Morpheus- Manipulating and Optimizing Brain Rhythms for Enhancement of Sleep

NCT05089682

January 13, 2023

MAYO CLINIC

Name and Clinic Number

Approval Date: **January 13, 2023**
Not to be used after: **January 12, 2024**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Morpheus- Manipulating and Optimizing Brain Rhythms for Enhancement of Sleep (Epilepsy Cohort)

IRB#: 19-001216

Principal Investigator: Dr. Gregory Worrell and Colleagues

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.	
It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part.
Research Purpose	The purpose of this research is to investigate whether we can improve sleep quality in patients with deep brain stimulators by delivering targeted stimulation patterns during specific stages of sleep You have been asked to take part in this research because you have had deep brain stimulation (DBS) and have difficulty sleeping.
What's Involved	Study participation involves two separate overnight stays (2 nights each) in the Epilepsy Monitoring Unit (EMU) and a saliva sample. You will have a sleep study, EEG and ECG while in the EMU.
Key Information	This study does not include new medications or changes to your stimulation frequencies. Your hospital stays and testing will be covered by the study. Because you will have 2 separate stays of 2 nights each, you may miss out on some work. You will receive payment for each overnight stay as well as having some travel expenses reimbursed.

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Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep. A copy of this form will be put in your medical record.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

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Contact Information

If you have questions about …	You can contact …
▪ Study tests and procedures ▪ Materials you receive ▪ Research-related appointments ▪ Research-related concern or complaint ▪ Research-related injuries or emergencies ▪ Withdrawing from the research study	**Principal Investigator:** Dr. Gregory Worrell **Phone:** (507) 284-4458 **Study Team Contact:** Karla Crockett **Phone:** (507) 538-4880 **Institution Name and Address:** Mayo Clinic 200 First Street SW Rochester, MN 55905
▪ Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681
▪ Rights of a research participant ▪ Any research-related concern or complaint ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study	**Research Subject Advocate (RSA)** **(The RSA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchsubjectadvocate@mayo.edu
▪ Billing or insurance related to this research study	**Patient Account Services** **Toll-Free:** (844) 217-9591

Other Information:

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 are you being asked to take part in this research study?

You are being asked to participate in this study because you have a neurological disorder, are currently implanted with a Deep Brain Stimulation (DBS) system and have difficulty sleeping.

The plan is to have about 15 people take part in this study at Mayo Clinic.

Why is this research study being done?

Treatment of sleep disturbances is mainly attempted through drug administration. However, certain drugs are associated with unwanted side effects or residual effects upon awakening (e.g. sleepiness, coordination issues) which can increase the risks of falls and fractures. In addition, there can be systemic consequences of long-term use. Many patients suffering from movement disorders, such as Parkinson's Disease (PD) and Multiple Systems Atrophy (MSA), also have disrupted sleep. Maintaining good sleep quality can also be an issue for patients with chronic pain. Currently, at stages where drug treatment no longer offers adequate control of their symptoms, these patients are implanted with a deep brain stimulation (DBS) system. This involves depth electrodes which deliver constant pulse stimulation to the targeted area.

The aim of this study is to investigate whether we can improve sleep quality in patients with deep brain stimulators by delivering targeted stimulation patterns during specific stages of sleep.

We will only use stimulation frequencies that have been proven to be safe for patients. We will examine the structure and quality of sleep as well as how alert you are when you wake up, while also monitor physiological markers such as heart rate and blood pressure. Upon awakening, we will ask you to provide your opinion of your sleep and complete some simple tests to see how alert you are compared to a night of no stimulation.

Information you should know

Who is Funding the Study?

The United States Department of Defense (DoD) is funding the study. The DoD will pay the institution to cover costs related to running the study.

Information Regarding Conflict of Interest:

Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation. If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.

How long will you be in this research study?

The study will include 2-3 visits. This study may be presented to you following a scheduled clinic visit or you may have a separate visit to be screened and review the consent form. The study involves 4 overnights in the hospital in the Epilepsy Monitoring Unit over 2 study visits.

What will happen to you while you are in this research study?

You will be asked to read and review this consent form. After all your questions have been answered by a member of the study team, and if you agree to participate, we will ask you to sign this form before any study-related procedures are performed.

Screening for this study is planned to take place during your normal treatment visit; therefore, there is no need for further clinic visits unless you would like to discuss any questions you have regarding the study at a separate meeting. This will be arranged.

