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ClinicalTrial.gov

Transcranial Direct Current Stimulation Therapy for Central Hypersomnia Without Cataplexy

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Ulysses J. Magalang, MD
The Ohio State University
Professor of Medicine and Neuroscience
Division of Pulmonary, Critical Care, and Sleep Medicine
Director Sleep Disorders Center
241 West 11th Avenue, Suite 5000
Columbus, OH 43201
Office: 614-292- 4307/Clinic: 614-293-4925

The Ohio State University Consent to Participate in Research

Study Title: **Transcranial Direct Current Stimulation Therapy for Central Hypersomnia Without Cataplexy**

Principal Investigators: **Ulysses J. Magalang M.D.**

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. Why is this study being done?

Transcranial direct current stimulation (tDCS) is a safe, noninvasive, and painless form of brain stimulation that uses a mild direct electrical current passed between electrodes on the scalp. It has been used in various conditions including depression, anxiety, Parkinson's disease, and chronic pain.

The objectives of this study are to determine if tDCS treatment in patients with excessive daytime sleepiness due to various conditions will improve daytime sleepiness and alertness.

The tDCS technique uses two electrodes, one placed on the head and one on another part of the body (such as the arm) to deliver a very small current through the electrode. A small percentage of the current is passed into the underlying brain tissue and the

remainder is dispersed through skin and bone. By controlling the direction the current flows through the electrodes, we can increase the activity in your brain under the electrode.

2. How many people will take part in this study?

Up to 60 subjects with excessive sleepiness (also known as hypersomnia) as a result of the different conditions below will participate in this study:

- Idiopathic Hypersomnia
- Narcolepsy without Cataplexy (Narcolepsy Type 2)
- Hypersomnia in obstructive sleep apnea (OSA) patients adequately treated with positive airway pressure (PAP) or dental device therapy
- Hypersomnia due to head trauma (Posttraumatic hypersomnia)
- Hypersomnia due to unknown reasons (Unspecified hypersomnia)

3. What will happen if I take part in this study?

The research will include **four (4) visits**. **The informed consent process may take place at a separate visit.**

After informed consent, some subjects with idiopathic hypersomnia will undergo actigraphy for one week to determine that their average sleep time is 10 hours per day or more. The research staff will let you know if this is needed for you.

Subjects will then be randomized to receive either the active form of tDCS or inactive form (also known as sham) of stimulation for 30 minutes daily for 4 sessions. **Once you have been assigned a group, you will receive either the active or the inactive form of tDCS for the entire duration of the study.**

STANDARD OF CARE PROCEDURES:

- **Sleep study.** This is done as part of routine clinical practice as ordered by your health care provider. This is a 6 to 8 hour recording of physical changes that occur while you sleep. You may also have undergone a daytime recording called multiple sleep latency test (MSLT). You have already undergone these tests prior to discussing and signing this consent form.

RESEARCH RELATED PROCEDURES:

After signing the consent you will have:

- **Questionnaires** about your health history and well-being and symptoms related to sleep disorders.
- **Pregnancy test, if applicable**

- **Medication List.** You will be asked about the medications that you regularly take including over-the-counter medications.
- **Weight, height** measurements.

- Sitting **blood pressure** and heart rate measurements.

- **Psychomotor vigilance task (PVT) testing and cognitive performance testing**. The PVT is a test that measures the speed with which subjects respond to a visual stimulus. It is a simple task where the subject presses a button as soon as the light appears. The light will turn on randomly every few seconds for 5–10 minutes. The purpose of the PVT is to measure sustained attention, and give a numerical measure of sleepiness by counting the number of lapses in attention of the tested subject. In addition, you will also be asked to make judgements or decisions on stimuli such as words or images presented to you on a computer screen to track you your memory and thought process (cognitive performance).

- **Download of your CPAP compliance** or questions about compliance to dental device treatment.

- **Actigraphy.** This device is the size of a small wristwatch that measures activity and is a non-invasive method of monitoring human rest/activity cycle. The instructions for the device use as well as a sleep diary will be provided. The data is then downloaded into a computer.

- **Transcranial Direct Current Stimulation (tDCS)**
  This battery-powered device will be used to deliver a mild direct electrical current passed between electrodes on the scalp as shown in Figure 1for 30 min. Gel and medical bandages are used to secure the electrodes to the scalp. The inactive form (sham) tDCS will be applied at the same intensity but for only 30 seconds.

