

Protocol Title

Automated Orientation & Mobility Training in Virtual Reality for Low Vision Rehabilitation

Study Protocol

Object

The objective of the randomized, controlled human subject training trial, VR-IOMS, is to assess the efficacy of a new, automated, virtual reality-based platform in training orientation and mobility (O&M) skills in individuals with low vision.

Design

The design of the VR-IOMS trial has 3 modules for 3 low vision O&M skills, safe crossing time for signalized streets (near lane parallel traffic, NLPT), safe crossing decision for uncontrolled streets (mid-block crossing, MBC), and learning street address system in unfamiliar communities (outdoor numbering system, ODNS). Each module has three arms, learning O&M skill with VR-IOMS in virtual street (Experimental arm), learning O&M skill with human Certified Orientation & Mobility Specialist (COMS) in real street (Active Control Arm), and watching low vision education videos (Placebo Arm). The VR-IOMS platform and the training materials of the 3 trail modules are developed by UAB and sub-awardee New Jersey Institute of Technology. Participants randomized to the Experimental arms are trained in the VR-IOMS platform, those randomized to Active Control arms are trained by COMS in real streets, and those randomized to Placebo receive no training.

Inclusion Criteria:

- 13 years or older.
- Having stable visual impairment.
- Not having formal O&M training, particularly, not having training on the three O&M skills to be trained in the trial (determined by the COMS in pre-training real street evaluation).
- Possessing sufficient task-specific functional vision to learn the O&M skills to be taught (determined by the COMS in pre-training evaluation in real streets).
- Normal mental capacity (Short Portable Mental Status Questionnaire ≤ 2 errors).
- Having O&M as a rehabilitation goal.
- Normal or corrected to normal hearing.
- Sufficient dexterity to operate a game controller.
- Sufficient physical stamina to walk a few street blocks under guidance of COMS and to sit for training sessions in the VR simulator which were usually 30 minutes.
- Speaking English clear enough to be recognized by speech-to-text software.

Exclusion Criteria:

- In the rapid progression phase of ocular diseases, such as wet macular degeneration.

- Under aggressive treatment of ocular diseases, such as VEGF injection for retinal diseases.
- Having a history of epileptic seizure or are prone to motion sickness.
- Having difficulty in verbal communication with human COMS or the VC in English.

Study Sites

University of Alabama at Birmingham (UAB) and Alabama Institute for Deaf and Blind (AIDB) participate in the clinical trial. The same VR-IOMS platform and training protocol are used on both sites.

Participants Recruitment, Enrollment, and Randomization

Recruitment: On UAB site, potential participants are recruited from UAB School of Optometry (UABSO) Low Vision Clinic, UAB Center for Low Vision Research (CLVR). Low vision optometrists in UABSO and UAB CLVR review the records of existing low vision patients and send recruiting letters to potential participants. The potential participants who were interested in participating initiated contact with the UAB team to schedule enrollment visits. UAB team also recruited self-referred patients. On AIDB site, potential participants were recruited from AIDB's E.H. Gentry Facility, a residential teaching/training facility. In each semester, an AIDB team member reviews the list of new students to be admitted to the Gentry, select those who may meet the inclusion criteria, and meet with them to determine their interest and ability in participating in the clinical trial.

Enrollment: Potential participants are interviewed by COMS to obtain demographic information, physical and mental health, history of visual impairment, visual functions, and prior O&M and low vision rehabilitation training. All potential participants are taken to real streets by COMSs for pre-training evaluation. Participants who meet the inclusion criteria, are not familiar with the O&M skills to be taught and have got satisfied answers to all questions about the trial are invited to sign the informed consent form. They are usually enrolled and randomized on the same day.

Evaluations

All enrolled participants are evaluated by COMS in real streets twice, before training and after completing assigned training. The evaluations assess the participant's O&M skills. The procedures of the pre- and post-training evaluations are the same. COMS who conducted real street evaluations were blinded to the participant's training assignments. COMS who were not involved in evaluations are assigned to conduct training in experimental, active control and placebo arms.

