Scotoma Perimetry Oculomotor Training

Study Protocol & Statistical Analysis Plan

NCT05456581

Date of Last Protocol Approval: August 12, 2024

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UAB INTEGRATED RESEARCH ADMINISTRATION PORTAL

IRB ePortfolio

1. GENERAL QUESTIONS

Protocol Number IRB-300008064

Principal Investigator Name Visscher, Kristina M

Title of proposed project:

New Methods to Quantify and Train Eye Movement Strategies in Macular Degeneration

* Select the type of application you are submitting to the IRB for review. Revision/Amendment

NOTE: The ePortfolio should NOT be used for Revision/Amendments to protocols not INITIALLY submitted on the ePortfolio. Please see instructions for submitting the appropriate form here.

The OIRB has developed **a list of tips and best practices for IRB submissions. Review the document here for assistance in developing your application.**

Initial IRB Protocol Application

* **PURPOSE:** In non-technical, lay language, provide the purpose of the project. The contents of this section are copied to other areas of IRAP. As such, provide **only** the purpose of the project here.

This proposal tests a novel 'scotoma awareness' approach to aid those with Macular Degeneration (MD). MD is the leading cause of central vision loss worldwide

BACKGROUND: In 2-3 paragraphs, summarize the past experimental/clinical findings leading to the design of this project. Include any past or current research that informed the study design and any previous results that are relevant to understanding the project. Lastly, list the study outcomes that will be measured to evaluate the purpose of the project . It is not necessary to include methodology in this section. NOTE: Technical terms must be defined in simple language. Abbreviations must be spelled out. Provide references for any specific citations.

Macular Degeneration (MD) patients spontaneously develop oculomotor strategies to overcome loss of central vision, such as developing a new peripheral fixation spot to replace the fovea (preferred retinal locus, or PRL). However, development of a PRL and the rate of success in developing one vary greatly, meaning some patients live years without making effective use of their spared vision.

Recent, studies in Vision Science show that training healthy participants with gaze-contingent displays, obstructing central vision (*'simulated scotoma'*), leads to development of PRLs at a faster time scale than found for MD patients. Additionally, oculomotor metrics developed in our lab, are effective in characterizing individual eye movement patterns in simulated scotoma participants. The ability to describe differences in compensatory strategies in MD represents a crucial step towards individualized rehabilitative strategies, which could be further improved by accelerating PRL development. However, it is unclear whether these results can be reproduced in those with MD. It has been suggested that the visible, sharp-edged occluder in the gaze-contingent displays increases scotoma awareness, thus accelerating PRL development.

Many MD patients are unaware of the location of their scotoma, with some persisting to use their damaged fovea as a fixation spot. No study to date has translated the use of a simulated scotoma to promote rapid PRL development in MD patients. As a first step towards addressing individual differences in patients and examine whether Vision Science paradigms can be used as a rehabilitative tool in MD, we propose two Aims: In Aim 1 we will use a set of oculomotor metrics to characterize individual profiles of compensation. In Aim 2 we will test the effectiveness of the visible, simulated scotoma as a technique to promote the rapid development of a PRL. Patients will undergo a *'scotoma awareness'* training, in which a simulated scotoma, individually tailored for each patient, will be used to help them visualize their region of vision loss. Patients will be tested on the same metrics from Aim 1 and a battery of visual and cognitive assessments before and after the *'scotoma awareness'* (or control) sessions. This will enable quantification of the effect of scotoma awareness both in terms of visual abilities and oculomotor strategies, and test the hypothesis that awareness of the location and extent of retinal damage promotes fast PRL development. While challenging, the use of eye tracking techniques in patients could be highly rewarding if this scotoma awareness procedure proves to be effective. A null result would be equally informative, suggesting fundamental differences between physiological and simulated scotomas, thus providing a limit in the use of simulations of retinal damage as a framework for the study of retinal pathologies such as MD. This will provide a unique data set to help those developing interventions for central vision loss understand how approaches to visual rehabilitation, and individual differences, give rise to training outcomes.

METHODS: Describe the procedures for all aspects of your protocol. Tell us what you are doing.

At the beginning of the study, we will obtain consent as well as demographic variables (age, education, SES), health variables (chronic disease, medications, blood pressure, BMI). MD participants will be randomly assigned into one of two training conditions (scotoma awareness' or control). 8 participants will be assigned to each group.

Phase 1 - Baseline Behavioral Testing- A battery of baseline and post-tests is designed to evaluate learning associated with each of the factors listed below:

PRL evaluation – In order to measure both general and location-specific effects on the intervention (see below), individual PRLs for each participant will be measured before training and baseline assessment. This procedure is common to both Vision Science studies using artificial scotoma and clinical interventions using microperimetry. Key personnel occupational therapist Jason Vice will provide expertise in determining the PRL before and after the intervention.

Quantification of oculomotor metrics - We employ a task in which each trial begins with participants fixating a target presented in the center of the screen with their individual PRL for 500-1500ms. In case of participants with an underdeveloped or absent PRL, they will be simply asked to fixate the target in a way that will make it entirely visible (e.g., not partially covered by the scotoma). A 2-degree white circle target (flickering at 2hz; 250ms on 250ms off) will then appear in a random location. The task is to press a button when the circle reappears with the color red (rather than white), which will randomly occur 2-4 seconds after the first appearance of the circle, for 80 trials to ensure a larger number of eye-movements per participant.

MNread - In this task participants read out loud a series of short sentences for which the font size decreases progressively, sentence by sentence, until the font is too small for the participant to successfully read the text (a measure of visual acuity). Additionally, average reading speed and critical print size, the text dimension at which reading speed begins to decrease, are computed as measures of behavioral proficiency.

Trail-Making Task - While reading involves a known trajectory of eye movements, in the trail-making task, which requires connecting a sequence of consecutive target letters and numbers, participants must do a visual search for the location of the next letter or number in the sequence. In addition to the standard measure of time to completion, we can also look at the number of

saccades required, and saccade accuracy.

l. Visual sensitivity Charts: Standard Visual acuity (ETDRS) and Contrast sensitivity (Robson-Pelli) charts.

