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2	Benefit of an electronic head-mounted Low Vision Aid
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4	Michael D. Crossland <sup>1</sup> , Sandra D. Starke <sup>2,3</sup> , Piotr Imielski <sup>3</sup> , James S. Wolffsohn <sup>4</sup> , Andrew R. Webster <sup>1</sup>
5	
6	<sup>1</sup> NIHR Biomedical Research Centre for Ophthalmology at Moorfields Eye Hospital and UCL Institute
7	of Ophthalmology, London, UK
8	<sup>2</sup> School of Engineering, University of Birmingham, Birmingham, UK
9	<sup>3</sup> GiveVision, Birmingham, UK
10	<sup>4</sup> Aston University, Birmingham, UK
11	
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16	Correspondence to:
17	Michael Crossland
18	Department of Optometry
19	Moorfields Eye Hospital NHS Foundation Trust
20	162 City Road
21	London
22	EC1V 2PD
23	UK
24	Email: mcrossland@nhs.net
25	

## 26 DISCLOSURE

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- 30

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- 34 necessarily those of Moorfields Eye Hospital, the National Institute for Health Research or the
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- 36

38 ABSTRACT

39

40 **Purpose:** To evaluate the efficacy of electronic head-mounted Low Vision Aid (ehLVA) SightPlus
41 (GiveVision, UK) and to determine which people with low vision would see themselves likely using an
42 ehLVA like this.

43 Methods: Sixty participants with Low Vision aged 18 to 93 used SightPlus during an in-clinic study 44 session using a mixed methods design. Visual acuity (ETDRS), contrast sensitivity (Pelli Robson) and 45 reading performance (MNREAD) were measured binocularly at baseline (no device), with the device 46 in 'normal' mode (zoom only), and with preferred enhanced mode (zoom and one out of four digital 47 image enhancements). At the end of the session, a short questionnaire recorded willingness to use an ehLVA like SightPlus, potential use cases, positive/negative comments and adverse effects. 48 49 Results: Binocular distance visual acuity improved significantly by 0.63 logMAR on average 50 (p<0.0001) to 0.20 logMAR. Contrast sensitivity improved significantly by 0.22 log units (p<0.0001) to 51 1.21 log units with zoom only and by 0.40 log units to 1.37 log units with zoom and preferred image 52 enhancement. Reading performance improved significantly for near visual acuity and critical print 53 size (p<0.015), however reading speed significantly decreased (p<0.0001). Nearly half (47%) of the 54 participants indicated they would use an ehLVA like SightPlus, especially for television, reading and 55 entertainment (e.g. theatre). Multivariate logistic regression showed that proportion of lifetime 56 affected, baseline contrast sensitivity and use of electronic LVAs explained 41% of the variation in 57 willingness to use.

58 Conclusions: SightPlus improves visual function in people with low vision and would be used in its 59 current form by half of the people who tried it. Adverse effects were rare and resolved when the 60 device was removed. Future work should focus on comparing ehLVAs through repeatable real-world 61 tasks and impact on quality of life.

#### 63 Introduction

64 Electronic head-mounted Low Vision Aids (ehLVAs) have experienced a technological step change over the last decade.<sup>12</sup> A 2017 review of head-mounted displays for people with low vision 65 66 highlighted the advantages of such technology over conventional desk-mounted or handheld sight 67 aids.<sup>3</sup> Since early commercial devices such as the Low Vision Enhancement System were first produced in the 1990s,<sup>4</sup> advances in consumer technology have led to the availability of smaller, 68 69 lighter, more versatile ehLVAs, including SightPlus (GiveVision, Birmingham, UK), eSight (eSight 70 Corporation, Toronto, ON, Canada), IrisVision (IrisVision Global, Pleasanton, CA, USA), OxSight 71 (OxSight Ltd, Oxford, UK) the new JORDY (Enhanced Vision Services, Huntington Beach, CA, USA), 72 with several other devices being developed. <sup>5-8</sup> SightPlus is a commercially available ehLVA and 73 registered as a Class I medical device. It is designed around a smartphone (serving as a camera, 74 image processor and display) inserted into a virtual reality (VR) headset serving as the optical 75 system. To date, clinical evidence for the efficacy of VR-and-smartphone-based ehLVAs such as 76 SightPlus is lacking.