Sample size

Because the field of low vision O&M skill training lacks existing effect sizes from high-quality clinical research, especially for a clinical trial that intends to introduce VR and Intelligent Tutoring System into O&M rehabilitation, the VR-IOMS trial adopts a practical feasibility design. Specifically, because the VR-IOMS training courses for the three modules of the trial are developed in sequence, participant enrollment and

training begin when the development of one course is completed and ends when the next course is ready to go.

Methods

The three VR-IOMS trial modules use different methods to teach different skills. The training in the 3 arms of each module is also conducted using different methods and in different environments.

NLPT Module

The experimental arm training is conducted in VR. The training course has 5 lessons, identifying parallel and perpendicular streets, identifying near lane parallel traffic (NLPT), detecting NLPT stopping, detecting NLPT surge (idling car moving forward), and confirming NLPT surge (waiting for the car entering the intersection). Each lesson has a concept instruction and a skill practice session. There is skill assessment at the end of a lesson. The participant has to pass the assessment before moving to the next lesson or completing the training. The active control arm is conducted by COMS in real street intersections. The COMS uses her experience to teach the NLPT surge skill and makes her judgement on the participant's proficiency. The procedures of the placebo arms of the three modules are the same. The participant sits in a private, quiet room to watch video clips and discuss low vision with a COMS.

MBC Module

The experimental arm training is in VR. The training course has 4 lessons, learning the time to cross a street from an avatar, learning the time to cross a street by imagining, distinguishing narrow or wide traffic gaps, and selecting safe traffic gaps. There is skill assessment at the end of a lesson. The participant has to pass the assessment before moving to the next lesson or completing the training. The active control arm is conducted by COMS in real street intersections. The COMS uses her experience to teach the MBC skill and makes her judgement on the participant's proficiency.

ODNS Module

The experimental arm training is in VR. The participant uses a VR game controller to conduct first-person exploration in 4 virtual residential streets which differ by the locations of the address numbers, on mailboxes, on plaques in front lawn, on front door, and on the mix of the three. The participant walks along a virtual sidewalk, approaches the location of the address number, reads it, and, if read correctly, moves to the next house. At the end of visiting 4 consecutive houses, the participant is asked to plan a trip to a destination in the same street. After 5 explorations of the houses, the correctness of participant's trip plans are summed up to make a trip plan score. He has to have a good score to move to the next street or complete the training. In active control training, COMS walks with the participant on a real street that has address numbers on mailboxes or front doors. The COMS observes the participant's behavior, asks the participant to make trip plans, and makes her judgement on the participant's proficiency.

Statistical Analysis Plan

In the VR-IOMS trial, Analysis of covariance (ANCOVA) is used to analyze the NLPT, MBC and ODNS modules. In each of the modules, the Percentage of Success (PoS) obtained from the post-training real street evaluation is the dependent variable, and the PoS obtained from the pre-training evaluation is a covariate. Given our limited sample size ($N \leq 16$ per arm), ANCOVA is suitable for mathematically controlling the residual pre-training variations among the arms.

The percentage of successes are different in the three trial modules. In the NLPT module, the PoS is the safety of the participant's timing to initiate crossing a signalized street. In the MBC module, the PoS is the safety of the participant's decision to cross an uncontrolled street or not. In the ODNS module, the PoS is the correctness of the participant's trip plan. In real street evaluations, COMS collects multiple categorical data, such as Safe/Unsafe, Safe/Safe but missing crossing opportunity/Unsafe, or Correct plan/Partial correct plan/Wrong plan. Numerical numbers, such as 1/0, 1/0.5/0, are assigned to each categorical data. The average of the numerical numbers of a participant is her/his individual PoS. The average of individual PoSs of all participants in one trial arm is the arm's group PoS. ANCOVA is used to compare the group PoSs of the pre-training evaluations and the post-training evaluations.