Phase 2 – training: Participants will be assigned to one of two conditions: 'scotoma awareness' or control. In the ' *scotoma awareness*' training, patients will perform visual search and orientation discrimination tasks while an opaque occluder, custom-tailored to overlap each patient's retinal scotoma, is constantly presented on the computer screen. In the control group, the task will be performed without the visible scotoma. In each trial, participants will be asked to locate the target and perform an emotion recognition task (identify whether the emoji face is 'happy' or 'sad'). The size and contrast of the target will change adaptively depending on the participant's performance. The training will consist of 10 sessions (two per visit), and each session will be composed by 4 blocks of 100 trials each. To optimize learning gain, the two daily sessions will be separated by a period of quiet rest, which has been shown to improve learning consolidation. Participants will be tested on a series of baseline assessments (visual acuity, contrast sensitivity, reading speed, visual crowding, see below) before and after training, alongside our oculomotor metrics from Experiment 1.

Phase 3 – Post training Behavioral and oculomotor Testing This will be the same as the baseline testing.

Phase 4 – Long term follow-up. This will be the same as the baseline testing but will be conducted 2 months after training is completed.

REQUIRED - SELECT ONE OR BOTH: Will this be a retrospective study and/or a prospective study?

☐ Yes ☑ No * Retrospective

☑ Yes ☐ No * Prospective

☑ Yes ☐ No * Will the study involve the prospective collection or analysis of data, documents, or records?

☐ Yes ☑ No * Will the study involve the prospective collection or analysis of biospecimens?

What is the expected end date of the study (including data analysis)? 31-Aug-2026

* Provide the total number of subjects to be included at all sites, both retrospectively (including records) and prospectively. 100

* Provide the total number of subjects to be included at UAB, both retrospectively (including records) and prospectively. 100

Select the status of the Principal Investigator.

☑ Faculty/Staff

☐ Student/Trainee

☐ Yes ☑ No Are any of the investigators listed on the IRB Personnel Form students using this research for their capstone project, thesis, or dissertation?

☐ Yes ☑ No Is the project to be conducted internationally?

Procedure List

Select all study procedures and indicate whether the procedures are research only or routine.

Procedure	Select whether the procedure is research or routine.
Surveys, questionnaires, or interviews (one-on-one)	Protocol Driven

☑ Yes ☐ No Does the protocol involve any procedures not described in the above table?

Describe the procedure(s), including whether the procedure(s) are research only or routine.

Routine vision and retinal testing.

Research Area

Select the type of research.

☐ Biomedical (non-oncology)

☑ Behavioral (non-oncology)

☐ Oncology

4. AMENDMENT

Amendment

This form may NOT be used for submitting personnel changes, submitting short forms and translated documents, or changing funding sources. Make all relevant changes in the main application.

This amendment was requested by: Select all that apply

☐ Study sponsor

☐ DSMB

☐ Audit

☐ IRB

☑ Study team

☐ Other

Indicate the status of your study.

☐ Not yet open

☑ Open

☐ On hold

☐ Closed to enrollment

☐ Completed

Provide the number of subjects currently active (receiving study intervention, active follow-up, etc.) by participant groups, sites, and/or sub-study, if applicable.

Participant Group/Sub-study	Number Active
Enrolled	0

Provide the number of subjects enrolled since the start of the study by participant groups, sites, and/or sub-study, if applicable.

Partcipant Group/Sub-study	Number Enrolled
Control	6
Intervention	5

Provide a summary of the changes, including the rationale for the changes. Update the appropriate sections of the ePortfolio to reflect the changes. Do not remove completed phases or activities from the ePortfolio.

Adding a partial HIPAA waiver for recruitment to gain access to the EMR through Callahan Eye Hospital for screening potential participants.

Addition of instagram to the social media website posting list in the prospective section.

Addition to prospective that the flyer will also be distributed around local clinics, businesses, support groups, and labs in the downtown Birmingham area surrounding UAB.

Once potential participants are identified by Dr. Jason Vice, the Visscher lab research team, consisting of Dr. Kristina Visscher and Elliot Maxwell, will reach out to them via their preferred method of contact (letters, phone calls, or emails). The content of our initial contact letter is already included in the approved documents.

We have made a change to the consent form in regard to the time required during the vision testing visits. We have added 2 computerized assessments (included in the computerized assessments mentioned in our consent form). After assessing the amount of time it takes participants to complete these new assessments during their vision testing visits, we have found that it takes on average 1.5 to 2 hours instead of 1 to 1.5 hours for them to complete. We have changed the times accordingly.

☑ Yes ☐ No * Are you submitting revisions to previously approved documents or adding new documents to the project?

Upload the new or revised documents to the applicable sections of the ePortfolio, including both clean and tracked copies. **Remove previous versions of revised documents.**

☑ Yes ☐ No Will the change(s) affect consent documents?

Add the new or revised consent documents to the consent document table on Page 29 or 30 as applicable, including both clean and tracked copies. **Remove previous versions of revised consent documents.**

☑ Yes ☐ No * Will the change(s) affect subjects?

Select all that apply.

☐ Additional Risks

☐ Additional Study Visits

☐ Additional Study Procedures

☐ Additional Study (e.g., sub-study)

☑ Other

Explain.

Vision assessment visions may take longer than initially estimated, meaning participants may need to stay close to 30 minutes longer for these visits.

☐ Is there a plan to reconsent existing participants?

If you wish to add any information for the IRB to consider (e.g., any information that the IRB has not already asked for or the study team has not already provided and the study team believes will aid the IRB in their review), please add it here.

5. RESEARCH DETERMINATION

Research Determination Form

☑ Yes ☐ No * Is the activity a systematic investigation?

☑ Yes ☐ No * Is the activity designed to develop or contribute to generalizable knowledge?

☑ Yes ☐ No * Does the project involve obtaining information about living individuals?

☑ Yes ☐ No * Does the project involve an intervention or an interaction with participants?

☐ Yes ☑ No * Does the project involve an FDA regulated test article?

☐ Yes ☑ No * Is the project defined as a clinical investigation?

Briefly describe the proposed project, including what materials are being obtained and their sources. **If you provided this information on Page 1 (General Questions), enter "See above."**

see above

Risk Level - Not FDA Regulated

* **REQUIRED: Select whether the project involves** minimal risk **or greater than minimal risk to participants.**

Minimal Risk

☐ Exempt Categories

☑ Expedited Categories

Expedited Categories

Select the categor(ies) that apply to the project. If none of these categories apply, select none of the above apply to this project.