77

78 Modern ehLVAs can embed digital sight enhancement algorithms that have been proven effective in laboratory settings for decades.<sup>9-16</sup> A 2015 review of 37 research papers highlighted the benefit of 79 80 various image processing techniques for the visually impaired, albeit with inconsistent preferences 81 between people.<sup>1</sup> A more recent review of ehLVAs illustrated existing strategies to sight enhancement and showed improvements in contrast sensitivity.<sup>2</sup> However, to date, only two studies 82 83 have been published demonstrating efficacy of wearables across substantial patient numbers: one for the eSight ehLVA device,<sup>17</sup> and one for Orcam, a spectacle mounted text-to-speech system.<sup>18</sup> The 84 eSight study showed improvements in visual acuity, contrast sensitivity, reading performance and 85 86 functional vision in a self-selected group of 51 adults who had demonstrated motivation to wear the 87 device. Data are lacking for people unaware of ehLVAs or for a more general population of people 88 with visual impairment.

In this study, we evaluated the performance of SightPlus (GiveVision, Birmingham, UK; Figure 1).
This device was chosen as it was commercially available in the United Kingdom, was relatively
affordable, and there were anecdotal reports of significant visual benefits associated with this
device. We hypothesised that acuity, contrast sensitivity and reading speed would improve similarly
to a different ehLVA using different technology (eSight). We anticipated that poorer baseline acuity
and familiarity with electronic low vision aids would predict willingness to use the device.



## 

98 Figure 1. The SightPlus device, with its wireless remote control.



Benefit of a head-mounted augmented reality sight enhancement aid for people with low vision.



Benefit of a head-mounted augmented reality sight enhancement aid for people with low vision. C





Benefit of a head-mounted augmented reality sight enhancement aid for people with low vision. d





- 101 Figure 2. Text and a pictorial scene as displayed through five different modes offered by SightPlus.
- 102 a. Reference image; b. Normal mode, c. Enhanced mode, d. Contrast mode, e. Inverted mode, f. Text
- 103 mode.
- 104

- 105 Materials and Methods
- 106
- 107 Ethics
- 108 Ethical approval for the study was obtained from the Health Research Authority (IRAS number
- 109 237229), and local approval was obtained from the North Thames Clinical Research Network.
- 110 Participants gave written informed consent after the purpose of the study was explained and prior
- 111 to any data collection.
- 112
- 113 Participants

Sixty participants were recruited from low vision and medical retina clinics at Moorfields Eye Hospital. This clinic is in a tertiary centre with a relatively high proportion of younger patients with inherited retinal disease.<sup>19</sup> All participants met the definition of visual impairment suggested by Leat: having best monocular or binocular visual acuity of worse than 6/7.5, horizontal visual field of less than 146 degrees to Goldmann III4e targets, or contrast sensitivity worse than 1.5 log units.<sup>20</sup> All were over 18 years of age, fluent in written and spoken English and able to hear and understand instructions whilst wearing the device.

121

122 Materials

123 SightPlus offers proprietary sight enhancement software through a smartphone (S8, Samsung, South 124 Korea) mounted in a virtual reality headset (Prime, Homido, France), controlled through a handheld 125 Bluetooth remote control. The device weighs 465g. The smartphone has a total screen resolution of 126 2960 x 1440 pixels (approximately half width used per eye) and presents a digital image on an 127 AMOLED screen. The headset's lenses provide an approximately 110 degree diagonal (80 degree 128 horizontal) field of view, while the software offers approximately 0.7x to 24.3x magnification (38x 129 relative zoom). Brightness, exposure, blue light filter and inter-pupillary distance are customisable. 130 SightPlus has five image enhancement modes (Figure 2), each of which modifies the whole image: 131 'Normal mode' shows a full colour video feed. 'Enhanced mode' enables subtle feature 132 enhancement by modulating selected spatial frequency components, resulting in sharper edges and 133 smoother colours. 'Contrast mode' offers strong edge enhancement. 'Inverted mode' displays an 134 inverted greyscale image, rendering white as black and vice versa. 'Text mode' offers a binary image 135 (default: yellow on black) based on edge detection and thresholding, making it most suitable for 136 reading.

