CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title of Study: Fall-recovery training for those with chronic stroke and low falls self-efficacy

Principal Investigator(s): Jeremy R. Crenshaw, PhD

KEY INFORMATION

Important aspects of the study you should know about first:

- **Purpose:** The purpose of the study is to understand the benefits of an exercise program focused on balance. We are interested in how this program may change your balance, your balance confidence, and your physical activity.
- **Procedures**: If you choose to participate, you will be asked to complete three assessment visits and six training visits. On assessment visits, you will complete questionnaires about your balance, physical function, activity, exercise, and depression. You will complete several tests of your balance and walking ability, including tests of how you react to a balance perturbation. If you are 50 years of age or older, we will scan your bones to evaluate their density and your safety in participating in this study. You will also wear an activity monitor for three separate one-week periods. In the training sessions, you will stand or walk on a treadmill, and that treadmill will accelerate rapidly. You will have to regain your balance to prevent falling into a safety harness.
- **Duration:** This study will involve nine visits. The 3 assessment visits will last 2-3 hours. The 6 training visits will last 1 hour and 30 minutes. If you have a bone scan, that will take approximately 30 minutes. These visits will occur over approximately two months. In addition, you will wear an activity monitor on your ankle for three one-week periods.
- **Risks**: The main risk or discomfort from this research is the risk of falling into a safety harness. You may also have muscle soreness, and you may experience heightened levels of excitement or nervousness during assessments or training.
- **Benefits:** The main benefit to you from this research is the possibility that you may learn about your balance and mobility.
- **Alternatives:** There are no known alternatives available to you other than not taking part in this study.
- **Costs and Compensation:** If you decide to participate there will be no additional cost to you and you could be compensated up to $180 ($20 per visit).
- **Participation:** Taking part or not in this research study is your decision. You can decide to participate and then change your mind at any point.

Please carefully read the entire document. You can ask any questions you may have before deciding If you want to participate.

You are being invited to participate in a research study. This consent form tells you about the study including its purpose, what you will be asked to do if you decide to take part, and the risks and benefits of being in the study. Please read the information below and ask us any questions you may have before you decide whether or not you want to participate.

PURPOSE OF THE STUDY

The purpose of the study is to understand the benefits of an exercise program focused on balance. We are interested in how this program may change your balance, your balance confidence, and your physical activity.

WHO IS BEING ASKED TO PARTICIPATE?

You will be one of approximately 15 participants in this study.

You are being asked to participate because you are 18 years of age or older, you have had a single stroke, and you have reported that you have low balance confidence. You will not qualify for this study if any of the following exclusion criteria pertain to you:

- You have had more than one stroke.
- You are unable to walk one block without stopping or assistance from a walker or another person. You may use a cane, if needed.
- You are feeling ill or sick.
- You weigh more than 300 lbs.
- You have had a shoulder, hip, or knee replaced in the last year.
- You have had both your left and right hip replaced.
- You have had surgery to your spine in the last year.
- You have dementia.
- You have Parkinson's disease.
- You have had more than one occurrence of back or neck pain that limited activity in the month prior to participation.
- You have bulging vertebral discs.
- You have fractured your spine, hip, or any lower-extremity bone (including foot bones) in the last year.
- You have any open lesions on the lower extremity.
- You have insulin-dependent diabetes.
- You use a pacemaker.
- You use an ostomy pouch.
- You are pregnant.
- You have osteoporosis.
- You do not have low balance confidence, as determined by a questionnaire.
- A doctor has recommended that you avoid moderate physical activity or exercise.
- You have any neural, muscular, or skeletal condition or injury that makes it unsafe for you to participate in the study or makes it difficult to interpret the results of the study. This will be determined by study staff.

PROCEDURES: WHAT WILL YOU BE ASKED TO DO?

As part of this study you will be asked to…….

- Visit the UD STAR Campus up to nine times over the course of about two months. Your participation in this study requires three evaluation sessions that are 2-3 hours each, six training sessions that are 1.5 hours each, and three weeklong periods in which you wear an activity monitor on your ankle.
- The first visit involves a thorough explanation of the study and questions to make sure you qualify for it. If you are 50 years of age or older, we will measure your bone density using a DXA scan, which involves a small dose of radiation. This scan is to measure your bone mineral density. In order to limit the risk of fracture during our study, we will not permit you to continue in the study if your bone density is at levels associated with osteoporosis. At this initial visit, you will also complete questionnaires about how your body functions, your physical activity, your balance confidence, the support you have for exercising, and depression. We will also collect your heart rate and blood pressure and ask you questions about recent falls. We will record the date and affected brain regions of your stroke. We will also test your balance and ability to walk with different clinical tests. For one test, you will stand on our unique treadmill, and you will try to react to rapid treadmill movements that may cause you to lose balance (See Figure). You will wear a safety harness during this test. Please note that you will not receive a copy of test results unless they show any values that we think you should discuss with your doctor.

