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Title of Study: Bright Light Treatment At Home to Manage Chronic Pain in U.S. Veterans

Sponsor: National Institutes of Health

RUSH

Subject Information Sheet and Consent Document
Main Study

Introduction

This form provides you with information so you can understand the possible risks and benefits of participating in this study; so that you can decide whether or not you want to be a part of this research study. Before deciding whether to participate in this study, you should read the information provided on this document and ask questions regarding this study. Once the study has been explained and you have had all your questions answered to your satisfaction, you will be asked to sign this form if you wish to participate.

Why are you invited to participate in this study?

You are being asked to take part in this study because you have met our study entry requirements. These include that you are a U.S. veteran, have been diagnosed with chronic low back pain, are over 18 years old, and are not taking any over the counter melatonin pills. You have informed us of all medications and over the counter supplements that you are taking. Furthermore, you are not pregnant, trying to get pregnant or breastfeeding.

Research studies include only people who choose to take part. Please take your time to make your decision and discuss it with your friends, family and/or physician. Remember that your participation is completely voluntary. There is no penalty if you decide not to take part in this study or decide later that you want to stop participating in this research study. Your care at Rush University Medical Center will not be affected if you decide not to participate.

What is the purpose of this study?

The purpose of this study is to measure your pain, pain sensitivity, sleep and timing of your internal circadian (body) clock, before and after bright light treatment at home.

How many people are expected to take part in the study?

About 50 study subjects will be enrolled in this study.

What will you be asked to do?

The study will take 53 days and consists of:
1) A home sleep section (7 days)
2) A lab visit and later that same day a home saliva collection in the evening (1 day)
3) Another home sleep section, this time with a morning bright light treatment you administer to yourself (6 days)
4) Another lab visit and later that same day a home saliva collection in the evening (1 day)
5) Another home sleep section, with a morning bright light treatment you administer to yourself (7 days)
6) Another lab visit and later that same day a home saliva collection in the evening (1 day)

7) A 30 day follow up where you rate your pain, sleep and mood every day for a month on an electronic diary (30 days). There will be a final lab visit about halfway through the 30-day follow up to allow us to download data from your electronic diary.

During the home sleep sections of the study, you will sleep at your usual sleep times and fill out a few daily questionnaires.

The first three lab visits will consist of downloading data from the wrist monitor, a 1 hour pain testing session, followed by a training session to teach you how to collect your saliva at home in dim light in the evening. After the first saliva collection, research staff will visit you in your home to deliver 2 light boxes and train you how to use them. They will also collect your saliva samples. Staff will visit you in your home a further 2 times to collect saliva samples and the light boxes.

Before you agree to participate, you will be shown a schedule of when you will need to sleep at home and when you will have to visit the laboratory.

RESPONSIBILITIES/EXPECTATIONS AND PROCEDURES

1) Sleep at Home: When you sleep at home, you will be asked to follow your usual bed and wake times. It is very important your sleep schedule is not influenced by special events (for example: weddings, vacations, concerts, exams, etc.).

2) Wrist Activity Monitor: You will be required to wear a wrist activity monitor, which looks like a wrist watch, for the entire study, even when sleeping or showering. It will record your movements and tells us when you are asleep. It also has a light sensor on it so you will need to make sure it is not covered by your sleeves. The light sensor will tell us if you used the light boxes as instructed (see below).

3) Daily Sleep, Mood and Pain Questionnaires: You will be required to complete a sleep, mood and pain questionnaire every day. We may call you during the first week of the study and ask you for your sleep times.

4) Height, Weight, Vision Tests and PROMIS Scales: On Day 1, after you are enrolled in the study, we drug test you (see below) and will measure your height and weight, test your eyesight, and test if you are color blind. You will also be asked to complete a psychological Computerized Adaptive Test (CAT) called PROMIS. The test may take up to 30 minutes to complete.

5) Laboratory Visits: After the start of the study you will need to visit the lab 4 times. During the first three visits we will breathalyze you (you will blow into a meter that measures the alcohol in your body), check over the logs you completed at home, and the data collected by the wrist monitor. After this you will participate in a 1 hour pain testing session. At the end of the pain testing you will be trained in how to collect your saliva at home that evening. The fourth and last lab visit will only consist of us downloading data from your e-diary.

To assess your pain sensitivity, you will first be asked to exercise your non-dominant (least favored) hand for two minutes by squeezing a hand-grip exerciser. A blood pressure cuff will then be inflated (blown up) on that arm (slightly higher than when you normally have your blood pressure taken). This level of inflation is not harmful, but will result in a slowly building "aching" pain in that arm (this task is called an "ischemic" pain task because it decreases blood flow temporarily). You will be asked to indicate when the sensation first becomes painful, and then indicate when you wish to stop the task (because you have reached your maximum

tolerance for this type of pain). This task will last a maximum of 8 minutes. At 30 second intervals during this task, you will be asked to rate the level of pain you are experiencing on a 0-100 scale, with 0 being "no pain" and 100 being the "worst possible pain." Following completion of this task, you will be asked to rate the intensity of the pain you experienced using a questionnaire.