137

138 Procedure

139 Data collection was performed following a low vision assessment conducted as part of a routine low 140 vision clinic assessment by the first author. As part of this initial assessment, baseline visual acuity 141 was measured binocularly with best refractive correction on a retro illuminated distance logMAR 142 chart (Lighthouse Series ETDRS chart, Precision Vision, Woodstock, IL, USA). Letter-by-letter scoring 143 was used and participants were encouraged to guess until no letters were correctly identified on a 144 line. Where no letters were read at 4m, the chart was moved to 2 metres, 1 metre, and 50cm. If no letters were identified from 50cm, hand movements and perception of light was used. Contrast 145 146 sensitivity was measured using a Pelli-Robson chart at 1 metre (Precision Vision, Woodstock, IL, USA) 147 with the triplet being scored as read correctly when two of three letters were read. Reading 148 performance (near visual acuity, critical print size, reading speed) was measured using the iPad version of the MNREAD test (Regents of the University of Minnesota, Minneapolis, MN, USA).<sup>21</sup> 149 150 Visual field data were extracted from the participant's medical records. Those with loss only within 151 the central 15 degrees were classified as having central loss, those with loss only beyond 15 degrees 152 as peripheral loss, those with loss in both regions as mixed, and without field loss as no field loss.

153

154 During the study session, each participant wore SightPlus for approximately 10-15 minutes under 155 the supervision of the first author. Interpupillary distance of the device was adjusted optically and in 156 software to ensure there was no diplopia and participants were allowed to become comfortable 157 with its controls. All image enhancement modes were demonstrated. Once the participant was 158 comfortable with the device and its controls, visual acuity, contrast sensitivity and reading 159 performance were then assessed with the device: first in normal mode, and subsequently in the 160 preferred image enhancement mode. Free choice of enhancement mode was allowed to explore the 161 best-case scenario achievable with SightPlus; time constraints did not allow a systematic assessment 162 of all modes. Participants were able to use a freely chosen zoom level for a given task. Data 163 collection was terminated if participants self-reported nausea or any other unpleasant effects 164 preventing them from continuing the session or if they expressed the wish to withdraw.

165

## 166 Statistical analysis: efficacy

A repeated measures ANOVA was performed to compare between baseline, normal mode and
 preferred enhanced mode for distance visual acuity, contrast sensitivity and reading performance
 metrics (near visual acuity, critical print size and reading speed). In case of significance, pairwise
 post-hoc tests with Bonferroni correction were conducted.

171

#### 172 Statistical analysis: willingness to use device

173 Willingness to use an ehLVA like SightPlus was assessed against the following 15 individual predictor

variables through sub-group analysis: *demographic factors* (age, gender, work status (working, not

175 working), current use of electronic magnifiers (yes, no)); disease factors (progressive or stable, time

since diagnosis, percentage lifetime with sight loss); visual metrics (type of visual field loss (central,

177 visual, peripheral, mixed, none) as well as baseline, difference and end point in normal mode for

binocular visual acuity and binocular contrast sensitivity. For continuous variables, an independent t-

test was performed, with 'would use' as the grouping variable. For nominal data, a X<sup>2</sup> test was

180 performed. Stepwise multivariate regression was performed using the same demographic, disease

and visual factors.

182

183 *Qualitative analysis* 

184 At the end of the session, a semi-structured questionnaire was administered, where each participant

- 185 was asked four of the following five questions:
- 186 1. 'Would you be willing to use a device like this?'
- 187 2. (If response to question 1 is 'yes'): 'what would you use it for?';
- 188 3. (If reponse to question 1 is 'no'): 'why not?'
- 189 4. 'What are the strengths of the device at present?'
- 190 5. 'What are the weaknesses of the device at present?'

Participants were encouraged to answer each question as fully as possible. Key points were written, and the investigator confirmed the responses with the participant. A grounded theory approach was used for analysis, where responses were coded and grouped into categories. Categories of responses are reported.

195

196 Adverse effects

197 Participants were asked whether they experienced nausea, claustrophobia, headache, eyestrain, or198 any other adverse response.

199

200 Results

201 Mean (SD) participant age was 51.4 (18.7) years. 23 participants (38%) were female. Mean (SD)

visual acuity with both eyes open was 0.82 (0.39) logMAR (6/40; 20/132) with a range of 0.04

logMAR (6/7; 20/22) to hand movements. Eight participants (13%) had no visual field loss, 27 (45%)

had central field loss, 17 (28%) had peripheral field loss, and eight (13%) had both central and

205 peripheral field loss.