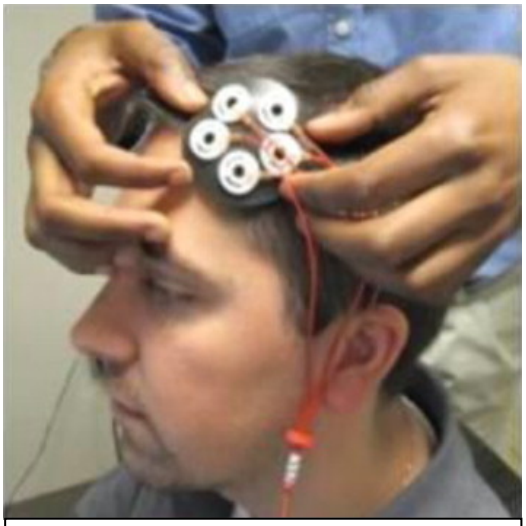
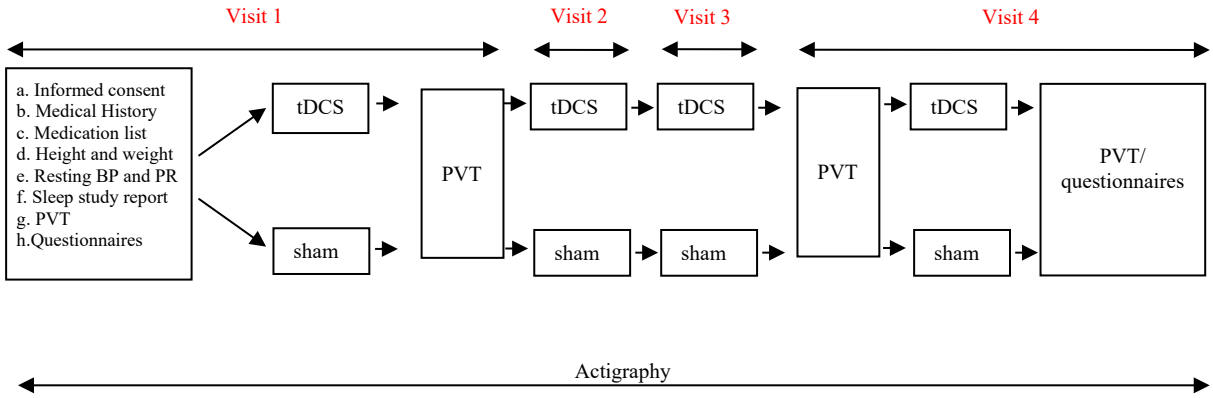


Figure 1. tDCS set-up.

Study Schema



4. How long will I be in the study?

The duration of the study is one week. However, it may take up to 4 weeks for those who will have actigraphy. The duration of the individual research visits are as follows:

Visit Schedule

1) **Visit 1**

During this visit, the following will be obtained for all subjects **prior** to sham or active tDCS:

a. Informed consent (if not obtained on a prior separate visit)
b. Medical History
c. Pregnancy test, if applicable
d. Medication list
e. Height and weight
f. Resting blood pressure and pulse rate
g. Sleep study report
h. Psychomotor Vigilance Test (PVT)
i. Cognitive Tasks results
j. Responses to questionnaires (ESS, SSS, FOSQ-10, VAS, CES-D, side effects)

They will then receive either sham or active tDCS for 30 mins after randomization. PVT and side effects questionnaire will be repeated **during** the sham or active tDCS

k. VAS/Side effects Questionnaire **after** the sham or stimulation.
l. Actigraphy. Subjects will be provided instructions on how to wear an actigraph device around their wrist that measures both the rest-activity cycle. A sleep diary will also be provided.
m. Expected visit length: 90 minutes

2) **Visit 2**

During this visit, the following will be obtained for all subjects:

a. Resting blood pressure and pulse rate
b. Changes to Medication
c. Side effects questionnaire

They will then receive either sham or active tDCS for 30 mins after randomization. PVT/side effects questionnaire **during** the sham or active tDCS

d. Side effects questionnaire **after** the sham or active tDCS
e. Expected visit length: 60 minutes