If you decide to participate and after signing the consent form, you will complete the following screening activities:

Visit-1 Screen/Enrollment

- Have a physical and neurological examination
- Review your current medications and medication history
- Review your medical history

- Complete the following questionnaires and assessments:
  - **Mini-Mental State Examination (MMSE)-**this tests your orientation, attention, calculation, recall, language and motor skills. This test will take approximately 20 minutes to complete
  - **Liverpool Seizure Severity Scale (LSSS)-**this scale assesses your perceptions of changes in your seizure severity. It will take approximately 5 minutes to complete.
  - **Seizure Severity Questionnaire (SSS)-**this scale measures the components of seizures that cause patients the most disturbances. It will take approximately 5 minutes to complete.
  - **Mayo Seizure Assessment –** this is a questionnaire about your seizures.
  - **Mood assessment with Beck Inventory for Anxiety and Depression-**this questionnaire asks questions about whether you have symptoms of depression or anxiety. It takes approximately 5 minutes to complete.
  - **Quality of Life Inventory in Epilepsy (QOLIE-31)-**this questionnaire will be completed by you and will be used to measure the impact of your seizures on your day-to-day quality of life. It takes approximately 10 minutes to complete.
- You will be provided with a Smart Watch device and instructions of its use. This device will be worn like a watch and measure your daily activity. You will be required to wear the device to measure your electrodermal activity (EDA), heart rate and sleep habits.
- Receive a sleep diary and instructions on how to complete it

You will be asked to keep your medications at a stable dose throughout the study.

You will wear your Smart Watch until your first admission to the hospital. Information received from the Smart Watch will assess how you are sleeping prior to your visit for the overnight polysomnography (PSG) studies.

<u>Visit -2 Baseline Visit (2 consecutive overnight stays in the EMU)</u>
You will stay overnight for 2 nights in the St. Marys Hospital Epilepsy Monitoring Unit (EMU).

Upon arrival, you will be familiarized with the testing battery and EEG equipment. Staff will run a battery of questionnaires and tests while you are on your usual stimulation parameters and medications.

Based on your sleep diary and Smart Watch information, we will determine a bedtime that corresponds with your usual time. Night one will be used to characterize your sleep state with your typical therapy parameter settings. During night two, different stimulation patterns will occur during different sleep stages, based on the information received during night one. All of the changes in stimulation will be within the clinical range used and approved for DBS patients.

During each of these overnight visits, the following tests will be conducted to obtain the required information:

- Polysomnography (PSG)-a type of test that requires hooking up a machine to measure brain waves, eye movement, breathing, muscle activity and heart rhythm. It is used to diagnose sleep disorders.
- Electroencephalogram (EEG)-an EEG is a routine test that involves attaching small wires to your head to read the electrical activity of your brain. Video will be collected with video being time-locked to the PSG EEG data.

Visit-2 Baseline night 1:
The main purpose of this first night of recording is for the study team to become familiar with your typical sleep patterning/sleep stages and your different sleep stages and EEG responses during those stages. During this time, your EEG results will be observed, as well as your respiratory and blood pressure results. At the end of this first night, dominant EEG characteristics for each sleep stage should be defined and provide a model for you. This analysis will enable the study staff to generate patient-specific stimulation patterns based on sleep stages. Data collected during this night will be used as the baseline for the rest of the study.

Upon waking, the following will occur:

- Provide a single saliva sample to test for cortisol (cortisol helps the body use sugar and fat for energy, and it helps the body manage stress) upon waking each morning (approximately 6:00 am)
- The following study related questionnaires/tasks will be completed at the time of awaking and again at 30 minutes and 60 minutes after you wake up. These questionnaires/task will be completed each day while you are in the EMU.
    - **Karolinska Sleepiness Scale (KSS)-**an assessment that measures your level of tiredness at a particular time during the day. It takes about 1 minute to complete.
    - **Psychomotor Vigilance Task (PVT)**-this test measures your sleepiness and reaction speed. In this test, you will press a button an on electronic device as soon as a light appears (every few seconds for 10 minutes).
    - **Karolinska Drowsiness Test (KDT)-**a scale that measures the level of sleepiness at a particular time during the day
    - **Profile of Mood States Scale (POMS**)-a self-assessment to determine how you feel at a certain moment. It takes approximately 5 minutes to complete

During the day, you will be allowed to read, watch television, and socialize, as well as complete tasks and questionnaires.

Visit-2 Baseline Night 2/Testing-Stimulation:
During this night visit, the same tasks as the previous night will occur, except your programmer will utilize pre-determined stimulation patterns to see if a pattern can help optimize sleep stages and sleep patterns.

