Combining tDCS and Neurorehabilitation to Treat Age-related Deficits of Mobility and Cognition: UPfront Walking Study

NCT03122236

04/03/2019

UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and

AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

Please read this form which describes the study in some detail. A member of the research team will describe this study to you and answer all of your questions. Your participation is entirely voluntary. If you choose to participate you can change your mind at any time and withdraw from the study. You will not be penalized in any way or lose any benefits to which you would otherwise be entitled if you choose not to participate in this study or to withdraw. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the Title of this research study?

Combining tDCS and neurorehabilitation to treat age-related deficits of mobility and cognition: UPfront Walking Study

3. Who do you call if you have questions about this research study?

Principal Investigator: David J. Clark, ScD
352-376-1611 x5244 (office phone)
352-443-0655 (mobile phone)

4. Who is paying for this research study?

The sponsor of this study is the National Institutes of Health.

5. In general, what do you need to know about this Research Study?

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

a) <u>In general, what is the purpose of the research, how long will you be involved?</u>

The purpose of this research is to better understand how the brain controls walking, including if mild electrical stimulation delivered to the brain during walking rehabilitation/exercise can improve outcomes. You will be in this research study for up to 6 months. Most procedures will be completed within the first two months, but there is also a follow-up visit that occurs 3 months after the exercise program ends.

b) <u>What is involved with your participation, and what are the procedures to be followed in the research?</u>

We will test your walking and balance abilities, cognitive (e.g., memory) abilities, as well as ask other questions about your health. We will deliver mild electrical stimulation to your brain, which is considered safe and which is comfortable for most people. You will participate in a walking rehabilitation/exercise program for six weeks.

c) <u>What are the likely risks or discomforts to you?</u>

There is a risk of falling or experiencing other injuries during walking and balance procedures. Electrical stimulation can cause mild sensations of itching or tingling.

d) <u>What are the likely benefits to you or to others from the research?</u>

Participating in the rehabilitation/exercise program may improve your walking abilities, and/or will provide physical activity that is considered beneficial to health.

e) <u>What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?</u>

The only alternative is not to participate in the study.

Additional and more detailed information is provided within the remainder of this Informed Consent form, please read before deciding if you wish to participate in this study.

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.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this research study)?

Nothing in this research study is part of your normal clinical care.

7. What will be done only because you are in this research study?

We will test your ability to perform a variety of walking tasks such as stepping over obstacles and making turns. During some walking tests we may ask you to wear textured shoe insoles that have many small "bumps" on the surface. We will also test your ability to do cognitive tasks such as remembering information. We will also measure your reaction time. During these tests, you will be asked to wear sensors on your head that measure how hard your brain is working. This is called functional near infrared spectroscopy (fNIRS). With fNIRS, infrared light passes through your skull and is absorbed or reflected by blood and other tissues in your head. The amount of light absorption/reflection tells us how active your brain is. fNIRS causes no sensations (other than the feeling of sensors strapped onto your forehead). It is safe and has no effect on your brain. You may also be asked to wear sensors on your fingers that can measure tiny amounts of sweating, which tells us how excited the nervous system is. These tests will be done at three time points in the study: before you begin the exercise program, after you complete the exercise program, and again about 3 months after completing the exercise program.

You will then participate in a walking exercise program for about 6 weeks. You will come to our research center 3 days per week (18 sessions total) for this program. Each visit will last about 90 minutes. Our study uses two different types of exercise programs, and you will be randomly assigned to one of them. The two types are 1) regular walking exercise; and 2) complex walking exercise, which includes tasks such as stepping over obstacles, walking on a soft surface (exercise mat), and doing cognitive tasks while you are walking. If you feel tired during exercise, you will be allowed rest breaks as often as you want them.

