Title: Proactive and reactive perturbation training to reduce falls and improve gait stability in people with chronic stroke

NCT number: NCT04855032

Approval date of document: 10/29/24

Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Proactive and reactive perturbation training to reduce falls and improve gait stability in people with chronic stroke

SUMMARY

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. The purpose of this research study is to test a new method of improving walking balance in individuals who have experienced a stroke. You are being asked to participate in this study because you have experienced a stroke.

If you agree to participate, you will be enrolled in the study for a period of up to a year. We will ask you to walk across the floor, walk on a treadmill, and perform clinical tests of how you move and balance. In these clinical tests, you will be asked to move your legs in different ways, asked questions about your feeling in your legs, asked about your confidence in your balance, and asked to walk in several ways. While you walk on a treadmill, we will sometimes use machines to push your leg or trunk sideways, so you will need to respond in order to keep your balance. These machines involve cords that will be attached to straps around your legs and trunk. Sometimes the cords will pull to the left or to the right as you walk, in order to test how you keep your balance. These machines are investigational, which means that they have not been tested by the Food and Drug Administration (FDA), like a drug or a device like a pacemaker would be. Each experimental session will last about 2 hours.

You may experience some muscle soreness if the walking activities are harder than your usual level of activity. You may feel like you are going to lose your balance while walking. A loss of balance could result in a fall, although for this study you will wear a harness attached to an overhead support for all trials to prevent you from falling to the ground. We will place small lights on your legs and trunk to measure where your body is in space, and sensors on your legs to measure when your muscles turn on as you walk. There is a risk of minor skin irritation due to the use of adhesive tape to secure these markers and sensors. There is a risk of loss of confidentiality as a result of your participation in this study. It is possible that participation in this study could improve your balance, although this cannot be guaranteed. If you choose not to participate in this study, an alternative treatment for balance problems after a stroke is physical therapy, involving methods such as practicing standing or walking under different conditions, or improving your strength or sensation in your legs. You do not have to participate in this study to have your condition treated.

If you are interested in learning more about this study, please continue reading below.

A. PURPOSE OF THE RESEARCH

Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. You are being asked to participate in this study because you have experienced a stroke. The study is sponsored by the National Institutes of Health. The investigator in charge of this study at MUSC is Jesse Dean, PhD. Portions of Dr. Dean's and his research team's salaries will be paid by this grant. The study is being done at MUSC (the Medical University of South Carolina). Approximately 110 people will take part in this study.

This study involves an experimental device that has been developed by the research team. This device will occasionally push your trunk or legs sideways (to the left or right) as you walk. By doing this, the device will challenge your balance, so we can measure how you respond. The device allows you to practice responding to pushes in a safe environment, as you will wear a safety harness that will prevent you from falling to the ground if you lose your balance.

The device consists of cords that will attach to straps around your trunk and legs. These cords are attached to computer-controlled motors that will produce forces on the cords as you walk. The largest force that will be produced by the motors will be 15% of your body weight, for example 30 pounds if you weigh 200 pounds. These forces are much smaller than those your legs and trunk experience during regular walking.

B. PROCEDURES

If you agree to be in this study, the following will happen:

1. You will complete an Enrollment session in which clinical tests will be performed. In these clinical tests, you will be asked to move your legs around in several ways (bending and straightening your hip, knee, and ankle while standing, sitting, and lying down). You will also be asked questions about your feeling in your legs (whether you can feel touch or movement).
2. You will complete a 12-week period in which you will report any falls that you experience in daily life activities. You will be asked to return stamped, addressed postcards to the research team every 2-weeks. On these postcards, you will indicate whether you experienced a fall on each day during that 2-week period. If you reported experiencing a fall, a researcher will contact you to ask you about the circumstances of the fall.
3. You will complete a Pre-Intervention Assessment session in which clinical tests will be performed. In these clinical tests, you will be asked about your confidence in keeping your balance during several activities. You will also be asked to walk in several ways (fast, slow, while turning your head, etc.). You will also walk on a treadmill and across the floor. In some treadmill trials, you will experience sideways pushes to your leg and trunk as you walk. Before performing these walking trials, small lights will be placed on your legs and trunk, which will allow us to measure how your body moves as you walk. Also, sensors that measure your muscle activity will be placed over muscles of your legs, allowing us to measure when your muscles turn on and off.

4. After this 12-week period, you will be randomly assigned to one of two groups. This means that you have a 50/50 chance (like flipping a coin) of being in either group. Neither the researchers nor you will make the choice to which group you are assigned. The two groups are Group A and Group B. If you are assigned to Group A, the study device will apply sideways pushes to your legs while you walk. These pushes will require you to control the movement of your legs as you take a step, and are designed to train you to put your foot in a stable location when walking. If you are assigned to Group B, the study device will apply sideways pushes to your trunk while you walk. These pushes will give you practice with the type of pushes you may experience when walking in the community, such as if someone bumps into you.
5. You will complete 16 training sessions in which you walk on a treadmill at a speed that feels safe to you and experience sideways pushes, as described for Group A and Group B. These sessions will occur twice a week for 8 weeks. Before performing these walking trials, small lights will be placed on your legs and trunk, which will allow us to measure how your body moves as you walk. Each training session will last about 2 hours.
6. You will complete a Post-Intervention Assessment session in which clinical tests will be performed, as in the Pre-Intervention Assessment. You will also walk on a treadmill and across the floor. In some treadmill trials, you will experience sideways pushes to your leg and trunk as you walk. Before performing these walking trials, small lights will be placed on your legs and trunk, which will allow us to measure how your body moves as you walk. Also, sensors that measure your muscle activity will be placed over muscles of your legs, allowing us to measure when your muscles turn on and off.
7. You will complete another 12-week period in which you will report any falls that you experience in daily life activities. You will be asked to return stamped, addressed postcards to the research team every 2-weeks. On these postcards, you will indicate whether you experienced a fall on each day during that 2-week period. If you reported experiencing a fall, a researcher will contact you to ask you about the circumstances of the fall.