1 ☐ 2 ☐ 3 ☐
4 ☑ 5 ☑ 6 ☐
7 ☑

Expedited Category 1: Clinical studies of drugs and medical devices when either of these conditions are met.

Expedited Category 2: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture under these conditions.

Expedited Category 3: Prospective collection of biological specimens by noninvasive means (examples here).

Expedited Category 4: Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x rays or microwaves (more information here).

Expedited Category 5: Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

Expedited Category 6: Collection of data from voice, video, digital, or image recordings made for research purposes.

Expedited Category 7: Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

☐ None of the above apply to this project.

Sources of Private Information

Indicate the information that may be obtained, accessed, used, disclosed, or shared from an individual (living or deceased). Select all that apply.

☐ An individual's genetic tests

☐ Genetic tests of family members of a particular individual (including an embryo or fetus)

☐ Genetic manifestation of a disease or disorder in family members of a particular individual

☐ Any request for, or receipt of, genetic services, or participation in a clinical study which includes genetic service, by the individual or any family member of the individual

☐ Education records of an individual

☐ Alcohol or substance abuse information, including diagnosis, treatment, or referral of treatment for alcohol abuse, substance abuse, or chemical dependency

☑ Yes ☐ No Will the PI or others obtain, review, or make other use of participants' "protected health information" (i.e., information, whether oral or recorded in any form or medium that (a) is created or received by a health care provider and (b) relates to past, present, or future physical or mental health or condition of an individual; or provision of health care; or payment for provision of heath care)?

☑ Identifiable, but not private, information

Describe what identifiers will be collected, **and** provide justification for the identifiers not being private.

Names, geographic subdivisions smaller than a state, elements of dates(except year) related to an individual, telephone numbers, and email addresses. The justification for these identifiers is that we need the information to contact participants, and to send them payment by mail. Such identifiers will be maintained on a HIPAA compliant computer RedCap form, and will be available only to trained study staff

☐ Other identifying information

☐ Yes ☐ No * Is the project subject to the 2023 NIH Data Management and Sharing (DMS) policy?

☑ Yes ☐ No * Will information be received from outside of UAB?

From where will the information be received?

Informa??on will be received from outside healthcare providers to verify diagnosis for participant eligibility.

☐ Yes ☑ No * Will you share the information with an institution other than UAB?

☑ Yes ☐ No * Will you need to obtain information from a department other than your own?

Provide the names of the department(s).
UAB Ophthalmology

Provide any additional information for the IRB to consider. Upload any relevant files in the Attachments section.

6. NON-AFFILIATED PERSONNEL

Non-UAB/CoA Personnel

☐ Yes ☑ No * Are there any NON UAB, Children's of Alabama (CoA), Lakeshore Foundation, or Birmingham Veteran's Affairs Medical Center (BVAMC) key personnel on this study? NOTE: UAB, CoA, Lakeshore Foundation, and BVAMC investigators must be listed on the IRB Personnel Form. Additionally, this page does not apply to adding sites for Single IRB or multi-site research.

7. SPONSORS AND ENTITIES

Funding, University Contracts, Subcontracts, MTAs, or DUAs

☑ Yes ☐ No * Is this project funded in any way?

☐ Yes ☑ No * Is the funding internal?

☐ Yes ☑ No * Is this project industry sponsored?

Select the study sponsor and/or the entity(ies) providing support for the study.

Study Sponsor/Entity(ies)
NIH - National Institutes of Health/DHHS

Provide the OSP Assigned Number(s). NOTE: The OSP assigned number is 9 digit number.
NOT PROVIDING THE OSP NUMBER WILL RESULT IN DELAYS OF YOUR REVIEW.

000531929 This is a subaward from an R21 to the NEI from NIH. We have been asked to give just in time information. The "Prime Principle Investigator" is Dr. Marcello Maniglia.

Is the project funded by either of the 20 common rule agencies? Yes

☐ Yes ☑ No Does the project involve any University Contracts, MTAs, DUAs, or subcontracts/subawards? NOTE: Subawards are identified by the OSP Assigned Number with a three digit suffix (e.g., 000500000-001).

☐ Yes ☑ No Will the project receive non-monetary support (i.e., drugs, devices, services, etc.) from another entity?

9. PROSPECTIVE

In

☐ Yes ☑ No * Drugs/Dietary Supplements

☐ Yes ☑ No * Biologics

☐ Yes ☑ No * Radiopharmaceuticals

☐ Yes ☑ No * Medical Devices

☐ Yes ☑ No * In-vivo imaging, image guided interventions (e.g., CT, PET/CT, MRI, PET/MRI, x-ray, DEXA, fluoroscopy, nuclear imaging, ultrasound) or radiation therapy

☐ Yes ☑ No Is this a multi-site study?

☑ Yes ☐ No Does the study involve access, review, or disclosure of Protected Health Information (PHI) ?

☑ Yes ☐ No Does the study involve randomization?

Include the risks and benefits of randomization in the consent form.

☐ Yes ☑ No Does the study require clinical services at any of these sites?

☐ Yes ☐ No Will this study involve direct interaction with participants who have an infectious disease?

Target Accrual Information

200 Approximately how many subjects will need to undergo screening procedures to determine whether they qualify to be enrolled? Enter 0 if not applicable. NOTE: This number is an approximation based on previously completed projects.

100 How many subjects do you intend to enroll at UAB? Enter 0 if not applicable.

Describe how the screening and enrollment numbers above are determined (e.g., provide a power analysis, explain the pilot data, or reference prior studies.

Participants screening and enrollment numbers comprise groups who will undergo each of two similar training paradigms. One of these paradigms makes the edges of the scotoma more visible to the participant. Pilot data indicate that 30 participants in each group should be sufficient to see effects between the groups. More participants are expected to be enrolled because of attrition or poor data quality due to decreased ability for people with macular degeneration to keep their eyes

steady during testing.

What are the target age range(s) of the potential subjects with which you will interact?

1. <18 ☐
2. 18-89 ☑
3. >=90 ☐

Indicate which of the following populations you will be **targeting** (enrolling, interacting, or intervening with) for your study. Select all that apply.