During the exercise program we will also deliver a small amount of electricity to your brain using a method called transcranial direct current stimulation, or tDCS. It is a weak form of electrical stimulation that comes from two 9-volt batteries. During tDCS we place two moist pads on your head, which are connected to the stimulation device. It is common to feel a "tingling" sensation on your skin during tDCS, but it should not hurt. Because of the low level of stimulation that we use, you may hardly feel it or may not feel it at all. tDCS will be delivered for up to 30 minutes per session. tDCS has been used widely in prior research, and it is considered to be safe. The purpose of tDCS is to help your brain learn better or more quickly.

We may take photos or video recordings of you while you walk or perform other study tasks. We will try to avoid recording images of your face, but sometimes we accidentally record facial images. Videos will be securely stored on a password protected computer server. At the end of this form you can decide whether or not we can take photos and video, and if so, how we may use them.

Once this research study is completed, any information that could identify you **might** be removed from any identifiable private information or identifiable biospecimens collected and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

If you have any questions now or at any time during the study, please contact one of the research team members listed in question 3 of this form.

8. How long will you be in this research study?

You will be in this research study for up to 6 months. Most procedures will be completed within the first two months, but there is also a follow-up visit that occurs 3 months after the exercise program ends.

9. How many people are expected to take part in this research study?

Up to 100 people may participate in this research study, but many will not pass the screening tests. Up to 30 people will pass the screening tests and then take part in the exercise program.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

10. What are the possible discomforts and risks from taking part in this research study?

As with all physical activity, there is a risk of falling while we test or train your walking ability. It is possible that you may experience fatigue, soreness, and discomfort due to physical activity associated with this study. These are unlikely to be worse than what you would experience due to increased physical activity outside of our study. These are normal responses to exercise and generally disappear within 2-3 days.

tDCS is considered safe, but some people from prior studies have experienced some side effects. The most common side effects are itching and tingling of the skin in the area of stimulation, as well as headache. Other possible temporary side effects that have been reported include dizziness and nausea. These side effects are not

considered serious, are relatively uncommon, and normally disappear shortly after the stimulation is stopped or within 1 day.

fNIRS and skin conductance measurements are considered safe. The fNIRS sensors are attached to your head using elastic straps or adhesive tape. The skin conductance sensors are secured to your fingers using adhesive tape. Tape may cause minor skin irritation in some people, or more substantial irritation in people who are sensitive/allergic to adhesives. If you have a known issue with adhesives please let us know.

There is a risk that you will find cognitive and functional tests challenging or uncomfortable because it may be difficult to remember the things that you are asked to remember or because you have trouble succeeding with the tasks.

Researchers will take appropriate steps to protect any information they collect about you. However, there is a small risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information, such a release could upset or embarrass you, or possibly affect your insurability or employability. Questions 17-21 in this form discuss what information about you will be collected, used, protected, and shared.

This study may include risks that are unknown at this time.

Participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another research study, please inform one of the research team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

Throughout the study, the researchers will notify you of new information that may become available and might affect your decision to remain in the study.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the research team members listed in question 3 in this form.

11a. What are the potential benefits to you for taking part in this research study?

Your walking or cognitive abilities might improve with exercise and/or with tDCS brain stimulation. However, there is no guaranteed benefit.

11b. How could others possibly benefit from this study?

Others may benefit from this study if the findings contribute to new therapies that improve in walking ability and/or cognitive ability in older adults.

11c. How could the researchers benefit from this study?

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator listed in question 3 of this form may benefit if the results of this study are presented at scientific meetings or in scientific journals.

12. What other choices do you have if you do not want to be in this study?

The alternative to not taking part in this study is doing nothing. If you do not want to take part in this study, tell the Principal Investigator and do not sign this Informed Consent Form.

13a. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled.

If you decide to withdraw your consent to participate in this study for any reason, please contact one of the research team members listed in question 3 of this form. They will tell you how to stop your participation safely.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

13b. If you withdraw, can information about you still be used and/or collected?

If you withdraw from the study before it is completed, the data already collected might be used for analysis, but no further data will be collected.

13c. Can the Principal Investigator withdraw you from this study?