Next, you will engage in a task that involves repeated brief applications of a computer-controlled heat stimulus to several areas of your non-dominant forearm. The equipment used in this task is safe and only produces heat at 127 degrees Fahrenheit or less, which is well below the level that causes burns. You will be asked to participate in four brief heat stimulation trials during which you will be asked to tell us when the heat stimulus first becomes painful (your heat pain threshold), and four brief trials during which you will be asked to tell or show us when your heat pain tolerance has been reached. For each trial, as soon as your tolerance is reached, the equipment will rapidly cool your skin to normal body temperature, ending the pain stimulus. Immediately upon completion of the final heat pain tolerance trial, you will be asked to rate the intensity of the pain you experienced.

6) Saliva Collection at Home: You will provide a saliva sample every half hour starting 6 hours before your usual bedtime and up until your usual bedtime. You will collect your saliva by rolling a piece of cotton around in your mouth. These samples will be tested at a later time to measure the amount of melatonin in your body. Melatonin is a chemical that your body produces that acts as an indicator of body clock time. We will give you a saliva collection kit to take home. This kit will include a checklist, ipod with preset alarms, salivettes (plastic tubes to place the piece of cotton in), a test tube rack to hold the salivettes, a label dispenser to label the salivettes, an insulated travel bag to return the salivettes to the lab, and a white bottle containing pieces of cotton. The white bottle contains a microchip and will record the time when you take each piece of cotton. You will be asked to dim your lights, and will need to wear a photosensor pinned to your outermost clothing to record the light levels during saliva collection. You must make sure it is not covered. Starting 2 days before and until the end of each saliva collection you will not be permitted to consume caffeine or alcohol. On the day of saliva collection you will not be permitted to consume caffeine, alcohol, bananas, decaffeinated tea or coffee or food with red coloring. You will also not be permitted to use toothpaste, mouthwash, lipstick or shower or exercise intensely during the hours of saliva collection. These restrictions are because they interfere with the measurement of melatonin. The day after each saliva collection, staff will visit you to collect the kit and read the data from the wrist monitor, light sensor and white bottle into a computer. These data will help us determine if you correctly followed the checklist for saliva collection at home.

7) Light Treatment at Home: After the first saliva collection at home, research staff will visit you at home to deliver 2 light boxes. They will set the light boxes up and train you how to use them and when to use them. You will be asked to use the light boxes for 1 hour each morning, immediately after you wake up. We will call you everyday to check if you are having any problems with the light treatment.

The light boxes will produce bright light that is brighter than most indoor lighting, but not as bright as being outside on a cloudy day. The light boxes are safer than sunlight because they do not contain ultraviolet (UV) light. There are no known harmful effects from light of this intensity, but rarely people experience headaches.

8) Alcohol: You will **not** be allowed to drink beverages containing alcohol beginning 2 days before each home saliva collection. **You will be breathalyzed when you come to the**

laboratory (you will blow into a meter that measures the alcohol in your body). If you test positive, indicating the presence of alcohol, you will be dropped from the study, but this information will be kept confidential.

9) Caffeine: You will **not** be allowed to drink beverages containing caffeine beginning 2 days before each home saliva collection because caffeine interferes with the measurement of melatonin.

10) NSAIDS: You will not be allowed to use any non-steroidal anti-inflammatory drugs (NSAIDS), such as ibuprofen, aspirin, naproxen, Aleve and Advil for 3 days before each home saliva collection session, because they will interfere with the measurement of melatonin. You will be given a list of over the counter medication that are NSAIDS, and that are prohibited. It is okay to take acetaminophen (Tylenol) at any time during the study and we will provide you with Tylenol to take in case of pain.

11) Recreational Drugs and Nicotine: You must refrain from taking recreational (street) drugs and tobacco products during the entire study. Tobacco products include nicotine patches, cigarettes, cigars and pipes (regular or hookah). You will be asked to give a urine sample on the day you start the study, to test for common drugs of abuse and nicotine. If it is positive, indicating the presence of drugs or nicotine, you will be dropped from the study, but this information will be kept confidential.

12) Menstrual Cycle: We need to keep track of where you are within your menstrual cycle during the study. When you enroll in the study we will ask you when your last menstrual period started. If you do not start your menstrual cycle during the study, we will follow up with you after the study has ended to find out the start date of your next menstrual cycle. We need to know this for research purposes only, in order to analyze the data properly. If you are menopausal we will not need to ask you about your menstrual cycle.

How long will you be in the study?

The study takes 53 days.

What are the possible risks of the study?

