Effectiveness of portable electronic and optical magnifiers for near vision activities in low vision

Taylor, John J.; Bambrick, Rachel; Brand, Andrew; Bray, Nathan; Dutton, Michelle; Harper, Robert A; Hoare, Zoe; Ryan, Barbara; Edwards, Rhiannon T; Waterman, Heather; Dickinson, Christine

Ophthalmic & physiological optics : the journal of the British College of Ophthalmic Opticians (Optometrists)

DOI:
10.1111/opo.12379

Published: 27/06/2017

Peer reviewed version

Effectiveness of portable electronic and optical magnifiers for near vision activities in low vision: a randomised crossover trial

Running head

Using p-EVES for near vision in low vision

Authors

J Taylor[1], R Bambrick[2], A Brand[3], N Bray[4], M Dutton[5], R A Harper[2,1], Z Hoare[3], B Ryan[6], R T Edwards[4], H Waterman[7], *C M Dickinson[1,2].

[1]Division of Pharmacy and Optometry, School of Health Sciences, Faculty of Biology, Medicine and Health, University of Manchester, Manchester Academic Health Science Centre, Manchester, UK.
[2]Manchester Royal Eye Hospital, Central Manchester University Hospitals NHS Foundation Trust, Manchester Academic Health Science Centre, Manchester, UK.
[3]North Wales Organisation for Randomised Trials in Health (NWORTH), Bangor University, Bangor, UK.
[4]Centre for Health Economics & Medicines Evaluation, Bangor University, Bangor, UK
[5]The Macular Society, PO Box 1870, Andover, UK.
[6]Wales Optometry Postgraduate Education Centre, School of Optometry & Vision Sciences, Cardiff University, Cardiff, UK.
[7]*was* School of Nursing, Midwifery & Social Work, University of Manchester, Manchester, UK, *now* School of Healthcare Sciences, Cardiff University, Cardiff, UK.

*Corresponding Author

Keywords

electronic low vision aids; rehabilitation; visual impairment; instrumental activities of daily living

Disclosure

The authors report no conflicts of interest and have no proprietary interest in any of the materials mentioned in this article.

This publication presents independent research funded by the National Institute of Health Research (NIHR) under its Research for Patient Benefit (RfPB) Programme (Grant Reference Number PB-PG-0211-24105). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health. The funding organisation had no role in the design or conduct of this research.

Acknowledgements

This research was facilitated by the Greater Manchester Local Clinical Research Network. We thank Associated Optical, Bierley, Humanware, Optima Low Vision and Optelec for supplying electronic magnifiers to be used in the study.
We also thank John Collins, Paul Fletcher and Max Reinecker for their expertise regarding the p-EVES devices; Michael Crossland for his role as independent advisor to the study; and Kate Barugh for vital administrative support.
We thank Joan Stelmack for use of the algorithms for Rasch analysis of the VFQ responses; and Gordon Legge for permission to reproduce the MNRead charts in reduced contrast.

Abstract

Purpose: To compare the performance of near vision activities using additional portable electronic vision enhancement systems (p-EVES), to using optical magnifiers alone, by individuals with visual impairment.

Methods: A total of 100 experienced optical aid users were recruited from low vision clinics at Manchester Royal Eye Hospital, Manchester, UK, to a prospective two-arm cross-over randomised controlled trial. Reading, performance of near vision activities, and device usage were evaluated at baseline; and at the end of each study arm (Intervention A: existing optical aids plus p-EVES; Intervention B: optical aids only) which was after 2 and 4 months.

Results: A total of 82 participants completed the study. Overall, maximum reading speed for high contrast sentences was not statistically significantly different for optical aids and p-EVES, although the critical print size and threshold print size which could be accessed with p-EVES were statistically significantly smaller ($p<0.001$ in both cases). The optical aids were used for a larger number of tasks ($p<0.001$), and used more frequently ($p<0.001$). However p-EVES were preferred for leisure reading by 70% of participants, and allowed longer duration of reading ($p<0.001$). During the study arm when they had a p-EVES device, participants were able to carry out more tasks independently ($p<0.001$), and reported less difficulty with a range of near vision activities ($p<0.001$).

