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Documents

Informed Consent

Study Title

Adapting Sleep and Yoga Interventions for Maximal Effectiveness: Phase 3

Date Modified:

2/25/2018

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4/11/2018

NCT Number

NCT03392194

Partners HealthCare System
Research Consent Form

Subject Identification

General Template
Version Date: August 2016

Protocol Title: Adapting Sleep and Yoga Interventions for Maximal Effectiveness: Phase 3

Principal Investigator: Susan Redline, MD, MPH

Site Principal Investigator:

Description of Subject Population: 18-75 year old adults with sleep duration <6 hours per night

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.

Why is this research study being done?

Too little sleep in very common, especially in communities in cities. We are conducting a study to learn how to help people sleep better by improving their understanding of sleep health and through use of yoga. This study will help us understand what aspects of sleep education and yoga are most effective in improving sleep in individuals living in neighborhoods in Boston.

We are asking you to take part in this research study because you are an adult living in a Boston neighborhood and have reported usually sleeping 6 or fewer hours per night. You will be invited to participate with about 40 other people over about 12 weeks. All subjects will attend 2 in-

person healthy sleep education sessions. Across the study, you will be asked to make changes in your sleep and keep track of your sleep using a simple log.

In addition, 20 people will be asked to attend 8 yoga classes that will teach yoga breathing and poses, as a means for achieving better sleep through relaxation and stress reduction. These subjects will be asked to practice yoga while at home to relax before bed.

The other 20 people will not participate in yoga but will participate in two sleep education classes.

Information will be collected from all subjects using questionnaires, interviews, and by directly observing the sessions. This information will help researchers better understand what aspects of the sleep and yoga seem to be working best, and which aspects need to be further improved so that they make a bigger difference for people like you.

The National Institute of Health is paying for this research to be done.

How long will I take part in this research study?

It will take about 12-weeks to complete this research study.

What will happen in this research study?

[redacted]

You will be randomly put into the "sleep education group" or the "yoga and sleep education group". Participants in the "sleep education group will be asked to attend 4 in-person visits. Participants in the "yoga and sleep education group" will attend 12 visits. Study visits will occur at the at BWH (221 Longwood Ave), BWH's Wellness C[redacted] You will also be asked to participate in two phone calls throughout the twelve-week study period. Each in-person visit occurs about a week after the prior visit.

The first visit is called a "baseline visit" (when consent and questionnaires are obtained). It is like the final visit called a "follow-up visit", which will occur 12 weeks after the study begins. At both visits, you will be asked to complete several short surveys that ask questions about your health, sleep habits, beliefs about sleep, mood, and stress. We will also measure your height, weight, blood pressure, and heart rate. At the baseline visit, we will randomly assign you to the

"sleep education group" or the "yoga and sleep education group". Everyone participating has the same random chance of being put in either group.

After the baseline visit, you will begin attending group sessions. The sessions may be audio recorded so that the research team can make sure research staff follow the study protocol. The recordings will be kept on secure computers. Each group session, or class, will include 10 to 20 other subjects plus several research staff members, including specialists in sleep health or yoga. At the first group session, you will participate in an interactive session where good sleep habits are discussed. The group leader will be an expert in behavioral sleep medicine. You will be asked to reflect on your own sleep habits as you choose changes you can make to improve your sleep. One week after this session, you will attend another group session to review changes you have made in your sleep and help you identify more ways you can improve your sleep. At the first group session, you will be given a short daily sleep log; this is a tool for you to keep track of your sleep, how you are feeling, and what you are working on to sleep better. Each log entry should take just a few minutes to complete in the morning.

The "yoga and sleep education group" will be asked to attend 8 more group sessions. If you are in this group, you will learn about practicing yoga to see if it can reduce stress and improve sleep. Each yoga class will include time for a check-in, warm-up poses, active yoga poses, and time for relaxing and slow breathing. Poses increase slightly in difficulty over each session; all poses are beginners level and there are options for modifications in every pose. You will be asked to practice yoga poses and breathing while at home, especially before bedtimes. An experienced yoga instructor will help you understand how to do the breathing and poses.

All participants will also be asked to participate in two phone calls to check-in and see how you are doing, answer any of your questions, and ask if you have been having any issues. You will also have the option to receive reminder text messages from study stuff through the SMS software 'Red Oxygen'. You can receive reminders to attend sessions, work on your sleep goals and yoga home practice. The text messages are unencrypted and you have the option to opt-out at any time.

At the beginning and end of the study, you will be asked to wear wrist-watch like device that measures movement (an actigraph) for 8 days. This device is used to estimate sleep and wake times. Your information will be kept secure and private; researchers are interested in how the research group as a whole is sleeping, not your individual sleep patterns.

At the very end of the program, you may be invited to share your experience and your honest feedback about the program in an optional focus group.

