Informed Consent Form

TITLE: Innovative Biofeedback Interface for Enhancing Stroke Gait Rehabilitation

NCT NUMBER: NCT04013971

IRB APPROVAL DATE: September 5, 2023

You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

Title: **Innovative Biofeedback Interface for Enhancing Stroke Gait Rehabilitation**

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 40 people who are being studied at Emory University.

Why is this study being done?
This study is being done to answer the question: Can a game-based system be used to provide feedback during walking training? As part of this project, we designed and developed a new game-based interface, and our goal is to obtain feedback from users about this game, as well as test the short-term effects of the game-based walking on walking patterns.

Do you have to be in the study?
It is your decision to be part of this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?
If you are eligible and want to be part of the study, you will participate for 1 to 3 sessions. The sessions may include clinical evaluation of your walking function and leg strength, asking you to provide your feedback and comments about the game, and collecting data while you walk on a treadmill with or without the new game-based feedback. Some of these procedures will be paid for by the study.

How is this study going to help you?
If you are in the study, you will be helping the researchers answer the study question. In the long run, this study will help improve our understanding of how game-based therapies can help to improve engagement and effectiveness of rehabilitation.

What are the risks or discomforts I should know about before making a decision?
The study will take time. The game-based interface that is being tested may not work any better than regular treadmill walking, and may even cause harm. The evaluation sessions may cause discomfort or minor risks as well. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include risk of falls, muscle soreness or injury, fatigue, skin irritation or burns, headaches, dizziness, other risks associate with walking exercise, loss of privacy, and breach of confidentiality. A full

list of expected risks, their frequency and severity are in the “What are the possible risks and discomforts?” section of this document.

Alternatives to Joining This Study

Because this is not a treatment study, the alternative is not to participate.

Costs

You WILL NOT have to pay for any of the study procedures.

What Should I Do Next?

Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.). Take time to consider this, and talk about it with your family and friends.

Emory University
Consent to be a Research Subject / HIPAA Authorization

Title: **Innovative Biofeedback Interface for Enhancing Stroke Gait Rehabilitation**

Principal Investigator: **Trisha Kesar, PT, PhD, Department of Rehabilitation Medicine**

Sponsor: **National Institutes of Health (NICHD)**

Investigator-Sponsor: **Trisha Kesar, PT, PhD**

Study-Supporter: **NIH NICHD R21 research grant**

Introduction
You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

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 is the purpose of this study?
The purpose of this study is to develop and conduct preliminary testing on a new game-based interface for providing feedback to stroke survivors during walking training. Our goal is to use gaming interfaces to improve motivation, engagement, and benefits of walking rehabilitation. If you are eligible and want to be part of the study, you will participate in 1 to 3 sessions.

Who can participate in the study?
You are being asked to participate because you have had a stroke. To be eligible, we will confirm that you meet the study criteria, can walk safely for short distances, and can understand instructions and communicate with the study team. We will not include individuals who have other medical or neurologic diagnoses that limit walking or cause pain during walking.

What will I be asked to do?

If you are eligible and want to be part of the study, you will participate in 1 to 3 test sessions. We will request you to visit our laboratory at Emory University. Each session or visit will last about 2.5 to 4 hours. All study procedures are experimental.

Screening to confirm that you are eligible for the study:

We will ask about your medical history to confirm that you qualify for the study. We may use clinical tests to measure aspects of your walking function such as walking speed, lower limb strength and sensation, etc. We will use this information to confirm that you meet the study criteria and to document your current clinical status and walking capacity.

Study methods:

The study methods are listed below. One or more of the procedures described below may be combined during each of the study sessions.

