

Cover page

Study Official Title: Use of Bioboosti Non-pharmacologic Device for Insomnia Treatment - a pilot study

NCT#: NCT02924116

Version Date of the Document: 06/04/2018

Partners HealthCare System Research Consent Form

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|------------------------|
| Subject Identification |
|------------------------|

General Template

Version Date: October 2014

Protocol Title: Use of Bioboosti Non-pharmacologic Device for Insomnia Treatment - a pilot study

Principal Investigator: Milena Pavlova, MD

Site Principal Investigator: Sandra Horowitz, MD

Description of Subject Population: Adults diagnosed with Insomnia

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?

Partners HealthCare System Research Consent Form

| |
|------------------------|
| Subject Identification |
|------------------------|

General Template

Version Date: October 2014

Insomnia is a common health complaint, seen in almost 25% of the population. Insomnia can be associated not only with discomfort, but also with loss of productivity, poor health, and a higher use of healthcare. Too little sleep or poor quality sleep increases the risk of a variety of disorders, leading to abnormalities of endocrine and immune function. Insomnia probably has some of the same consequences as insufficient sleep from other causes. For example, in a recent study in our group, we found that disrupted sleep, as measured by wake after sleep onset predicts diabetes risk in insomnia patients.

The use of non drug treatments of insomnia has gained much attention in recent years. We are doing this research because a safe, non drug treatment of insomnia would benefit patients with insomnia, especially those with other medical conditions. We are doing this research study to see if the Bioboosti device is an effective treatment for insomnia. Sleep disturbances can serve as a trigger for migraines, and insomnia in particular, is a common comorbidity in patients with chronic migraine. Addressing insomnia in patients with chronic migraine can result in reductions in migraine frequency. We are doing this research study to also see if the device is effective for patients with both insomnia and comorbid migraine.

Approximately 50,000 people, primarily in China, have received the Bioboosti before.

We are asking you to take part in this research study because you have insomnia.

This is a pilot study. Pilot studies are done on a small group of subjects to learn if a larger study would be useful.

About 20 subjects will take part in this research study. We will enroll subjects at Brigham and Women's (BWH) and Faulkner Hospitals (FH).

About 20 Subjects will take part in the study who have both insomnia and comorbid migraine.

Biomobie (Shanghai) Regenerative Medicine Technology Co., Ltd is paying for this research to be done.

How long will I take part in this research study?

For Insomnia, it will take you about one month to finish this research study. During this time, we will ask you to make 5 visits to BWH or FH.

Partners HealthCare System Research Consent Form

| |
|------------------------|
| Subject Identification |
|------------------------|

General Template

For participants with both insomnia and comorbid migraine, it will take about 3 months to finish this research study. During this time, we will ask you to make 6 visits at FH.

If your interest in the device continues after the end of the study, you could participate in the long term (1 year) use of BioBoosti for the *potential* treatment of Insomnia.

What will happen in this research study?

If you choose to take part in this study, we will ask you to sign this consent form before we do any study procedures.

Partners HealthCare System Research Consent Form

| |
|------------------------|
| Subject Identification |
|------------------------|

General Template

Version Date: October 2014

For Insomnia Patients

Visit 1

Visit 1 will take about 1 hour. At this visit, we will:

- Go over the consent form
- Do a physical exam
- Collect your vital signs (blood pressure, heart rate, pulse rate, respiratory rate)
- If you are female and able to become pregnant, we will test your urine for pregnancy and you must be on a form of contraceptive to participate in the study. You cannot take part in this research study if you are pregnant or breastfeeding.
- Give you a sleep log to record when you sleep and wake up. You will complete the sleep log during the entire study, starting with this visit.
- Give you an actiwatch to wear on your wrist every day. The actiwatch is a sensor that measures sleep/wake information. You will wear this during the entire study, starting with this visit.

Visit 2

Visit 2 will take about 2 hours. This will be completed at FH within a few days of Visit 1, at your convenience. At this visit, we will:

- Ask you questions about your sleep
- Complete questionnaires (Pittsburgh Sleep Quality Inventory (PSQI), Insomnia Severity Index (ISI), Epworth Sleepiness Scale (ESS), and Karolinska sleepiness scale (KSS))
- Test your urine for hormones associated with sleep
- Give you a sleep log to record when you sleep and wake up
- Place electrodes attached to wires on your scalp and connect the wires to a recorder for an ambulatory (at home) electroencephalogram (EEG). You will have the EEG on for a full 3 days straight however, if this doesn't work then you will have an option for a full 2 day straight EEG.

Ambulatory EEG:

Partners HealthCare System Research Consent Form

| |
|------------------------|
| Subject Identification |
|------------------------|

General Template

Version Date: October 2014

We will perform an at home test called an ambulatory EEG. This is a recording of the brain's activity over an extended period of time. A technologist will place electrodes, attached to wires, on your scalp and connect the wires to a recorder.