The following list briefly describes each visit:

Baseline Visit:

- Review informed consent
- Complete several short questionnaires and measurements
- Be randomly put into the "sleep education group" or the "yoga and sleep education group"
- Visit length: 90 minutes

Sleep Hygiene 1: Group Visit

- Participate in a class where you hear about healthy sleep habits
- Receive a sleep log and learn how to use it
- Visit length: 90 minutes

Sleep Hygiene 2: Individual Follow-up (Call or in person)

- Participate in a group discussion and receive feedback on ways to improve your sleep
- Visit length: 90 minutes

Yoga Class 1-8: Group visit *(yoga group only)*

- Participate in 1-hour yoga class
- Receive free yoga mat and blankets for home practice at the first class
- Visit length: 60 minutes

Interim Phone Calls

- Receive a check-in call from a research staff to review your progress and report any issues
- Phone call length: 5-15 minutes

Follow-up Visit:

- Complete several short questionnaires and measurements
- Visit length: 60 minutes

At-home daily:

- Weeks 1-12: Complete sleep log (1-3 minutes every morning)
- Weeks 3-12: Do yoga relaxation before bed (~10-20 minutes) *(yoga group only)*

Optional focus group:

- You **may** be asked to participate in a focus group at the very end of the study to discuss what you liked, what you thought worked best, and what you would change. You will not have to answer any questions that make you feel uncomfortable, and you can choose to stop participating at any time. Participation will be voluntary and your views and privacy will be protected. The discussion will be video and/or audio taped so that the research team can correctly capture what is discussed.

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

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Research Coordinator or Principal Investigator if you have any questions.

Actigraphy skin irritation: The actigraphy device is battery powered with minimal risk. The main risk may be irritation under the band. To reduce the risk of getting irritated, you can remove the band and dry your skin, if the band gets wet.

Actigraphy and sleep disruption: It is possible that by wearing special monitoring devices, you may feel you sleep is not as good as usual. We tried to reduce this risk by choosing devices that are as minimally intrusive as possible. We will also provide you with clear instructions on how to use these devices to minimize discomfort. We will also explain how to remove and replace the devices if needed, or stop wearing it if necessary.

Loss of privacy: We will make every effort to keep all of your information private. Only first names will be used in group settings. All research information obtained will be kept securely in locked files and secure computers. When reporting information, we will only report about the group, not about individual people.

Discomfort in answering survey questions: It is possible that you may feel uncomfortable answering some of the questions. You can skip any questions you feel uncomfortable answering, and you can stop a survey at any time for any reason. We do not anticipate that any questions will be so upsetting to you will need extra support but we will have a referral sheet available in the unlikely event that additional resources are needed.

Muscle strain/sprains/injury: Yoga can cause muscle strain or sprain, resulting in pain and limited movement. Very rarely, there may be nerve damage or risk of certain types of stroke. Due reduce this risk, the yoga classes will be taught by experienced instructors who are familiar with proper technique and ways to reduce injury. In the beginning of each class, you will be encouraged to take stock of your current physical condition and check with the instructor if experiencing pain before or during yoga. The instructor will make adjustments to address your needs.

Untreated sleep disorders: Sleep disorders, such as sleep apnea and insomnia, require treatment beyond that offered in this study. If you report symptoms suggesting these conditions, we will help refer you to medical programs for further evaluation and treatment.

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

By participating in this study, you will gain knowledge and skills about healthy sleep, and maybe yoga if you are randomized to this group. You will receive feedback on your sleep patterns

which may be helpful for you to manage your own health. Your involvement will also contribute to the development of a research project that we will be conducting.

What other treatments or procedures are available for my condition?

Short sleep duration may result from sleep disorders such as insomnia. Treatment for insomnia includes cognitive behavioral therapy (which includes elements of relaxation and sleep hygiene but also includes other interventions such as shortening sleep times) or sleeping medications.

You do not have to take part in this study to be treated for short sleep or insomnia. You can discuss other available treatment plans for short sleep duration and stress with your physician.

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?

If you choose to participate in this study, will be paid.

A. Sleep education group: if you are in this group with you receive up to $75 in gift cards to Stop&Shop. You will receive a $25 for the baseline visit: $10 at the visit and $15 when you return the actigraphy device one week later. You will receive $10 for the 3 in-person visits

and $10 for each phone call. You will receive these remaining gift cards at the follow-up visit. In addition, a light dinner will be served at the sleep education sessions.

B. Yoga and sleep education group: if you are in this group with you receive up to $110 in gift cards to Stop&Shop. You will receive a $25 for the baseline visit: $10 at the visit and $15 when you return the actigraphy device one week later. You will receive $10 for the 9 in-person visits. You will receive these remaining gift cards at the follow-up visit. You will also receive your own free yoga mat, yoga blankets, and a yoga belt at the first yoga class. Additional compensation will be provided if needed for parking and transportation.

In addition, a light dinner will be served at the sleep education sessions and a healthy snack will be offered after all the yoga classes.

If you have young children, we will offer complimentary childcare available through RTH. When classes are during dinner time, we will provide a light dinner (e.g., pizza) at the on-site childcare center.

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

You will not have to pay to take part in this research study.

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.

Susan Redline, MD, MPH is the person in charge of this research study. [redacted]

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?

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as "health information." In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so.

In this study, we may collect health 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 health information and why they may need to do so:

- Partners research staff involved in this study
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- Other researchers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- Non-research staff within Partners who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The Partners ethics board that oversees the research and the Partners research quality improvement programs.
- People from organizations that provide independent accreditation and oversight of hospitals and research
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review research)
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
- Other: Research collaborators working at Beth Israel Deaconess Medical Center and Dana Farber Cancer Center.

Some people or groups who get your health information might not have to follow the same privacy rules that we follow and might use or share your health information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your health information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your health information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your information for any mailing or marketing list. However, once your information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain 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 health information.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying 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 health 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 health 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.

You have the right to see and get a copy of your health 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 health information to be used and shared as described above.

Subject	Date	Time (optional)

Consent Form Version: 3

Consent Form Created on: 02/25/2018

[redacted]