Cover Page

Official Title: HOMEStudy: Development of a Home-based Self-delivered Prehabilitation Intervention to Proactively Reduce Fall Risk in Older Adults

NCT Number: NCT05583578

Document Date:10/18/2023

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:_____

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the title of this research study (this "Research Study")?

Development of a Home-based Self-delivered Prehabilitation Intervention to Proactively Reduce Fall Risk in Older Adults

3. Whom do you call if you have questions about this Research Study (the "Study Team")?

Principal Investigator:
Clayton Swanson, Ph.D.
352-376-1611 x107538 (office phone)
503-887-9745 (mobile phone)

Other research staff:
David J. Clark, Sc.D.
352-376-1611 x105244 (office phone)
352-443-0655 (mobile phone)

4. Who is paying for this Research Study?

The sponsor of this study is the National Institute of Aging.

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) In general, what is the purpose of the research? How long will you be involved?

The purpose of this research is to implement a home-based self-delivered pre-rehabilitation intervention using mild electrical stimulation to the brain during a variety of imagined mobility learning tasks to see if changes in mobility can be observed. Volunteers who qualify for the study will attend approximately 3 laboratory visits and 6 home-based self-delivered visits over the course of roughly 6 weeks.

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

In the laboratory we will test your walking and balance abilities, cognitive (e.g., memory) abilities, as well as ask other questions about your health. Although most of the study will be performed in your home, you will be trained on how to self-deliver the mild electrical stimulation to your brain. This is considered safe and comfortable for most people. While this brain stimulation is delivered, you will practice performing imagined and observed movements. For instance, you will be asked to watch on a TV or computer screen somebody walking, balancing, and performing common movements made on a daily basis. During this practice you will rehearse these movements while you are seated and will be asked to think about completing them to the best of your ability without *actually* performing the movements during the practice sessions. Additionally, an activity monitor will be secured to your thigh with waterproof tape for seven days at the beginning and end of the study. This activity monitor will allow us to observe the number of movements you take on a daily basis.

c) What are the likely risks or discomforts to you?

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

d) What are the likely benefits to you or to others from the research?

There is no direct benefit to those who participate in this study.

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

The only alternative is not to participate in the study.

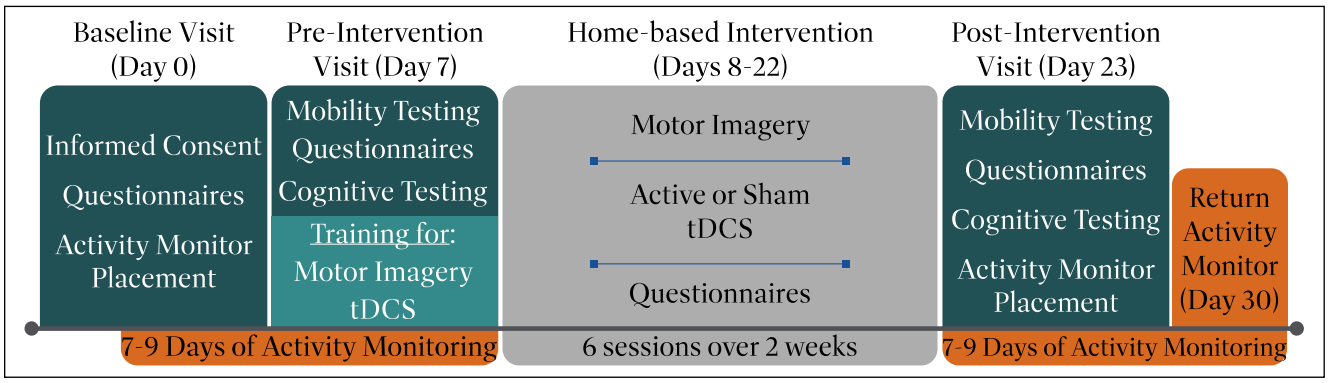
Additional and more detailed information is provided within the remainder of this Informed Consent form. Please read before deciding if you wish to participate in this study.

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)?