Upon waking, the following will occur:

- Provide a single saliva sample to test for cortisol (cortisol helps the body use sugar and fat for energy, and it helps the body manage stress) upon waking each morning (approximately 6:00 am)
- The following study related questionnaires/tasks will be completed at the time of awaking and again at 30 minutes and 60 minutes after you wake up. These questionnaires/task will be completed each day while you are in the EMU.
    - **Karolinska Sleepiness Scale (KSS)-**an assessment that measures your level of tiredness at a particular time during the day. It takes about 1 minute to complete.
    - **Psychomotor Vigilance Task (PVT**)-this test measures your sleepiness and reaction speed. In this test, you will press a button an on electronic device as soon as a light appears (every few seconds for 10 minutes).
    - **Karolinska Drowsiness Test (KDT)-**a scale that measures the level of sleepiness at a particular time during the day
    - **Profile of Mood States Scale (POMS**)-a self-assessment to determine how you feel at a certain moment. It takes approximately 5 minutes to complete

Visit 3 (2 consecutive overnight stays in the EMU)
This second visit consists of two nights of sleep recordings at the St. Mary's Hospital EMU. This visit will be mostly informed by the sleep characteristics and stimulation results of the first visit

During these overnight visits, the following tests will be conducted to obtain the required information:

- Polysomnography (PSG)
- Electroencephalogram (EEG)

Upon waking, the following will occur each day:

- Provide a single saliva sample to test for cortisol (cortisol helps the body use sugar and fat for energy, and it helps the body manage stress) upon waking each morning (approximately 6:00 am)

- The following study related questionnaires/tasks will be completed at the time of awaking and again at 30 minutes and 60 minutes after you wake up. These questionnaires/task will be completed each day while you are in the EMU.
    - **Karolinska Sleepiness Scale (KSS)-**an assessment that measures your level of tiredness at a particular time during the day. It takes about 1 minute to complete.
    - **Psychomotor Vigilance Task (PVT**)-this test measures your sleepiness and reaction speed. In this test, you will press a button an on electronic device as soon as a light appears (every few seconds for 10 minutes).
    - **Karolinska Drowsiness Test (KDT)-**a scale that measures the level of sleepiness at a particular time during the day
    - **Profile of Mood States Scale (POMS**)-a self-assessment to determine how you feel at a certain moment. It takes approximately 5 minutes to complete

During the day, you will be allowed to read, watch television, and socialize, as well as complete tasks and questionnaires.

During the sleep study, your sleep movements and sounds will be recorded by a video camera. The video camera will record sounds and images of your body movements and facial expressions when you sleep. Since these images are very detailed, they can disclose your identity. The video and audio data will only be reviewed by a few experts who will evaluate your sleep behaviors in this trial. Your data will be identified by your initials and assigned patient number. The videotape will be retained as part of your medical record. The data will be stored in a secured location.

During this study, we will ask you to fill out questionnaires about depression, your sleep and seizure activity, quality of life, memory and mood. We hope that you will answer all of the questions, but you can skip any questions you don't want to answer. The questionnaires will take about 1 hour to complete between all of them.

During this study, we will ask you to answer questions about your emotional health and mood by completing the Becks Depression Inventory-II (BDI-ll). The BDI-ll contains questions about depression, anxiety, suicidality and mood. In order to participate in this study you must agree to provide responses to these questions. The reasons for this to ensure you are in the right frame of mind to participate in this study.

The questions contained in BDI-ll will take about 5 minutes to complete.

Tests done only for research purposes are not meant to provide clinical information or help care for you. The results are only important for research. Therefore, the results of tests done with your information and samples will not be provided to you. In the rare event that a finding might affect

the health of you or your family, we will contact you and you can choose whether to receive or refuse the information. If you decide to follow up and further medical testing or care is needed, the costs will be billed to you or your insurance.

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

Given the non-invasive nature of all procedures involved in this study, we do not expect any side-effects to occur during participation. The experimental setting has been tested and used safely in combination with your DBS system. In addition, the frequencies that we will be programming your DBS system to deliver when you sleep have already been tested, clinically approved and used in patients worldwide.

There are no known risks of tailoring the stimulation frequency to sleep stage.

Seizure risk
Participating in this study could provoke an epileptic seizure by the electrical stimulation. This risk is minimized by using previously established safe stimulation parameters as determined by the clinicians.

Sleep Disruption
Sleep disruption and/or arousal during the first attempt to optimize may occur. If so, those parameters will not be used further and may establish additional information for optimal sleep depth and appropriate arousal times.

Electroencephalogram (EEG)
An EEG is a painless way to show your brain activity will be done during this study. To do the EEG, you will have pads placed on different parts of your scalp. There is no pain or discomfort during an EEG; however, removing the pads may cause irritation to your skin.

Electrocardiogram (ECG)
This test uses small sticky pads that are placed on your chest and limbs to measure the electrical activity of your heart. There may be mild discomfort from the sticky pads and a possibility of the skin being irritated by the adhesive on the sticky pads.

Polysomnography (PSG)
A PSG is a noninvasive, painless test. Complications are rare. The most common side effect is skin irritation caused by the adhesive used to attach test sensors to your skin. There is the possibility of becoming entangled with the wires attached to you if you attempt to get out of bed during the sleep study without assistance or if you attempt to disconnect the electrodes and monitors by yourself.