3) **Visit 3**

During this visit, the following will be obtained for all subjects:

a. Resting blood pressure and pulse rate
b. Changes to Medication
c. Side effects questionnaire

They will then receive either sham or active tDCS for 30 mins after randomization. PVT/side effects questionnaire **during** the sham or active tDCS

d. Side effects questionnaire **after** the sham or active tDCS
e. Expected visit length: 60 minutes

4) **Visit 4**

During this visit, the following will be obtained for all subjects **prior** to sham or active tDCS:

a. Return actigraph device
b. Resting blood pressure and pulse rate
c. Changes to Medication
d. Psychomotor Vigilance Test (PVT)/VAS results/side effects questionnaire

They will then receive either sham or active tDCS for 30 mins after randomization. PVT/side effects questionnaire will be repeated during the sham or active tDCS

e. The following will be obtained after the sham or active tDCS
    i. PVT
    ii. Cognitive Tasks results
    iii. Responses to questionnaires (ESS, SSS, VAS, FOSQ-10, CES-D)
    iv. Side effects Questionnaire
f. **Expected visit length: 90 minutes**

Visit Schedule

PROCEDURES	Clinical Care	Visit 1	Visit 2	Visit 3	Visit 4
Consent		•			
Sleep study*	•				
Medical History		•			
Pregnancy test		•			
Medication List		•	•	•	•
BP and Pulse rate		•	•	•	•
Height and weight		•			
Questionnaires**		•			•
PVT/Cognitive Tasks***		•	•	•	•
tDCS (sham or active)		•	•	•	•
Actigraphy		•	•	•	•

*

Sleep study is completed per standard clinical care.
** Done prior to stimulation during visit 1 and after stimulation during visit 4
*** Done prior to and after stimulation during visits 1 and 4

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

- **Risks associated with tDCS:**

The most common side effect of tDCS is a slight itching or tingling on the scalp. It is also possible to have scalp and skin irritation as a result of the electrodes. Most individuals report mild, transient tingling at the stimulation site resulting from tDCS. No studies thus far have provided evidence that tDCS produces more than a minimal risk. A recent review of studies involving tDCS in different conditions found that to date, the use of tDCS protocols in human trials has not produced any reports of a Serious Adverse Effect or irreversible injury across over 33,200 sessions and 1000 subjects with repeated sessions.

Pain: If you feel any pain during tDCS, inform the investigator or the research monitor or an alternate immediately. We will terminate the stimulation at once.

*Headache and Nausea***.** Any report of significant or headache/nausea will result in the immediate termination of stimulation.

- **Risks associated with Actigraph:**

There is no risk associated with this device as it is like wearing a wrist watch. You will be asked to take off the device when taking a shower or when swimming.

- **Risks associated with Questionnaires:**

You may become bored or uncomfortable completing the questionnaires.

- **Risks associated with Blood Pressure Measurement:**

You may feel uncomfortable when the blood pressure cuff inflates.

- **Risks associated with PVT/cognitive performance tests:**

There is no risk associated with this testing as you are merely pushing a button during the testing. However, you may become bored or uncomfortable during the testing.

7. What benefits can I expect from being in the study?

There are no expected direct benefits to you by participating in this study. In the future, you may benefit, if new strategies to manage patients with sleepiness emerge as a result of this research.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office records. Authorized Ohio State

University staff not involved in the study may be aware that you are participating in a research study and have access to your information.

You may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form if the study involves the use of your protected health information.

10. What are the costs of taking part in this study?

You will not be billed for any research procedure performed in the study. You and/or your insurance company will be billed for all costs associated with your **routine medical care and normal physician visits.**

11. Will I be paid for taking part in this study?

Participants who qualify for the study will receive up to $300 compensation for participating in the study. You will receive $75 for each study visit which will be provided to you in the form of a check at the end of Visit 2 and Visit 4. The 4 study visits must be completed within the 5-day period.

12. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

13. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to

applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact **Dr. Ulysses Magalang. Tel: 614-293-4925.**

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact **Dr. Ulysses Magalang. Tel: 614-293-4925.**

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form**.**

Printed name of subject	**Signature of subject**
	AM/PM
	Date and time
Printed name of person authorized to consent for subject (when applicable)	**Signature of person authorized to consent for subject (when applicable)**
Relationship to the subject	**AM/PM**
	Date and time

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time