Collision warning device for blind and visually impaired

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Consent form

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Schepens Eye Research Institute
Massachusetts Eye and Ear
20 Staniford Street
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Research Consent Form
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PROTOCOL TITLE: Wearable collision warning device for blind and visually impaired: clinical trial

As part of: 'Development of a Vision Assistive Device for Veterans with TBI-Associated Visual Dysfunctions'

HSC PROTOCOL #: IRBnet #1007377

PRINCIPAL INVESTIGATOR: Gang Luo and Alex Bowers

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Throughout the consent form, "you" always refers to the person who takes part in the study.

Why is this research study being conducted?

We are asking you to take part in a research study to evaluate whether a new collision warning device helps to reduce collisions with obstacles in everyday walking. People with vision impairment and blindness sometimes bump into obstacles when walking around and are at higher risk for collisions and falls than people with normal vision.

We are asking you to take part because you have a diagnosis of hemianopia (loss of vision on the same side in both eyes), tunnel vision (loss of peripheral vision), or very severe vision loss (including complete blindness).

We expect to enroll about **90** subjects at Schepens Eye Research Institute.

Who is doing this research study and where will the study take place?

The principal investigators for this study are Dr. Gang Luo and Dr. Alex Bowers. The study takes place at the Schepens Eye Research Institute. The U. S. Army Medical Research and Materiel Command is providing funding for the study.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov,* as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

How long will this study take and what will happen in this study?

It will take you about 2.5 months to complete this research study. During this time, we will ask you to attend 3 or 4 study visits at Schepens Eye Research Institute and use the device at home for up to 2 months. Each visit will take about 2 hours.

At your first visit, screening tests will be conducted to determine whether you meet the inclusion criteria for this study. These screening tests will include measurements of your vision (described below) and a brief test of cognitive function. If you have hemianopia, you will also be asked to complete simple paper-and-pencil tests for neglect. You must meet the study criteria in order to participate in the rest of the study.

Vision measures
You may have your visual acuity (ability to read letters) measured using a computer-based system or a chart. You may also have your visual fields (extent of vision) measured using a conventional clinical instrument, or a new computer-based system. For the visual fields measurements you will sit with your chin in a chin rest and press a response button when you see targets appear on a screen in front of you.

Collision warning device
The device is about the size of a smart phone and looks very similar to a smart phone. It has a small camera with a wide field of view that monitors the area ahead and to the side of where you are walking. The device uses the information from the camera to calculate the risk of colliding with moving and stationary objects in your travel path. The device will give simple warnings of the direction of potential obstacles and the collision risk to help you avoid contact with them when walking. Warnings will be given only when you approach obstacles which are a collision risk. Warnings will not be given when you are close to objects which are not a collision risk. The warnings will be auditory sounds (e.g. a series of beeps) and vibrations (from vibrating wrist bracelets). The device will be used in conjunction with any other visual aids or mobility devices, such as a long cane, that you already use. The device is very light and is worn in a pouch attached to a belt, or can be placed in a pocket (provided the camera has an unobstructed view of the path ahead). The device is battery-operated. We will provide you with separate instructions about how to operate the device and how to charge the battery.

If you qualify for the study, you will be given training in how to operate the collision warning device, how to interpret the warnings, and how to integrate the device with any mobility devices you already use. You will have sufficient opportunity to practice using the device in the lab space, the corridors and when walking outdoors, so that you are comfortable using the device. An orientation and mobility specialist, as well as trained study personnel, will conduct this training. At the end of the training, the mobility specialist will determine whether you can take the device home, based on his/her assessment of your ability to operate and use the device correctly. If you cannot use the device sufficiently well, you will not be allowed to take it home.

Use of collision warning device at home

If you are permitted to take the device home, we will ask you to use it as much as possible when walking indoors and outdoors for approximately 2 months. In order to evaluate how helpful the collision warnings are, the device will sometimes go into a "silent" mode where no warnings will be given. The device will not give any indication of when it is in the "silent" mode. Therefore you should always be vigilant about collision hazards. The device will not warn you of all potential collision hazards because it will sometimes be in the "silent" mode and because it is a prototype device.

In the "active" mode the device will give warnings of the direction of potential obstacles and the collision risk to help you avoid contact with them when walking. When the device does give a warning, you should make use of the warning to avoid a collision. You will be instructed to cover the camera for a few seconds every time when a collision incident occurs. You will be given instructions to take home on how to use the device. The device will automatically record video snapshots of all potential and actual collisions that happen. We will use a computer algorithm to automatically detect any faces in the snapshots and mask them so that they will be unrecognizable to preserve anonymity.

An investigator will call you every week after you take the device home to check on your progress with the device.

Questionnaires

At the first and last visits we will ask you to complete a questionnaire about your mobility and the difficulties you encounter when walking around. At the final visit we will also ask you to complete a questionnaire about the device so that you can give us your feedback and comments.