Visit 3

Visit 3 will take about 1 hour. You will return to BWH or FH for the EEG to be removed. At this visit, we will:

- Remove the EEG
- Provide the Bioboosti device and show you how to use it
- Give you a sleep log to record when you sleep and wake up

Treatment phase:

We will give you the study device, Bioboosti, and show you how to use it during the two weeks of treatment. The Bioboosti is a device that produces a pulsed micromagnetic field. You will be asked to use the Bioboosti once a day about one hour before your usual sleep time. You will place the Bioboosti in the palm of your hand for 8 minutes. Once the light on the device changes, the 8 minutes have passed and you will place it on the other hand. You will repeat this up to 6 times, alternating hands at the end of each 8 minute cycle.

During the entire study period, you are advised to maintain your current lifestyle in regards to diet and exercise.

Visit 4

Visit 4 will take about 2 hours. We will ask you to return after the two weeks of treatment. This will be completed at FH. During this visit, we will:

- Complete the same questionnaires as you did in Visit 2
- Collect the completed sleep logs
- Collect a urine sample
- Ask you questions about your sleep
- Place electrodes attached to wires on your scalp and connect the wires to a recorder for an ambulatory (at home) electroencephalogram (EEG). You will have the EEG on for a full 3 days straight or an option for the EEG for a full 2 days straight.
- Give you a sleep log to record when you sleep and wake up

Partners HealthCare System Research Consent Form

| |
|------------------------|
| Subject Identification |
|------------------------|

General Template

Version Date: October 2014

Visit 5

Visit 5 will take about 1 hour. During this visit, we will:

- Remove the EEG
- Collect the Bioboosti, actiwatch and your completed sleep logs

We will check the Bioboosti device when it is returned to the study staff. You may be asked to redo the study if it is not functioning properly.

Sustained Efficacy Phase

If you choose to participate in the long-term Study. We will ask you to continue to use the BioBoosti for a year.

Regular follow ups will be done at 3rd, 6th, 9th and 12th month. You will keep sleep logs during the entirety of the study. And complete the ISI form and PSQI during each visit.

Also, to objectively evaluate the sleep patterns, you will be asked to wear the actiwatch one month prior to each visit.

For Patients with Insomnia and Migraine

We do not anticipate for this longer testing period to increase the risk, as to date, none of the individuals with insomnia have reported any negative effects from the treatment.

Visit 1

Visit 1 will take about 1 hour. At this visit, we will:

- Go over the consent form
- Do a physical exam
- Collect your vital signs (blood pressure, heart rate, pulse rate, respiratory rate)
- If you are female and able to become pregnant, we will test your urine for pregnancy and you must be on a form of contraceptive to participate in the study. You cannot take part in this research study if you are pregnant or breastfeeding.
- Give you a sleep log to record when you sleep and wake up. You will complete the sleep log during the entire study, starting with this visit.

Partners HealthCare System Research Consent Form

| |
|------------------------|
| Subject Identification |
|------------------------|

General Template

Version Date: October 2014

- Give you an actiwatch to wear on your wrist every day. The actiwatch is a sensor that measures sleep/wake information. You will wear this during the entire study, starting with this visit.
- Give you a headache diary to record for a month.

Visit 2

Visit 2 will take about 2 hours. This will be completed at FH after a month of Visit 1, at your convenience. At this visit, we will:

- Ask you questions about your sleep
- Complete questionnaires (Pittsburgh Sleep Quality Inventory (PSQI), Insomnia Severity Index (ISI), Epworth Sleepiness Scale (ESS), and Karolinska sleepiness scale (KSS))
- Test your urine for hormones associated with sleep
- Give you a sleep log to record when you sleep and wake up
- Place electrodes attached to wires on your scalp and connect the wires to a recorder for an ambulatory (at home) electroencephalogram (EEG). You will have the EEG on for a full 3 days straight however, if this doesn't work then you will have an option for a full 2 day straight EEG.

Ambulatory EEG:

We will perform an at home test called an ambulatory EEG. This is a recording of the brain's activity over an extended period of time. A technologist will place electrodes, attached to wires, on your scalp and connect the wires to a recorder.

Visit 3

Visit 3 will take about 1 hour. You will return to BWH or FH for the EEG to be removed. At this visit, we will:

- Remove the EEG
- Provide the Bioboosti device and show you how to use it
- Give you a sleep log to record when you sleep and wake up
- Give you a headache diary to record for a month

Treatment phase:

Partners HealthCare System Research Consent Form

| |
|------------------------|
| Subject Identification |
|------------------------|

General Template

Version Date: October 2014

We will give you the study device, Bioboosti, and show you how to use it during the one month of treatment. The Bioboosti is a device that produces a pulsed micromagnetic field. You will be asked to use the Bioboosti once a day about one hour before your usual sleep time. You will place the Bioboosti in the palm of your hand for 8 minutes. Once the light on the device changes, the 8 minutes have passed and you will place it on the other hand. You will repeat this up to 6 times, alternating hands at the end of each 8 minute cycle.

During the entire study period, you are advised to maintain your current lifestyle in regards to diet and exercise.

