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Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH:	A Randomized Crossover Trial of Bright Light Therapy in Irritable Bowel Syndrome
NCT06676488	
SPONSOR:	NIH- National Institute of Diabetes & Kidney Diseases (NIDDK)
INVESTIGATOR:	Caitlin Green, MD
STUDY-RELATED:	843-792-7974
PHONE NUMBER:	843-792-5555 (24 hours)
ADDRESS:	Medical University of South Carolina 30 Courtenay Dr.

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. The purpose of this research study is to assess whether morning bright light therapy (BLT) using a wearable device called a Re-Timer could potentially improve Irritable Bowel Syndrome (IBS) symptoms and decrease intestinal permeability (leaky gut). Morning bright light therapy will be administrated through a safe-wearable glasses device called a Re-Timer. The Re-Timer glasses are lightweight and deliver blue-green light at 500nm, mimicking exposure to natural light.

If you agree to participate in this study, your participation will last approximately 6 weeks. You will be asked to complete 4 separate study visits, which may take 15 mins to two hours each. The study procedures include having your blood drawn twice (at Visit 2 and Visit 4), completing questionnaires, wearing the actigraph (which is a watch-like device to measure your sleep-wake activity), providing 2 stool and 2 urine samples, taking a urine pregnancy test if you are of childbearing potential, wearing the Re-Timer device for 60 minutes in the morning, and keeping a log of your Re-Timer use. You will be asked to wear the Re-Timer glasses for 4 weeks total. For 2 of those weeks, you will be wearing the Re-Timer device that will be providing BLT and for the other 2 weeks, you will be wearing the device not providing BLT. The device not providing BLT is called a placebo device.

Participation in this study may improve your Irritable Bowel Syndrome (IBS), but that cannot be guaranteed. The risks of this study include risks from the Re-Timer glasses (headache, eyestrain, nausea, agitation); risks from the sugar solution (gas, bloating, headache, nausea, vomiting, diarrhea, constipation); risks from the stool and urine collections (mild discomfort); risk of randomization (you will not be receiving active treatment for 2 weeks while using the placebo device); risks from the blood collection (including momentary discomfort and/or bruising, infection, excess bleeding, clotting, or fainting is possible, although unlikely); and risk to your confidentiality. There may be unknown risks that we have not identified. You do not have to participate in this study. There are alternative treatments for IBS that Dr. Caitlin Green can discuss with you.

If you are interested in learning more about this study, please continue to read below.

A. PURPOSE OF THE RESEARCH

You are being invited to participate in a research study because you have been diagnosed with Irritable Bowel Syndrome (IBS). Research studies answer important questions that might help change or improve the way we do things in the future.

Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. The investigator in charge of this study is Dr. Caitlin Green. The study is only happening at MUSC and approximately 30 people will take part.

B. PROCEDURES

If you agree to be in this study, the following will happen:

VISIT 1 (Enrollment/Randomization):

- During the initial enrollment, you will be asked to complete questionnaires to collect clinical and socio-demographic data, as well as past medical, surgical, and family history.
- In addition, you will be asked to complete questionnaires to evaluate your IBS severity; sleep and wake schedules; sleep and wake disturbances; the timing of your meals and snacks; fatigue levels; depressive symptoms, risk of sleep apnea; and symptoms of restless leg syndrome. You will take a urine pregnancy test if you are of child bearing potential.
- If you qualify, you will then be randomized (50/50 chance like flipping a coin) to either wear the investigational device called a Re-Timer or a placebo device for 2 weeks. The placebo device looks like the Re-Timer but does not provide BLT. During the 6-week course of the study you will be assigned to both the Re-Timer device and to the placebo device for 2 weeks each, but the order of the BLT or placebo (no BLT) will be determined at random. You will not be told whether you are receiving the BLT or placebo BLT. You will be asked to wear the device for 60 minutes every morning for 2 weeks and keep a log of the times you wear it. It is best to wear the device during the first hour you are awake and to stay indoors. You can wear the device freely throughout your home or work location, but you should avoid activities that could potentially be harmful (i.e., driving, contact sports, operating heavy machinery). You will also be asked to wear a wrist actigraphy device, which is a watch like device called an actigraph for the same 2 weeks to objectively assess whether you have disruptions in your circadian rhythm. Your circadian rhythm is your sleep-wake pattern over the course of a 24-hour day. This wrist actigraph device will record your sleep cycle during the night and be able to assess your circadian rhythm.
- You will be given stool collection kit that you will return at Visit 2 in 2 weeks.
    - All supplies necessary for stool collection will be provided by study staff.
    - Collecting a stool sample involves placing a "hat" on your commode (toilet) before you are seated. This hat will collect the stool and then you can use a wooden spatula to transfer a sample of your stool into a bag.
- You will be given a 24-hour urine collection kit that you will return at Visit 2.
    - In order to collect the urine, you will be provided a urine jug/container and a urine hat (that you place over the toilet seat). Collect all urine over the next 24 hours in the urine "hat" and add it to the jug/container for storage.

