CONSENT DOCUMENT FOR PARTICIPANTS IN RESEARCH PROECTS INVOLVING HUMAN SUBECTS

Locomotion Research Laboratory
Virginia Polytechnic Institute and State University

TITLE OF PROECT: Effects of perturbation training methods on reducing slip-induced falls in older adults

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I. Purpose of this Research Project

Older adults are at a higher risk of falls due to the way they walk and problems with their posture. They face a greater risk when walking on slippery surfaces. More than 25% of older adults fall every year, with emergency departments treating more than 1.6 million seniors due to fall-related injuries annually, resulting in the hospitalization of 373,000. Due to increases in life expectancy in the past century, the size of older population (above 65 years) is growing and is expected to reach 54.6 million by 2020 (U.S. Census Bureau, 2006). Because the prevalence of fall injuries is high among older adults, there is a need for prevention strategies that may help reduce the risks associated with falls. Several exercise programs have been suggested to improve balance in the elderly, but their success in preventing falls post training is not well documented. A training intervention may be effective in reducing falls, if it can help older adults to practice movements related to recovering from a fall.

The aim of the current study is to develop training methods to reduce fall incidence in older adults. The training will be designed to help participants practice movements related to recovering from a fall. The idea here is to induce a balance loss similar to that of slipping. By providing a repetitive exposure to such a balance loss in a controlled manner, participants may learn movements necessary to prevent a fall. The study will evaluate the effectiveness of two different training methods- one using a moveable platform, and the other using a treadmill along with a visual display. The moveable platform training will utilize a motorized plate which will move as participants step on it, inducing a balance loss similar to slip. By repetitive practice on such a platform, participants may learn movements required to prevent a fall. The treadmill and the visual display training will utilize a virtual display of a regular street. Here, participants will walk on the treadmill wearing a visual display. The visual display will move in the same speed as that of the treadmill. At random instants, there will be a sudden movement of the display, which may induce a balance loss similar to slip. By repetitive practice of walking on the treadmill after the balance loss, older adults may learn movements required to prevent a fall.

The effectiveness of these training programs will be tested by recording motion data (using reflective markers) and muscle activity (using electrodes) before, during, and after the training intervention. The new training programs are expected to improve balance reactions specific to slip-induced falls in older adults. If the training program is effective, it may be easily

incorporated in the nursing home facility, or hospitals to improve balance in fall-prone elderly.

II. Procedures and Project Information

A. Participant Selection

Solicitation and Selection of Study Participants - A total of seventy two (72) young adult (18-30 yrs) and elderly individuals (65-85yrs) will be enrolled and participate in this study.

Inclusion Criteria – To be considered for this study, you must be an adult, in the 18-35 or 65-85 year age groups, with none of the exclusionary criteria listed below.

'Exclusion Criteria', 'or any other diseases or medical conditions that would make participation unsafe' – Individuals with a history of, or signs and symptoms of cardiovascular, neurological, or bone and joint problems should not participate in this study. The study physician must approve subjects' participation.

- ***Cardiovascular problems:*** e.g. chronic heart failure; enlarged heart (cardiomyopathy), bulging of the aorta, weakened heart; pain in the feet due to chronic diabetes; disorder of blood clotting system (hemophilia).
- ***Respiratory problems***: e.g. getting tired easily or difficulty in breathing upon normal walking.
- ***Neurological problems***: e.g. stroke resulting in weakness of one or both legs; Parkinson's disease; pinched spinal nerves causing pain or affecting walking.
- ***Musculoskeletal problems***: e.g. persistent muscle weakness; muscle wasting conditions; unrepaired hernia; thinning of bone (osteoporosis); previous knee or hip replacement; previous ankle or shoulder surgery; moderate to severe arthritis; routine back or neck pain; previous surgery on the spine; previous knee surgery; knee ligament problems that have not been surgically repaired; fallen arch(es) - flat feet.
- ***Allergy or sensitivity to the adhesive tape used to affix electrodes***

B. Time Requirements

You will be asked to come the lab for two separate sessions, each session lasting upto two hours, for a total of four hours to complete the study.

C. Study Procedures

First Session

On the first day, during the consent process, we will describe what you will be doing in the experiment, show you the equipment you will be wearing, and let you walk on the experimental track. You will undergo a general physical examination by the study physician, to review your health history form, and to assess the flexibility of your joints and range of motion of your limbs. If it is determined that you have any of the exclusionary criteria, or that you have some other pre-existing condition of concern to the physician which would adversely affect the experimental data collection, you will be thanked and excused from the study, and will be provided with $10 compensation for your participation to that point.

If you are accepted into the study and sign the consent form, you will then be given an opportunity to walk around the laboratory wearing the safety harness, to allow familiarization with the equipment (e.g., the harness and fall-arresting rig) and the normal floor surface on the

"track". The harness system is designed to protect you during the slip and fall experiments. The fall arresting rig will only allow you to fall 20 cm or less, preventing you from falling to the floor. You may feel a small jerk in your torso as the harness stops your fall. During the first session, you will be assigned to Group A, Group B or Group C.

