SLEEP AND CIRCADIAN TREATMENTS FOR SHIFTWORKERS

NCT03813654

MASS GENERAL BRIGHAM IRB Protocol ID: 2018-P-002341

RESEARCH CONSENT FORM

10-29-2021

Partners HealthCare System
Research Consent Form

Subject Identification

Certificate of Confidentiality Template
Version Date: January 2018

Protocol Title: Sleep and Circadian Treatments for Shift Workers

Principal Investigator: Jeanne F. Duffy, MBA, PhD

Site Principal Investigator:

Description of Subject Population: Shift Workers age 50 and older - Field Study

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you have any questions about the research or about this form, please ask us. Taking part in this research study is up to you. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

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.

Why is this research study being done?

We are doing this research to test in actual shift workers a sleep timing intervention that we have developed in laboratory studies. We will test whether this intervention improves sleep duration and quality; overall mood, fatigue and well-being; as well as on-shift performance and alertness.

We are asking you to take part in this study because you told us you are age 50 or older and work at least four night shifts per month, and you indicated your interest in this study after completing an online shift work questionnaire. You also told us that during the time you are in the study you will not have competing activities after your night shifts. You told us you are able and willing to spend up to 8 hours being in bed at times selected by us, and staying in bed trying to sleep.

Up to 100 people will take part in this segment of the study.

The National Institute on Aging, part of the National Institutes of Health, is paying for this research study to be done.

How long will I take part in this research study?

You will take part in the study over two weeks. During each of the two weeks, you must be able to work at least three night shifts in a row. During the second week, you must be able to spend 8 hours in bed attempting to sleep in the afternoon-evening before each night shift. While we prefer that the two study weeks take place back-to-back, if it is more convenient for you or if your work schedule requires it, the study weeks can be separated by up to three weeks.

After the study is complete, you may be invited to take part in a virtual Focus Group by secured videoconferencing. This is a small group discussion about your experiences during the study. It will last for about two hours and will be scheduled within 1-3 months after you finish the study.

What will happen in this research study?

You will be studied for two weeks during which you will work at least three 8-hour night shifts in a row each week. At the start of the two weeks we will send you an activity monitor, and a tablet computer. Participants in the Greater Boston Area who agree to give us two optional saliva samples will also receive a saliva sample kit. For all of the two weeks, you will wear the activity monitor on your wrist to monitor your sleep and light exposure. You will use the tablet computer to complete a daily eDiary about your sleep and work times, how you spend your leisure time, and when you use caffeine and medications.

On three successive 8-hour night shifts each week, you will use the tablet computer to rate your alertness and take a short (~5 minutes) performance test three times each night: just before you go on shift, during a mid-shift break, and just after leaving shift (before traveling home).

At the end of the third night shift, we will ask you to complete a questionnaire about your fatigue, stress, and quality of life on the tablet computer. If you agree to provide us with a saliva sample, we will meet you in person at this time to collect the sample.

During the second week of your study, we will collect the same information from you (the activity data, the eDiary, the thrice nightly performance and alertness assessments, the questionnaire, and the saliva sample) as in the first week. In addition, before the first night shift you will be randomized to a specific sleep schedule that you must follow before the second and third night shifts. You must be able to spend up to 8 continuous hours in bed trying to sleep at times we determine. It is important for the study that you follow the sleep schedule that you are assigned before the next two night shifts. This might require you to do what you normally do, or it might require you to not go to bed until the afternoon, or it might require you to spend 8 hours in bed trying to sleep (either at a time of your choosing, starting at the time you normally go to sleep after a night shift, or starting in the early afternoon).

At the end of the second week, we will ask you to complete a questionnaire about your fatigue, stress, and quality of life on the tablet computer. We will then ask you to send the study equipment (activity monitor, tablet computer) back to us in the prepaid packing materials sent to you. If you agree to provide us with a saliva sample, we will meet you in person at this time to collect both the sample and the study equipment.

At the end of the study we will also inform you of the opportunity to take part in a virtual focus group discussion about the study. The focus group is a discussion about shiftwork, sleep, and your study experiences with about 4-6 other shift workers. It will be moderated by one of our study team members and another team member will be present to take notes and we make an audio recording of the discussion.

Participants in the virtual discussion will be asked questions related to their shift work and sleep by the moderator. The questions will include such topics as when and how long you sleep when working nights vs. other shifts, factors that limit when you sleep or how long you sleep, how you spend your free time when working nights vs. other shifts, concerns you have about how shift work impacts your health or safety, etc. The moderator may ask follow-up questions or move the direction of the discussion to another shiftwork-related topic at any time during the session.

All together, the discussion will last up to two hours. You will be scheduled for a time and location that is convenient for you, and we will try to schedule this within a month after you complete the study.

What are the risks and possible discomforts from being in this research study?

We will ask you to answer a lot of questions and to give us personal information primarily about your work and sleep schedules and habits. Some of the questions we ask may make you feel uncomfortable.

The alertness rating and performance test you take three times each night do not pose any risk to you. However, they will require 7-10 minutes of uninterrupted time each time you take them. We have asked you to take them at times when they should not interfere with your work responsibilities (just before and after your night shift, and during a mid-shift break). Because you will be taking the tests many times over the course of the two-week study, you may feel bored or frustrated from having to take them.