Normal clinical care is medical or other treatment or services that you would receive 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?



Here we describe the assessments that are planned for each laboratory- and home- based study visit. The exact assessment schedule might differ slightly based on availability of equipment, research personnel, and your availability. If we are not able to complete a particular visit, we will attempt to reschedule any missed assessments.

At the first visit (Baseline), all participants will complete the informed consent, several questionnaires and assessments that include demographic information, health/medical information, physical abilities, and cognitive (mental) abilities. These assessments help us to determine if you meet the eligibility criteria for the full study, and include:

Baseline assessments:

- asking questions about falls and your history of falling
- blood pressure and heart rate
- measuring your height and weight
- asking you questions about your health and medical history
- ask you questions about your sleep habits
- obtaining a list of medications that you use

Many of the people who undergo these assessments will not qualify for the full study. During the baseline visit, we will evaluate your assessments and medical records to determine if you meet all eligibility criteria and will be notified about whether or not you qualify.

For those participants who do qualify for the full study, you will be invited to attend approximately 2 or 3 additional laboratory-based and 6 home-based visits spread across approximately a 4-6-week time span. The visit schedule and content will be:

Activity Monitor

Baseline: In addition to the items described above you will also be asked to complete several questionnaires asking about your sleep, cognition (thinking), activities of daily living, quality of life, independence, and mental imagery. This visit lasts about 1.5 hours.

First activity monitor placement will take about 15 minutes and will be completed at the end of the screening visit or as a stand-alone visit for those who qualify without further assessment. Placement will entail securing a small, thin, and lightweight activity monitor to the right upper thigh. The activity monitor will be secured to the skin using a clear medical grade adhesive tape.

Pre-Intervention Assessment will take about 2 hours and will be completed after the activity monitor has been worn for roughly one week. During this visit you will be asked to complete a set of computer-based assessments meant to measure your cognition (thinking). Then, for all the movement assessments we will place small (watch size) motion sensors on your forehead, around your chest, waist, wrists, legs, and feet so that we can measure your movement patterns during all the different mobility assessments. During these tests you will wear a gait belt that will help us support you if your balance becomes unsteady.

Motion Sensors

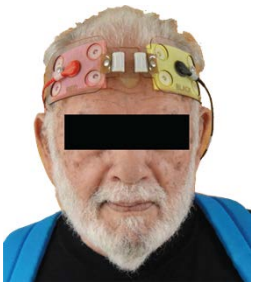
Mobility assessments will include:
You will be asked to perform a series of different walking trials either at your natural walking pace, your fast walking pace, or walking while having to think about something else. We will ask you to walk over a special "floor" that will measure gait (e.g., step length, swing time, etc.) while you perform basic walking tasks such as straight walk, 90 degree turns, 180 degree turns, and 360 degree turns. You will be asked to perform a balance test by standing with your feet together on either a firm or foam surface with eyes open and closed. You will be asked to sit up and down from a chair and sit up from a chair walk for a few steps, turn around then sit back down in the chair.

Home-based Intervention Sessions: This portion of the study includes 6 sessions occurring every other day for two-weeks. Each home session will last about 30 minutes.

Imagined and observed movement practice with brain stimulation:

During each session at home, you will deliver a small amount of electricity to your brain using a method called transcranial direct current stimulation (tDCS). tDCS is a weak form of electrical stimulation that has been widely used in prior research and is safe both in the laboratory and at home. We will randomly determine (like a coin flip) whether you receive a higher or lower amount of brain stimulation. During tDCS, you will snap two moist pads on to the headband that is connected to the stimulation device. It is common to feel a slight "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 20 minutes per session.

You will be provided specific directions (both verbally, physically, and on paper) on how to appropriately place the brain stimulation headband and use the device during the baseline laboratory visit. For each session you will be provided a specific code which will be required to turn on the device for each session.



Brain Stimulation Headband

While you are receiving the brain stimulation you will be asked to practice the imagined and observed movements while seated in front of a computer or television screen for roughly 30 minutes. We will ask you to practice each set of movements by observing the movement being performed adequately and through imagination without moving your body.