Conclusions: The study provides evidence that p-EVES devices can play a useful role in supplementing the range of low vision aids used to reduce activity limitation for near vision tasks.

Introduction

A major difficulty reported by individuals with visual impairment (VI) is their inability to carry out simple tasks, especially those involving reading. However, optical low vision aids (LVAs) can restore that ability, at least partially. Among the LVA users surveyed by Watson et al[1], 97% of hand and stand magnifiers were used for reading, with other popular uses being writing, repairing and cooking. Despite the reported usefulness of optical LVAs, users identified problems and limitations with them such as insufficient magnification, difficulty with lighting the task, and the awkward positioning required. It is also often necessary for users to have more than one device if they wish to carry out different tasks. There is evidence that some optical LVAs are never used[2], which may be related to the limitations of these devices, and it may be that some optical LVAs are not used to their full potential.

In the UK, National Health Service (NHS) low vision clinicians, typically based in hospital ophthalmology departments, provide assessment of individuals with VI and dispense optical LVAs, such as hand or stand magnifiers, free of charge on permanent loan to help support those with sight loss. Moderately priced portable (hand held) electronic vision enhancement systems (p-EVES) have recently become available, which offer potential benefits in comparison to optical LVAs. For example, p-EVES devices can be used more naturally (binocular viewing and habitual working distance) and also incorporate many features not seen in optical LVAs (e.g. variable magnification, different contrast settings and freeze frame facility). These p-EVES devices are currently on the market to buy privately, but are not provided through the NHS in England. In Wales, approximately one third of all optometrists are accredited as part of the Low Vision Service Wales and supply optical LVAs within the NHS from their community practices.[3] For the past few years, it has been possible for them to supply one specified p-EVES device, with anecdotal reports from patients and practitioners suggesting that these devices are popular and successful. However more research was required to evaluate whether this new technology offers real benefits in comparison to current optical LVAs, and to establish the exact role that p-EVES devices could play within low vision service provision.

The p-EVES Study was designed to determine the acceptability, effectiveness and cost-effectiveness of p-EVES devices in addition to existing optical LVAs for near vision activities in adults with moderate to severe VI. In this paper we report on acceptability and effectiveness: cost-effectiveness is reported elsewhere[4] The primary hypotheses investigated were that p-EVES devices would (i) allow faster reading, and (ii) be preferred (used more often) than a single optical LVA. In addition, a broad range of secondary outcome measures were included to explore near vision performance in more detail, and

investigate how p-EVES devices affected the user-reported difficulty in carrying out near vision activities.

Methods

Participants

The p-EVES Study was a single-site study conducted at Manchester Royal Eye Hospital (MREH), UK. Inclusion criteria for the study were adults (over 18 years), currently using optical LVAs only (not used p-EVES before), stable VI, and visual acuity (VA) of 0.7 logMAR (6/30) or worse and/or log contrast sensitivity (CS) of 1.20 or worse (in the better eye). Additional criteria were adequate hearing, and English being the habitual language, to meet the study demands. Exclusion criteria were a physical disability that prevented the participant operating the p-EVES device, or a score of <19 on the Mini-Mental State Examination (MMSE-Blind).[5] Potential p-EVES trial participants were screened by optometrists in the low vision clinics at MREH. Those individuals meeting the inclusion/exclusion criteria were given information about the study and then contacted by the trial's clinician researcher.

Trial Design

The study design and methodology have been presented and discussed in a previous publication[6] and are summarised briefly here. Experienced optical LVA users were recruited to a prospective two-arm cross-over randomised controlled trial (RCT). All participants underwent an initial p-EVES assessment with the clinician researcher. This assessment determined eligibility and informed consent. Participants were subsequently randomised to the two arms of the study (Group 1 and Group 2) in a 1:1 ratio. Group 1 received the two interventions A and B in the order AB, while Group 2 received the two interventions in the order BA. Intervention A was a two month period with both their existing optical LVAs and a p-EVES device, and Intervention B was a two month period with their existing optical LVAs only. Within each study arm, age (<60, ≥60 years) and visual acuity (VA) (<1.3 LogMAR (6/120), ≥1.3 LogMAR (6/120), were binary stratification variables.