Second Session

During the second session, you will be asked to change your clothes in a private change room, where you will put on clothes supplied by the lab (e.g., black tank top and shorts). During this session, we will have you wear normal lab supplied shoes (sneakers).

At this time, retro-reflectors (white styrofoam balls similar to ping-pong balls) will be attached, to the laboratory-supplied clothing that you are wearing, over anatomically significant locations on your body, such as your joints. Retro-reflectors will be placed over the joints of the ankle, knee, hip, shoulder, elbow and wrist, as well as on the toes of each foot, calf and thigh of the legs, pelvis, trunk, and head. This will allow us to create computerized stick figure models of your movements during the experiment. To address modesty or cultural concerns, you will be given the choice of having someone of the same gender to affix the retro-reflectors to your garments/body.

We will also attach some electrodes in the calf and thigh muscles of both your legs to record muscle activity. The electrodes are in form of adhesive tape, which can be easily removed. To address modesty or cultural concerns, you will be given the choice of having someone of the same gender to affix the electrodes. We will ask you which of your feet is your dominant ("kicking") foot.

1. First Experimental Component - Baseline

Wearing the normal lab shoes, you will be asked to walk back and forth along the test "track" for 10 minutes. At both ends of the track, there will be a station where you will receive written instructions directing you to perform specified filing tasks, e.g., separate 4 blue pieces of paper and file them. You will also receive written instructions to look at the TV screen at the opposite end of the track, as you are walking to that end, to count the number of dots on the screen of a certain color. When you reach that end of the track, you will be asked to tell how many you observed. You may be supplied with a Walkman audio player during the walking experiment, playing old comedy routines, to conceal any noises associated with laboratory activities. If you become tired during walking, please let the lab staff know that you would like to stop and rest. If you wish to withdraw from the study, you may request to do so.

2. Second Experimental Component – Training

Based on your Group assignment you will either perform A, B, or C in the next session. Please read A, B or C based on your group assignment.

A. **Group A**: During the next 30 minutes, you will keep walking on the track and at random intervals, the researchers may or may not induce simulated slips on the track (by a moveable platform). You may or may not slip but the harness will protect you in case you do. You will be asked to maintain balance and continue walking even after you experience a slip. You will go through 10-15 trials of the simulated slips. Please let the lab staff know if you would like to stop

and rest at any point or if you wish to withdraw from the study, you may request to do so.

If you choose not to continue on to the next session on this day, you will, at the conclusion of the test, change back into your personal clothes, and will be paid for your participation in this session. If you decide, and are permitted to continue on to the next session on the same day, you will remain in the lab supplied garments with the retro-reflectors and electrodes attached.

B. **Group B**: During the next 30 minutes, you will be asked to walk on a treadmill in a comfortable speed. You will be provided with a harness even when you are walking on the treadmill. After walking for 5 minutes and getting used to the treadmill, you will be asked to wear a visual display. This display will consist of a virtual scene of a regular street. As you walk on the treadmill, you will have a sense of walking in the virtual environment. After walking for 5-10 minutes, you will be exposed to a visual tilt that may or may not induce some balance loss. If you slip, the harness will protect you from falling. You will be asked to try to keep your balance while walking on the treadmill. If the visual scene is making you dizzy, please let the lab staffs know that you would like to stop. You will go through 10-15 trials of visual tilts. Please let the lab staff know if you would like to stop at any point and rest or if you wish to withdraw from the study, you may request to do so.

If you choose not to continue on to the next session on this day, you will, at the conclusion of the test, change back into your personal clothes, and will be paid for your participation in this session. If you decide, and are permitted to continue on to the next session on the same day, you will remain in the lab supplied garments with the retro-reflectors and electrodes attached.

C. **Group C:** During the next 30 minutes, you will be first asked to walk on the track at a comfortable speed. After walking on the track for 10 minutes, you will be asked to walk on the treadmill at a speed of 2.0mph for 10 minutes. After completing the treadmill walking, you will be brought back to the track and would be asked to walk at your comfortable speed for another 5 minutes. Please let the lab staff know if you would like to stop at any point and rest or if you wish to withdraw from the study, you may request to do so.

If you choose not to continue on to the next session on this day, you will, at the conclusion of the test, change back into your personal clothes, and will be paid for your participation in this session. If you decide, and are permitted to continue on to the next session on the same day, you will remain in the lab supplied garments with the retro-reflectors and EMG electrodes attached.

3. Third Experimental Component – Slippery Conditions

All of the groups (A, B and C) will perform this section. During the next 15 minute session, you will conduct similar filing tasks as described above. At one random time point, the researchers will, without your knowledge, create a slippery condition on the track. You will slip, but as mentioned previously, the harness will prevent you from falling on the floor. You may experience a jerk in the shoulders and neck as the harness prevents your fall. If you become tired during

walking, please let the lab staffs know that you would like to stop and rest. If you wish to withdraw from the study, you may request to do so.