You may be withdrawn from the study without your consent for the following reasons:

- The Principal Investigator decides that continuation could be harmful to you.
- You do not qualify to be in the study because you do not meet the study requirements. Ask the Principal Investigator if you would like more information.
- A change in your health and physical functioning making it difficult for you to comply with the protocol
- You need treatment not allowed in the study
- Other reasons affecting administration of the research project.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

14. If you choose to take part in this research study, will it cost you anything?

Study Device

tDCS stimulation will be provided at no cost to you while you are participating in this study. The amount of stimulation that you receive will vary based on what group you are randomly assigned to. You will not be told what group you are in until your involvement with the study is fully completed.

Study Services

The Sponsor will pay for or provide all study services/activities required as part of your participation in this study. There will be no cost to you, except that you will be responsible for paying any incidental costs of participation such as transportation expense. If you receive a bill related to this study, please contact Dr. Clark at 352-376-1611 x5244.

Items/Services Not Paid for by the Sponsor

Any other medical services provided to you that are not directly required by this study will be billed to you or your insurance company in the usual manner.

15. Will you be paid for taking part in this study?

Yes, you will be paid $20 for every scheduled visit to our research center, not to exceed $500. To reduce the administrative effort of issuing payments, we may wait 2-3 weeks between issuing payments if this acceptable to you.

If you are paid more than $75 for taking part in this study, your name and social security number will be reported to the appropriate University employees for purposes of making and recording the payment as required by law. You are responsible for paying income taxes on any payments provided by the study. If the payments total $600 or more or you are a nonresident alien, payment will be processed through the University of Florida Accounts Payable department and the University must report the amount you received to the Internal Revenue Service (IRS). The IRS is not provided with the study name or its purpose. If you have questions about the collection and use of your Social Security Number, please visit: http://privacy.ufl.edu/SSNPrivacy.html.

Your payment for participation in this research study is handled through the University of Florida's Human Subject Payment (HSP) Program. Your information which will include your name, address, date of birth, and SSN (depending on amount of money you are paid) is protected. Access to the (HSP) Program site is limited to certain staff with the assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity.

The study team will provide you with an informational form called the Prepaid Card Facts document. If you have any problems regarding your payment call the HSP Office (352) 392-9057.

16. What if you are injured because of the study?

If you are injured as a direct result of your participation in this study, only the professional services that you receive from any University of Florida Health Science Center healthcare provider will be provided without charge. These healthcare providers include physicians, physician assistants, nurse practitioners, dentists or psychologists. Any other expenses, including Shands hospital expenses, will be billed to you or your insurance provider.

You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information.

The Principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is routinely offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact Dr. David Clark at 352-443-0655 if you experience an injury or have questions about any discomforts that you experience while participating in this study.

17. How will your health information be collected, used and shared?

If you agree to participate in this study, the Principal Investigator will create, collect, and use private information about you and your health. This information is called protected health information or PHI. In order to do this, the Principal Investigator needs your authorization. The following section describes what PHI will be collected, used and shared, how it will be collected, used, and shared, who will collect, use or share it, who will have access to it, how it will be secured, and what your rights are to revoke this authorization.

Your protected health information may be collected, used, and shared with others to determine if you can participate in the study, and then as part of your participation in the study. This information can be gathered from you or your past, current or future health records and from procedures such as physical examinations or from other procedures or tests. This information will be created by receiving study treatments or participating in study procedures, or from your study visits and telephone calls. More specifically, the following information may be collected, used, and shared with others:

- Information about your medical history

- Information about your physical abilities
- Information about your cognitive abilities
- Information will be collected from your participation in the study

This information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices.

Some of the information collected could be included in a "limited data set" to be used for other research purposes. If so, the limited data set will only include information that does not directly identify you. For example, the limited data set cannot include your name, address, telephone number, social security number, photographs, or other codes that link you to the information in the limited data set. If limited data sets are created and used, agreements between the parties creating and receiving the limited data set are required in order to protect your identity and confidentiality and privacy.