☐ Cognitively impaired adults

☐ Economically or educationally disadvantaged

☑ UAB employees

☐ Fellows

☐ Individuals with Limited English Proficiency (LEP) or non-English speakers. Recruitment of study with LEP or non-English speakers is generally required, if the study holds the prospect of a direct therapeutic benefit to the participant.

☐ Individuals of specific racial, religious, or ethnic groups

☐ Individuals living outside the 50 US states

☐ Pediatric and neonates

☑ Patients (This includes existing patients)

☐ Persons who are institutionalized

☐ Pregnant women or fetuses

☐ Prisoners

☐ Medical Residents

☐ Study Staff or investigators named on this application

☐ Students

☑ Others

Describe.

Participants with macular degeneration, especially age-related macular degeneration will be targeted for this study.

☐ None of the above, not targeting specific populations

How will the study team identify potential subjects? Select all that apply.

☐ Non-UAB physicians ☑ Non targeted/unknown (e.g., chart review) ☐ Other

If chart reviews will be used to identify potential subjects that are not your own patients, request a partial waiver of HIPAA Authorization for the purpose of identifying individuals for recruitment.

*Describe participant inclusion/exclusion criteria, including sex, race/ethnicity, age, and health status.

Inclusion criteria for MD patients are: (1) diagnosis of late stage MD, (2) Presence of bilateral scotoma near the fovea (3) Severely impaired vision in both eyes (20/100 or worse), (4) Medical record review indicating this level of disease severity has been present for at least 2 years, (5) aged 18-89. These inclusion criteria ensure patients will have considerable central vision loss and rely on peripheral vision for everyday activities. Exclusion criteria are (1) comorbidity with cognitive pathologies, (2) bilateral retinal scotomas larger than 20° diameter. No inclusion or exclusion criteria on sex or race/ethnicity.

Describe the estimated time commitment of each subject. Examples: 1) One hour once a week for 52 consecutive weeks; 2) Twenty minutes to complete a one-time survey; 3) One interview lasting 60 minutes. Enter "N/A" if participants are not directly involved.

Participating in this study will require about 9 visits total. The first visit is for retinal testing, like at your optometrist or ophthalmologist's office. This should take around 1.5 hours. Three visits are for vision testing, one at the beginning, one after training, and one long term follow-up after two months. These visits should take around 1 hour, and not more than 1.5 hours. The remaining five training visits should be about 1.5 - 2 hours each.

☑ Yes ☐ No * Will a Certificate of Confidentiality be obtained from the NIH?

NOTE: Specific language must be added to the informed consent document and approved by the NIH. In addition, the consent documents must not be filed in the medical record.

What recruitment materials/methods will be used to recruit subjects. Select all that apply.

☑ Flyer

Where will the flyer be distributed?

Local ophthalmologists will be asked to distribute flyers to patients who meet study criteria. The flyer will also be distributed around local clinics, businesses, support groups, and labs in the downtown Birmingham area surrounding UAB.

☑ Internet posting/website

Website URL (Note: if your study is posted on clinicaltrials.gov, you do not need to include the URL)

posting of the flyer to social media such as facebook, instagram, and twitter.

☐ ResearchMatch

☐ Subject pool/repository

☐ Printed brochure

☐ Letter to healthcare providers

☐ Letter to potential subjects

☐ Printed ad

☐ Radio/TV ad

☐ Email solicitations

☐ Direct subject contact

☑ Electronic Medical Record query using i2b2, Electronic Data Warehouse, or IMPACT

Describe.

Dr. Jason Vice, Ph.D at the UAB Callahan Eye Hospital. will also assist in recruitment by supervising review of the NextGen EHR system for the purpose of reviewing potential participants for this study who are identified using ICD-10 diagnostic criteria matching persons with macular degeneration and/or central vision loss.

☐ Other

*Describe all activities to identify and recruit prospective participants.

Potential participants will be recruited through flyers. Local ophthalmologists will be asked to distribute flyers to patients who meet study criteria. Those flyers instruct potential participants to contact our lab by phone, email, or by going to our website. Local Ophthalmologists who will be approached to assist in recruitment by offering flyers in their waiting rooms are: Retinal Specialists of Alabama, LLC of 2208 University Blvd. Drs. Morris, Sapp and Oltmanns, who specialize in macular degeneration.

In addition, Key personnel Dr. DeCarlo, as a clinician within the Ophthalmology department at UAB, sees patients who may be eligible for this study. In addition to making flyers available to potential participants who are in her waiting room, Dr. DeCarlo may send a letter (see attached letter) to patients, who would then be called later by study coordinators (who are also key personnel on this project).

If participants are found to be eligible for the study, they will be asked to sign a "Authorization for Use or Disclosure of information" form (see attachment "Authorization for Disclosure"), requesting confirmation of the patient's diagnosis (as having Macular Degeneration, including what etiology, for example, Stargardt's Disease or Age-related Macular Degeneration), as well as year of diagnosis and duration of disease at current severity. This form will be faxed to their retinal physician, who will return this information.

Dr. Jason Vice, Ph.D. will also assist in recruitment by supervising review of the NextGen EHR system for the purpose of reviewing potential participants for this study who are identified using ICD-10 diagnostic criteria matching persons with macular degeneration and/or central vision loss.

Once potential participants are identified by Dr. Jason Vice, the Visscher lab research team, consisting of Dr. Kristina Visscher and Elliot Maxwell, will reach out to them via their preferred method of contact (letters, phone calls, or emails). The content of our initial contact letter is already included in the approved documents.

(For assistance with the development of a Recruitment Plan, please contact CRSP.)

Select the types of data collection tools that will be used in this study. Select all that apply.

☑ Survey/questionnaire(s) (UAB recommends using Qualtrics or RedCap for electronic surveys)

☐ Audio or video recordings

☐ Interview guides/scripts

☐ Subject diaries

☐ Mobile or web application

☐ Electronic Medical Record query using i2b2, Electronic Data Warehouse, or IMPACT

☑ Other

Describe.

Computerized responses to game-like tasks. No identifying information is included.

Clinical Trials

* Select whether this protocol meet the definition of a clinical trial. ◉ Clinical Trial ○ Non-clinical trial

This protocol must be registered on clinicaltrials.gov. Provide the National Clinical Trial (NCT) identifier. not identified yet.

