PARTICIPANT INFORMATION SHEET

Key Points
In this information sheet you will find details about the study including:

- Who is leading the study.
- What you will be asked to do.
- What information we will collect and how we will look after it.
- The benefits or any risks involved in taking part.
- Who to contact with questions or concerns.
- If you are unhappy how you can complain or withdraw.

If you need this information in a different format, please contact Andrew Miller 07423 297410

Section A: The Research Project

1. **Title of project**
Are wearable Electronic Vision Enhancement Systems (wEVES) a beneficial solution for people with age-related macular degeneration: an interventional study.

2. **Purpose of study**
Wearable Electronic Vision Enhancement Systems are a new and emerging type of aid that has the potential to help people with visual impairment including those with Age-Related Macular Degeneration (AMD). The purpose of this research is to understand how people with macular disease may want to use these devices in their daily life.

The outcomes will help manufacturers, clinicians and other patients understand the types of tasks these devices may be best suited for, as well as the cost-effectiveness of these devices in supporting people with AMD.

3. **Who are the researchers?**
The project team are:
Mr Andrew Miller (Macular Society PhD Scholar ARU): 07423 297410
adm157@pgr.aru.ac.uk
Prof Kez Latham (ARU staff): Keziah.latham@aru.ac.uk, 01223 698536.
Dr Jane Macnaughton (ARU staff)
Dr Michael Crossland: UCL Institute of Ophthalmology, 11-43 Bath Street, London EC1V 9EL

4. **Why have I been asked to participate?**
People who are aged 18 years or over, speak English and have vision loss due to AMD that affects their daily life are being approached to take part in this research.

As this research will be undertaken with face-to-face clinic and home visits, we recommend that people with a suppressed immune system that puts them at increased risk of COVID-19 do not take part in this research project.

5. **How many people will be asked to participate?**
Approximately 50 people will be asked to participate.

6. **Do I have to take part?**
No - you can refuse to take part without giving a reason and can withdraw from the study at any point. Taking part in the study is entirely voluntary.

7. **Has the study got ethical approval?**
Yes, the study has approval from the Faculty Research Ethics Panel (FREP) of Anglia Ruskin University.

8. **Source of funding for the research, if applicable**
The study has been funded by a Macular Society scholarship.

9. **What will happen to the results of the study?**
The research will be written up to be published in PhD thesis, journals and presented at conferences.

10. **Contact for further information**
Mr Andrew Miller (Macular Society PhD Scholar ARU):
adm157@pgr.aru.ac.uk 07423 297410
Prof. Kez Latham (ARU staff): Keziah.latham@aru.ac.uk, 01223 698536.

Section B: Your Participation in the Research Project

1. **What will I be asked to do?**

The research takes the form of a 16 week trial split into two sections of 8 weeks. For part of the study you will be given a wearable Electronic Vision Enhancement System (wearable electronic magnifier). You will be trained in how to use the device and asked to use the device at home. You will be asked for information about when you use the device, your opinions compared to your existing aids, as well as any adverse effects you may have noticed.

The initial appointment will take place at:
Focus Birmingham Low Vision Centre; 62 Woodville Road, Harborne, Birmingham, B17 9AT 0121 393 4849.
Follow up support and interviews will be by pre-arranged appointment over the phone and in your home.

The Low Vision Centre follows all the appropriate infection control procedures for a healthcare setting advised by the College of Optometrists.

The study will last 16 weeks and consist of:

- One low vision assessment; this will take approximately 90minutes and involves:
    - A check to ensure you have appropriate magnifying aids.
    - Help to ensure you can use your existing low vision solutions.
    - An introduction to the wearable magnifier and basic training in its use.
    - Assessing your ability to read letters on a chart that get progressively smaller (distance visual acuity).
    - Assessing your ability to read words on a reading chart that get progressively smaller (reading acuity).
    - Assessing your ability to see contrast by reading letters that get progressively fainter (contrast sensitivity).
- 3 home check-ups to deliver further training, swap over the device and complete an activity questionnaire. This questionnaire will ask you to think about what solutions you use and how much help you need to complete some simple daily tasks. This will take approximately 60 minutes and rest breaks can be taken at any time, as desired.
  The completion of the questionnaire will be audio recorded and transcribed. This information will help us understand how different

people are using the devices and what solutions they find preferable for different tasks.

- Between 3-6 phone call training check-ups depending on your needs, to answer any questions you have and to help you get the best from any devices that you use.
- 2 phone calls to ask you questions about any changes you have noticed in the quality of your daily life due to the new device. This interview will take approximately 30 minutes.

2. **Who owns and is responsible for the devices?**
   The wearable electronic magnifiers are owned and insured by the university. Whilst we ask you to take care of the devices you are **NOT** responsible for any financial costs should the device break or be stolen whilst in your care.

