HEALTH AND EXERCISE SCIENCE

COLORADO STATE UNIVERSITY

ADULT PARTICIPANT INFORMED CONSENT

FORMAL STUDY TITLE:

Impact of light therapy on sleep and performance

PRINCIPAL INVESTIGATOR: Josiane Broussard, PhD;
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WHAT IF I HAVE QUESTIONS?

For questions or concerns about the study, you may contact Josiane Broussard at (970) 491-6418, or Josiane.Broussard@colostate.edu. For questions regarding the rights of research subjects, any complaints or comments regarding the manner in which the study is being conducted, contact the CSU Institutional Review Board at: CSU_IRB@colostate.edu ; 970-491-1553.

CONCISE STATEMENT OF STUDY

This research study aims to determine if short durations of daily exposure to certain colors of light can improve the sleep quality of people with insufficient sleep. You may be interested because you have difficulty falling asleep or experience frequent awakenings after falling asleep and are 18 years of age or older. This research study will take 15 days. Your participation will include 2 weeks of wearing a continuous glucose monitor (CGM), wearing and providing information through various modes of technology, and daily use of light therapy devices during the second week of the study. There are minimal risks to participating in this study, like skin irritation from adhesives or the monitoring watch and discomfort associated with exposure to bright light. We hope that this research will benefit people who experience insufficient sleep and help us learn more about the role visible light plays in promoting sleep quality and overall health. You can find more details on this study in the body of this consent form. If you are interested in continued discussion about this study, we would like to discuss more with you through this consent presentation.

WHAT IS THE PURPOSE OF THIS STUDY?

Our primary goal is to test a potential non-drug therapy for improving the quality of sleep in adults who suffer from insufficient sleep.

WHY AM I BEING INVITED TO TAKE PART IN THIS RESEARCH?

You are being invited to take part in the study because you fit these criteria: 18 years of age or older and currently suffering from insufficient sleep that has not been diagnosed as a sleep disorder.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The study consists of 3 visits (one of which may be virtual) that will take place at the Sleep and Metabolism (SAM) Laboratory housed in the Human Performance Clinical Research Laboratory (HPCRL) at Colorado State University. In between visits 2 and 3, you will continue your habitual routine in your natural environment for 15 days.

- Visit 1, Informed consent and subjective sleep quality assessment, will take approximately 1 hour at the SAM Lab or virtually.
- Visit 2, Equipment pickup, will take approximately 30 minutes at SAM Lab. During visit 2, the research team will provide you with all the materials required to complete at-home assessments.
- Visit 3, Equipment return, will take approximately 30 minutes at the SAM Lab.
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WHAT WILL I BE ASKED TO DO?

If you volunteer to take part in this study, you will be asked to do the following during the next month. Procedures will occur at the SAM Lab within the HPCRL at CSU or virtually (visit 1 only)

Visit 1: Informed Consent and subjective sleep quality assessment (~1 hour)

At this visit, you will meet with the SAM Lab staff who will provide you with detailed descriptions of the research procedures in this study and show the research equipment (e.g., sensors, light set-up, ActiWatch familiarization, and how to complete digital assessments on your smartphone). This meeting may occur virtually if desired. You will be invited to sign the consent form and complete an interview with laboratory staff who will determine if you meet the criteria for inclusion in this study. You will be asked to inform us of your current health status and complete a short, subjective assessment of your sleep quality. If you meet the study requirements and provide your consent, we will schedule Visit 2.

Visit 2: Study equipment pickup (~30 minutes)

At this visit, the research team will further familiarize you with the equipment used in this study. You will pick up 2 light therapy devices and 2 pieces of monitoring equipment from the SAM Lab and wear them for the next 2 weeks. These devices collect information about your movement, light exposure, sleep, and blood glucose levels. You will be provided collection tubes for 4 separate saliva collections. We (nor the device company) use the collected information for purposes other than this research. We do not collect geolocation information from the devices.

- One device is called an Actiwatch and is the size and shape of a smartwatch. The Actiwatch measures your movement and light recognition. We will ask you to wear this device on your non-dominant wrist, only taking it off to shower or swim.
- The second piece of equipment is called the continuous glucose monitor (CGM) and is a small sensor inserted in the skin to check glucose levels in tissue fluid. The sensor sends information about glucose levels via radio waves to a pager-like wireless monitor. Placement of the device is typically painless and will be done by trained staff.

Starting on this day and continuing for the next 15 days until visit 3, you will be asked to:

- Remain in the mountain time zone,
- Complete daily assessments of your sleep quality, general well-being, and sleepiness,
- Keep a digital sleep log,
- Complete digital cognitive assessments on 6 of the 15 days (~20 minutes each),
- Provide saliva samples by spitting in a tube before and after waking on two separate occasions,
- Engage in 2 hours of morning and evening light therapy during the second week of the study.

You will be asked to download and use 2 smartphone apps to maintain your sleep log, track light exposure, and complete digital assessments.