At the conclusion of this session, you will change back into your personal clothes, and will be paid for your participation in this session.

At least two graduate research assistants will be present during all testing periods. Staff members running the tests will strongly emphasize, in both spoken and written instructions, that you are free to discontinue participation at any time. All lab-supplied garments that you will wear will be laundered after each use, with all subjects provided with clean, laundered garments.

III. Risks Involved in Participation

While this study involves the use of safety equipment to prevent contact with the floor during an experimentally induced slip or fall, it does involve more than minimal risk for individuals with bone, joint, or muscle problems. For that reason, individuals with any of the exclusionary criteria have been excluded from the study.

You might encounter the following risks during your participation:

Emotional – You may feel disappointment or self-doubt in not being as agile as when you were at a younger age. You may feel embarrassed at what you perceive as a "poor performance".

Physical – You could experience minor muscle sprain (similar to those encountered in regular daily activities), joint pain (shoulder, knee, ankle), or neck sprain. To minimize injuries, you will be wearing a fall arresting rig and harness system to protect you from any harm caused by slips and falls. Prior to your participation, the harness system will be adjusted to your individual height, ensuring that falls are limited to 20 cm or less limiting the downward and forward progression of your body to reduce physical risks noted above. The experiment will be terminated if one of the following conditions occurs: if you decide to discontinue participation; or, you experience any pain in the back, knees or ankles following walking or slipping. Potential participants will be excluded if bone or joint problems are present that would make participation unsafe or which would compromise the integrity of the research results.

Over 120 human subjects have been tested using the walking surfaces and safety harness, and to date, no injuries have occurred. However, in the event that you are injured while participating in the study, you will be responsible for any expense associated with emergency medical treatment, as neither the researchers nor the University have money set aside for medical treatment expenses.

IV. Benefits from Participation

You are not promised any specific/direct benefits for your participation in this study. The results of this study may yield benefits to adults and seniors through development of training paradigms for fall prevention.

V. Extent of Anonymity and Confidentiality

You will be assigned a unique individual code number. The code number will be used on all of your study documents and data files. The Principal Investigator (PI), Dr. Lockhart, will maintain a code key list to link your personal information to the code number used on your data.

The code key list will be kept locked in a filing cabinet in the PI's office, and will not be accessible to anyone who is not a project staff member. Coded data will be stored on a computer with password-protected access, and hard copies of data will be kept in a locked filing cabinet in the lab or in the PI's office. At the conclusion of the study, the data will be analyzed, and will be published in scientific journals. You will not be identified in the publications, and your anonymity and confidentiality will be maintained. As required by federal law and Virginia Tech IRB Policy, study records will be maintained for 3 years after the conclusion of the study, after which time they will be destroyed.

Your movements will be monitored/recorded by an infrared camera used to detect movements of the retro-reflectors, so that we can create computerized stick figure models of your movements during the experiment. The camera will not yield images from which your likeness would be identified, only the highlighted white retro-reflectors.

VI. Compensation

Participants enrolled in the study will receive $20 per session in the lab. You will spend two sessions (2 hours each) in the lab, for a total compensation of $40. Compensation will be pro-rated, that is if you withdraw during the first session, you will be compensated $10. If you withdraw during the second session, you will be compensated $20 for partial completion of the study.

VII. Freedom to Withdraw

You are free to withdraw from the study at any time and for any reason. Should the researchers determine that you should be removed from the study, you will be thanked and excused, and provided with pro-rated compensation.

VIII. Subject Responsibilities

You are expected to provide accurate information on your Medical History form. You are expected to adhere to your scheduled participation dates, advising the PI if the date(s) need to be rescheduled, unless you decide to withdraw from the study.

IX. IRB Review of Research

The Virginia Tech Institutional Review Board (IRB) for Projects Involving Human Subjects, has reviewed this proposed study, and has determined that it is in compliance with federal laws and Virginia Tech policies governing the protection of human subjects in research. However, you should recognize that the review does not constitute an endorsement of the research, and that it is up to you to determine whether you are willing to participate in the study after having been informed of the risks, benefits, and procedures involved in this study.

X. Subject / Participant's Permission

I have read the Consent Form and conditions of this project and have discussed it with the research staff or PI. I have had all my questions answered to my satisfaction. I hereby acknowledge the above and give my voluntary consent to participate in this study:

_____ Date_____

Subject's Signature

Subject's Project Identification Code: _____

Should you have any questions about this research or its conduct, research subjects' rights, and whom to contact in the event of a research-related injury to the subject, you may contact:

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NOTE:

- **You must be given a complete copy (or duplicate original) of the signed Consent Document.**
- **This Consent document must bear an official IRB date stamp.**