  - Before the urine collection, you will need to fast for 8 hours and then drink 8 oz of liquid containing sugars called lactulose, mannitol, sucrose, and 8 capsules with 250 mg of sucralose.
- This visit will last approximately 1 to 2 hours.

VISIT 2 (2 weeks after initial enrollment/Washout):

- During this visit, you will be asked to repeat some of the questionnaires you completed at Visit 1.
- You will return the stool and urine collections.
- You will have 5 tubes of blood drawn (5 teaspoons total) from your vein to evaluate for markers of inflammation**.**
- You will return the actigraph.
- This visit will last approximately 1 hour.

VISIT 3 (4 weeks after initial enrollment/Condition 2):

- You will be given a new actigraph to continue wearing until Visit 4.
- You will be given stool collection kit that you will return at Visit 4 in 1-2 weeks.
  - All supplies necessary for stool collection will be provided by study staff.
  - Collecting a stool sample involves placing a "hat" on your commode (toilet) before you are seated. This hat will collect the stool and then you can use a wooden spatula to transfer a sample of your stool into a bag.
- You will be given a 24-hour urine collection kit that you will return at Visit 4.
  - In order to collect the urine, you will be provided a urine jug/container and a urine hat (that you place over the toilet seat). Collect all urine over the next 24 hours in the urine "hat" and add it to the jug/container for storage.
  - Before the urine collection, you will need to fast for 8 hours and then ingest 8 oz of liquid containing sugars called lactulose, mannitol, sucrose, and 8 capsules with 250 mg of sucralose.
- You will now crossover to the other group (if you wore the device providing BLT prior, you will now wear the placebo device not providing BLT or vice versa) for 2 weeks. You will be asked to keep a daily log of the times you wore the device.
- This visit will last approximately 15 minutes.

VISIT 4 (6 weeks after the initial enrollment/Completion)

- During this visit, you will be asked to repeat the questionnaires you completed at Visit 2.
- You will return the stool and urine collections.
- You will have 5 tubes of blood drawn (5 teaspoons total) from your vein to evaluate for
- markers of inflammation.
- You will return the Re-Timer or placebo device and wrist actigraphy device.
- This visit will last approximately 1 hour.

You may decide to stop your participation in the study at any time.

The researchers and Sponsor also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interests;
- You do not follow the instructions;
- The study is canceled for any reason.

C. DURATION

Participation in the study will take about 4 visits over a period of 6 weeks.

D. RISKS AND DISCOMFORTS

Side effects, risks, and/or discomforts from participation in this study may include:

Risks from Re-Timer Glasses:
You may experience side effects such as headache, eyestrain, nausea, and agitation. Prior participants have noted that these side effects only last a short time and resolved without intervention. If side effects do occur, you will have direct access to the study's research staff, and if decided together with the PI, the usage of the device will be discontinued.

Risks from the ingested sugar solution:
You may experience gas, bloating, headache, diarrhea, constipation. Nausea and vomiting have been reported.

Risks from the stool and urine collections:
You may experience mild discomfort during the collection of the stool and urine specimens. You will be explained the process and will be given written instructions.

Risks from randomization:
You will be wearing the Re-Timer glasses for a total of 4 weeks. For 2 weeks you will be receiving the BLT and for the other 2 weeks you will be receiving the placebo (wearing the device that does not provide BLT). The BLT may prove to be less effective or to have more side effects than other available treatments. For the 2 weeks that you are wearing the placebo device you will not be receiving active treatment.

Risks from blood collection:
Risks associated with drawing blood from your arm include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting is possible, although unlikely.

Risks to confidentiality:
All precautions will be taken to protect your personal identity and medical information from third parties. However, there still remains a risk of a loss of confidentiality of your personal information as a result of participation in this study.

Unknown risks:
There may be unknown risks that we cannot predict. The researchers will let you know if they learn anything during the course of the study that might make you want to change your mind about participating in this study.

