

Exploring the benefits of wearable electronic vision enhancement systems for people with age-related loss of central vision

Submission date 29/03/2023	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 30/03/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/09/2025	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

This study aims to determine the usefulness of wearable electronic vision enhancement systems (wEVES) for individuals with vision impairment caused by age-related macular degeneration (AMD). Wearable electronic vision enhancement systems (wEVES) were developed in the 1990s to provide hands-free magnification for people with vision impairment. wEVES consist of a camera to capture images which are then displayed on screens set close to the eye. Users can then use the device to magnify and enhance images over a range of different distances. The study will examine whether wEVES can help users complete tasks more efficiently. Also, it will assess the impact of wEVES on quality of life and cost-effectiveness compared to other solutions.

Who can participate?

The study will invite adults with AMD causing most of their sight loss to participate, but those who fail a memory test, cannot speak English or have a balance-affecting disease will be ineligible. As some aspects of the study will be conducted over the phone, participants who cannot use the telephone due to hearing loss will also be excluded.

What does the study involve?

At the beginning of the trial, we will check the participants' low vision aids and spectacles to make sure they are up to date. Their ability to read letters and words will then be measured with and without the wEVES. Participants will use the wEVES for 8 weeks out of a 16-week trial, with randomisation to receive it either at the start or at week 9.

A questionnaire will be used to understand how challenging and important 48 everyday activities are for the participants. The activities have been chosen as they are common problems for people with sight loss, such as reading, crossing the road, and watching TV. The questionnaire will be completed at the start of the study and repeated at weeks 8 and 16. We will then measure how the wEVES affected the participants' difficulty in completing activities and their preferred solution to carry out a task.

What are the possible benefits and risks of participating?

This trial will allow participants to test one of the latest types of wEVES in activities they choose, helping them understand if the device can support them with problems arising from their sight loss. At the end of the trial, the purchased devices will be given away to trial participants. Previous research has shown that adverse effects from wEVES are typically minor, such as motion sickness that goes away once the device is removed. Participants will be monitored for adverse effects through follow-up welfare calls and a dedicated questionnaire and are free to leave the trial at any time.

Where is the study run from?
Anglia Ruskin University (UK)

When is the study starting and how long is it expected to run for?
January 2023 to May 2024

Who is funding the study?
The Macular Society (UK)

Who is the main contact?
Andrew Miller, adm157@pgr.aru.ac.uk (UK)

Contact information

Type(s)

Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

ETH2223-3787

Study information

Scientific Title

Exploring the benefits of wearable electronic vision enhancement systems for people with age-related macular degeneration. A randomised crossover trial.

Study objectives

Compared with conventional low-vision solutions, wearable electronic vision enhancement systems (wEVES) will:

Hypothesis 1: Be the preferred solution and be used more often than existing solutions.

Hypothesis 2: Reduce self-reported activity limitation.

Hypothesis 3: Be more versatile, allowing use for tasks without a current solution.

Hypothesis 4: Improve Vision Related Quality of Life (VRQoL)

Hypothesis 5: Be a cost-effective solution in improving the QoL for people with AMD

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 16/02/2023, Faculty of Science and Engineering Research Ethics Panel (Anglia Ruskin University, East Road, Cambridge, CB1 1PT, UK; +44 (0)1245 493 131; research.ethics@aru.ac.uk), ref: ETH2223-3787

Study design

A 16-week prospective two-arm randomized crossover trial with no masking to the active treatment and concurrent control of participants' prescribed and purchased low-vision devices

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

People with age-related macular degeneration as the principal cause of vision impairment.

Interventions

This is a 16-week crossover study to assess the effect of adding a wearable electronic vision enhancement system (wEVES) to participants' existing prescribed and purchased low-vision solutions. The Eyedaptic Eye5 AR wEVES (<https://eyedaptic.com/eye5/>) will be used by participants for 8 weeks of the 16-week study. Participants will be randomised using a web-based random plan generator into an additional treatment group and an active standard treatment concurrent control group and receive the two interventions using an AB/BA crossover design.

Group A: 8-week home trial with wEVES plus existing conventional low-vision devices followed by an 8-week follow-up with conventional low-vision devices only.

Group B: 8-week existing conventional low-vision devices (waiting list) followed by an 8-week home trial with wEVES plus existing low-vision devices.

Spectacles and low vision aids will be optimised at a single initial low vision clinic visit by an optometrist with higher qualifications in low vision. At this visit readings of clinical vision function will be taken with spectacles and again with the wEVES. Training protocols have been developed and time to achieve these goals will be recorded.

Questionnaires will be used to assess activity limitations and adverse effects, delivered in a face-to-face interview at the participant's home. To reduce the question load, quality-of-life questionnaires will be delivered over the phone prior to the home visits. All interventions will be carried out individually using a standardised script by the same qualified optometrist with higher qualifications in low vision. Assessments will be made at baseline, at 8 weeks and again at 16 weeks.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Eyedaptic Eye5

Primary outcome(s)

The following primary outcome measurements will be taken at baseline, week 8 and week 16:

1. Activity limitation, task importance, and the participants' preferred solution measured using The Veterans Affairs Low Vision Visual Functioning Questionnaire (VA LV VFQ-48)
2. Vision-related quality of life measured using the Vision-related quality of life Core Measure (VCM1)
3. Vision-related utility instrument assessing gains in health-related quality of life measured using the Vision and Quality of Life Index (VisQoL)

Key secondary outcome(s)

1. Adverse effects of the wearable electronic vision enhancement system (wEVES) measured using the Virtual Reality sickness questionnaire (VRSQ) at baseline, week 8 and week 16.

2. Participants' willingness to pay and qualitative thoughts about the device's strengths and weaknesses will be measured using a bespoke questionnaire at week 16

Completion date

31/05/2024

Eligibility

Key inclusion criteria

1. People who are aged 18 years or over
2. Vision loss primarily due to AMD and affects their daily life
3. Able to undertake assessments in English
4. Pass on the short form Mini-mental State Evaluation (MMSE: adapted for vision loss).
5. Not a current wEVES user

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

34

Key exclusion criteria

1. Under 18 years of age
2. Other forms of maculopathy or significant causes of vision impairment
3. Reported significant deterioration in vision in the two months before entry
4. Planned curative ocular surgery (e.g. cataract operation) in the study time
5. Balance-related disorders
6. Hearing loss significant enough to affect answering telephone questions

Date of first enrolment

01/04/2023

Date of final enrolment

29/02/2024

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Anglia Ruskin University Optometry Clinic

East Road

Cambridge

United Kingdom

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Sponsor information

Organisation

Macular Society

ROR

<https://ror.org/02j172648>

Funder(s)

Funder type

Charity

Funder Name

Macular Society

Alternative Name(s)

Macular Disease Society, The Macular Society

Funding Body Type

Government organisation

Funding Body Subtype

Associations and societies (private and public)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and analysed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/09/2025	04/09/2025	Yes	No
Other publications	Qualitative results	24/01/2025	04/09/2025	Yes	No
Participant information sheet	version 1.1	23/01/2023	30/03/2023	No	Yes
Protocol (other)		23/03/2023	30/03/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes