BROOKS® Rehabilitation

TITLE	Assessing the Impact of eSight Go At-Home Usage in Individuals with Visual Impairment
SHORT TITLE	eSight
PROTOCOL NO.	00085670
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Brief Overview

The purpose of the study is to assess the effect of the updated version of Gentex's device, eSight Go, an image-enhancing wearable device to assist those with vision impairment. The study will comprise at least 50 vision impaired individuals to evaluate the efficacy or improvements in visual, quality of life, and mobility arising from the use of eSight Go. The primary aim of the study is to measure the effect of eSight Go on visual acuity, reading performance, and quality of life. The secondary aim is to measure the impact of eSight Go on mobility, balance, cybersickness, and user satisfaction. The study assessments will take place at the Brooks Rehabilitation Clinical Research Center at 4 time points:

1) at visit 1 before using the device;
2) during visit 1, while using the device;
3) at visit 2, while using the device; and,
4) during visit 2 without the device.

Participants will receive a personal eSight device and comprehensive training on its operation at visit 1. They will then use the unit in daily living, such as home, work, or school settings, over a period of 4 weeks, and then return for visit 2. If prescription lenses are determined to be needed to correct refractive error, visit 1 will be divided into 2 visits to allow time for the lenses to be ordered prior to starting the at-home trial period.

Section 1: Procedures

1.1 Screening/Recruitment Procedures

Potential participants may be identified by healthcare staff who are part of their normal clinical care or research staff. Potential participants may also hear about the study by word of mouth or by their ophthalmologist.

1.1.1 Inclusion/Exclusion Criteria

Inclusion Criteria

- Aged 18 to 90.
- Best-corrected visual acuity between 20/50 to 20/400 in the better eye.
- Subjects who have been diagnosed with an ocular condition causing visual impairment
- Have a functional binocular field of view of at least 20 degrees.
- Visual status stable for at least six months.
- Demonstrate visual benefit from magnification.
- Agree to wear the eSight Go in a variety of situations in the home and community.
- Score ≥ 20 on the Short Orientation-Memory-Concentration Test of Cognitive Impairment (OMCT).
- Subject must be able to provide an informed consent
- Subject must agree to use eSight Eyewear only under conditions that will not jeopardize the safety of either the user or the device.

Exclusion Criteria

- Participant must not be currently undergoing any medical or surgical procedures resulting in unstable vision.

- Participants who have undergone cataract, refractive, or other surgical procedures related to vision in the six-month period prior to study enrollment.
- Severe (>20/400) visual impairment in the better seeing eye.
- Cognitive limitations (< 20 on OMCT).
- Participants who have undergone any vision-related injections (e.g. anti-VEGF) in the two-month period prior to the study because of active bleeding in the retina. Ongoing anti-VEGF treatments are permitted if the participant is in a "Treat and Extend" or pro re nata ("PRN") disease management, and macula is dry.
- Participants are unable or unwilling to adhere to the examination schedules as they are described in the study protocol. This may also include participants already enrolled, who for whatever reason, have become unable or unwilling to continue the study. This may also include participants for whom the travel time to/from the study site is unacceptable.
- Participants who self-report a history of alcoholism, drug abuse, or psychosis.
- Participants who exhibit clinical evidence of depression, poor motivation, emotional or intellectual problems, or any other conditions which would likely limit validity of consent or appropriate responses to participate in the study or who are deemed unsuitable psychologically or physiologically for study participation by the investigator.
- Participants who may have a conflict of interest with eSight Corp, which could reasonably influence their participation in the study.
- Refractive error outside the range correctable by lens inserts in the device (> +/-8.00 D sph or -4.00 cyl)

1.2 Informed Consent Process

Informed consent will be obtained by approved study staff in a quiet area to allow for answering all questions.

- Participants must be able to provide consent
    - Must give accurate yes/no responses
- This study does not allow consent to be provided by a legally authorized representative (LAR)

1.3 Assessments

Participants will complete assessments four times, twice at visit 1 and twice at visit 2, except for the OMCT and the refraction which will only be performed once at visit 1.