During the second week of your study when you are randomized to a specific sleep schedule to follow before the second and third night shifts, you might be asked to spend 8 consecutive hours in bed. You might find it difficult to remain asleep for this entire time. If you wake up, we will ask you to remain in bed attempting to sleep for the entire scheduled time. You may find this difficult or frustrating. We may ask you to not go to bed until the afternoon and then sleep into the evening (from ~1pm-9pm). You may find it difficult to remain awake from the time you get home after the night shift until it is the scheduled time for sleep.

We will need to schedule a brief meeting over the phone or by secure videoconference with you before the start of the first week and before the start of the second week. If you agree to complete the optional saliva samples, we will need to schedule an in-person meeting at the end of the third night shift during the first week and at the end of the third night shift during the second week to collect the samples.

Working the night shift puts you at increased risk for a drowsy driving accident the following day. You should take precautions to avoid a drowsy driving accident on the way to and from work during the study. If your typical sleep schedule is altered during the second week of the study, you should use extra caution when driving during your free time following night shifts because you will likely be drowsier than usual.

There are no risks associated with wearing the wrist activity monitor.

If you take part in the virtual focus group discussion, we will ask you to discuss personal information with the group during the discussion. Some of the questions or topics may make you feel uncomfortable. You can refrain from answering any questions or discussing any topics that you do not want to talk about. We will make an audio recording of the discussion. That audio

recording will be transcribed by a professional transcription service. You will be identified by a code name or number in the transcript.

There may be other risks or side effects, in addition to those described in this consent form, that are not known at this time. We will give you any new information that we learn during the course of the study. This new information might affect your willingness to be in or stay in the study.

What are the possible benefits from being in this research study?

You may not benefit from taking part in this research study. You may find that the study schedule you are asked to keep allows you to sleep longer or makes you feel more alert when working the night shift. The sleep wake cycles you follow in the study while you are on the night shift may be different from what you usually do, and may cause more disruption of your sleep. Although we hope our scheduling might help you function better, this cannot be guaranteed, and your drowsiness might increase.

The study may benefit society by giving the researchers a better understanding of how the timing and duration of sleep impacts people who work at night.

Can I still get medical care within Partners if I don't take part in this research study, or if I stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should I do if I want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will I be paid to take part in this research study?

You will receive $10.00 per day for wearing the wrist activity-light recorder and maintaining the daily sleep e-Diary during the Baseline week and the Intervention week (total up to $140.00).

You will receive $15.00 per day for completing the thrice-daily subjective alertness/mood/ performance assessments on three successive night shifts in the Baseline week and the Intervention week (total $90.00).

You will receive $10.00 per day for collecting an optional saliva sample after the third night shift in the Baseline week and after the third night shift in the Intervention week (total $20). The optional saliva samples can only be collected from participants in the Greater Boston Area.

You will receive $50.00 per day for maintaining the assigned sleep schedule following the two night shifts during the Intervention week (total $100.00).

You will not be paid for study procedures that you do not complete. You will not be paid for any study procedures until you return the activity monitor and the tablet computer.

If you complete all the study procedures (not including the optional saliva samples) you will also receive a $150.00 study completion bonus.

If all the procedures are completed, you can therefore earn up to $480 ($500 if both optional saliva samples are collected).

It will take several weeks from the time the study ends for the check to be mailed to you.

If you complete the virtual Focus Group discussion session you will receive an additional $75.00. This will be a separate check, and it will take several weeks after the focus group for the check to be mailed to you.

What will I have to pay for if I take part in this research study?

Study funds will pay for study-related items and services. We do not expect that you will have to pay for any items or services related to the study.

We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

What happens if I am injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this consent form.

If I have questions or concerns about this research study, whom can I call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Jeanne F. Duffy, MBA, PhD is the person in charge of this research study. You can call him/her at 617-732-7995 during weekday working hours [M-F 10-6]. You can also call Laura K. Barger, PhD at 530-753-2876 during weekday working hours [M-F 9-5] with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call Audra Murphy at 617-525-8904.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

If I take part in this research study, how will you protect my privacy?

Federal law requires Partners to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information."

In this study, we may collect identifiable information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable information and why:

- Partners researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Partners ethics board or an ethics board outside Partners that oversees the research
- A group that oversees the data (study information) and safety of this study
- Non-research staff within Partners who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections) state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other researchers within or outside Partners, for use in other research as allowed by law.

Certificate of Confidentiality

A federal Certificate of Confidentiality (Certificate) has been issued for this research to add special protection for information and specimens that may identify you. With a Certificate, unless you give permission (such as in this form) and except as described above, the researchers are not allowed to share your identifiable information or identifiable specimens, including for a court order or subpoena.

Certain information from the research will be put into your medical record and will not be covered by the Certificate. This includes records of medical tests or procedures done at the hospitals and clinics, and information that treating health care providers may need to care for you. Please ask your study doctor if you have any questions about what information will be included in your medical record. Other researchers receiving your identifiable information or specimens are expected to comply with the privacy protections of the Certificate. The Certificate does not stop you from voluntarily releasing information about yourself or your participation in this study.

Even with these measures to protect your privacy, once your identifiable information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain completely private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your information does not expire.

The results of this research may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my identifiable information to be used and shared as described above.

_____	_____	_____
Subject	Date	Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

_____	_____	_____

Study Doctor or Person Obtaining Consent Date Time (optional)

Consent Form Version Date: September 16, 2020