206

216

207 Eleven participants had retinitis pigmentosa or Usher syndrome, 11 had other inherited retinal 208 diseases, 11 had inherited macular diseases, 6 had age-related macular disease, 6 had optic neuritis, 209 3 had albinism, 2 had glaucoma, and 2 had diabetic eye disease. One participant had each of optic 210 atrophy, optic neuritis, congenital cataract, aniridia, achromatopsia, paediatric glaucoma, congenital 211 stationary night blindness, chronic central serous retinopathy, and Leber's congenital amaurosis. 212 A. Efficacy 213 214 Visual acuity (Table 1, Figure 3) was significantly different between conditions (F = 223.14, p < 215 0.0001,  $\eta_p^2 = 0.817$ ). Post hoc analysis revealed a significant difference between baseline and normal

mode (p < 0.0001) as well as baseline and preferred enhanced mode (p < 0.0001), but not between

normal and enhanced mode (p = 0.292). Visual acuity improved by a mean (SD) of 0.63 (0.34)
logMAR – more than 6 lines on the sight chart – to 0.20 (0.28) logMAR in normal mode (N = 58) and
by 0.70 (0.32) logMAR – 7 lines – to 0.16 (0.26) logMAR in preferred enhanced mode (N = 51). Visual
acuity improved in all but one participant, achieving 0.2 logMAR or better irrespective of baseline
acuity in 67% of participants.

222

223 Contrast sensitivity (Table 1, Figure 3) was significantly different between conditions (F = 52.45, p < 224 0.0001,  $\eta_p^2 = 0.527$ ). Post hoc analysis revealed a significant difference between all pairwise 225 comparisons (p < 0.0001). Contrast sensitivity improved by a mean (SD) of 0.22 (0.30) log units to 226 1.21 (0.47) log units (6%) in normal mode (N = 55) and by 0.40 (0.31) log units to 1.37 (0.50) log units 227 (4%) in preferred enhanced mode (N = 48).

228

229 For reading performance (Table 1), near visual acuity (Figure 3) was significantly different between conditions (F = 6.07, p = 0.015,  $\eta_p^2$  = 0.155). Post hoc analysis revealed a borderline significant 230 231 difference between baseline and normal (p = 0.051) and preferred enhanced mode (p = 0.049), but 232 not between the two modes (p = 1.000). Near visual acuity improved by a mean (SD) of 0.15 (0.35) 233 logMAR to 0.44 (0.32) logMAR – about font size 9 pt – in normal mode (N = 47) and by 0.16 (0.35) to 234 0.46 (0.31) logMAR in preferred enhanced mode (N = 34). Critical print size was significantly different 235 between conditions (F = 5.87, p = 0.005,  $\eta_p^2$  = 0.168). Post hoc analysis revealed a significant 236 difference between baseline and normal (p = 0.043) and baseline and preferred enhanced mode (p = 0.043) 237 0.028), but not between the two modes (p = 1.000). Critical print size improved by a mean (SD) of 238 0.22 (0.33) logMAR to 0.54 (0.33) – about font size 11 pt – in normal mode (N = 43) and by 0.21 (0.34) logMAR to 0.55 (0.33) in preferred enhanced mode (N = 30). Peak reading speed was 239 significantly different between conditions (F = 11.47, p < 0.0001,  $\eta_p^2$  = 0.283). Post hoc analysis 240 241 revealed a significant difference between baseline and normal (p = 0.002) and preferred enhanced 242 mode (p = 0.007), but not between the two modes (p = 0.604). Peak reading speed fell by a mean

(SD) of 24.98 (30.55) words per minute to 56.02 (37.30) words per minute in normal mode (N = 43)
and by 24.07 (34.16) words per minute to 62.23 (40.56) words per minute in preferred enhanced
mode (N = 30).

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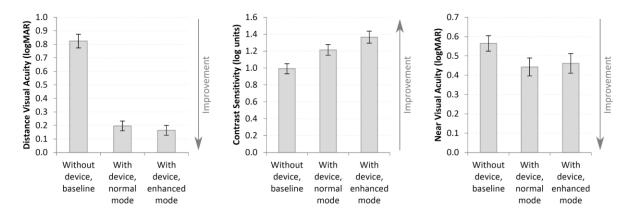
# 247 Table 1. Efficacy metrics.