You may not fall asleep as easily or sleep as well in the hospital as you do at home.

Questionnaires
There are no risks completing the questionnaires, but you may experience momentary embarrassment or discomfort when you are asked to rate the changes in your attention, mood, sleep and seizure intensity/duration. You may also feel uncomfortable when you are asked about your quality of life and disability. You do not have to answer any questions that make you feel uncomfortable.

Birth Control Requirements for Female Participants
If you are sexually active and able to become pregnant, you must agree to use one of the birth control methods listed below:

- Barrier methods (such as a condom or diaphragm) used with a spermicide (a foam, cream, or gel that kills sperm)
- Barrier Intrauterine device (IUD). Hormone IUDs are not acceptable.
- Abstinence (no sex)

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the Principal Investigator or Mayo Clinic may stop you from taking part in this study at any time:

- If it is in your best interest,
- If you don’t follow the study procedures,
- If the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to stay in the research study.

What if you are injured from your participation in this research study?

Where to get help:

If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries:

Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. You will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance.

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

This study may not make your health better. However, improving sleep depth through stimulation could lead to physical, psychological and cognitive benefits for the clinical population.

What alternative do you have if you choose not to participate in this research study?

This study is only being done to gather information. You may choose not to take part in this study.

What tests or procedures will you need to pay for if you take part in this research study?

You won't need to pay for tests and procedures which are done just for this research study. These tests and procedures are:

- EEG and polysomnography
- Neurological examinations
- Study assessments
- Use of the Empatica actigraphy (Smart Watch) during the study
- Hospital overnights stays in the EMU specifically for the study
- Saliva sample for Cortisol testing

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care, including co-payments and deductibles.

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.

Will you be paid for taking part in this research study?

You will receive $200 per day for each overnight stay in the EMU that you complete. If you are able to complete the entire study, you will receive up to $800.

Payment for participation in research is considered taxable income and reportable to the Internal Revenue Service (IRS). Accounts Payable at Mayo Clinic will be given your name, address and Social Security number in order to issue a check for your study participation. If you receive research payments totaling $600 or more in a calendar year, a tax Form 1099 will be sent to you. For Mayo Clinic employees, research payments are included in your paycheck with applicable taxes withheld and reported on your Form W2 after calendar year-end.

We will pay for the cost of your food for travel days up to $20/trip for your overnight stay. In order to receive reimbursement, you must provide a copy of the original receipts for those expenses.

You will receive a parking voucher to cover parking during your overnight stays.

You may be reimbursed for travel to and from the study site for any study visit that you attend if you live greater than 60 miles from Mayo. Your reimbursement for travel is calculated based on the round trip number of miles you travel from your home address to the site address and back as determined by a web-based mileage calculator (e.g., MapQuest). This distance (miles) will be documented in your study file. You will receive reimbursement per mile at the current IRS mileage rate.

There is a very small chance that some commercial value may result from the use of your sample. This could include new products like a drug or a test to diagnose a disease. If that happens, you will not be offered a share in any profits.

Will your information or samples be used for future research?

Identifiable information such as your name, Mayo Clinic number, or date of birth may be removed from your information collected in this study, allowing the information to be used for future research or shared with other researchers without your additional informed consent.

Your saliva sample will be discarded after the results have been obtained.

How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study.

We will make every attempt to protect your confidentiality and to make sure that your personal identity does not become known. You will be assigned a study ID that will be utilized throughout this study instead of your name. This signed consent form will be stored in a locked office area that will be accessible only to a very small number of authorized people involved in this project. We will carefully follow the coding, storage, and release plan explained in this document. All study information is stored on password protected servers.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, 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. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or “authorization”) to Mayo Clinic.

Your health information may be collected from:

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

Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.
- Other Mayo Clinic staff involved in your clinical care.
- Researchers involved in this study at other institutions
- The sponsor(s) of this study and the people or groups hired by the sponsor(s) to help perform this research (including the U.S. Department of Defense).
- The Mayo Clinic Institutional Review Board that oversees the research.
- 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 United States agencies) or government agencies in other countries that oversee or review research.
- A group that oversees the data (study information) and safety of this research.

How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you, but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media), information that identifies you will not be used.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

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Is your health information protected after it has been shared with others?
Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
201 Building 4-60
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Subject Advocate at: researchsubjectadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts forever, unless you cancel it.

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There is no expiration or end date related to the Sponsor's use of your health information received from Mayo Clinic as part of this study.

Enrollment and Permission Signatures

Your signature documents your permission to take part in this research.

	/ /	: AM/PM
Printed Name	Date	Time

Signature

Person Obtaining Consent

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

	/ /	: AM/PM
Printed Name	Date	Time

Signature