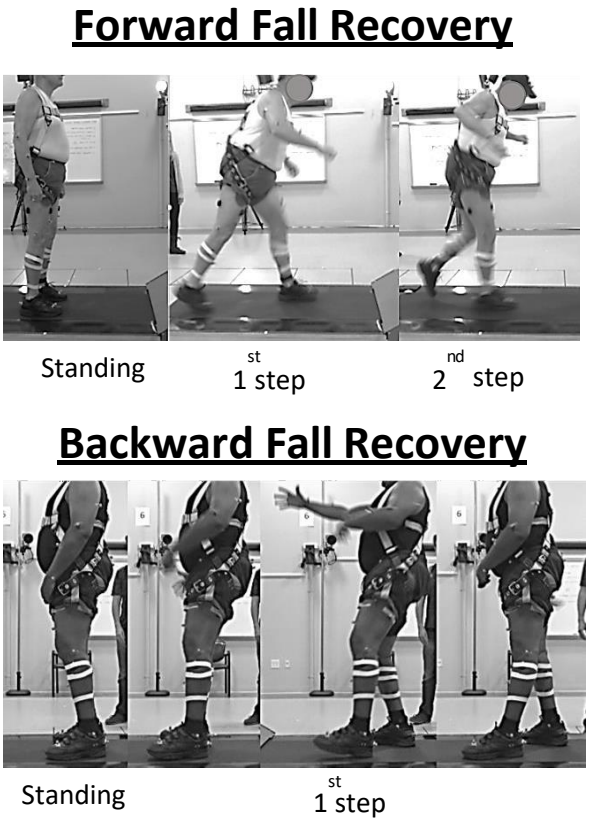

Figure 1. Top: A study participant recovers balance after the treadmill induces a forward fall. **Bottom:** A study participant recovers balance after the treadmill induces a backwards fall.

- After this visit, you would wear an activity monitor on your ankle for one week.
- The second visit will take place three weeks after your first visit. On the second visit, you will repeat all the questionnaires and tests related to balance, walking, and physical activity. Again, you will wear an activity monitor for one week after the visit.
- Then, on the third through eighth visits, you will do our balance exercise program. This program involves standing or walking on our treadmill and responding to rapid treadmill belt movements that may cause you to lose balance (See Figure). Again, you will wear a

safety harness, and the size of the perturbations is dependent upon your ability and willingness to increase the perturbation size. If you use a cane, you will only receive perturbations while standing. This exercise program has not been tested before and it is considered experimental.

- On the last visit, you will repeat all the questionnaires and tests related to balance, walking, and physical activity. We will also interview you about your perceptions of the exercise program. Again, you will wear an activity monitor for one week after this visit.
- You will be video recorded during assessments, exercises, and interviews. You may choose to give or not give us permission to use images and videos in publications or presentations.

WHAT ARE POSSIBLE RISKS AND DISCOMFORTS?

Possible risks of participating in this research study include ……

- It is possible that you could fall during assessments of your mobility and balance. To minimize this risk, you will be appropriately guarded by study staff, you will wear a gait belt, and/or you will be attached to a harness system.
- Soreness may occur during or after assessments and training. However, if you experience soreness, we anticipate that is should get better within a week or two of participation. It is possible that a muscle injury, such as a muscle strain, may occur as a result of assessments or training. Recovery from a muscle strain may take longer than two weeks. In the case of such injury, we will not have you continue with the study.
- During assessments or training, you may feel a heightened level of excitement or nervousness. Should you report these feelings, you will be given the option to rest or end your participation in the session or study. If a study team member determines that such feelings are unreasonably high, to the point where it affects your safe participation in the study, they will end your participation in that part of the study.
- You may receive a hip DXA scan. You will be exposed to radiation from this scan. The amount of radiation has a negligible risk of harmful effects. This effective dose is less than 0.1% of the dose received from a spine X-ray, and it is comparable to the amount of radiation exposure from three hours in natural surroundings.

WHAT ARE POTENTIAL BENEFITS FROM THE STUDY?

- Potential benefits to you the participant
  - There is a possibility that you may learn more about your balance and mobility through participation in the assessments.
  - There is a possibility that, if you receive a DXA scan, you may learn more about your bone density.
- Potential future benefits to others or to society
  - There is a possibility that this exercise training may improve balance confidence and physical activity for individuals with chronic stroke.

NEW FINDINGS THAT COULD AFFECT YOUR PARTICIPATION

During the course of this study, we may learn new important information. This may include information that could cause you to change your mind about participating in the study. If any new important information becomes available while you are a participant we will let you know.

CONFIDENTIALITY: WHO MAY KNOW THAT YOU PARTICIPATED IN THIS RESEARCH?

Your study data will be handled as confidentially as possible. If results of this study are published or presented, individual names and other personally identifiable information will not be used.
Your participation in this study requires us to collect some personal information from you. Any information you provide that could identify who you are (e.g., your name, your date of birth, etc.) will be stored in paper format in a locked file cabinet or electronically on encrypted and password-protected computer files.

