Effect of head-mounted displays on the ability of individuals with poor eye sight to see and read

Submission date	Recruitment status No longer recruiting	Prospectively registered		
14/01/2015		☐ Protocol		
Registration date 08/07/2015	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
19/04/2021	Eve Diseases			

Plain English summary of protocol

Background and study aims

Conditions that affect sight are more likely to result in partial blindness than in total loss of sight; the ratio of people with low vision to blindness is 10 to 1 in Europe according to the World Health Organization. The most common cause of blindness in the west is age-related macular degeneration, a condition that affects the central area of vision but not the peripheral (side) vision. Most people with visual impairment need some kind of vision aid to make best use of their residual vision. This aid can be an optical magnifier or, for stronger magnification and better field of view, an electronic magnifier connected to a computer monitor. These head-mounted displays (HMDs) are comprised of one or two small screens (monocular or binocular) placed close to the eyes, with lenses that make the display appear at a comfortable viewing distance. The screens can be opaque, like conventional monitors, or transparent. This study aims to gain further knowledge of the usefulness of HMDs for people who are partly sighted and compare two available models.

Who can participate? Adults with partial sight.

What does the study involve?

Participants are allocated to one of two groups. Those in group 1 (intervention) wear the Epson Moverio BT-200 HMD. Those in group 2 (intervention) wear the Oculus Rift HMD. All participants wear the HMDs for around 45 minutes during the study, and ability to see the display and speed of reading is assessed.

What are the possible benefits and risks of participating? The benefits are improvement in the ability to see and read.

Where is the study run from? Princess Alexandra Eye Pavilion (UK)

When is the study starting and how long is it expected to run for? September 2014 to June 2016

Who is funding the study? Heriot-Watt University (UK)

Who is the main contact?

1. Mr H Moshtael (scientific)

2. Dr L Fu (public)

lfu@doctors.org.uk

Contact information

Type(s)

Scientific

Contact name

Mr Howard Moshtael

ORCID ID

http://orcid.org/0000-0001-6805-2710

Contact details

Scottish Microelectronics Centre, Kings Buildings West Mains Road Edinburgh United Kingdom EH9 3JF

Type(s)

Public

Contact name

Dr Lana Fu

ORCID ID

http://orcid.org/0000-0003-1959-9749

Contact details

Princess Alexandra Eye Pavilion, 45 Chalmers Street Edinburgh United Kingdom EH3 9HA +44 (0)1315361772 Ifu@doctors.org.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2

Study information

Scientific Title

Effect of head-mounted displays on the ability of patients with macular disease to see and read: a pilot study

Study objectives

- 1. To gather data on the ability of patients with age-related macular disease to see and read from two head-mounted displays (HMDs); the results will inform the development of techniques to modify the presentation of text on the display in order to enhance patients' reading ability.
- 2. A pilot trial will measure the extent to which patients can see the displays and their ability to read from them.
- 3. A subsequent main trial will then test the efficacy of these techniques.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Health Research Authority, 07/01/2015, ref: 14/EM/1322

Study design

Single centre interventional study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

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

Macular disease, particularly age-related macular degeneration

Interventions

The usefulness of the two kinds of HMDs for people with a central scotoma will be investigated:

- 1. Epson Moverio BT-200, a transparent glasses-like HMD.
- 2. Oculus Rift, an opaque and immersive HMD.

Intervention Type

Device

Primary outcome measure

Extent to which patients can see the display, measured with a perimetry-style test.

Secondary outcome measures

Reading speed will be measured using the Radner reading chart at baseline, to be compared with reading speed using the head-mounted display.

Overall study start date

01/09/2014

Completion date

24/06/2016

Eligibility

Key inclusion criteria

- 1. Macular disease, including Stargardt's macular dystrophy and age-related macular degeneration
- 2. Not undergoing active treatment
- 3. Able to provide consent

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

10

Total final enrolment

10

Key exclusion criteria

- 1. Undergoing intravitreal therapy
- 2. Does not have mental capacity to consent or comply with the trial protocol

Date of first enrolment

02/02/2015

Date of final enrolment

20/03/2015

Locations

Countries of recruitment

Scotland

United Kingdom

Study participating centre
Princess Alexandra Eye Pavilion
Edinburgh
United Kingdom
EH3 9HA

Sponsor information

Organisation

Heriot-Watt University

Sponsor details

Edinburgh Campus Edinburgh Scotland United Kingdom EH14 4AS +44 (0)131 449 5111 enquiries@hw.ac.uk

Sponsor type

University/education

Website

www.hw.ac.uk

ROR

https://ror.org/04mghma93

Funder(s)

Funder type

University/education

Funder Name

Heriot-Watt University (UK)

Results and Publications

Publication and dissemination plan

We intend to publish an article on the pilot trial during summer 2015.

2017 results published in thesis: https://www.ros.hw.ac.uk/handle/10399/3411?show=full (added 25/03/2021)

Intention to publish date

01/06/2015

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details results	Date created	Date added	Peer reviewed?	Patient-facing?
Book results		04/06/2016	22/03/2021	No	No
Results article		01/12/2019	25/03/2021	Yes	No
HRA research summary			28/06/2023	No	No