UNIVERSITY OF WASHINGTON
CONSENT FORM
Evaluating Technology-based Fall Prevention Interventions

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Researchers' statement

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

The purpose of this study is to study is to assess whether participation in computer learning activities reduces the risk of falls and improves functional ability. We will be comparing two different technology-based interventions in this study.

STUDY PROCEDURES

We are asking you to participate in the study for 20 weeks.

During the first visit you will be asked to fill out questionnaires (with demographic information like age, gender and education. We will also ask you about pre-existing health conditions, medications and social support). You will be asked to complete a series of games and quizzes using a computer to assess cognitive abilities (such as reaction time, etc). Finally during this visit, we will assess physical performance and gait (walking), asking you to stand, walk or briefly stand on one leg to assess risk for fall and walk back and forth. This physical activity will be measured using a sensor system placed on your arms, legs and around your waist. This visit takes approximately 75-90 minutes to complete.

In the next week we will visit with you two additional times (approximately 45 minutes per visit) to perform: 1) vision screen and medication review and 2) home fall safety check as well as additional computer assessments. These are areas in which intervention is known to decrease risk of fall. We will provide you with information that you may use to reduce your fall risk based on these assessments. We will also have you complete a fall calendar daily during this week to track any falls you may experience. Following the home safety check, you will be randomized to one of two computer-based interventions. The first possible intervention is a web-based health education series. The second intervention is a web-based program of brain training exercises.

For the next 16 weeks we will ask you to complete the assigned computer activities. We will do a follow up assessment 4 weeks later (at 20 weeks) to see if there are still any effect from the computer activities.

We will also ask you to fill out a monthly falls calendar tracking any falls you may experience during your participation in the study.

At weeks 8, 16 and 20, we will assess the effect of the interventions. At weeks 8, 16 and 20 you will again be asked to complete a short series of games and quizzes using a computer to assess cognition. We will also assess risk of fall using the same physical performance and gait measures done at the first visit at weeks 8, 16 and 20. University of Washington Physical Therapy students may be assisting with or observing these procedures. Following completion of the study, if you wish, we will provide you with access to whichever of the two computer-based interactions you were not assigned to during the study.

RISKS, STRESS, OR DISCOMFORT

There is the possibility that you may experience some discomfort answering questions about yourself or with using computer technology if you are unfamiliar.

There is potential that some participants may experience physical symptoms (e.g. fatigue, lightheadedness) while performing functional and gait tests.

We will have a trained investigator walk parallel to every participant during these tests, providing contact guard during assessment. You will be asked to report any lightheadedness, dizziness, or fatigue to the team member immediately. We will also have a team member present who is a physical therapy or nursing student available during the assessment sessions to further assist participants if necessary.

In order to maximize protection for privacy and confidentiality of your health information, we will store all your information in a secured file cabinet without your identifiers but rather using a code number. The file linking your code to your own information will be stored separately in a secure location.

ALTERNATIVES TO TAKING PART IN THIS STUDY

If you choose not to take part in the study, you may seek alternatives to reduce your risk of fall with your health care provider.

BENEFITS OF THE STUDY

You may benefit from study participation through the identification of issues placing you at increased risk for fall. During the first week of the study we will be using validated fall prevention activities that may reduce your fall risk. Further, the information about the effectiveness of technology-based learning activities and their impact on fall risk may benefit others in the future based on data collected in this study.

SOURCE OF FUNDING

The study team is receiving financial support from the National Institutes of Health for this study.

CONFIDENTIALITY OF RESEARCH INFORMATION

Study data will be confidential. Your data will be stored separately from identifiable information. The code linking your information to the data will be stored in a separate spreadsheet in a secure location. The link to identifiers will be broken by September 2020.

Data you provide may be collected and/or used by Cognifit and CANTAB as per their user agreements and privacy policies.

All of the information you provide will be confidential. Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

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.

We have a Certificate of Confidentiality from the federal National Institutes of Health. This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the University of Washington, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA; state or other local authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

OTHER INFORMATION

You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled.

As a token of appreciation for your participation, you will receive remuneration in the form of $125 in gift cards paid in five $25 installments (at one week randomization visit, and weeks 4, 8, 16 and 20 of the study).

RESEARCH-RELATED INJURY

If you think you have an injury or illness related to participation in this study, contact the principal investigator Dr. Hilaire Thompson (206-616-5641) right away. She will refer you for treatment.

Printed name of study staff obtaining consent Signature Date

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098. I will receive a copy of this consent form.

Printed name of subject Signature of subject Date

Copies to: Researcher
Subject