NCT identifiers are **required** for IRB approval of a clinical trial; however, if all other information is complete and accurate, pending NCT identifiers can be obtained in parallel with the IRB's review of the submission.

All key personnel must complete Good Clinical Practices (GCP) training.

Institutional Biosafety Committee (IBC)

☐ Yes ☑ No * Does this project involve gene transfer, recombinant DNA, or CAR T cells?

11. LOCATIONS

In

☑ UAB Hospital

☐ The Kirklin Clinic of UAB Hospital

☑ UAB Callahan Eye Hospital

☐ Children's of Alabama (CoA)

☐ Jefferson County Department of Health (JCDH)

☐ UAB Hospital - Highlands

☐ The Kirklin Clinic at Acton Road

☐ UAB Clinical Research Unit

☐ Jefferson County Department of Health (JCDH)

☐ Other (i.e., any performance site not listed above, including those covered by subawards related to this protocol)

☐ Yes ☑ No * Is this a field study?

18. PATIENTS

☐ Yes ☑ No * Will the investigators (any investigator listed as key personnel) be recruiting their own patients?

19. EMPLOYEES AND STUDENTS

Provide the rationale for inclusion of students and/or employees.

Because UAB is the largest employer in Alabama, there may be some people with Macular Degeneration who are UAB employees or students. Students or employees of study PIs or study staff will not be enrolled.

What safeguards are in place to ensure students/employees are not coerced into participation.

Students/employees of the study PI and study staff will not be enrolled.

☐ Yes ☑ No * Will students and staff that work under or are students of key personnel on the project be included in the study?

25. COST AND PAYMENT

Cost, Reimbursement, or Compensation

☐ Yes ☑ No * Will subjects (or their insurance providers) experience costs associated with any of the procedures, drugs, biologics, devices, tests, or any aspect of their participation in the study?

☑ Yes ☐ No * Will subjects receive any reimbursement or compensation for their participation (compensation should not be an amount that could be considered coercive or create undue influence)?

Select whether participants will receive payment and/or reimbursement.

☑ Payment

Provide the payment details, including amount, frequency of payment (e.g., $20 at visits one, two, and three), and the method of payment (e.g., cash, check, direct deposit, etc.).

$250 at the completion of the study. Method will be check or gift card. If participant does not complete the study they will be paid $10 per hour that they performed the study.

NOTE: If subjects are being paid for their participation (not reimbursed for study-related expenses) in an amount of $600 or more in a single calendar year, their information will be reported to the IRS in accordance with federal requirements. This must be clearly stated in the informed consent form.

☐ Reimbursement

26. RISKS

Risks and Risk Minimization

Determine any anticipated risks or potential discomforts experienced by subjects for this study. Select all that apply.

☐ Physical risks (e.g., pain, bruising, and infection associated with venipuncture, adverse reactions to drugs, muscle soreness and pain as a consequence of exercise testing, heart attack induced by maximal exercise test, radiation risk (e.g., x-ray, CT scan, radiation therapy, radioisotopes, fluoroscopy))

☐ Psychological risks (e.g., depression and confusion as a result of administration of drugs, feelings of guilt precipitated by a sensitive survey)

☑ Social risks (e.g., invasion of privacy, breach of confidentiality, loss of community standing)

Provide details of the risks, including expected frequency and severity.

Breach of Confidentiality: As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk. frequency is low, severity is relatively low, as few details are known.

Describe any steps taken to mitigate the expected risks.

All data are saved with code numbers not names. Anything that could identify the participant (e.g. address for check mailing, etc) is kept behind two locks.

☐ Economic risks (e.g., loss of employment, loss of potential monetary gain)

☑ Other risks

Provide details of the risks, including expected frequency and severity.

Expected freqency of all risks below is very minimal. Severity could be minimal to moderate.

Psychological stress during training, cognitive tests or questionnaires: You will be asked to complete vision, thinking and memory tasks that might be difficult. You might feel frustrated or uncomfortable during these tasks. Understand that the tests are designed to challenge people.

You will also be asked to complete questionnaires that ask questions about your feelings, behaviors, and medical history. Some of the questions may deal with issues that make you feel uncomfortable or cause you to feel stress. You do not have to answer a question that makes you feel uncomfortable.

Study staff will be available to answer any questions.

Phone Interviews: There is a risk the questions may make you uncomfortable. If this occurs, you can refuse to answer the question.

Retinal Testing visit: The risks and discomforts associated with the retinal testing are the same as those associated with having a standard eye examination. You may be surprised at the very brief light flash during the vision testing. However, the staff member administering the test will tell you when the test is about to begin. The drops used to dilate your eyes may cause brief minor discomfort in your eyes (for example, burning, tingling, or watering), which typically goes away within 5 to 30 seconds.

Describe any steps taken to mitigate the expected risks.

Participants will be assured that they never have to answer questions that make them feel uncomfortable. Staff members administering eye drops will warn participants about the drops and help with eye wash if needed.

Indicate how safety is being monitored in this study.

☐ Data Safety Monitoring Board (DSMB)

☐ Independent medical monitor

☑ Data will be monitored by PI.

Describe how safety will be monitored locally and, if this is a multi-center study, how data and safety will be monitored across sites. Additionally, describe how often data will be monitored. If the only risk is breach of confidentiality, descrbe the method of monitoring for breaches.

Data will be stored on a secure Redcap database. A list of participants names (that does not link them with personal health information) will be kept in a password-protected, encrypted file, behind the UAB Hospital firewall. This list is necessary to identify whether an individual has previously participated in a given segment of the study. Vision testing data will be identified by a study code number only. This coded data will be kept on a password and firewall protected database. This research data will be accessible only to inves??gators involved in the study. Only coded information with a subject number will be given to collaborators or made available for NIH-mandated data sharing. Data breaches are monitored by the systems used and the PI is notified if breaches occur.
In case of any event that causes a participant to withdraw from the study, or study staff is aware of any discomfort, study staff and PIs will discuss the event. If an adverse event occurs, IRB staff will be notified within 48 hours.

☐ Data will not be monitored.

27. BENEFITS

What are the potential benefit(s) of the study (e.g., benefits to society, increased knowledge of the particular disease, increased scientific knowledge, etc.)?

