ISRCTN16865847 https://doi.org/10.1186/ISRCTN16865847

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	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/03/2023	**Overall study status** Completed	
Last Edited 12/01/2024	**Condition category** Eye Diseases	

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)

Study website
https://doi.org/10.25411/aru.22325182.v1

Contact information

Type(s)
Principal Investigator

Contact name
Mr Andrew Miller

ORCID ID
http://orcid.org/0000-0001-7811-0152

Contact details
Anglia Ruskin University
Coslett 306
East Road
Cambridge
United Kingdom
CB1 1PT
+44 (0)7423 297410
adm157@pgr.aru.ac.uk

Type(s)
Scientific

Contact name
Prof Keziah Latham

ORCID ID
http://orcid.org/0000-0002-4060-0006

Contact details
Anglia Ruskin University
Coslett 306
East Road
Cambridge
United Kingdom
CB1 1PT
+44 (0)1223 698536
keziah.latham@aru.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised cross over trial

Study setting(s)
Home, Telephone, University/medical school/dental school

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure
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)

Secondary outcome measures
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

Overall study start date
05/01/2023

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

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
England

United Kingdom

Study participating centre
Anglia Ruskin University Optometry Clinic
East Road
Cambridge
United Kingdom
CB1 1PT

Sponsor information

Organisation
Macular Society

Sponsor details
PO Box 1870
Andover
England
United Kingdom
SP10 9AD
+44 (0)1264 350 551
info@macularsociety.org

Sponsor type
Charity

Website

https://www.macularsociety.org/

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/03/2025

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?
Participant information sheet	version 1.1	23/01/2023	30/03/2023	No	Yes
Protocol (other)		23/03/2023	30/03/2023	No	No