Outcomes for five efficacy metrics across the three study conditions. Conditions with the same superscript (<sup>a,b</sup>) were significantly different from each other in pairwise post-hoc tests (Bonferroni correction) following a repeated measures ANOVA. Not all participants completed all conditions: for example, some participants were unable to align the device for certain tests, and some participants were unable to read with it. Where participants disliked all enhanced modes, assessment was not performed with the enhanced mode.

254

	No device, baseline		With device, normal mode		With device, preferred enhanced mode	
	Mean (SD)	Ν	Mean (SD)	Ν	Mean (SD)	Ν
Distance Visual Acuity (ETDRS, in logMAR)	0.82 (0.39) <sup>a,b</sup>	59	0.20 (0.28)ª	59	0.16 (0.26) <sup>b</sup>	52
Contrast sensitivity (Pelli- Robson, in log units)	0.99 (0.45)ª	57	1.21 (0.47) ª	56	1.37 (0.50) ª	49
Near Visual Acuity (MNREAD, in logMAR)	0.56 (0.30)	57	0.44 (0.32)	49	0.46 (0.31)	36
Critical Print Size (MNREAD, in logMAR)	0.75 (0.24)	53	0.54 (0.33)	44	0.55 (0.33)	31
Reading Speed (MNREAD, in words/minute)	79.34 (47.82) <sup>a,b</sup>	53	56.02 (37.30)ª	44	62.23 (40.56) <sup>b</sup>	31

255



257

Figure 3. Mean (SE) distance visual acuity, contrast sensitivity and near visual acuity across the three study conditions. 'Enhanced mode' describes the preferred enhanced mode chosen by participants.

260

261 B. Willingness to use ehLVA

A total of 28 participants (47%) indicated that they would use an ehLVA like SightPlus, 27

263 participants (45%) would not and 5 participants (8%) were not sure.

264

265 Examined individually, seven variables had a significant effect on willingness to use an ehLVA like

266 SightPlus (Table 2): age, affected proportion lifetime, baseline contrast sensitivity, difference in

visual acuity with SightPlus (baseline vs. normal mode), history (acquired vs. inherited), use of e-LVAs

268 including smartphones/tablets (yes / no) and work status (working / not working).

269 Multivariate logistic regression resulted in a model with three variables: proportion of lifetime

affected ( $X^2 = 6.4$ , p = 0.012), baseline contrast sensitivity ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs ( $X^2 = 5.6$ , p = 0.018) and use of e-LVAs (

271 13.1, p < 0.001). This model explained 41% of the observed variation (Cox and Snell pseudo R<sup>2</sup> =

272 0.405).

273

274 Table 2. Willingness to use ehLVA vs. individual variables.

275 Predictive power of individual variables for willingness to use an ehLVA like SightPlus. Outcomes of

276 independent t-tests for continuous variables and X<sup>2</sup> tests for categorical variables. Effect size

# 277 calculated as the mean difference between 'yes' and 'no' cohort. \* significant effect with alpha =

278 0.05.

	Would yo	ou use an e	hLVA like S	ightPlus?		
	No		Yes			
Variable	N	Mean (SD)	ean N Mean (mea	Effect size (mean difference)	p-value	
Age (years)	27	58 (20)	28	43 (16)	15	0.003*
Time since diagnosis (years)	27	15 (18)	28	23 (13)	-7	0.082
Proportion lifetime with sight loss (fraction, 0 to 1)	27	0.30 (0.35)	28	0.58 (0.31)	-0.28	0.003*
Binocular VA, baseline (logMAR)	27	0.72 (0.42)	27	0.89 (0.35)	-0.17	0.113
Binocular CS, baseline (log units)	25	1.18 (0.35)	27	0.92 (0.46)	0.25	0.031*
Binocular VA, end point in normal mode (logMAR)	26	0.20 (0.31)	28	0.15 (0.23)	0.05	0.476
Binocular CS, end point in normal mode (log units)	23	1.39 (0.43)	28	1.19 (0.42)	0.19	0.108
Binocular VA, difference in normal mode (logMAR)	26	-0.53 (0.33)	27	-0.74 (0.33)	0.20	0.029*
Binocular CS, difference in normal mode (log units)	23	0.19 (0.30)	27	0.28 (0.30)	-0.09	0.278
	Count A	Count B	Count A	Count B		
Gender (male (A)/ female (B))	16	11	17	11		1.000
History (inherited (A)/ acquired (B))	15	12	25	3		0.007*
Progression (progressive (A)/ stable (B))	20	7	22	6		0.758
Use of e-LVAs (yes (A)/ no (B))	5	22	20	8		<0.001*
Work status (working (A)/ not working (B))						0.015*
Visual field status (central, full, mixed, peripheral)						0.394