While participating in this research study, do not take part in any other research project without approval from the investigators. This is to protect you from possible injury from things such as extra blood drawing, extra X-rays, or potential drug interactions. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

C. DURATION

Participation in the study will take about 19 visits over a period of 8 months.

D. MEDICAL RECORDS AND/OR CERTIFICATE OF CONFIDENTIALITY

Information about your study participation will not be in your medical record. This means that neither your research participation nor any of your research results will be included in any MUSC medical record.

This research is covered by a Certificate of Confidentiality from the Federal government. This means that the researchers may not disclose information or biospecimens that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, nor can the information or biospecimens be used as evidence, unless you have consented to this disclosure. Information or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless you have consented to the disclosure. More specifically, identifiable information or biospecimens will not be shared with your medical providers who are not involved in this research unless you authorize the study to disclose information to them, or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

Information about your study participation will not be in your MUSC medical record. This means that neither your research participation nor any of your research results will be included in any MUSC medical record. A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must authorize the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law. Examples of required disclosure include: child abuse and neglect, or harm to self and others, but there could be others.

Finally, a Certificate may not be used to withhold information from the Federal government needed for auditing or evaluating Federally funded projects or information needed by the FDA.

E. BENEFITS

The potential benefit to you is that the treatment you receive may prove to be more effective than the other study treatment or than other available treatments, although this cannot be guaranteed.

Either Group A or Group B may be a more effective treatment at improving walking balance and reducing the risk of falls than current physical therapy treatments. In this case, you may benefit from participating in the study; however, this cannot be guaranteed.

F. COSTS

There will be no cost to you as a result of participation in this study. You have the option of receiving appointment reminders through text messages. Should you elect to receive text messages, normal cellular data usage and rates will apply.

____ Yes, I agree to be contacted via text message for appointment reminders.

____ No, I do not agree to be contacted via text message for appointment reminders.

G. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will be paid $950 for participation in this study. If you do not complete the study, you will receive $50 for each completed visit. Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

H. ALTERNATIVES

If you choose not to participate in this study, you could receive other treatments for your condition. The standard therapy for balance problems after a stroke is physical therapy, involving methods such as practice standing on foam or with your eyes closed, strengthening your leg muscles, practicing walking on a treadmill, and practicing feeling where your legs are in space. However, no physical therapy treatments have been shown to reduce fall risk after a stroke.

I. DATA SHARING

Information about you (including your identifiable private information and/or any identifiable biospecimens) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative.

We would like to include data collected in this study and from other stroke related studies you may participate in with the Registry for Stroke Recovery (RESTORE). RESTORE provides MUSC's stroke recovery research community with a database containing information on research participants including stroke type, disability status, and demographics to assist in recruitment. By including data from this study in RESTORE, MUSC researchers will have access to a more complete database with key elements of physical function characteristics for more targeted recruitment efforts in the future. Additionally, this could reduce the burden placed on subjects by reducing the duplicative efforts of collecting common data and assessments requested by multiple studies and storing them in one centralized and secure location.

Your data from this study, including your personal health information, will be included in the RESTORE registry.

J. DISCLOSURE OF RESULTS

This study will not produce clinically-relevant research results. Research results will not be disclosed to participants.

K. AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, your study doctor and his/her research team will keep records of your participation in this study.

The health information MUSC may use or disclose (release) for this research study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.

Your study doctor and his/her research team will use and disclose (release) your health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
- Health insurer or payer in order to secure payment for covered treatment;
- Federal and state agencies and MUSC committees having authority over the study such as:

    - The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.

Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You do not have to sign this consent form. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study or, if you are participating in a study designed for the development of a drug or device, your authorization will remain in effect until the drug or device is approved by the FDA or until the company's application to study the drug/device is withdrawn. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.

L. STUDENT PARTICIPATION

Your participation or discontinuance will not constitute an element of your academic performance, nor will it be a part of your academic record at this Institution.

M. EMPLOYEE PARTICIPATION

Your participation or discontinuance will not constitute an element of your job performance or evaluation, nor will it be a part of your personnel record at this Institution.

N. CLINICAL TRIALS.GOV

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.

MUSC STANDARD PARAGRAPHS:

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event that you are injured as a result of participation in this study, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact ***Jesse Dean at (843) 792-9566***. I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.

_____ _____

Signature of Person Obtaining Consent Date *Name of Participant

_____

Signature of Participant Date