Additionally, at the beginning and end of each session you will be asked to complete two questionnaires: one assessing how well and effectively you were able to practice the imagined and observed movements called the Daily Vividness of Imagined Tasks Questionnaire and another questionnaire asking you to assess the level of stimulation you felt called the tDCS Sensation Questionnaire.

Post-Intervention Test <u>one day</u> after Home-based Intervention Sessions

This visit will take place in the laboratory and will lasts about 2 hours. We will repeat the questionnaires, cognitive (thinking) test, and mobility assessments you completed during the Pre-Intervention Assessment.

Second activity monitor placement will take about 15 minutes at the end of the post-test assessment. Similar to the first time wearing the activity monitor placement will entail securing a small, thin, and lightweight activity monitor to the right upper thigh. The activity monitor will be secured to the skin using a clear medical grade adhesive tape. You will be asked to wear this activity monitor for 1 week then return it to the laboratory.

If any identifiable information or data was collected as part of this research, it is possible that your research information or data, with all personally identifiable information removed, 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 this Research Study, please contact one of the Research Team members listed in question 3 of this form.

8. What identifiable health information will be collected about you and how will it be used?

The Research Team will collect:

- Resting blood pressure
- Height, weight, age, sex, education level, socioeconomic status
- Medical history
- Obtain list of medications that the participant is currently using
- Montreal Cognitive Assessment (MoCA)

The Research Team may collect this information from other healthcare providers, such as laboratories, which are a part of this research, as well as healthcare providers that are not part of this research (other doctors, hospitals or clinics). Other professionals at the University of Florida or Shands Hospital who

provide study-related care, and the University of Florida Institutional Review Board (IRB), may also collect your health information.

The Research Team listed in question 3 above will use or share your health information as described below to carry out this research study.

9. With whom will this health information be shared?

This health information may be shared with:

- the study sponsor (listed in Question 4 of this form);
- United States governmental agencies which are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections;
- government agencies which are responsible for overseeing public health concerns, such as the Centers for Disease Control and federal, state and local health departments, and
- the IRB that reviewed this Research Study and ensures your rights as a Study Subject are protected.

Otherwise, your identifiable health information will not be shared without your permission unless required by law or a court order. Once your health information is shared with those listed above, it is possible that they could share it without your permission because it would no longer be protected by the federal privacy law.

10. How long will you be in this Research Study?

If you do not meet the eligibility study for the criteria, you will be in the research study for only one visit. If you do meet the eligibility criteria and decide to enroll, you will be in the research study for 8 additional visits spread over the course of 4 to 6 weeks. There will be a total of 3 visits to the laboratory (baseline, pre-intervention visit, and post-intervention visit), and 6 sessions which will take place within your own home.

This Authorization to use and share your health information expires at the end of the study, unless you revoke it (take it back) sooner.

11. How many people are expected to take part in this Research Study?

We expect up to 34 people to complete the full study. A total of 80 potential participants may complete the screening visit but will not qualify for the full study.

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

12. What are the possible discomforts and risks from taking part in this Research Study?

For the laboratory sessions there is a risk of falling while we test your walking and balance ability. Falls can lead to injuries ranging from mild (e.g., bruising) to serious (e.g., head injury). There is also a risk of musculoskeletal injury such as an ankle sprain.

It is possible that you may become tired, sore, or uncomfortable due to physical activity either during or after your visit. These symptoms are unlikely to be worse than what you would experience due to physical activity outside of our study. These are normal responses to exercise and generally disappear within 2-3 days.

It is not possible to identify all potential risks in research procedures, but the researcher(s) have taken reasonable safeguards and trainings to minimize any known and potential, but unknown, risks. Researchers will take appropriate steps to protect any information they collect about you. However, there is a slight 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 even affect your insurability or employability.

This Research Study may also include risks that are unknown at this time.

Please note, participating in more than one research study or project may further increase the risks to you. If you are already enrolled in a 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.