279

280 C. Preferred mode

281	A total of 35 participants (58%) preferred the 'normal' mode, ten (17%) preferred 'inverted', three
282	(5%) preferred 'contrast', two preferred 'enhanced' and one preferred 'text'. The remaining seven
283	participants reported that preference depended on the task.
284	
285	D. Qualitative analysis
286	The 33 participants who indicated that they would use an ehLVA like SightPLus or that were not sure
287	reported a total of 20 different activities as envisaged use cases: television (N=14), reading (N=7),
288	theatre (N=6). reading with children (N=3), finding things (N=3), low light conditions (N=3),
289	cinema/films (N=3), school/college (N=3), watching sports (N=2), signs (N=2), faces (N=2), computer
290	(N=2), buses (N=1), board games (N=1), gardening (N=1), needle threading (N=1), seeing packets
291	(N=1), form filling (N=1) and video games (N=1).
292	
293	The most commonly cited strengths of the device were the image clarity (N=10), the image
294	brightness (N=6), the level of zoom (N=5) and its comfort (N=2).
295	
296	The most frequent criticism of the device was its weight (too heavy, N=26), aesthetic appearance
297	(N=14), image movement or image lag (N=12), preference of own magnifiers (N=9) and not being
298	able to walk with the device (N=6). Other reasons included occlusion of the far periphery through
299	the headset (N=5), not finding it helpful (N=4) and disorientation or problems with depth perception
300	(N=4).
301	
302	Adverse reactions
303	Most of the participants did not report any adverse reaction (48 of 60 participants, 80%). Twelve
304	participants (20%) reported a single adverse reaction and none reported multiple adverse reactions.
305	The most frequently reported adverse reactions were nausea (N=4, 7%) and dizziness (N=4, 7%).

306 Three participants experienced a headache with the device and one participant (with a documented

history of dry eye) described "sore eyes". No participants reported claustrophobia or eye strain. In
all cases, symptoms resolved on removal of the headset while participants were in clinic. For six
participants (three with nausea, and one with each of headache, sore eyes and dizziness), reactions
were severe enough for the investigator to terminate the study session early. Data for these
participants until the point of termination were analysed.

312

- 313 Discussion
- 314

315 Summary of findings

316 This study investigated improvements in vision and the willingness to use an ehLVA using SightPlus 317 (GiveVision, UK). SightPlus provided clinically significant and functionally relevant improvements in 318 visual acuity and contrast sensitivity: distance visual acuity improved by more than 6 lines on a 319 logMAR chart, and contrast sensitivity improved by 8 letters with image enhancement. Half of our 320 study population indicated willingness to use the device. Examining predictor variables individually, 321 we found a significant effect for willingness to use an ehLVA for those with younger age, longer 322 proportion of lifetime with visual impairment, lower baseline contrast sensitivity, greater 323 improvement in visual acuity with SightPlus (baseline vs. normal mode), inherited sight loss 324 (compared to acquired sight loss), existing use of electronic LVAs (including smartphones/tablets) 325 and working. Multivariate logistic regression reduced this parameter space to the proportion of 326 lifetime affected, baseline contrast sensitivity and use of electronic LVAs, explaining 41% of the 327 variation in the data. This illustrates that while the examined factors may predict the likelihood of 328 uptake to a degree, factors beyond the scope of this study also play a role. While we anticipated that 329 current use of electronic LVAs would predict willingness to use, we were surprised to find that 330 baseline acuity was not a predictor. This shows that lifestyle and other factors maybe more 331 important for the relevance of ehLVAs.