NCT#: NCT04639531

Date of Last Protocol Approval

Last Protocol Approval was 10/29/2025. It will expire on 10/28/2026.

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CONSENT FORM TO BE PART OF A RESEARCH STUDY

Title of Research: Automated Orientation & Mobility Training
in Virtual Reality for Low Vision Rehabilitation

UAB IRB Protocol #: IRB-300003874

Principal Investigator: Lei Liu, PhD

Sponsor: National Eye Institute/National Institute of Health

For Children (persons under 18 years of age) participating in this study, the term “You” addresses both the participant ("you") and the parent or legally authorized representative ("your child").

General Information	You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form.
Purpose	The purpose of the study is to develop and test a new method to teach individuals with visual impairment the skills they need to navigate their environment. These are called orientation and mobility or O&M skills. In this new method, a computer will conduct skill training automatically and the learner will learn from a computer-generated virtual environment shown on a screen that looks like and sounds like real streets and neighborhoods.

Duration & Visits	You will be in this study for one to two weeks. During this period of time, you will visit our laboratory 4 or 5 times. Each visit may last one to one and half hours.
Overview of Procedures	Over the course of the study, you will be taken to real streets by certified orientation and mobility specialists. They will test your ability to perform several O&M tasks, such as to say “GO” when you feel safe to start crossing a street (without actually stepping into the street). You will then be randomly given one of the following three training assignments, to learn O&M skills with the computer in virtual streets, to learn O&M skills with a certified orientation and mobility specialist in real streets, and to watch videos about visual impairment. After you complete your training assignment, you will be taken by certified orientation and mobility specialist to real streets where they will test your ability to perform O&M tasks again.
Risks	The most likely risks are feeling sick or nausea in the virtual environment and being exposed to the hazards in real streets. The flicker of visual display of a virtual environment may trigger epileptic seizure in individuals with a history.
Benefits	You may learn a few O&M skills in the study but these skills are not enough for you try to navigate streets yourself. Your participation will help better O&M skill train methods so that more individuals with impaired vision can benefit from such training.
Alternatives	If you do not want to take part in the study, the researcher will discuss with you about getting

Purpose of the Research Study

We are asking you to take part in a research study because you have visual impairment. The purpose of this research study is to develop and test a new method to teach individuals with visual impairment the skills they need to navigate their environment. These are called orientation and mobility or O&M skills. In this new method, a computer will conduct skill training automatically and the learner will learn from a computer-generated virtual environment shown on a screen that looks like and sounds like real streets and neighborhoods. The computer system that carries out the new training, called a Virtual Reality-based Intelligent Orientation and Mobility Specialist, or VR-IOMS, is an investigative device. This study tests the effectiveness the VR-IOMS in conducting O&M skill training, relative to the conventional training. This study will enroll 102 participants in two research sites in Alabama, half of them will be enrolled at UAB.

Study Participation & Procedures

This study will test the ability of VR-IOMS to teach three O&M tasks. 1) Timing to cross a signalized street (crossing at a street intersection with traffic lights); 2) Timing to cross an uncontrolled street (crossing a street with no traffic lights nearby); 3) Learning the layout of a neighborhood (where you are in the neighborhood and how to get to another location in the neighborhood). The training does not involve your stepping into street with traffic. If you agree to join the study, the following research procedures will be followed.

- Pre-training evaluation - Your ability to perform the three O&M tasks will be evaluated by a certified O&M specialist in real

streets. You will be led to a street corner or the curb of a street and will be asked to say “GO” when you feel it is safe to start crossing the street (without actually stepping into the street). Or you will be led to a neighborhood and be asked to describe how to plan a route from your current location to another location in the neighborhood (without actually making the trip). This procedure will be repeated in several different places. The specialist will evaluate your performance and decide which O&M task you will learn. You will also be asked to rate the difficulty of the O&M tasks, 0 is not difficult at all and 5 is too difficult to do.