Some of the PROMIS scales (questionnaires) may ask you very personal information about your physical and mental health and this may be uncomfortable for you.

You will experience brief, moderate intensity acute pain upon application of the ischemic and heat pain stimuli that will be used both for acute pain evaluation and assessment of your natural pain control systems. However, you have total control over the duration of your exposure to these pain stimuli because you may stop each task by indicating when you have reached your tolerance limit. Previous research indicates that these tasks are safe, but to further maximize safety, people experiencing cardiovascular (heart and blood vessel) problems will be excluded from this study. In addition, the device that generates the heat for the heat pain task can only produce heat up to 127 degrees Fahrenheit – which is well below the heat level that causes burns – and automatically shuts off if it reaches that temperature. Because you have total control over the duration of each task, its impact on your distress level is expected to be minimal.

The light treatment at home may shift your circadian (body clock) and you may experience symptoms of "jet-lag" like those experienced by jet travelers. These symptoms may include an

upset stomach (nausea and/or diarrhea), fatigue, sleepiness, and/or headache. Your pain may get better or worse during the study.

Are there any anticipated pregnancy risks?

If you are pregnant, planning on becoming pregnant or breastfeeding, you cannot take part in this study. If you still get your periods we need to keep track of when you get your menstrual period during the study. You must indicate whether or not you get your period on your daily logs. We need to know this for research purposes only, in order to analyze the data properly. If you become pregnant, you must notify the study coordinator immediately. If you become pregnant, we will have to drop you from the study.

Are there benefits to taking part in the study?

You may find the bright light treatment improves your pain.

What other options are there?

The only alternative to participating in this study is not to participate. All subjects have the right to withdraw from the study at any time. If you want to withdraw you can tell any of the study staff you interact with that you wish to withdraw. Any data already collected will be kept on file.

What about confidentiality of your information?

Records of participation in this research study will be maintained and kept confidential as required by law. Coded names will be used to identify research-related materials, such as saliva samples, wrist activity recordings and answers to questionnaires. In addition to our staff, the National Institutes of Health (which funds this study) will be granted direct access to the data you provide, without violating your confidentiality, to the extent permitted by the applicable laws and regulations.

Confidentiality and disclosure of your personal information is further described in the attachment to this form. The attachment is entitled HIPAA Authorization to Share Personal Health Information in Research (2 pages).

Your identity will not be revealed on any report, publication or at scientific meetings.

The Rush Institutional Review Board (IRB) will also have access to your files as they pertain to this research study. The IRB is a special committee that reviews human research to check that the rules and regulations are followed.

A description of this study 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 web site will include a summary of the results. You can search this website at anytime.

What are the costs of your participation in this study?

There is no cost to you for participating in this study. All the equipment and procedures will be covered by the study. You or your insurance will not be billed for any tests or procedures performed.

Will you be paid?

If you complete the entire study, you will be paid a total of $825. The check may take up to 4 weeks to arrive. The payment will be reported to the Internal Revenue Service. We will collect

your social security number when you begin the study in order to process your payment. We will need all the equipment returned before we process any payment for you.

The schedule of payments is as follows. You will be paid $200 after you complete each of three home saliva collection sessions. You will be paid an additional $225 after the 30 day follow up period, which is the end of the study.

If we have to drop you for not following the rules (for example: failing the breathalyzer or drug tests, taking off wrist monitor or not using light box every day) you will not be paid. Unless you complete the entire study, your data will not be useful for us. We will pay for your parking in the attached parking garage for each visit to the laboratory.

What happens if you experience a research related injury?

If you experience any injury or illness as a direct result of your participation in this research study, immediate treatment will be provided. However, the cost of that treatment will be billed to you or your insurance company. Your insurance company may not pay.

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study. No funds have been set aside for any other losses such as lost wages, disability or discomfort relating to injury or illness as a result of your participation in this study. You will be responsible for any costs resulting from participation in this research study, if your insurance does not pay.

Whom do you call if you have questions or problems?

Questions are encouraged. If there are any questions about this research study or if you experience a research related injury, please contact: Dr. Helen Burgess, (312) 563-4785. Questions about the rights of research subjects may be addressed to the Rush Research and Clinical Trials Administration Office at 312-942-5498.

By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study personnel. You do not waive any of your legal rights by signing this consent document. You will be given a copy of the signed and dated consent document for your records.

SIGNATURE BY THE SUBJECT:

_____	_____	_____
Name of Subject	Signature of Subject	Date of Signature

SIGNATURE BY THE WITNESS:
I observed the signing of this consent document.

_____	_____
Signature of Witness	Date of Signature

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:
I attest that all the elements of informed consent described in this document have been discussed fully in non-technical terms with the subject. I further attest that all questions asked by the subject were answered to the best of my knowledge.

_____	_____
Signature of Principal Investigator or Individual Obtaining Consent	Date of Signature