18. For what study-related purposes will your protected health information be collected, used, and shared with others?

Your PHI may be collected, used, and shared with others to make sure you can participate in the research, through your participation in the research, and to evaluate the results of the research study. More specifically, your PHI may be collected, used, and shared with others for the following study-related purpose(s):

- To determine the extent to which tDCS combined with walking exercise might improve walking and/or cognitive abilities.

Once this information is collected, it becomes part of the research record for this study.

19. Who will be allowed to collect, use, and share your protected health information?

Only certain people have the legal right to collect, use and share your research records, and they will protect the privacy and security of these records to the extent the law allows. These people include:

- the study Principal Investigator (listed in question 3 of this form) and research staff associated with this project.
- other professionals at the University of Florida or Shands Hospital that provide study-related treatment or procedures.
- the University of Florida Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research).

20. Once collected or used, who may your protected health information be shared with?

Your PHI may be shared with:

- the study sponsor (listed in Question 4 of this form).
- United States governmental agencies who are responsible for overseeing research.
- Government agencies who are responsible for overseeing public health concerns.
- professionals at the University of Florida who are involved with scientific or administrative aspects of this project.

Otherwise, your research records will not be released without your permission unless required by law or a court order. It is possible that once this information is shared with authorized persons, it could be shared by the persons or agencies who receive it and it would no longer be protected by the federal medical privacy law.

21. If you agree to take part in this research study, how long will your protected health information be used and shared with others?

Your PHI will be used and shared with others until the end of the study

You are not required to sign this consent and authorization or allow researchers to collect, use and share your PHI. Your refusal to sign will not affect your treatment, payment, enrollment, or eligibility for any benefits outside this research study. However, you cannot participate in this research unless you allow the collection, use and sharing of your protected health information by signing this consent and authorization.

You have the right to review and copy your protected health information. However, we can make this available only after the study is finished.

You can revoke your authorization at any time before, during, or after your participation in this study. If you revoke it, no new information will be collected about you. However, information that was already collected may still be used and shared with others if the researchers have relied on it to complete the research. You can revoke your authorization by giving a written request with your signature on it to the Principal Investigator.

SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

Signature of Person Obtaining Consent and Authorization	Date

☐ Every page of this consent form includes an IRB stamp in the upper right corner.

Initials of person obtaining consent

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described in sections 17-21 above. By signing this form, you are not waiving any of your legal rights.

Signature of Person Consenting and Authorizing	Date

Consent to be Photographed, Video and/or Audio Recorded

With your permission, you may have the following done during this research (check all that apply):

☐ photographed ☐ video recorded ☐ audio recorded

Your name or personal information will not be identified on the photograph(s), video or audio recordings, and confidentiality will be strictly maintained. However, when these photograph(s), video and/ or audio recordings are shown or heard, others may be able to identify you.

The Principal Investigator (PI) of this study, Dr. David Clark, or his successor, will keep the photograph(s), video and/or audio recordings in a locked cabinet, in a folder on a password protected computer server drive, or as an encrypted electronic file. These photograph(s), video and/or audio recordings will be shown under his direction to students, researchers, doctors, or other professionals and persons.
Please indicate under what conditions Dr. Clark has your permission to use the photograph(s), video and/or audio recordings, and sign and date below.

☐ The following will be **destroyed once the study is closed** (initial next to all that apply):

____ photograph(s) _____ video recording(s) _____ audio recording(s)

☐ As described in the Informed Consent Form, and for the purposes of **education at the University of Florida Health Science Center**. The PI may keep the following for an indefinite period of time in a locked file, in a password protected computer server drive, or as an encrypted electronic file (initial next to all that apply):

____ photograph(s) _____ video recording(s) _____ audio recording(s)

☐ As described in the Informed Consent Form; for the purposes of **education at the University of Florida Health Science Center; and for presentations at scientific meetings outside the University**. The PI may keep the following for an indefinite period of time in a locked file, in a password protected computer server drive, or as an encrypted electronic file (initial next to all that apply):

____ photograph(s) _____ video recording(s) _____ audio recording(s)

_____ _____

Signature Date