The study researcher was masked to the participants' Group allocations when the baseline assessments (Visit 1) were carried out. Participants were seen by the study researcher three times: Visit 1 (baseline) and then at the end of each arm of the study (Visit 2 at 2 months and Visit 3 at 4 months).

To determine the ways in which individuals incorporated the p-EVES devices into their everyday lives, and to obtain their opinions about the different LVAs used during the trial, one-to-one semi-structured interviews were conducted after the cross-over study, with a sample of participants selected using maximum variation sampling.

No changes to the protocol were made during the study. The p-EVES Study was registered with clinical trials.gov (Identifier: NCT01701700), received National Research Ethics Service (NRES) approval and conformed to the tenets of the Declaration of Helsinki. Written informed consent was obtained from all participants.

Intervention

At the initial assessment with the clinician researcher, demographic data were recorded, consisting of age, gender, ethnicity, registration status (i.e., not registered, sight impaired (SI), severely sight impaired (SSI)), residential status and employment status. Registration as SI or SSI is voluntary, and is certified by the ophthalmologist, who takes visual field and functional performance into account. However guidelines suggest that the VA for SSI registration should be >1.3 logMAR (6/120), and for SI registration should be ≥1.0 logMAR (6/60). Diagnosis was determined (from hospital records of previous clinical examinations), and refraction was performed at 3m (based on least-negative prescription with maximum achievable VA) followed by measurement of best corrected distance VA (logMAR; ETDRS, scored by letter), best corrected near VA at 25cms (point size; English Continuous Text Near Vision Card (Precision Vision, La Salle, IL, USA)), and log CS (using the Pelli-Robson chart). The California Central Visual Field Test (CCVFT)[7] was used to determine the presence of a binocular scotoma, and the location of any preferred retinal locus (PRL). The supplier's instructions for CCVFT use were followed, but a grading scale was devised to classify the results (for details see **Supplementary Information S1**).
The refractive correction and the participant's optical LVAs were updated and replaced if necessary: the participant then had time to incorporate these into everyday routine usage, before the baseline assessment. The preferred p-EVES device was selected from the four models which were used in the study (Optelec *Compact*+, Optelec *Compact 4HD*, Schweizer *eMAG 43*, and Eschenbach *Mobilux Digital*). These models had been previously chosen by a focus group of individuals with VI. These devices are shown in **Figure S3** and manufacturers' specifications of these devices are provided in **Table S2 (**see **Supplementary Information S2)**. During the initial assessment all participants had the opportunity to try all four p-EVES devices and choose the one which best matched their requirements, with guidance from the clinician researcher based on an analysis of their

needs using Part 1 of the Manchester Low Vision Questionnaire (MLVQ).[8] Instruction on the operation and basic handling of the selected p-EVES device was given, but no formal training was provided (equivalent to the typical situation with NHS hospital provision of optical LVAs). To avoid bias, this instruction was also carried out with all optical LVAs. Participants attempted five practical tasks with their LVA(s) (p-EVES when in that study arm, optical otherwise) to ensure that they were using the devices correctly. Participants underwent these task-based practice sessions with the clinician researcher immediately following study Visits 1 and 2 (i.e. at the start of each of the 2-month Intervention periods). The time taken to carry out the instruction and task-based practice session was recorded for each participant.

The clinician researcher made a scripted telephone call to all participants, 1 week after the start of each arm of the study to administer a difficulties questionnaire (whether in Group 1 or Group 2). The aim of the questionnaire was to identify difficulties with the LVAs being used in that arm of the study. If the device was not working properly, or the participant did not know how to operate it, an extra visit was conducted for replacement/re-instruction.