333 Efficacy

334 Improvements in performance on standard sight tests were similar to those reported for the eSight 335 ehLVA device, which gave a mean (SD) of 0.20 (0.31) logMAR (compared to 0.20 (0.28) logMAR in 336 the present study) and contrast sensitivity of 1.44 (0.44) log units (compared to 1.21 (0.47) log units in normal mode and 1.37 (0.50) log units with preferred enhanced mode in the present study).<sup>17</sup> 337 338 While participants in the eSight trial were self-selected through wanting to use eSight, participants in 339 the present study were a random sample from a low vision clinic. Given the similarity between our 340 results and the eSight study, a prior disposition of wanting to use an ehLVA is unlikely to predict 341 efficacy.

342

For reading performance, we found a smaller positive effect compared to eSight:<sup>17</sup> near visual acuity 343 344 and critical print size improved significantly with SightPlus, albeit to a smaller degree (near visual 345 acuity improved from 0.90 to 0.33 logMAR with eSight and 0.56 to 0.44 logMAR with SightPlus; 346 critical print size improved from 1.08 to 0.59 logMAR for eSight and 0.75 to 0.54 logMAR with 347 SightPlus). While in the eSight study there was no significant effect of the ehLVA on reading speed,<sup>17</sup> 348 we detected a significant decrease in reading speed with SightPlus (from 79 to 56 words per minute 349 in normal mode and to 62 words per minute in preferred enhanced mode). A reduction in reading 350 speed could be explained by reduced visual span, or by image movement. A 2018 review of studies 351 evaluating reading aids for people with low vision found that reading speed may be highest in stand-352 mounted electronic CCTVs compared to optical devices, with further evidence for longer reading durations and better ease of use.<sup>22</sup> Comparing stand-mounted CCTV and head-mounted devices 353 354 (HMDs), the review reported similar performance between the two: for HMDs, on average 66 words 355 per minute and near visual acuity of 0.92 logMAR; for CCTVs, 3.1 words per minute more for reading 356 speed and 0.05 logMAR more for near visual acuity. It is important to note that near visual acuity for 357 the ehLVAs reported here substantially exceeded those outcomes. Despite the reduced speed in our 358 study, several participants indicated that they would choose to use SightPlus for reading, perhaps

because of the increased working distance, comprehension or comfort of reading, none of which weassessed.

361

362 Willingness to use

Half of our study population indicated that they were willing to use an ehLVA like SightPlus,

364 especially for activities such as television, reading or theatre, with many individual activities named.

365 Similarly, a recent large-scale review into functional sight in AMD reported that face recognition,

366 perception of scenes, computer use, meal preparation, shopping, cleaning, watching TV, reading and

367 self-care are among the tasks negatively affected by sight loss.<sup>23</sup> Future ehLVAs should aim to

368 support such common activities to enable independence and improvement in quality of life.

369

370 Seven individual variables predicted a higher willingness to use an ehLVA like SightPlus. Our results 371 agree with the literature summarised in a recent review:<sup>24</sup> for example, younger age has been found 372 to be a predictor of better compliance; duration of vision loss may predict greater uptake (similar to 373 our 'proportion of lifetime affected' predictor). In our study, as in most previous work, there was no 374 effect of baseline acuity on uptake or benefit. Our univariate and multivariate analysis showed that 375 existing use of electronic devices was a strong predictor for willingness to use an ehLVA like 376 SightPlus. It is not clear whether comfort with technology was a significant factor in this. The role of 377 technological literacy should be explored in future studies, especially for older people. Proportion of 378 lifetime affected and baseline contrast sensitivity also had an effect in this model. Those diagnosed 379 for proportionally longer may have adapted more to their sight loss and be more willing to seek assistance,<sup>25</sup> although this requires further research. 380

381

The most common reasons for not wanting to use the device were its weight, 465g (26 of 60
participants), its appearance (14 of 60 participants) and perceived image movement or image lag (12

384 of 60 participants). Weight and appearance are inherent to virtual reality (VR) headset-based

solutions like SightPlus or IRIS Vision, although can be overcome through bespoke designs such as
 that pioneered by eSight. In future, creating lighter and more comfortable to wear devices will be an
 important design consideration. Perceived image movement and image lag can arise from head
 movement, throttled processing speed or optical image stabilisation resulting in slight lag of the
 scene relative to head movement. Improved image stabilisation, zero-lag image processing and
 compensation for fast changes in head orientation could all make this effect less noticeable.