(1) Clinical tests of walking and leg muscle function:

We will check your leg function and walking capacity. For example, we may measure how fast you walk over ground and on a treadmill, how far you can walk in 6 minutes, how much you can bend your knee, how much sensation you have in your legs, your balance, etc. During this session, we may also measure how strong the muscles surrounding your hip, knee, and ankle are. To test your muscle strength, we may use our hands to resist your muscles or use a special chair that has a force measuring device. During the strength tests, we may use straps to keep your trunk, thighs, and lower leg stable. For example, for testing the knee, we may ask you to 'kick out' or 'pull your leg in' with as much force as you can. For testing the ankle, we may ask you to pull your foot toward you or to push it away from you with as much force as possible. In addition, we may ask you to complete some questionnaires about your activity levels, community participation, balance confidence, cognition, etc. This part may take 45-minutes to 1.5 hours.

(2) Play-testing of the game:

During play-testing, we will show you the game-based interface on a computer screen. We will explain what the screen is showing, and how the game works. We may ask you to click on a computer mouse or tap on keyboard keys to move the game forward or respond to the game. You will be seated comfortably in a chair during play-testing. We will ask you to rate the game interface on features such as engagement, color-scheme, aesthetics, and ease-of-use. We may ask you to provide comments and suggestions about how to improve the game design.

(3) Motion capture to measure your movement patterns while you walk with the game interface:

For motion capture, you will walk over ground and/or on a treadmill. When you walk over ground, an investigator will be close by to assist you if needed. During treadmill walking, throughout the session, you will walk wear a safety harness. A set of 7 special cameras placed around the room will be used to precisely measure your movements during walking.

Elastic bands will be wrapped around your thighs, calves, and pelvis. Small reflective balls will be attached to your shoes, your upper back, shoulder, hip, knee, and ankle joints with non-irritating skin tape. We will also attach small sensors to the skin over muscles of your thigh and calf with skin tape. These sensors will help us to measure how hard your muscles are working. We may also attach a small sensor to your fingers to measure skin resistance.

During all the treadmill walking trials, we will provide you a secure harness wrapped around your torso and suspended from an overhead support rail. This harness is provided for safety. Additionally, while walking on the treadmill, you can also rest your fingertips on the handrail if needed. We will slowly increase the treadmill speed and first, let you get comfortable with the treadmill walking. We may collect data while you walk at a range of speeds (slow, medium, fast). The baseline walking trials will be 15-seconds to 6-minutes long. To test the effects of how the game-based interface changes your walking, we may ask you to walk during different conditions.

To test the effects of how the game-based interface changes your walking, we may ask you to walk during 2-3 different conditions such as.

(i) Walking with a projector screen display that is blank and provides no feedback.

(ii) Walking with a projector screen display showing you your current pushoff and a simple, 2-dimensional 'target' to encourage you to pushoff more with the leg affected by the stroke. You may also receive a visual and/or sound cue when you succeed at reaching your target.

(iii) Walking while a projector screen display is providing you a game-like visual interface to encourage you to walk with more pushoff with the leg affected by the stroke. Prior to this, we will let you try the projector display in a standing position and explain to you how the game-like interface works. You may receive visual and/or sound cues to inform you when you succeed at the target goal. You may also get a score to inform you of your success rate during the game.

In addition, in a separate session, we may also request you to walk while a head-mounted immersive display headset or goggles are providing you a game-like visual interface to encourage you to walk with more pushoff with one of your legs. Prior to this, we will let you try the head-mounted display in a standing or seated position and explain to you how the game-like interface works. You may receive visual and/or sound cues to inform you when you succeed at the target goal. You may also get a score to inform you of your success rate during the game.

During the session, we ask you to rate how tired you feel at regular intervals. Also, your heart rate and blood pressure will be checked at regular intervals. If you feel tired, you can take a seated break. This part may take 45-minutes to 3 hours.

(4) **Other user feedback and comments about the game:**
After you have been exposed to the game-based interface, we may ask you about your opinion and feedback about the game. Your feedback may be obtained through rating scales, written survey forms, or verbal discussion.

Who owns my study information and samples?