Outcome measures

Outcome measures were assessed at Visit 1 (baseline) and then at the end of each arm of the study: Visit 2 (at 2 months) and Visit 3 (at 4 months) by the study researcher (a different researcher to that carrying out the initial p-EVES assessment). All measurements taken when participants were using either the p-EVES or optical LVAs, were with the device set up as chosen by the user. In the case of p-EVES, this set-up may not have been at the optimum contrast and/or magnification for the particular task, but this was done to better reflect the situation with “real world” usage. All reading performance data were analysed from audio recordings.

Three non-visual measures were collected at Visit 1 to investigate whether these tests were potentially prognostic for p-EVES success. These were the Brief Resilience Scale[9], Finger-to-Nose Test[10], and an adaptation of the Addenbrooke’s Cognitive Examination (ACE-III)[11] (excluding the items which use visual information). These measures determined ability to bounce back after set-backs, manual dexterity, and cognitive status, respectively.

Primary outcomes

The two primary outcome measures were

(i) the maximum reading speed (MRS) measured with high contrast (≈90%) MNRead Acuity Charts (Minnesota Laboratory for Low-Vision Research, MN, USA), using the p-EVES device (at the end of Intervention A – the 2 month period in which the p-EVES was available) compared to the preferred optical LVA (at the end of Intervention B – the 2 month period in which only optical aids were available),
and
(ii) frequency of use (rated on a scale of 0-4) of the p-EVES device during Intervention A compared to the optical LVA used most frequently for near vision during Intervention B, measured using the MLVQ (Part 2).[8]

Secondary outcomes relating to near vision activities

In addition to MRS (primary outcome measure), the critical print size (CPS) and threshold print size (TPS) were determined using the high contrast MNRead charts and compared between p-EVES and preferred optical LVA.[12] To investigate whether the contrast enhancement features of the p-EVES devices offer a measurable improvement in reading performance in reduced contrast conditions, MRS, CPS and TPS were also determined using reduced contrast (50%) versions of the MNRead charts.
The MLVQ was used to determine a number of secondary outcome measures. For those participants who at baseline used an optical magnifier to “read books and newspapers”, the MLVQ (Part 1) was used to determine whether (i) they subsequently used a p-EVES for this task during Intervention A, and, if so, (from MLVQ Part 2) (ii) what is the longest time they could read with the p-EVES device (graded on a scale of 0-4). It was also used in each Intervention to determine which tasks the participant could perform independently with the p-EVES device (when available), and which with an optical magnifier, and which could not be performed, or could only be performed with assistance.
The International Reading Speed Texts (IReST)[13,14] was used to determine reading speed and accuracy.[15] These parameters were compared for participants who identified preferring to use the p-EVES to perform a leisure reading task (“read books and newspapers” (on MLVQ Part 1)), and those who preferred to use an optical LVA.
A set of five timed instrumental activities of daily living (5-TIADLs) were designed to determine whether the p-EVES device was spontaneously chosen by the participant to carry out a range of everyday tasks, and whether this device allowed faster and/or more accurate performance of each task. The five tasks used were: finding a number in a telephone book, writing a phrase within a designated space on a piece of paper, reading ingredients on a can of food, finding two items from a selection of items on a shelf, and reading information on a pill bottle. Speed was assessed as time taken to perform the task (measured on a stop-

watch to the nearest 0.1 second) and accuracy was assessed using a 5-point grading scale (0-4). If the task could not be performed, a grade of 0 was assigned.
To investigate a wider range of activities than it was practical to test directly, participants were asked to rate perceived difficulty during the periods of Intervention A and Intervention B respectively, using a 15-item questionnaire (NV-VFQ-15) based on selecting appropriate "near vision" items from the VFQ-48 questionnaire.[16]

Data analysis

MNRead was used to determine MRS (in words per minute (wpm)), and CPS and TPS (print size specified in log point notation).
MRS was calculated as the mean of the 3 highest reading speeds[17] for the sentences read with the LVA (participants often began reading the largest print without the LVA, and were allowed to choose when to start to use it). Participants' performances without sufficient data points were treated as missing data. CPS was calculated as the smallest print size that supports a reading speed equal to 80% of the MRS.[17]
The TPS gives a measure of the smallest print size to which the participant's LVA gives them access (also sometimes termed reading acuity). This was calculated as:
Log print size = 1.9 – (number of sentences read x 0.1) + (number of errors x 0.01)
Where: number of errors = number of errors in the last 3 sentences read (approaching TPS).