Visit 4

Visit 4 will take about 2 hours. We will ask you to return after the one month of treatment. This will be completed at FH. During this visit, we will:

- Complete the same questionnaires as you did in Visit 2
- Collect the completed sleep logs
- Collect a urine sample
- Ask you questions about your sleep
- Place electrodes attached to wires on your scalp and connect the wires to a recorder for an ambulatory (at home) electroencephalogram (EEG). You will have the EEG on for a full 3 days straight or an option for the EEG for a full 2 days straight.
- Give you a sleep log to record when you sleep and wake up

Visit 5

Visit 5 will take about 1 hour. During this visit, we will:

- Remove the EEG
- Collect the Bioboosti, actiwatch and your completed sleep logs
- Give you the headache diary to record for another month.

Visit 6

Visit 6 will take about 15mins. We will collect the headache diary.

We will check the Bioboosti device when it is returned to the study staff. You may be asked to redo the study if it is not functioning properly.

Partners HealthCare System Research Consent Form

| |
|------------------------|
| Subject Identification |
|------------------------|

General Template
Version Date: October 2014

Study Information Included in Your Electronic Medical Record

A notation that you are taking part in this research study may be made in your electronic medical record. Information from the research that relates to your general medical care may be included in the record (for example, list of allergies, results of standard urine tests done at the hospital labs).

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

When wearing the ambulatory EEG, you may feel soreness or see reddening of the skin from the glue that is used. There is a risk that the cables could become wrapped around the neck, so tape the cables to your back when sleeping.

You may feel some discomfort when wearing the actiwatch. The wristband is adjustable to fit you comfortably.

While we don't anticipate any serious adverse effects, it is possible that you may experience adverse effects of Bioboosti. As a possible device to treat insomnia, you may experience sleepiness when using it. You cannot drive while using the Bioboosti.

Please report all side effects immediately to the treating physician and the study staff. If any significant events occur, these may lead to need to discontinue the treatment.

You cannot use the Bioboosti if you have a cardiac pacemaker or other implanted electrical devices as they may be affected by the Bioboosti's magnetic fields.

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

You may not benefit from taking part in this study. Others with insomnia and migraine may benefit in the future from what we learn in this study.

Partners HealthCare System Research Consent Form

| |
|------------------------|
| Subject Identification |
|------------------------|

General Template
Version Date: October 2014

What other treatments or procedures are available for my condition?

We will not change the treatments that your doctor has prescribed.

You do not have to take part in this study to be treated for insomnia. Other treatments that are available to treat insomnia include: sleeping and waking daily at regular times, antihistamines and some prescription medicines like Ambien and Lunesta.

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 be paid \$400.00 if you complete the study. You will receive \$100 after the first EEG is complete and the remaining \$300 at the end of the study.

Partners HealthCare System Research Consent Form

| |
|------------------------|
| Subject Identification |
|------------------------|

General Template

Version Date: October 2014

You will not be paid for participation in the study if you do not complete all the study visits, or if you do not return the Bioboosti or actiwatch without damage at the end of the study. Damage and/or unreturned Bioboosti or actiwatch is considered incompleteness of the study.

We will cover the cost of parking up to \$40.00 for your study visits.

Sustained Efficacy Phase: You will be paid \$350.00 if you completed the study. You will receive \$50.00 after each visit and the remaining \$200.00 at the end of the study. We will cover the cost of parking up to \$5.00 for each visit.

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

Study funds will pay for certain study-related items and services. 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 copayments 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.

Partners HealthCare System Research Consent Form

| |
|------------------------|
| Subject Identification |
|------------------------|

General Template

Version Date: October 2014

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.

Milena Pavlova, MD is the person in charge of this research study. You can call her at 617-9837580, Monday through Friday 8:30 AM-4:30 PM. You can also call Nirajan Puri at (857) 3072374, Monday through Friday 9:00 AM-5:00 PM. You can also email him at NPuri@bwh.harvard.edu with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call Nirajan Puri at (857) 307-2374.

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.

Partners HealthCare System Research Consent Form

| |
|------------------------|
| Subject Identification |
|------------------------|

General Template

Version Date: October 2014

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:

Partners HealthCare System Research Consent Form

| |
|------------------------|
| Subject Identification |
|------------------------|

General Template

Version Date: October 2014

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.

**Partners HealthCare System
Research Consent Form**

| |
|------------------------|
| Subject Identification |
|------------------------|

General Template
Version Date: October 2014

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)

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)

Partners HealthCare System Research Consent Form

| |
|------------------------|
| Subject Identification |
|------------------------|

General Template
Version Date: October 2014

Consent of Non-English Speaking Subjects Using the “Short Form” in the Subject’s Spoken Language

Statement of Hospital Medical Interpreter

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Hospital Medical Interpreter

Date

Time (optional)

OR

Statement of Other Individual (Non-Interpreter)

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject’s own language, and that the subject was given the opportunity to ask questions.

Name

Date

Time (optional)

Signature of Subject for Sustained Efficacy Phase:

I give my consent to take part in **additional long term use of the device.**

Subject

Date

Time (optional)

**Partners HealthCare System
Research Consent Form**

General Template
Version Date: October 2014

Consent Form Version: 06042018

| |
|------------------------|
| Subject Identification |
|------------------------|