If you join this study, you will be donating your data and study information. You will not receive any compensation if your data are used to make a new product. If you withdraw from the study, data that were already collected may be still be used for this study.

What are the possible risks and discomforts?

There may be side effects from the study procedures that are not known at this time.

The most common risks and discomforts expected in this study are:

- There is a risk of falls during the walking testing or training. To avoid falls, a physical therapist will remain near you while you walk. You will wear a harness and be able to hold a handrail when you walk on the treadmill.
- You may experience fatigue and/or muscle soreness similar to the soreness that you might feel after you lift weights or exercise vigorously after a long break.
- Injuries such as muscle strains are possible.
- When you wear the headset, goggles, or watch the projector display, there is a chance that you feel dizzy, nauseous, faint, or disoriented. To minimize this risk, we will give you time to get familiar with the visual interfaces in a comfortable seated or standing position before walking.

The less common risks and discomforts expected in this study are:

- Minor skin irritation may occur from the adhesive tape.

If you are a woman: to protect against possible side effects of the study procedures (fast treadmill walking, etc.), women who are pregnant may not take part in this study. These risks are not yet known. If you are or plan to get pregnant, you should not be in the study.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?

This study is not designed to benefit you directly. This study is designed to learn more about how game-based interfaces can be used during walking training, and the study results may be used to help others in the future.

Will I be compensated for my time and effort?

You will be compensated for being in this study. You will get $30 for each completed study visit, to compensate you for your time and effort. If you do not finish the study, we will compensate you for the visits you have completed.

What are my other options?

If you decide not to enter this study, there is care available to you outside of this research study. For example, you may be able to enroll in walking rehabilitation or physical therapy at a clinic. The study doctor will discuss these with you. You do not have to be in this study to be treated for rehabilitation of walking after stroke.

Taking part in this study, however, may make you unable to participate in some other research studies, if they exclude people who have ongoing participation in other experimental studies. You should discuss this with the researchers if you have concerns. You may wish to research other study options at websites like clinicaltrials.gov and ResearchMatch.org.

How will you protect my private information that you collect in this study?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

De-identified data from this study (data that has been stripped of all information that can identify you) may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Your data from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your deidentified data and/or specimens to other researchers. If we do, we will not include any information that could identify you. If your data or specimens are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

We will use your data only for research. We will not sell them. However, the results of this research might someday lead to the development of products (such as a commercial product or rehabilitation device) that could be sold by a company. You will not receive money from the sale of any such product.

As they become available, do you want us to contact you and ask whether you want to receive your results? If so, let the study team know, and they will contact you as the results become available.

Medical Record

If you have been an Emory Healthcare patient before, then you already have an Emory Healthcare medical record. If you have never been an Emory Healthcare patient, you do not have one. An Emory Healthcare medical record will be made for you if an Emory provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory Healthcare medical record you have now or any time during the study.

Costs

There are no costs, research or standard of care related, associated with the study.

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities. If the study procedures result in any medical complications that would not fall under “injury”, the cost of treatment for those complications may be charged to you or your insurance.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

These are the expected reasons why the researchers may stop your participation:

- Lower limb injury or pain that interferes with your walking
- Change in your medications that influence your walking or tone
- Unanticipated events that affect your walking
- Unexpected responses such as dizziness that increase your risk of falls during walking

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the study.

PHI that Will be Used/Disclosed:
The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.
- Data collected during evaluation procedures, tests, and gait sessions before and during the study.
- Laboratory test results

Purposes for Which Your PHI Will be Used/Disclosed:
We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information.

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study.

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- Emory may use and disclose your PHI run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- National institutes of health (NIH) is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including: Office for Human Research Protections.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely

and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at: Trisha Kesar, [redacted].

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information
Contact Trisha Kesar at [redacted]:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

Name of Subject

Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

Name of Person Conducting Informed Consent Discussion

Signature of Person Conducting Informed Consent Discussion **Date** **Time**