For the primary and secondary outcome measures two models for the AB/BA crossover design were used. The main analysis used was the CROS t test which accounts for treatment, period and carry-over effects.[18,19] Effect sizes (ES) are presented as an unstandardised effect size estimate: positive effect size estimates indicate that the value in Intervention A/using a p-EVES is higher than in Intervention B/using an optical aid. Conversely negative effect size estimates indicate that the value in Intervention A/using a p-EVES is lower than that in Intervention B/using an optical aid.During analysis of the secondary outcome measures, Bonferroni correction to the p-value to adjust for multiple comparisons was used. The NV-VFQ-15 results were used to calculate person visual ability scores using previously published algorithms: a spreadsheet provided by the authors was used, rather than the formulae given in the published paper.[16]
A number of parameters (Group allocation; test order (version sequence); age; distance and near VA; CS; CCVFT grade; finger-to-nose test; Brief Resilience Scale and ACE-III scores) were investigated in statistical models for their ability to predict : the MNRead high contrast MRS using p-EVES (a mixed effect linear model); the frequency of use rating (0 to 4) for p-

EVES (a cumulative link model[20]): and the "NV-VFQ-15 score in Intervention A" (a linear model).

Results

Recruitment took place between 1st May 2013 and 31st October 2014, with all follow-up visits completed by 1st April 2015. The flow of participants through each stage of the study (screening, enrolment, randomisation, follow-up and analysis) is shown in **Figure 1**. A total of 780 patients were screened, of whom 247 met the inclusion criteria. Of the 100 patients enrolled, 49 were randomised to Group 1 and 51 to Group 2: reasons for non-enrolment of 147 eligible participants are detailed in Figure 1. The baseline demographic and visual characteristics of the participants are summarised for each study arm in **Table 1.** Overall in the study population the mean age was 71.4 years (SD 18.3; range 20 to 93), with 79% retired, 62% female, 93% white British. The mean binocular distance VA was 0.96 logMAR (6/55) (SD 0.27; range 0.30 to 1.68 (6/12 to 6/287)) and 86% of the participants had a certificate of visual impairment (CVI) (with a 50:50 split between those registered as SI and SSI).

A total of 18 participants (18%) dropped out at various points in the trial: 11 from Group 1 and 7 from Group 2 (Figure 1). A total of 38 participants in Group 1 and 44 in Group 2 completed the trial. Participants completing the study had a range of ocular pathologies (**Table 2**) although the majority (61%) had age-related macular degeneration as a primary diagnosis. The range of the optical LVAs used by the participants at baseline (and available throughout the study) is shown in **Table 3.** The majority of participants used a hand plus a stand magnifier, and 6x was the most common magnification. **Table 4** gives details of the p-EVES used in the study and the length of time spent in each study arm.

Table 5 shows the reading performance of the participants tested using both the standard (high contrast) (Table 5a) and reduced contrast (50%) MNRead test (Table 5b). MRS for high contrast sentences was a primary outcome measure, and showed no statistically significant difference for p-EVES in comparison to optical LVAs. However, in the assessment Visit at the end of Intervention A, 64% of participants chose to use the p-EVES rather than their optical aid to perform the MNRead test (those who chose to use their optical aid subsequently carried out a second test with the p-EVES). Considering the MRS for those individuals who preferred p-EVES (n=50), there was a small increase with p-EVES relative to optical LVAs (p=0.043), whereas there was a non-significant decrease (p=0.079) for individuals (n=28) who did not prefer it.

