Official title:
Blocking nocturnal blue light to treat insomnia: A pilot randomized controlled trial

NCT #:
NCT0268800

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# Columbia University Consent Form

## Protocol Information

**Attached to Protocol:** IRB-AAAQ6404
**Principal Investigator:** Ari Shechter (as4874)
**IRB Protocol Title:** Blocking nocturnal blue light to treat insomnia: A pilot randomized controlled trial

## General Information

**Consent Number:** CF-AABJ1300
**Participation Duration:** ~6 weeks
**Anticipated Number of Subjects:** 15
**Research Purpose:** To determine if wearing lenses of different colors before bedtime can be used as a non-drug based method to improve sleep in people with insomnia.

## Information on Research

The purpose of this form is to give you information to help you decide if you want to take part in a research study. This consent form includes information about:
- why the study is being done;
- the things that you will be asked to do if you are in the study;
- any known risks involved;
- any potential benefit; and
- options, other than taking part in this study, that you have.

The research assistant will discuss the study with you. If at any time you have questions about the study, please ask a member of the study team. Take all the time you need to decide whether you want to take part in this research study. The purpose of this research is described below.

PURPOSE

You are being asked to join this research study which will examine the effect of different color lenses worn as non-prescription glasses on your sleep quality and daytime alertness levels. You will be asked to wear 2 different colored lenses as glasses on your face for the 2 hours before you go to sleep each night for a full week. There is some research that suggests light exposure before bedtime can affect sleep. You are being asked to take part in this study because you have insomnia (difficulty initiating or maintaining sleep) or an experience of sleep that is unrefreshing. You will be one of approximately 15 men and women to enroll in this study at Columbia University Medical Center.

PROCEDURES

In order to qualify for the study, you must be between 18 and 65 years of age. You must experience insomnia, and have been experiencing this for at least 1 month. This typically includes difficulty falling asleep, difficulty staying asleep, waking up unrefreshed, and often feeling tired during the day. To participate you cannot have a prior diagnosis

of obstructive sleep apnea, narcolepsy, restless legs syndrome, deep vein thrombosis (blood clots in the deep veins), nocturia, or prostate conditions. You also cannot be a shift worker, taking beta blocker medication, current cigarette smoker, pregnant, breastfeeding, or have a child less than 1 year of age at home. You also cannot participate if you typically consume more than 5 cups or coffee a day, or 10 cans of soda per day, or have energy drinks daily.

There are two experimental phases in the study, each testing the effects of a different type of glasses lenses. Full participation in the study includes completing both phases. Once you are enrolled in the study, you will be randomly assigned, like a flip of a coin, to one of 2 experimental sequences: lenses A followed by lenses B, or lenses B followed by lenses A. Depending on the sequence, you will be given a pair of glasses with lenses A or lenses B and be asked to wear them for the 2 hours before you go to sleep, each night, while you are at home for 7 days (a full week). The difference between the lenses is that one of the sets of lenses blocks blue light from entering your eye. During this time we will also ask you to wear a small device called an Actigraph around your waist during the daytime and around your wrist during the night while you sleep. The Actigraph is a small device, about the size of a wrist-watch, that measures your movements. During the entire week that you are at home wearing the lenses before sleep and the actigraph, we will ask you to complete a questionnaire in the morning when you wake up. This questionnaire will ask you to write down when you went to sleep, when you woke up, when you put on the lenses, and will ask you about the quality of your sleep. At the start of the intervention, you will be asked to complete a 30-minute computerized test battery on memory, attention, and language. After the 7-day period at home wearing the lenses, you will be asked to enter the Clinical Research Resource (CRR) at Columbia University Medical Center at around 6:00 pm and stay onsite overnight until around 10:00 am the next day. During this time period in the laboratory, you will remain in dim lights (like the lighting of a small desk lamp) while you are awake, and in darkness while you are scheduled to go to sleep. Your scheduled sleep episode will last 8 hours and will be based on the times you slept at home during the week before your lab entry. During your laboratory stay, you will be asked to remain in bed without getting up. After your arrival in the lab, you will again be asked to complete the 30-minute computerized test battery on memory, attention, and language. Once per hour during your scheduled wake episode, you will be asked to stretch your legs by flexing and extending your feet 10 times. Instead of meals, your food intake will be separated into small servings of BOOST Plus Nutritional Drink that are calculated to give you all of your energy needs for the 15 hours you are in the lab. These servings of BOOST Plus drink will be served to you once per hour during your scheduled wake episode. During the time you are awake in the laboratory, you will be asked to complete a series of short questionnaires on your levels of sleepiness, alertness, mood, and appetite. While not filling out questionnaires, you will have free time to watch television, read, use a laptop computer or tablet, talk on the telephone, etc. We will obtain small blood samples each hour while you are in the lab, including while you are asleep. Each sample will be about 3 ml or just over a half a teaspoon. During the entire lab visit we will obtain about 45 ml in total, or just over 9 teaspoons of blood. We will obtain these samples by drawing your blood through a long blood line. After you enter the lab, a trained nurse will insert a needle into a vein in your arm, which will be replaced with a thin flexible tubing. This tubing will remain in your arm and you should not feel pain when blood samples are obtained. The blood line will be removed from your arm about 3 hours after you wake up in the morning. Starting 2 hours before you go to sleep you will be asked to wear the lenses as you did while you were at home. During this time, we will also bring in a bright light into the room that you will be exposed to for 2 hours. You will not be asked to look directly into the light but it will be in your line of vision. You will have an 8-hour sleep opportunity in the lab. This sleep episode will be based on the times you slept while you were at home during the 7 days (a full week) before you came into the lab. Before your sleep episode, a member of the technical staff will set up a portable polysomnographic (PSG) sleep recording device. The PSG recording will involve attaching electrodes to various locations on your scalp, and also on the skin near your eyes and chin. These electrodes are attached with the use of an adhesive paste and in some cases tape. When you wake up in the morning, we will remove the sleep electrodes. You will be asked to remain in bed, in dim lights, for about another 2 hours. After this, you will be permitted to get out of bed, and the procedures will be complete. You will have the opportunity to

shower before you leave if you choose.

