data collection will start on the next day after completion of the 14-day intervention protocol. Following the same protocol described in baseline data collection, the participants will report to the sleep laboratory 7 pm and then complete the MoCA and the NIH Toolbox Cognition Battery, administered by a research staff.

Before going to bed, the participants will be connected to the PSG recording at their regular bedtime hours and undergo overnight PSG monitoring. With the assistant from a research staff, the participant will self-insert the thermistor just before going to bed and will remove thermistor after final awakening in the morning. The PSG and core temperature recordings for the analysis will start at the time of lights out and will end after final awakening in the morning. During the post-treatment data collection, the participants will complete the daily log before going to bed and the following morning.

Before checking out of the sleep laboratory, the participant will return the daily log. All participants will receive an exit interview before checking out the sleep lab or within 3 days regarding issues or difficulties encountered during the study and complete a list of rating scales measuring levels of burden for study activities.