3. **In relation to this specific research project, we need to make you aware of the following:**

☐	We do not need your personal data at any stage of this research project		
We are responsible for the personal data you give to us as a:			
x	**Data Controller** (We are in sole control over the research)	Who are we? ARU	Mr Andrew Miller Prof. Kez Latham Dr Jane Macnaughton Dr Michael Crossland
☐	**Joint Controller** (Where ARU and another organisation are working together on research)	with:	
☐	**Data Processor** (Where the data will belong to another organisation and ARU is being engaged under contract/agreement to conduct the research and provide an outcome but has no rights over the personal data)	on behalf of:	

3. **I will be asking you for the following information:**

Personal Data				Sensitive Personal data	
Yes	Name/Contact details	No	Image (Photo or video)	Yes	Racial/Ethnicity data
Yes	Age	Yes	Experiences	No	Political/Religious beliefs
Yes	Address/location data	Yes	Opinions	No	Trade Union membership
No	Employment & Earnings	☐	[Other]	No	Genetic/Biometric data
No	ID Numbers(e.g. NHS)	☐	[Other]	Yes	Health
No	Online identifier	☐	[Other]	No	Sex life/orientation data

We do not intend to collect data held about participants from existing records.

4. **What will happen to your data?**
Your data will be pseudo-anonymised. Pseudo-anonymisation means that identifiable information, such as people's names, will be removed from the data and a code will be assigned. The data will, however, still be able to be linked together by the researcher should this be required.

The research data will be processed in the UK. Processing of any personal data will comply with UK law.

The data that is gathered from you will be securely held. It will be shared in pseudo-anonymised format between the members of the research team outlined in Section A of this document.

The activity interview will be audio-recorded and then transcribed to help us analyse the data. This data will also be securely held on a computer in pseudo-anonymised format and will be deleted when the PhD project is complete.

Care will be taken to adapt or omit quotes so that the information cannot be used to identify the contributors. Quotes will be attributed to broad demographic characteristics only, e.g. participant 5, a 75 year old male.

Data will be retained until the PhD has been completed and published, following which it will be securely deleted.

5. **Will I be reimbursed for travel expenses?**
No, we are not able to reimburse travel expenses.

6. **Is the research part of Focus Birmingham?**
No, the research is being conducted by the team at Anglia Ruskin University. Focus Birmingham is kindly providing rooms to conduct the initial research. Your care at Focus Birmingham will not be affected in any way if you chose not to take part in this research or withdraw whilst the research is underway.

7. **Will I receive any payment to take part in the research?**
No.

8. **Are there any possible disadvantages or risks to taking part?**
Studies show that these wearable magnifiers are safe and cause no long-term risks to the eyes.

Some people do report symptoms of mild seasickness, dizziness or headache whilst wearing the devices. These symptoms tend to resolve quickly after the removal of the device. If you are suffering from intense motion sickness or another disease that severely affects your balance, such as Ménière's disease, then this study is not suitable for you.

The wearable devices obscure part of the field of view and change how far away objects may appear to be. **We would strongly advise that they are not used for operating machinery or tasks where you are required to move around whilst wearing the device.**

If you see a significant benefit from any of the devices demonstrated and would like to continue to use one, they are not funded by the NHS.

Agreement to participate in the study does not affect the participant's legal rights.

9. **What are the likely benefits of taking part?**
You will be able to try on and experience some of the latest wearable low-vision devices and be able to see and understand how these work for you.

It is hoped that the study will produce useful information that can help practitioners, patients and manufacturers better understand the views of people with AMD regarding these devices.

At the end of the study the devices will be given away to participants who felt they were beneficial. Unfortunately, there will not be enough devices for everyone, and successful participants will be selected by a random draw. Successful participants will be asked if they would complete follow up interviews 3 months and 6 months after receiving the devices.

10. **Can I withdraw at any time, and how do I do this?**

Participants can withdraw from the study at any time without giving a reason. You can tell the researcher that you would no longer like to take part in the study. You can also contact Andrew Miller, the lead researcher, by email: adm157@pgr.aru.ac.uk or by phone 07423 297410.

If you withdraw from the study, we will ask you if we may have permission to use the data collected up to that point. If you agree, we will use any data collected. If you disagree, all data collected will be withdrawn from the study.

The last date that you can withdraw from the study will be 31st January 2024. After that point, data will have been analysed before publication.

11. **What will happen to my data?**

Our general privacy notice explaining our use of your personal data for research purposes is available here:

https://www.aru.ac.uk/privacy-and-cookies/research-participants

Please visit this link for information about how long we keep your data, how we keep your data secure, how you can exercise your rights over your data, and make a complaint over our use of your data.

12. **Can I withdraw my data from the study?**

I will be able to remove your data up to the point when I start to analyse it, which will be approximately 31st January 2024

13. **Are there any special precautions you must take before, during or after taking part in the study?**

If you suffer from, intense motion sickness, this study is not suitable for you.

14. **Will the researchers pass my answers and information on to anyone else?**

No. Your pseudo-anonymised data will only be available to the named members of the research team.

15. **Summary of research findings**

During the study appointment, we will ask if you would like to be sent a summary of the research findings when complete and will note the format you wish to be sent the findings. This will be sent once the project is complete.

16. **Contact details for complaints**

If participants have any complaints about the study, please speak to Professor Kez Latham (Keziah.latham@aru.ac.uk; 01223 698536) in the first instance. The contact details for ARU's complaints procedure are:
Email address: complaints@aru.ac.uk
Postal address: Office of the Secretary and Clerk, ARU, Bishop Hall Lane, Chelmsford, Essex, CM1 1SQ.

PARTICIPANTS SHOULD BE GIVEN A COPY OF THIS TO KEEP,
TOGETHER WITH A COPY OF THE CONSENT FORM (v1.1 23.01.2023)