Indoor obstacle course
At the final visit you might be asked to complete an indoor obstacle course. The course will be set up in our large conference room using soft and light obstacles. One of the investigators may also be a moving obstacle which you will be asked to yield to. He will ensure that you do not collide. You will be asked to walk through the obstacle course from start to finish once with the device and once without the device. While walking through the obstacle course you might also be asked to perform a secondary task recalling numbers you hear presented through headphones. The assessment will be video recorded in order to check the scoring of collisions and performance in the secondary task. Once the data is obtained from the video, the recording will be deleted.

What are the risks and possible discomforts from being in this research study?

Vision testing
The vision testing includes standard clinical tests carried out in an eye doctor's office. There might be slight discomfort during the visual fields test as you will have your chin in a chin rest. We will set the height of the rest so that it is comfortable for you.

Collision warning device
The risk of bumping into obstacles when using the collision warning device in the active or silent mode is no greater than you would normally encounter in daily activities. In the active mode, the device provides warnings to alert you to potential collision obstacles while you are walking. In the silent mode it does not provide any warnings. **Therefore you should always be vigilant about collision hazards. The device will not warn you of all obstacles because it will sometimes be in the silent mode and because it is a prototype device.**

You will be given training in how to use the device by an orientation and mobility specialist and as much time as needed to practice until you feel comfortable using and walking with the device. We will give you detailed instructions about how to operate the device. We recommend that you start by using the device at home or in a familiar environment until you feel confident about using it. You should continue to use any spectacles, visual aids (e.g. a telescope) or mobility devices (e.g., a long cane) that you normally use when walking around. The collision warning device is not meant to be a replacement for any of your existing glasses or devices.

Indoor Obstacle course
Potential risk when walking through the obstacle course is no greater than when walking in a crowded environment. Obstacles will be light, soft and not fixed on the floor. Kicking or colliding with them will only cause them to move, and you will not get injured. To minimize this risk, we will allow you to practice in a small scale obstacle course until you are comfortable with the task. Also an investigator will walk behind you to monitor your safety. His/her sole responsibility is to ensure your safety. A system of communication will be established between you and the "spotter" for any sudden stops that are necessary.

There are no known risks to videotaping as conducted in this study.

What are the possible benefits from being in this research study?

You will not be able to keep the device at the end of the study. However, you might benefit from the training aimed to help you use the device and improve your mobility. The information learned during the study will provide important insights about the ability of the device to assist people with vision loss to avoid potential obstacles. Your feedback may also make it possible to improve the design of the collision warning device.

Can I decide to stop taking part in this study?

Your taking part in this research study is voluntary, and you may withdraw from the study even after signing this consent. You may stop your participation or withdraw from the study at any time without penalty or loss of benefits. The quality of care you will receive will not be affected in any way if you decide not to participate or if you withdraw from the study.

Will I be paid to take part in this research study?

You may be reimbursed for your time at $15 per hour for study visits. You may also be reimbursed for travel expenses if you travel specifically for the study to the Schepens Eye Research Institute (not to exceed $50 per visit). There are no costs to you for participating in the study.

What happens if I am injured as result of taking part in this research study?

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for any injuries. You are not giving up any of your legal rights by signing this form.

If you think you have an injury or have experienced a medical problem because of taking part in this research study, tell the researcher in charge of the study as soon as possible. We have listed the researcher's names and phone numbers in the contact section of this consent form.

How will you protect my confidentiality?

We cannot guarantee total confidentiality. However, we will code your data so that we will not directly link information that identifies to your data. We will use a study code and keep the link between your identifiers and the code in a separate, password-protected file. We will keep all data in a locked area and allow access only to study staff.

We may publish the results of this research study in a medical book or journal or use the results to teach others. However, we will not use your name and other identifying information for these purposes without your specific authorization

Study records which contain your personal information or other information about you derived or maintained as part of this study may be made available to the study sponsor (including the U.S. Army Medical Research and Material Command, and the U.S. Department of Defense).

Contact information if you have questions or concerns about this study

You are free to ask any questions you may have about the study or your rights and treatment as a research subject. Further information about any aspect of this study is available now or at any time during the course of the study from the principal investigators, Dr. **Gang Luo** at **617-912-2529** or **Dr. Alex Bowers** at **617-912-2512** or the study coordinator, **Vilte Baliutaviciute** at **617-912-2588.** You can contact the principal investigator if you experience a complication or injury that you believe may be related to this study.

If you want to speak with someone not directly involved in this research study, please contact the Human Research Protections Program Office at (617) 573-3446. You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

CONSENT:

The purpose and procedures of this research project with its possible risks and benefits have been fully and adequately explained to me, and I understand them. I voluntarily agree to participate as a subject in this research study, and understand that by signing this consent form I am indicating that agreement. I have been given a copy of this consent form.

_____

Name of Subject (print)

_____ DATE: _____

Signature of Subject

_____

Name of Person Obtaining Consent (print)

_____ DATE: _____

Signature of Person Obtaining Consent

TIME: _____