You will be videotaped or photographed during this research. With your consent, the videotape or photograph will be used for educational or research purposes only.

All data and other information we collect will be de-identified to the extent possible, meaning that we will replace your personal information with a code. The key linking subject codes with individual names will be maintained on an encrypted and password-protected computer.

No identifying information will be used in any presentations or publications that result from this study. De-identified data may be presented in abstract, poster, presentation, or published manuscript format. All data will be stored indefinitely and may be used in future related studies by members of the research team.

The research team will make every effort to keep all research records that identify you confidential. The findings of this research may be presented or published. If this happens, no information that gives your name or other details will be shared.

The confidentiality of your records will be protected to the extent permitted by law. Your research records may be viewed by the University of Delaware Institutional Review Board, which is a committee formally designated to approve, monitor, and review biomedical and behavioral research involving humans. Records relating to this research will be kept for at least three years after the research study has been completed

We will keep your study data as confidential as possible, with the exception of certain information that we must report for legal or ethical reasons, such as child abuse, or intent to hurt yourself or others.

If required, your records may be inspected by authorized personnel in the following groups and agencies: the University of Delaware Institutional Review Board, and the National Institutes of Health (NIH).

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.

USE OF DATA COLLECTED FROM YOU IN FUTURE RESEARCH:

Identifiers about you might be removed from the identifiable private and after such removal, the information 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

COSTS AND COMPENSATION

- There are no costs associated with participating in the study.
- You will be compensated $20 for each assessment and training session at the UD STAR Campus. If you complete all 9 sessions, you will be compensated $180 dollars. One or two extra visits may be required to enroll you in the study, set up your activity monitor, and perform a DXA scan. These additional visits will not be compensated.
- You will be paid at the completion of the study or the end of your participation. You will be paid by check or direct deposit. The latter option is available to those who have already set up direct deposit with the university (e.g. employees).
- Should you withdraw from the study, or should your participation end for any other reason, you will be compensated the full $20 for that session, as well as $20 for any sessions completed prior to the end of participation.

WHAT IF YOU ARE INJURED DURING PARTICIPATION IN THE STUDY?

If you are injured during your participation in the study, you will be offered first aid at no cost to you. If you need additional medical treatment, the cost of this treatment will be your responsibility or that of a third-party payer (for example, your health insurance). By signing this document, you are not waiving any rights that you may have if injury was the result of negligence of the university or its investigators.

DO YOU HAVE TO TAKE PART IN THIS STUDY?

Taking part in this research study is your decision. You do not have to participate in this research. If you choose to take part, you have the right to stop at any time. If you decide later not to participate, or if you decide to stop taking part in the research, there will be no penalty or loss of benefits to which you are otherwise entitled.

Your decision to stop participation, or not to participate, will not influence current or future relationships with the University of Delaware.

The investigators reserve the right to remove you from the study without your consent at such time that he/she feels it is in the best interest. If, at any time, you decide to end your participation in this research study please inform our research team by telling the investigators. If you, or the investigators, stop your participation in the study we will keep any data collected of you until that point. If you do not complete all procedures listed in this form you will only receive compensation for the tasks you finished.

INSTITUTIONAL REVIEW BOARD

This research study has been reviewed and approved by the University of Delaware Institutional Review Board (UD IRB), which is a committee formally designated to approve, monitor, and review biomedical and behavioral research involving humans. If you have any questions or concerns about your rights as a research participant, you may contact the UD IRB at hsrb-research@udel.edu or (302) 831-2137.

CONTACT INFORMATION

If you have any questions about the purpose, procedures, or any other issues related to this research study you may contact the Principal Investigator, Jeremy Crenshaw, at (302) 831-4795 or crenshaw@udel.edu.

CONSENT TO PARTICIPATE IN THE RESEARCH STUDY:

I have read and understood the information in this form and I agree to participate in the study. I am 18 years of age or older. I have been given the opportunity to ask any questions I had and those questions have been answered to my satisfaction. I understand that I will be given a copy of this form for my records.

Printed Name of Participant (PRINTED NAME)	Signature of Participant (SIGNATURE)	Date
Person Obtaining Consent (PRINTED NAME)	Person Obtaining Consent (SIGNATURE)	Date

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OPTIONAL CONSENT TO BE CONTACTED FOR FUTURE STUDIES:

Do we have your permission to contact you regarding participation in future studies? If you agree to being contacted in the future, we will keep your contact information. Please write your initials next to your preferred choice.

_____YES _____NO

OPTIONAL CONSENT FOR ADDITIONAL USES OF IDENTIFIABLE VIDEO RECORDINGS/PHOTOGRAPHS

I voluntarily give my permission to the researchers in this study to use videos and photographs of me collected as part of this research study for publications, presentations, and/or educational purposes. I understand that no identifying information beyond that contained in the video recording will be provided to educational/scientific audiences; however my facial features may be seen.

(Printed Name of Participant)	(Signature)	(Date)