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

The University of Florida is required by law to protect your health information. Your health information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices, as required by University policy. However, there is a slight risk that information about you could be released inappropriately or accidentally. Depending on the type of information, a release could upset or embarrass you, or possibly affect your ability to get insurance or a job.

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.

13a. What are the potential benefits to you for taking part in this Research Study?

There are no direct benefits for participation in this study.

13b. How could others possibly benefit from this Research Study?

Others may benefit if we can increase our knowledge of how the brain contributes to successful walking and turning function. This may lead to future studies to assess longer term rehabilitation techniques for improving mobility function.

13c. How could the Research Team members benefit from this Research Study?

In general, presenting research results helps the career of a researcher. Therefore, the Research Team listed in question 3 of this form may benefit if the results of this Research Study are presented at scientific meetings or in scientific journals.

13d. Will you be allowed to see the research information collected about you for this Research Study?

This study is designed to be double-blind and randomized. This means that the neither the participants or the research team knows whether you will receive active or sham stimulation. The research team will not know what group you were randomized into until after all participants have completed the study. As such, you will not be allowed to know which group you were selected into until the study has concluded. If you would like to know which group you were placed you can follow up with the research staff after the study has fully concluded for additional information.

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

The other choice is not to participate in the study. If you do not want to be in this study, please tell a member of the research team and do not sign this consent form.

You may also refuse to authorize the use of your health information, but if you refuse, you may not be allowed to be in this research study or receive any research-related treatment that is only available in this research study. However, your decision not to sign this Authorization will not affect any other treatment you may be eligible to receive.

15a. Can you withdraw from this study?

You may withdraw your consent and stop participating in this Research Study at any time. If you do withdraw your consent, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. If you decide to withdraw your consent to participate in this Research Study for any reason, please contact the Research Team listed in question 3 of this form. They will tell you how to safely stop your participation.

You can also change your mind and take back this Authorization at any time by sending a written notice to the Research Team listed in question 3 of this form to let them know your decision. If you take back this Authorization, the Research Team may only use and disclose your health information already collected for this research study. No additional health information about you will be collected or disclosed to the Research Team. However, if you take back this Authorization, you may not be able to continue in this study. Please discuss this with a member of the Research Team listed in question #3.

15b. Can the Principal Investigator withdraw you from this Research Study?

You may be withdrawn from this Research Study without your consent for the following reasons:

- The Principal Investigator feels 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.
- There is 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.
- Unforeseen problems affecting administration of the research project.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

16. If you choose to take part in this Research Study, will it cost you anything?

No, there will be no additional costs to you or your health plan as a result of your participation in this study. There are no expected protocol-required items, services or procedures that will generate any charges at UF Health. However, if you feel you have received a bill related to this study, please contact the Principal Investigator.

If you receive any healthcare at UF Health that is not related to this study, this care will be billed as usual.

17. Will you be paid for taking part in this Research Study?

Yes. You will be paid $25 per visit for attending the screening visit, baseline visit, post-visit, and returning of the activity monitor. Additionally, participants will be compensated $100 for completing the 6 at-home intervention visits. If all visits are completed participants have the ability to be compensated a total of $200.

If you are paid more than $199 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. Payments to nonresident aliens must be processed through the University of Florida Payroll and Tax Services department. If the payments total $600 or more in a calendar year, 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.

If you have any problems regarding your payment contact the study coordinator.

18. What if you are injured while in this Research Study?

Since this is a observational study, there is a very low risk of study-related injury. However, 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 one of the research team members listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this study.

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

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 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

In order to better document our research procedures (e.g., placement of brain measurement sensors; responses to cognitive tests) and assess changes in your walking function over time, we would like to take photographs, audio recordings, or video of some research procedures.

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.

Study staff 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 may be shown to students, researchers, doctors, or other professionals and persons.
Please indicate under what conditions we have your permission to use the photograph(s), video and/or audio recordings, and sign and date below.

☐ I do NOT give permission for you to obtain:

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

☐ I give permission for research purposes and for the purpose of **education at the University of Florida; and for presentations at scientific meetings outside the University**. Study staff 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