E. MEDICAL RECORDS AND/OR CERTIFICATE OF CONFIDENTIALITY

CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the Federal government. This means that the researchers may not disclose information or biospecimens that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, nor can the information or biospecimens be used as evidence, unless you have consented to this disclosure. Information or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you are an MUSC patient you have an MUSC medical record. If you have never been an MUSC patient, a MUSC medical record will be created for the purposes of this study. Results of research tests or procedures will be included in your MUSC medical record. All information within your medical record can be viewed by individuals authorized to access the record. We will make every effort to keep confidential all research information in the medical record that identify you to the extent allowed by law; however, there is the possibility that your research information will be disclosed.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law. Examples of required disclosure include: child abuse and neglect, or harm to self or others

Finally, a Certificate may not be used to withhold information from the Federal government needed for auditing or evaluating Federally funded projects or information needed by the FDA.

F. BENEFITS

The potential benefit to you is that the treatment you receive may prove to be more effective than other available treatments, although this cannot be guaranteed.

G. COSTS

There will be no cost to you as a result of participation in this study.

H. PAYMENT TO PARTICIPANTS

You will be compensated $150 after visit 2, $150 after visit 3 and $200 after visit 4. If you do not finish this study, you will be paid for the study visits you have completed. You will be paid immediately after completing the activities for the paid visits using a ClinCard. If you complete all visits, you will be paid a total of $500 by the end of the study. Payment for study visits will be made using a pre-paid debit card, called a ClinCard. It works like a bank debit card and you may use the card to purchase goods or services everywhere Debit MasterCard is accepted. You will be given a ClinCard at the beginning of the study. Each time you receive payment for participation in this study, the money will be added to the card, as outlined in the payment schedule above. Details of the debit card system are explained on an additional sheet.

Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds

$600.00 in a calendar year, you will be issued a Form 1099.

I. ALTERNATIVES

You do not have to be in this study to have your IBS treated, alternative treatments include medications and therapies. Dr. Green can discuss these alternatives with you.

J. DATA SHARING

Information about you (including your identifiable private information and/or any identifiable biospecimens) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative.

K. DISCLOSURE OF RESULTS

Your individual study results will not be shared with you.

L. AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, your study doctor and his/her research team will keep records of your participation in this study.

The health information MUSC may use or disclose (release) for this research study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.

Your study doctor and his/her research team will use and disclose (release) your health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
- Health insurer or payer in order to secure payment for covered treatment;
- Federal and state agencies and MUSC committees having authority over the study such as:
    - The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.

Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You do not have to sign this consent form. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study or, if you are participating in a study designed for the development of a drug or device, your authorization will remain in effect until the drug or device is approved by the FDA or until the company's application to study the drug/device is withdrawn. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.

M. SIGNIFICANT NEW FINDINGS

If there are significant new findings during the course of the study, you will be notified.

N. CLINICAL TRIALS.GOV

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.

O. COLLECTION OF SPECIMENS

As part of this study, we would like to store blood, urine, and tissue specimens collected from you for future research on IBS. This future research may be conducted by Dr. Caitlin Green or by other researchers who obtain IRB approval for their research. This research will not involve genetic studies. There are several things you should know before allowing your (tissues, cells, urine, and/or blood) to be studied or to be stored.

1. The specimens will be labeled with a code that only study personnel can link back to you. Researchers outside of this study will not be given a link between the code number and your name or any other identifying information. While we hope this will prevent any potential loss of privacy or confidentiality, we cannot make any guarantees.
2. In addition to your name, other information about you might be connected to your sample. For instance, information about race, ethnicity, sex, your medical history, and so forth might be available to

investigators studying your specimen. Such information might be important for research or public health. It is possible that this information (including genetic information) might come to be associated with your racial or ethnic group.

3. The specimens obtained from you in this research may help in the development of a future commercial product. There are no plans to provide financial compensation to you should this occur.
4. In this study, investigators will not tell you what they find out about you, nor will they contact you if a test becomes available to diagnose a condition you might have or later develop.

You may request at any time that your research samples be removed from storage and not be used for future research. If you decide you want your samples removed, you may contact Dr. Caitlin Green via written communication at the following address: Medical University of South Carolina, 30 Courtenay Drive, Charleston, SC 29425. Once the request is received, and if your samples have not already been used for other research, they will be destroyed. If you do not make such a request, your specimens will be stored indefinitely or until completely used.

R. FUTURE CONTACT

The researcher in charge of this study might like to contact you in the future about other research opportunities. Please initial by your choice below:

____Yes, I agree to be contacted

____No, I do not agree to be contacted

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The sponsor and the Food and Drug Administration (FDA) will receive copies of the research records. The investigators associated with this study, employees of the sponsor, the FDA, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event of a study related injury, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. The data collected on you to this point remains part of the study database and may not be removed. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in

your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact Dr. Caitlin Green at 843-792-7974 I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.

Signature of Person Obtaining Consent Date	*Name of Participant

Signature of Participant Date