Study Timeline

5/2025	5/2025-4/2026			5/2026-7/2026
Open enrollment	Visit 1	4 Weeks At Home Usage	Visit 2	Complete Analysis, Study Close Out

Assessments will include the following procedures:

Primary Aim Assessments (Visual)

- Early Treatment Diabetic Retinopathy Study Chart (ETDRS)
- MNREAD
- MARS Test
- NEI VFQ-25
- Reading Behavior Inventory
- Refraction Test

Secondary Aim Assessments (Mobility & Cognitive)

- Dynamic Gait Index
- Timed Up and Go
- Spaciotemporal Gait Kinematics
- OMCT
- PROMIS Short Form v2.0 - Cognitive Function 8a

Questionnaires

- Demographic information
- Ophthalmic History
- 36-Item Short Form Health Survey
- Cybersickness in Virtual Reality
- Device Usage Willingness and Participation
- Activities Balance Confidence Scale

1.4 Intervention

Participants will take the device home for 4 weeks to use in daily living, such as the home and community settings. There will be regular follow-up phone calls once per week from a member of the research team (e.g., an occupational therapist, or low vision therapist) who is familiar with the device to assist with possible troubleshooting as well as device use strategies. The follow up calls will also collect information about device use time and activities. The device will be returned at visit 2.

1.5 Data Analysis

Data will be captured during all assessments. Data will be compared against normative values, when available and change scores from pre- to post-testing will be calculated for absolute differences. Continuous data will be compared pre- to post-testing using independent samples t-tests. Ordinal data, including all questionnaires, will be evaluated using a Mann-Whitney U test.

Section 2: Risk Information

2.1 Risks, Side Effects, and/or Discomforts

There are minimal risks to participating in this study. There is a minimal risk of visual or physical discomfort during the vision tests (though these tests are similar to standard vision testing). Participants might become uncomfortable or dizzy while using the device. We will do everything we can to ensure comfort, and the tests will be stopped if there is discomfort.

There is also the possibility of loss of confidentiality. All information will be stored within HIPAA compliant computers that are protected and deemed safe for university/hospital researcher data storage. We will not be sharing your data for anything other than reviewing the results for this study. We will also remove any identifying information from your information used for analysis of the computer program.

There is a mild risk of falls during any balance, gait, or mobility assessments. There will be a licensed PT supervising all mobility tasks and will assist to prevent a fall. If necessary, there is an overhead, body-weight support device that may be utilized for additional protection.

While we believe the risk of injury during this study is minimal, please be advised that Brooks Rehabilitation will manage the participant's care consistent with the management of all treatment-related adverse events. The participant's insurance will be responsible for any medical cost including deductibles, co-insurance, or co-payments. Any injury requiring medical care will be reported to the Institutional Review Board providing oversight of this study.

2.2 Alternatives to Participation

This study is for research purposes only. The alternative is to not participate in this study. By choosing not to participate, your care will not be altered in any way.

2.3 Cost

There is no monetary compensation for participation in this study. We will provide a travel reimbursement for enrolled participants of $25 per visit, up to $50 per participant. This will be paid to the participant in the form of a Visa gift card.

Section 3: Monitoring/Reporting of AE/SAE

Records of participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. The Investigator, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records. This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, they will be de-identified.

Participant vitals and visual and physical comfort will be monitored by study staff throughout the assessments. Participants will self-report any visual or physical discomfort during the weekly check ins with a study team member. Any abnormal or adverse responses to utilizing the device will be reported to the study physician who will provide medical recommendations for proceeding or terminating use of the device. Repeated and unresolved abnormal responses will result in withdrawal from the study under the advisement of the study physician. All adverse events will be tracked and reported to the IRB, primary investigator, and study physician.

Section 4: Study Oversight

Dr. Katelyn Jordan, who has been practicing for 12 years and participating in research for 10 years, will serve as the principal investigator and maintain administrative oversight of this study, ensuring compliance with this protocol, related policies and procedures of Brooks Rehabilitation, and relevant rules and regulations. Collection, recording, and reporting of data will be accurate and will ensure the privacy, health and welfare of participants. All study documents and procedures will be made available for monitoring, auditing, IRB review and regulatory inspection as required by the IRB and/or by law. The study will be discontinued if the principal investigator, the Brooks Center for Low Vision, or the IRB determines necessary. The principal investigator will promptly inform the IRB and provide the reason(s) for the termination or suspension of the study. Circumstances that may warrant termination include, but are not limited to:

- Determination of unexpected, significant or unacceptable risks to participants.
- Insufficient adherence to protocol requirements.
- Data that are not sufficiently complete and/or evaluable.
- Determination of futility.

The principal investigator may terminate a participants' participation in the study if:

- Any situation occurs such that continued participation in the study would not be in the best interest of the participant.

Section 5: Data Management

Data will be collected and stored on a HIPAA-compliant, encrypted, password-protected server at Brooks Rehabilitation that is only accessible to Brooks Rehabilitation Clinical Research Center or Brooks Center for Low vision authorized personnel. Paper copies will be kept in a locked storage cabinet within the Brooks Rehabilitation Clinical Research Center.