- Randomization – If you qualify for receiving training in an O&M task, you will be randomly assigned (like the flip of a coin) by a computer into one of the following three study groups
 - Experimental group: receiving training on an O&M task with a VR-IOMS in virtual streets
 - Active control group: receiving training on an O&M task with a human certified O&M specialist in real streets
 - Placebo group: receiving no training on O&M tasks (watching visual impairment related videos).
- Preferred walking speed – If you will learn the tasks of street crossing timing, a research assistant will measure your preferred walking speed. You will be asked to walk a 10 meters (~11 yards) long, straight, well illuminated, unobstructed, flat, corridor at your normal walking speed. Three walks will be measured.
- Training – You will learn O&M skills according to your study group assignment.
 - Training with VR-IOMS: In this experimental procedure, you will be standing in front of 3 large project screens or sitting in front of a computer monitor in the laboratory. You will see computer generated street scenarios, such as streets, buildings,

cars, pedestrians, and hear sound of traffic. A research assistant will show you how to interact with the computer using simple verbal commands, such as “GO” and “STOP”, or using simple devices such as a pointer or a joystick. When the training starts, you will see visual display that gives you the feeling of being at the corner of a virtual street intersection or on the side walk of a virtual street. You will hear human voice giving instructions explaining the concepts and skills you are going to learn. You will also be given problem-solving tasks on the virtual streets, such as “Say GO when you feel safe to start crossing the street” or “Let me know how you can travel from your current location to 242 Orchid Street”. Your performance in these tasks will be evaluated by the computer, which will determine if you have mastered the skill or need more practice.

- Training with COMS: In this routine O&M rehabilitation procedure, you will be taken to the real street by a COMS and will learn and practice the O&M skill with him or her. The COMS will use the same problem-solving tasks to evaluate your performance and determine you have mastered the skill.
- No training: Instead of receiving O&M training, you will watch visual impairment videos and discuss them with a member of the research team for about the same amount of time as that spent on training the skill in other study groups. Although you do not receive training, your ability to perform O&M tasks in real streets may change.

- Post-training evaluation – Your ability to perform the three O&M tasks will be evaluated again by a certified O&M specialist in real streets after you complete your training assignment. The evaluation procedure will be similar to the pre-training evaluation, but will be focused on the O&M task you are assigned to learn. If

you received the training with the VR-IOMS, you will be also asked to comment on your learning experience with it.

The study doctor will discuss with you your responsibilities as a participant. You will visit our laboratory 4 or 5 times in one to two weeks. The time you spent in the study may depend on your vision and your learning ability. On average, you may spend 5 hours in the study for learning one O&M skill. If you qualify and are willing to learn more, an additional 2 hours is needed for learning each additional skill.

We will collect your health information and test you vision solely for the research purposes described above. We do not expect to find anything about your eyes and vision that you and your doctor do not already know.

Risks and Discomforts

There may be some risk to you in participating in the study. If you are assigned to receiving training from VR-IOMS in a virtual environment

- People may feel sick in a virtual environment (cybersickness). However, the virtual environments we use in this study are less likely to induce cybersickness. If you are not prone to motion sickness, the chance your feeling sick in this study is low. If you begin to feel sick, you can order the VR-IOMS to stop at any time during training.
- The flicker of visual display of a virtual environment may trigger epileptic seizure in individuals with a history. However, the visual display used in this study does not produce flicker. There is no risk of epileptic seizure in participating in this study if you do not have a history.

- You may feel tired for prolonged training. We divide the skill training into short sessions with rest breaks in between to reduce fatigue. You can also request a break from the VR-IOMS any time during training.

If you are assigned to receiving training from a specialist in real street

- You may be exposed to the hazards of real streets. The specialist will use sighted-guide method to guide you in real streets. The specialist will always be on your side while you are on the real street to ensure your safety.
- You may get tired from walking from one testing/training location to another. The specialist will observe you during training and will give you short rest breaks during training.