391

Exactly half of those who met the World Health Organisation criterion for low vision (visual acuity poorer than 6/18) would use a ehLVA like SightPlus, compared to 47% of our complete sample. We could not determine the lower acuity limit for SightPlus to be useful: the participant with the poorest visual acuity (perception of light in the right eye, hand movements in the left eye) improved to 0.06 logMAR (6/7; 20/23) and would use the device for work and television.

397

398 Outlook

399 As more wearable low vision devices become available, a standardised test battery or unified task 400 inventory of real-life activities would enable true comparison of different devices and quantify their 401 impact on performance of common daily tasks. No such comparison has yet been performed, and 402 limited data are available on new wearable devices.<sup>2</sup> Assessment of visual function beyond acuity 403 and contrast sensitivity has been called for in a large-scale review of visual function and quality of 404 life in AMD<sup>23</sup> and would enable comprehensive evaluation and benchmarking of all types of low 405 vision aids. A comparative study of devices would be invaluable to clinicians, patients and carers. 406 Our clinical experience with this device suggests that existing inventories may need to be revised to 407 reflect common, modern real-world tasks across a broad age group. Any such evaluation package 408 should contain tasks most commonly needing visual aids by people with low vision while being 409 repeatable across different institutions. Examples of this include the inclusion of face recognition by Wittich<sup>17</sup> and a bespoke (albeit unvalidated) task inventory used by Orcam.<sup>18</sup> Future work should 410

411 expand on this to include measurable performance, avoiding the confounding effects of self-

412 reporting and observation. The impact of ehLVAs on quality of life needs to be established in order

413 to facilitate any future health economic assessments.

414

415 *Study limitations* 

Our inclusion criteria were deliberately broad in order to determine who would most benefit from this system. Since we did not find clear cut-offs with regards to minimum or maximum baseline visual acuity for those who benefit from an ehLVA, future work should either use a stratified sampling method with a larger sample size, or focus on specific disease conditions to identify patient beneficiaries more robustly. Visual acuity may not be a predictor of benefit or uptake, and future work should continue to examine a broad range of predictor variables.

422

423 In this study, we allowed participants free choice of the image enhancement mode which they found 424 most useful for a given task. Our results for 'preferred enhanced mode' hence contain different 425 modes. Although visual acuity and contrast sensitivity improved further with image enhancement 426 as well as zoom, 58% of participants preferred the 'normal' mode. It is important to note that the 427 outcomes we used were letter and text based. Enhancement mode preferences for images 428 containing a broader range of colours and spatial frequencies (such as natural scenes or TV) may 429 differ. Previous research has shown that participants tend to prefer the most natural looking image 430 rendering through lower level enhancements, and that preferences depend on the nature of sight loss and image content.<sup>16 26</sup> Further work is needed to link image enhancement modes to tasks and 431 432 sight loss conditions, as has been attempted by other groups.<sup>12 13</sup>

433

Adverse reactions were reported by 12 participants (20%), with nausea and dizziness being the most
 common unpleasant sensations. Nausea has been reported as a side-effect of wearable devices.<sup>817</sup>
 These symptoms resolved as soon as the device was removed. Six participants (10%) were not able

to complete the full study session due to adverse effects. Future work should investigate the causes
of these adverse effects and should endeavour to remove them by, for example, providing a less
enclosed design.

440

#### 441 Conclusions

- 442 This augmented reality low vision aid improves visual acuity, contrast sensitivity and near visual
- 443 acuity. Approximately half of the people we demonstrated it to would want to use it, primarily for
- 444 distance tasks. Uptake of the device would be higher if it was lighter and more cosmetically
- acceptable. We recommend that adults with low vision are given the opportunity to evaluate ehLVAs
- 446 until larger scale studies can help better characterise those for whom these devices will prove
- 447 particularly beneficial.
- 448
- The efficacy of ehLVAs has now been demonstrated in two devices with different form factor and
- 450 display technology (eSight and SightPlus). Research now needs to move beyond the clinic, to
- 451 quantify the benefits of these systems for visually impaired people at work, in education, and at
- 452 home. We hope that electronic, head-mounted low vision aids become more widely used and that
- 453 they will increase the number of tasks which can be easily performed by people with visual
- 454 impairment.
- 455

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