There are no direct benefits to participants. The only possible benefit to them would be the altruistic knowledge that their participation is helping to further understanding of the deficits underlying macular degeneration, and the effects of training on behavioral performance of macular degeneration patients. The benefit of the research to the larger would is to better understand the effects of training on macular degeneration patients. This will hopefully lead to better treatments and therapies for the disorder.

28. PRIVACY AND CONFIDENTIALITY

Select the identifiers.

☑ Names

☑ All geographical subdivisions smaller than a state, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000

☑ All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older

☑ Phone Numbers

☐ Fax Numbers

☑ Email Addresses

If you are a member of a HIPAA covered entity, electronic correspondence with research participants may require a HIPAA-compliant platform, such as encrypted email. Contact your Information Security team for additional information: UAB IT at DSO-RiskMgt@uab.edu or UABHS HSIS at infosec@uabmc.edu.

☐ Social Security Numbers

☐ Medical Record Numbers

☐ Health plan beneficiary numbers

☐ Account numbers

☐ Certificate/license numbers

☐ Vehicle identifiers and serial numbers, including license plate numbers

☐ Device identifiers and serial numbers

☐ Web universal resource locators (URLs)

☐ Internet protocol (IP) addresses

☐ Biometric identifiers, including finger and voice prints

☐ Full face photographic images and any comparable images

☐ Any other unique identifying number, characteristic, or code

☑ Medical history

☐ Surgical history

☐ Laboratory results

☐ Other

Provide the length of time the identifiers will be stored or retained.

The identifiers will be stored indefinitely. The length of the study is 5 years.

Describe how data will be collected, recorded, and shared, including the specific safeguards to protect the confidentiality of data. Select all that apply.

☐ Working with an entity outside of UAB to collect, record, share, or otherwise utilize the data.

☑ Data will be stored in REDCap.

☐ Data will be stored in ShareFile

☐ Data will be kept on a UAB encrypted device (i.e., computer, tablet, etc.).

☐ Data will be stored on a UAB encrypted server.

☑ Data will be stored in the UAB Cheaha Supercomputer

☑ Data will be recorded on paper.

Where will the paper records be stored?

in locked drawers in a locked office in the visscher laboratory.

☑ Data will be coded.

☑ Yes ☐ No * Will a key to the code be maintained?

Who will have access to the key?

Dr. Visscher and study coordinator

☑ Data will be kept in a locked office/filing cabinet.

What is the location of the office/filing cabinet?

in a locked office in the visscher laboratory.

☐ Data will be stored on a password protected computer/drive not maintained by UAB.

☐ Data will be stored in a location not described above.

☐ Data will NOT be coded.

Describe the plan to destroy the subject identifiers at the earliest opportunity consistent with the conduct of research, unless retention is required for reasons of health, research, or law (including the methods that will be used to discard data at the end of the study life cycle). NOTE: Research records must be retained and subsequently discarded in accordance with applicable regulatory guidelines.

HIPAA Authorization

Indicate whether you will obtain HIPAA Authorization, a HIPAA waiver, whether the data meet the specifications for a Limited Data Set, or whether the study does not involve access, review, or disclosure of Protected Health Information (PHI). Select all that apply.

☑ Request for partial HIPAA waiver for recruitment/screening purposes.

Indicate which identifiers will be included *under the request for partial HIPAA waiver* for recruitment/screening purposes.

☑ All geographical subdivisions smaller than a state, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.

☑ All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older

☑ Phone numbers

☐ Fax numbers

☑ Email addresses

If you are a member of a HIPAA covered entity, electronic correspondence with research participants may require a HIPAA-compliant platform, such as encrypted email. Contact your Information Security team for additional information: UAB IT at DSO-RiskMgt@uab.edu or UABHS HSIS at infosec@uabmc.edu.

☐ Social Security numbers

☐ Medical record numbers

☐ Health plan beneficiary numbers

☐ Account numbers

☐ Certificate/license numbers

☐ Vehicle identifiers and serial numbers, including license plate numbers

☐ Device identifiers and serial numbers

☐ Web universal resource locators (URLs)

☐ Internet protocol (IP) addresses

☐ Biometric identifiers, including finger and voice prints

☐ Full face photographic images and any comparable images

☐ Any other unique identifying number, characteristic, or code

☑ Medical history with no other identifiers or PHI

☐ Surgical history with no other identifiers or PHI

☐ Laboratory results with no other identifiers or PHI

☐ Other

☑ HIPAA Authorization will be obtained for some or all of the subjects.

NOTE: Ensure the appropriate HIPAA authorization language has been added to the consent form.

All * Will HIPAA authorization be obtained from all or some of the subjects?

☑ Yes ☐ No * Will the study team ensure HIPAA authorization is obtained in a private setting?

☑ Request for HIPAA waiver for some or all of the subjects (e.g., for retrospective review of PHI, and/or to review PHI for recruitment purposes and obtain HIPAA authorization during enrollment)

Explain why the study could not practicably be conducted without access to and use of the PHI.

Interested potential participants will undergo a telephone screening to determine study eligibility; the telephone screen includes obtaining some PHI. It would not be feasible for the study team to obtain signed informed consent on all interested individuals prior to screening.

All * Is the waiver for some or all of the subjects?

☐ The data meet the specifications for a limited data set. NOTE: A limited data set will only apply if you receive data from an outside source as a limited data set or if you are sending data to an outside source as a limited data set (in which case, documentation of authorization or a Waiver of Authorization will be required). A Data Use Agreement (DUA) is required for this option.

HIPAA Covered Entities

Indicate which of the entities would provide health information for this protocol, maintain health information as it was collected for this protocol, and/or store health information after it has been collected for this protocol.

☐ UAB Hospital or UAB Hospital - Highlands

☐ The Kirklin Clinic of UAB Hospital or Acton Road (and/or associated clinics)

☑ UAB Callahan Eye Hospital

☐ Children's of Alabama

☐ Jefferson County Department of Health

☐ School of Dentistry

☐ School of Health Professions

☑ School of Medicine

☐ School of Nursing

☐ School of Optometry

☐ University of Alabama Health Services Foundation

☐ Valley Foundation

☐ Medical West - UAB Health System Affiliate

☐ Birmingham Veteran's Affairs Medical Center

☐ Yes ☑ No Is the principal investigator requesting that the UAB IRB waive patient HIPAA authorization from another institution or entity (e.g., insurance company, collaborating institution)?