There may also be risks that are unknown at this time. You will be given more information if other risks are found.

You will be assigned to a group by chance, which may have more risks than the other study group or alternatives.

Benefits

You may learn a few O&M skills from taking part in this study, depending on your group assignment. However, the skills studies are only a small fraction of a comprehensive O&M curriculum. You should not try to navigate streets by yourself. To achieve your goal of independent travel, you should seek comprehensive O&M training. Our specialist will be happy to discuss your options with you. Regardless of your group assignment, your participation in the study will help to advance the science and technology that will eventually benefit the entire low vision population.

Alternatives

One alternative may be to not participate in the study. The study doctor will discuss with you the alternatives to participation and their risks and benefits.

Confidentiality and Authorization to Use and Disclose Information for Research Purposes

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The researcher must get your authorization (permission) to use or give out any health information that might identify you.

What protected health information may be used and/or given to others?

All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of any kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills; any other information related to or collected for use in the research study, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes; records about any study

drug you received or about study devices used; and consent forms from past studies that might be in your medical record.

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.

Who may use and give out information about you?

Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study.

Who might get this information?

All Individuals/entities listed in the informed consent document(s), including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere). Your information may also be given to the sponsor of this research. “Sponsor” includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor, or are providing support to the sponsor (e.g., contract research organization).

Information about you and your health which might identify you may be given to:

- the Office for Human Research Protections (OHRP)
- the U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies in other countries
- Governmental agencies to whom certain diseases (reportable diseases) must be reported

- the University of Alabama at Birmingham - the physicians, nurses and staff working on the research study (whether at UAB or elsewhere); other operating units of UAB, UAB Hospital, UAB Highlands Hospital, University of Alabama Health Services Foundation, Children's of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Health, as necessary for their operations; the UAB IRB and its staff
- the billing offices of UAB and UAB Health Systems affiliates and/or Children's of Alabama and its billing agents

Why will this information be used and/or given to others?

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

What if I decide not to give permission to use and give out my health information?

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

May I review or copy the information obtained from me or created about me?

You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

May I withdraw or revoke (cancel) my permission?

Yes, but this permission will not stop automatically. The use of your personal health information will continue until you cancel your permission.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date.

Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is my health information protected after it has been given to others?

If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others. Including others outside of UAB, without your permission.

Voluntary Participation and Withdrawal

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in it. If you decide not to be in the study, you will not lose any benefits you are otherwise owed.

You are free to withdraw from this study at any time. Your choice to leave the study will not affect your relationship with this institution.

You may be removed from the study without your consent if the sponsor ends the study, if the investigator decides it is not in the best interest of your health, or if you are not following the study rules.

If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation

There will be no cost to you for taking part in this study. All examinations, evaluations and training related to this study will be provided to you at no cost.

Payment for Participation

You will be paid \$20 per visit for participating in the study. Payments will be made at the end of each visit. If you receive training in one O&M task, the total payment you may receive is \$80. If you qualify and are willing to receive more training, you will be paid \$40 for each additional task training. If you live within 30 miles from the research site, we will reimburse the cost of your travel and parking will be provided free of charge. The payment will be made by a Greenphire clincard, which is a debit card under your name. Each payment will be added to the card after each visit. We need to know your social security number in order to make payment using the Greenphire clincard.

New Findings

You will be told by the investigator or the study staff if new information becomes available that might affect your choice to stay in the study.

Questions

If you have any questions, concerns, or complaints about the research, please contact the investigator. You may contact Dr. Lei Liu at (205) 996-6627.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights

You are not waiving any of your legal rights by signing this consent form.

Signatures

Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this study.

You will receive a copy of this signed consent form.

Signature of Participant 14 Years of Age and Older	Date
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Signature of Parent or Guardian	Date
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Signature of Person Obtaining Consent	Date
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