Shown below is a timeline of daily activities required during the 15 days of this at-home study:

Sample Study Timeline (*indicates week 2 only)

- Wake up naturally or at your desired time and complete a sleep/wake log, sleep quality assessment, and assessments of your general well-being (5 minutes)
- Complete a cognitive testing battery 2.5 hours after waking (~20 minutes on days 2, 4, 8, 9, 11, and 15)
- Complete an assessment of your general well-being 6 hours after waking (5 minutes)
- Complete an assessment of your sleepiness during your bedtime routine (2 minutes)
- Provide saliva samples and store them in your freezer (before and after your 7th and 14th sleep periods)
- *Complete 2 hours of AM blue light exposure immediately after waking and 2 hours of PM red light exposure before going to bed

Visit 3: Study equipment return (~30 minutes)
At this visit, you will return your study equipment after completing the 15-day at-home portion of the study. The research team will recover and safely store your saliva samples, assist you in removing apps from your smartphone, and inventory your Actiwatch and CGM devices (after assisting with removal).

ARE THERE ANY BENEFITS FROM TAKING PART IN THIS STUDY?
This study is not designed to directly benefit you; however, you stand to gain personal insights into your sleep patterns and the potential benefits of light therapy on sleep quality. We hope the data we collect in this study will help us learn more about non-drug alternatives to help people who suffer from insufficient sleep.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?
While the level of risk is minimal, you may become uncomfortable with some of the procedures as detailed below.

Exposure to light therapy devices

- As with the use of normal household LED lighting, you should avoid staring directly at the provided lights for more than a few seconds. The LED lighting used in this study is classified as Risk Group 1, commensurate with the typical rating of household and office LED lighting.
- To mitigate the minimal risk associated with light exposure, the research team will provide detailed instructions for proper lighting use, including placing the lights 3 to 6 feet away from your eyes and offsetting the light up to 45 degrees from your focal point (e.g., your laptop, a book, or desk environment).

Sleep/activity and glucose monitors

- Monitoring equipment for sleep and glucose levels may cause skin irritation from continuous wearing and/or adhesives. The CGM insertion might result in a bruise and slight pain.

Confidentiality and Privacy

- There is a risk that people outside of the research team will see your research information, though this risk is rare. The possibility of this risk increases when protected health information is collected. We do all we can to protect your information, but it cannot be guaranteed.
- Before you begin this study, please note that the data you provide may be collected and used by MetricWire as per its privacy agreement. This research is only for U.S. residents over the age of 18. Please be mindful to respond in private and through a secured Internet connection for your privacy. Your confidentiality will be maintained to the degree permitted by the technology used. Specifically, no guarantees can be made regarding the interception of data sent via the Internet by any third parties. To request that your data be removed from MetricWire, please contact us to facilitate this action at sleep-study@colostate.edu. Although tracking location services are provided by MetricWire, we have disabled these features, and they will not be collected in this project.

It is not possible to identify all potential risks in research procedures, but the researchers have taken reasonable safeguards to minimize any known and potential risks.

WILL I RECEIVE ANY COMPENSATION FOR TAKING PART IN THIS STUDY?

If you complete all procedures and visits of the study, you may retain the light therapy devices used in this study. The commercial value of the lights used in this study is estimated at $600.

WHO WILL SEE THE INFORMATION THAT I GIVE?

All information gathered in this study will be kept as confidential as possible. Your privacy is very important to us, and the researchers will take every measure to protect it. Your information may be given out if required by law; however, the researchers will do their best to make sure that any information that is released will not identify you. No reference will be made

in written or oral materials that could link you to this study. For this study, we will assign a code to your data so that the only place your name will appear in our records is on the consent and in our data spreadsheet which links you to your code. Only members of the research team will have access to the link between you, your code, and your data. All records will be stored in a restricted access folder and a locked drawer in a restricted-access office at CSU for three years after completion of the study. After the storage time, the information gathered will be destroyed.

The research team works to ensure confidentiality to the degree permitted by technology. It is possible, although unlikely, that unauthorized individuals could gain access to your responses because you are responding online. However, your participation in this online survey involves risks similar to a person's everyday use of the internet.

There are organizations that may inspect research records that may include yours. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- The Colorado State Institutional Review Board, IRB, is a group of people who review the research with the goal of protecting the people who take part in the study.
- Office of Human Research Protections, the Food and Drug Administration.

Your identity/record of receiving compensation (NOT your data) may be made available to CSU officials for financial audits.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at anytime.

WILL MY DATA BE USED FOR FUTURE RESEARCH?

If you choose to take part in this study, your private information & biospecimen will be collected. Any identifiers linking you to these things will be removed. After we remove those identifiers, the information & biospecimen could be used for future studies or distributed to another research for future research studies without you knowing about it at that time.

CAN MY PARTICIPATION IN THE STUDY END EARLY?

There are several reasons your participation could end early:
If you decline to complete all assessments or are unable to carry out procedures or answer questions, if there is a significant change in your health status, or if you repeatedly fail to attend scheduled appointments, the research team reserves the right to terminate your participation in the study without your consent.

If your participation ends early for any of the above reasons, we will contact you and let you know the reason why you will not be allowed to continue. We will make arrangements to send you the study results you have completed. You will receive compensation only upon completion of all assessments and return of all equipment.

DO I HAVE TO TAKE PART IN THE STUDY?

Your participation in this study is voluntary. You may refuse to participate in this study or in any part of this study. You may withdraw at any time without prejudice to your relations with CSU. You are encouraged to ask questions about this study at the beginning or any time during the research study.

PARTICIPANT CONSENT:

Your signature acknowledges that you have read the information stated and voluntarily wish to participate in this research. Your signature also acknowledges that you have received, on the date signed, a copy of this informed consent document containing 6 pages.

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Signature of participant Date

Name of participant

Signature of person obtaining informed consent Date

Name of person obtaining informed consent