29. CONSENT

Informed Consent

Indicate all that apply to the informed consent process.

☑ Informed consent with written documentation will be obtained from all or some of the subjects.

Select all types of consent forms that will be used.

Consent Form Types	Description of Document (50 words or less)	Clean Copy	Tracked Copy
Main Consent 1	Consent form with revisions		

All * Will written informed consent be obtained from all or some of the subjects?

Describe how written informed consent will be obtained, including confirmation that a copy of the signed consent document will be given to the individual who will

sign it.

Written informed consent will be obtained in person by the study coordinator at the participant's first appointment. The participant will receive a copy of the signed consent form and initial the lab copy of the consent form stating that a copy was of the signed consent was received.

Describe how the study team will ensure the subjects understand the information presented.

Potential participants will be sent the consent form by email, fax, or mail depending on the convenient preference of the potential participant. Their preference is determined by discussion over the phone during the phone screening that takes place after those interested in participating in the study have called the lab after viewing the flyer, or when we call them after they have expressed interest and left a message with us. After having at least 24 hours to review it, they will be contacted by phone, screened, and scheduled to come in for the first visit. At the first visit, they will meet with one of the study staff who is trained on appropriate policies and procedures and has gone through online NIH HIPAA training, to go over any questions about the protocol and give informed consent. Consenting of the participants will take place in private by the research staff that is experienced at administering the consent process.

What language will the prospective participant understand?

English

What language will be used to obtain consent?

English

☐ Yes ☑ No Will any potential participants be, or have been, in a stressful, painful, or drugged condition before or during the consent process?

☐ Request a Waiver of Documentation of Informed Consent (e.g., subject may not sign an informed consent document, but will be given an information sheet)

☐ Request a Waiver or Alteration of some or all elements of informed consent or a FULL waiver of informed consent.

31. ATTACHMENTS

Attachments

Document Name	Document Type	Description of Document (50 words or less)	Clean Copy	Tracked Copy	
Telephone Script	Consent/Assent Document (CF, AF, Info Sheet, Phone Script, etc.)	Telephone script and screening			
Email Script	Participant Communications	email script for sending with consent form			
Flyer	Participant Communications	Flyer for participant recruitment			
Recruitment Letter	Participant Communications	recruitment letter, from clinician.			
Protocol Oversight Review Form	IRB Submission Form	PORF			
Other Relevant Documents	Consent/Assent Document (CF, AF, Info Sheet, Phone Script, etc.)	Authorization of disclosure			
Other Relevant Documents	Other	Permission Letter for EMR Use			
Response Memorandum	Other	Response 07/10/24			

Updated By: Denise H Ball @ 12-Aug-2024 12:30:58 AM

Statistical Analysis plan, see next page.

Section 1 - Basic Information (Study 1)

1.1. * Study Title (each study title must be unique)

New methods to quantify and train eye movement strategies in macular degeneration

1.2. * Is this study exempt from Federal Regulations? ❍Yes ●No

1.3. Exemption Number ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8

1.4. * Clinical Trial Questionnaire

1.4.a. Does the study involve human participants?	●Yes	❍No
1.4.b. Are the participants prospectively assigned to an intervention?	●Yes	❍No
1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?	●Yes	❍No
1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?	●Yes	❍No

1.5. Provide the ClinicalTrials.gov Identifier (e.g. NCT87654321) for this trial, if applicable

Section 2 - Study Population Characteristics

2.1. Conditions or Focus of Study

❍ The goal the study is to test the efficacy of the 'Scotoma awareness' intervention in Macular Degeneration patients using a simulated scotoma training protocol that showed evidence of rapid development of PRL in healthy participants trained with visible,

2.2. Eligibility Criteria

MD participants will be recruited through the Center for Low Vision at the UAB Department of Ophthalmology and Dr. DeCarlo (see letter of support and biosketch) and patients who participated in our previous studies. Dr. DeCarlo is a recognized expert in low-vision rehabilitation, keeps a database of patients who are interested in participating in research, and has successfully recruited patients for Dr. Visscher's laboratory. Inclusion criteria for Macular Degeneration (MD) patients are: (1) Severely impaired vision in both eyes (20/100 or worse), (2) diagnosis of MD, (3) Light sensitivity in macular retina that is at least 10 dB units worse than in peripheral regions, as demonstrated by a scanning laser ophthalmoscope (SLO, MAIA), (4) Medical record review indicating this level of disease severity has been present for at least 2 years. These inclusion criteria ensure patients will have considerable central vision loss and rely on peripheral vision for everyday activities. Scores on Activities of Daily Vision Scale86 and SF-36 Short Form Health Survey87 will assess degree to which participants engage in standard everyday activities. Age-related MD (including geographic atrophy as well as neovascular forms) is the most common cause of macular disease, though other forms (including Stargardt's Disease) also occur.

2.3. Age Limits	Min Age:	18 Years	Max Age:	89 Years
2.3.a Inclusion of Individuals Across the Lifespan	Inclusionlifespan1011898764.pdf			
2.4. Inclusion of Women and Minorities	InclusionofWomenandMinorities1011898762.pdf			
2.5. Recruitment and Retention Plan	Recruitment_and_Retention1011898732.pdf			
2.6. Recruitment Status	Not yet recruiting			
2.7. Study Timeline	Timeline1011898767.pdf			
2.8. Enrollment of First Participant	05/01/2022	Anticipated		

Inclusion Enrollment Reports

Entry#	Enrollment Location Type	Enrollment Location
IER 1	Domestic	Birmingham, AL

Section 3 - Protection and Monitoring Plans

3.1. Protection of Human Subjects

Human_SubjectsStudy21011898884.pdf

3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site? ❍ Yes ● No ❍ N/A

If yes, describe the single IRB plan

3.3. Data and Safety Monitoring Plan

Data_and_Safety_Monitoring1011898734.pdf

3.4. Will a Data and Safety Monitoring Board be appointed for this study?

❍ Yes ● No

3.5. Overall Structure of the Study Team

Overall_Structure_of_the_Study_Team1011898885.pdf

Section 4 - Protocol Synopsis

4.1. Study Design
4.1.a Detailed Description
MD Participants: Participants will be recruited through the Center for Low Vision at the UAB Department of Ophthalmology. Participants will be compensated $10/h for their participation. At the beginning of the study, we will obtain consent as well as demographic variables (age, education, SES), health variables (chronic disease, medications, blood pressure, BMI). MD participants will be randomly assigned into one of two training conditions (scotoma awareness' or control). 8 participants will be assigned to each group.