After discharge from the lab, you will return home and will start the 4 week "washout" period during which time you will be asked not to use any lenses and to go about your typical routine. This "washout" period is used to reduce the effects of the first experimental phase on the second experimental phase.

After the 4-week period, you will be given the alternate lenses type (Lenses B if you started with Lenses A; or Lenses A if you started with Lenses B). You will then be asked to repeat each of the procedures from the previous testing period. This will include wearing the lenses at home each night for 7 days (a full week), wearing the actigraph, completing the post-sleep questionnaire, and finally, returning to the laboratory for the overnight visit to repeat the CRR lab procedures outlined above.

The total duration of the study will be about 6 weeks. This includes the two separate 7-day periods at home, the 2 separate 1 day periods in the lab, and the 4-week washout period.

## Benefits

There is no anticipated direct benefit to you individually for your participation in this study. You can be given the results of your individual tests as well as the average of all participants for each phase when the study is completed, if you request. Participation in this study will allow the scientific community to better develop methods for treating sleep complaints.

## Risks

There will be some minimal risks or discomforts if you take part in this study. There is no known risk associated with wearing the lenses before bedtime, or wearing the actigraph.

Blood Sampling

There are minimal risks associated with the blood sampling, which may produce some minor bruising at the insertion site for the needle. Risks of having blood drawn are soreness and/or a black and blue mark at the site from where the blood is drawn. Sometimes, people feel uncomfortable at the time of the blood draw. Occasionally people feel lightheaded or faint. There is also a small risk of infection whenever blood is drawn. Blood sampling will be carried out by a trained nurse following standard procedures. A physician will be on call during the entire procedure. You may also experience dizziness or fainting after the blood samples.

Sleep Recording

There are minimal risks associated with the in-lab PSG recording. Affixing or removing electrodes to the scalp and face for the PSG recording may cause mild irritation to some patients. Hypoallergenic materials will be used to minimize irritation associated with the PSG recordings.

## Voluntary Participation

Taking part in this study is your choice. You can decide not to take part in or stop being in the study at any time. Your choice will not affect the treatment you receive from doctors and staff at Columbia University Medical Center. Your participation will end if the investigator stops the study earlier than expected.

## Alternative Procedures

You may choose not to take part in this research study. You may choose to not enroll in the study, or leave the study at any time.

## Confidentiality

Any information collected during this study that can identify you by name will be kept confidential. We will do everything we can to keep your data secure, however, complete confidentiality cannot be promised. Despite all of our efforts, unanticipated problems, such as a stolen computer may occur, although it is highly unlikely. Your specimens and questionnaire responses will be assigned a code number, and separated from your name or any other information that could identify you. The following individuals and/or agencies will be able to look at and copy your research records: - The investigator, study staff and other medical professionals who may be evaluating the study; - Authorities from Columbia University and New York Presbyterian Hospital, including the Institutional Review Board ('IRB'); - The United States Food and Drug Administration ('FDA') and/or the Office of Human Research Protections ('OHRP'); - The sponsor of this study, the American Sleep Medicine Foundation, including persons or organizations working with or owned by the sponsor; - Other government regulatory agencies (including agencies in other countries) if the sponsor is seeking marketing approval for new products resulting from this research.

## Additional Costs

There are no costs to you for taking part in this study.

## Compensation

You will be compensated for your time and participation in the study. For full participation you will be compensated $300. You will receive compensation in the following way: $50 for phase 1 at home portion, $100 for phase 1-laboratory day, $50 for phase 2 at home portion, and $100 phase 2-laboratory day. You will also be able to keep the

glasses given during the study. It is possible that there will be a loss of confidentiality due to interactions with the Office of the Treasurer when processing your payment for participation in the study. We will take all efforts to limit this. There may also be delays in the receipt of payment due to unforeseen circumstances which can slow the processing of the payment.

## Additional Information

If you have any questions or are hurt while taking part in this research study, you should contact Dr. Ari Shechter, Ph.D, by phone at 212-851-5584 or by email at as4874@columbia.edu.
If you have any questions about your rights as a research subject, you should contact the Columbia University Institutional Review Board by phone at (212) 305-5883 or by email at irboffice@columbia.edu. More information about taking part in a research study can be found on the Columbia University IRB website at: http://www.cumc.columbia.edu/dept/irb.

## Statement of Consent

I have read the consent form and talked about this research study, including the purpose, procedures, risks, benefits and alternatives with the researcher. Any questions I had were answered to my satisfaction. I am aware that by signing below, I am agreeing to take part in this research study and that I can stop being in the study at any time. I am not waiving (giving up) any of my legal rights by signing this consent form. I will be given a copy of this consent form to keep for my records.

## Signatures

**Participant Signature Lines**

**Study Participant**
Print Name _____ Signature _____
Date _____

**Research Signature Lines**

**Person Obtaining Consent**
Print Name _____ Signature _____
Date _____