Phase 1 - Baseline Testing - A battery of baseline and post-tests is designed to evaluate learning associated with each of the factors listed below:

PRL evaluation – In order to measure both general and location-specific effects on the intervention (see below), individual PRLs for each participant will be measured before training and baseline assessment. This procedure is common to both Vision Science studies using artificial scotoma and clinical interventions using microperimetry. Key personnel occupational therapist Jason Vice will provide expertise in determining the PRL before and after the intervention.

Quantification of oculomotor metrics - We employ a task in which each trial begins with participants fixating a target presented in the center of the screen with their individual PRL for 500-1500ms. In case of participants with an underdeveloped or absent PRL, they will be simply asked to fixate the target in a way that will make it entirely visible (e.g., not partially covered by the scotoma). A 2-degree white circle target (flickering at 2hz; 250ms on 250ms off) will then appear in a random location. The task is to press a button when the circle reappears with the color red (rather than white), which will randomly occur 2-4 seconds after the first appearance of the circle, for 80 trials to ensure a larger number of eye-movements per participant.

MNread - In this task participants read out loud a series of short sentences for which the font size decreases progressively, sentence by sentence, until the font is too small for the participant to successfully read the text (a measure of visual acuity). Additionally, average reading speed and critical print size, the text dimension at which reading speed begins to decrease, are computed as measures of behavioral proficiency.

Trail-Making Task - While reading involves a known trajectory of eye movements, in the trail-making task, which requires connecting a sequence of consecutive target letters and numbers, participants must do a visual search for the location of the next letter or number in the sequence. In addition to the standard measure of time to completion, we can also look at the number of saccades required, and saccade accuracy.

Visual sensitivity Charts: Standard Visual acuity (ETDRS) and Contrast sensitivity (Robson-Pelli) charts.

Phase 2 – Training: Participants will be assigned to one of two conditions: 'scotoma awareness' or control. In the 'scotoma awareness' training, patients will perform visual search and orientation discrimination tasks while an opaque occluder, custom-tailored to overlap each patient's retinal scotoma, is constantly presented on the computer screen. In the control group, the task will be performed without the visible scotoma. In each trial, participants will be asked to locate the target and perform an emotion recognition task (identify whether the emoji face is 'happy' or 'sad'). The size and contrast of the target will change adaptively depending on the participant's performance. The training will consist of 10 sessions (two per visit), and each session will be composed by 4 blocks of 100 trials each. To optimize learning gain, the two daily sessions will be separated by a period of quiet rest, which has been shown to improve learning consolidation. Participants will be tested on a series of baseline assessments (visual acuity, contrast sensitivity, reading speed, visual crowding, see below) before and after training, alongside our oculomotor metrics from Experiment 1.

Phase 3 – Post training Behavioral and oculomotor Testing This will be the same as the baseline testing.

Phase 4 – Long term follow-up. This will be the same as the baseline testing but will be conducted 2 months after training is completed.
4.1.b. Primary Purpose Basic Science
4.1.c. Interventions

Type	Name	Description
Behavioral (e.g., Psychotherapy, Lifestyle Counseling)	Condition 1 – 'Scotoma awareness' Training	Participants will be asked to report the emotion of an emoji face ('happy' vs 'sad') that could appear anywhere on screen. For the entire duration of the training, an explicit, sharp outlined occluder surrounding the participant's true retinal scotoma will be rendered on screen. This occluder will be generated through a gaze-contingent display. The size and the contrast of the target will change adaptively in response to the patient's

		performance.
Behavioral (e.g., Psychotherapy, Lifestyle Counseling)	Condition 2 – Control Training	In the control condition, participants will perform the same task as the scotoma awareness training, without the artificial visible scotoma.

4.1.d. Study Phase
Is this an NIH-defined Phase III Clinical Trial?

Early Phase 1 (or Phase 0)

❍ Yes ● No

4.1.e. Intervention Model

Parallel

4.1.f. Masking

● Yes ❍ No

❑ Participant ❑ Care Provider ❑ Investigator ■ Outcomes Assessor

4.1.g. Allocation

Randomized

4.2. Outcome Measures

Type	Name	Time Frame	Brief Description
Primary	Visual Acuity	baseline, post-test, follow-up test	measured on EDTRS chart
Primary	Fixation stability	baseline, post-test, follow-up test	Dispersion of fixation locations averaged across trials for the PRL (expressed as the BCEA of the dispersion).
Primary	Saccadic re-referencing	baseline, post-test, follow-up test	Proportion of trials with first fixation using PRL (expressed as a % of the total number of trials).
Secondary	First saccade landing dispersio	baseline, post-test, follow-up test	The dispersion of the end point of the first saccade (expressed as the BCEA of the dispersion).
Secondary	Latency of target acquisition	baseline, post-test, follow-up test	The mean time until target is visible outside scotoma (expressed in seconds).
Secondary	Saccadic precision	baseline, post-test, follow-up test	The dispersion of the end point of the saccade that puts the target outside scotoma (expressed as the BCEA of the dispersion).
Secondary	Percentage of trials that are useful	baseline, post-test, follow-up test	How often participants place the target outside of the scotoma (% of dots in Saccadic precision relative to total trials).
Secondary	MNREAD	baseline, post-test, follow-up test	For the MNREAD test we will primarily rely upon reading speed and minimal print size (a secondary measure of acuity.
Secondary	Trailmaking B	baseline, post-test, follow-up test	We will look at time-to-complete the Trail Making B subtest
Secondary	Contrast Sensitivity	baseline, post-test, follow-up test	Measured via Robson-Pelli charts

4.3. Statistical Design and Power

Statistical_Design_and_Power1011898886.pdf

4.4. Subject Participation Duration

6-8 weeks

4.5. Will the study use an FDA-regulated intervention?

❍ Yes ● No

4.5.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status

4.6 Is this an applicable clinical trial under FDAAA?

❍ Yes ● No