A mixed effect linear model was constructed to examine the influence of: Group allocation; test order (version sequence); age; distance and near VA; CS; CCVFT grade; finger-to-nose

test; Brief Resilience Scale and ACE-III scores on the MNRead high contrast MRS using p-EVES. It was found that the model fitted the data better than the mean (null model) ($p<0.001$). It was not surprising that several visual factors had a statistically significant influence: as near VA increases by 1M, MRS decreases by 9.2 wpm ($p=0.014$), and as log CS increases by 1, MRS increases by 29.4 wpm ($p=0.041$). A CCVFT rating other than 0 (i.e. the presence of any paracentral scotoma), showed a tendency to reduce MRS relative to CCVFT grade 0, although only the decrease for CCVFT grade 2 (46 wpm) reached statistical significance ($p=0.013$). No demographic or non-visual factors were statistically significant.

The two other parameters derived from the MNRead (CPS and TPS) did however both show a highly statistically significant decrease (improvement) when using p-EVES in comparison to optical LVAs. This effect is still apparent (although reduced) for CPS, even for individuals who did not prefer p-EVES.

Considering the reduced contrast MNRead, MRS was statistically significantly worse with p-EVES than with optical LVAs ($p=0.04$). In addition, it appears that the MRS for reduced compared to high contrast decreases with p-EVES, but stays approximately the same with optical LVAs **(Table 5).** The CPS and TPS are both slightly larger (approximately 0.2 log units worse) with reduced contrast, compared to high contrast, in p-EVES, although similar for optical LVAs. The p-EVES allows a statistically significant decrease (improvement) in CPS overall ($p=0.0357$). Although there is a tendency for TPS to be improved with p-EVES in comparison to optical LVAs, this does not reach statistical significance.

The second primary outcome measure was frequency of use of p-EVES in comparison to the most used optical LVA. Usage was determined with the MLVQ and graded from 0 (never) to 4 (several times a day). Results show that the most used optical LVA for near vision, is used statistically significantly more frequently than the p-EVES ($p<0.001$) (**Table 6**). A cumulative link model[24] was constructed to predict the frequency of use rating (0 to 4) for p-EVES using the following factors: Group allocation; test order (version sequence); age; distance and near VA; CS; CCVFT grade; finger-to-nose test; Brief Resilience Scale and ACE-III scores. The model was statistically significant, χ^2 (18) = 30.27, $p= 0.035$. The only statistically significant participant factors were the CCVFT grades. CCVFT grades from 2 to 4 produced large and statistically significant increases in the rating: by 2.5 for Grade 2 ($p=0.016$) and 2.8 for Grade 4 ($p=0.010$).

When only optical LVAs were available (Intervention B), 65% of participants used them for leisure reading (reading books and newspapers), but 73% used p-EVES for this task in

Intervention A (p=1). For spot or survival reading (reading instructions), 84% used optical LVAs for this task, whilst only 54% used p-EVES (p=0.012). As survival tasks are likely to be more numerous, this finding corroborates the difference in frequency of use; as does the statistically significantly higher number of tasks performed with optical LVAs in comparison to p-EVES (p=0.002) (**Table 6**). Although the p-EVES device was not used so frequently, if we consider just those participants who performed leisure reading, there was a highly statistically significant increase (p<0.001) in the length of time for which p-EVES was used in comparison to optical LVAs (**Table 6**). In the arm of the study when the p-EVES was available, participants reported statistically significantly fewer tasks that they could not do or with which they needed help (p<0.001). Therefore, whilst the p-EVES does not appear to be used for as many tasks, it seems that it can be used for different tasks than optical LVAs; i.e. for tasks for which the individual's existing optical LVAs were not found to be appropriate. For example, when only optical LVAs were available, 34% of participants could not or did not read books, and 15% could not read instructions: these percentages fell to 11% and 2% respectively when p-EVES devices were available.

The IReST reading test involves longer paragraphs, and so is more representative of a leisure reading task. However this test showed no difference in reading speed between the preferred optical LVA and p-EVES (**Table 6**). **Table 6** also shows the difference in IReST performance for those who were habitually using p-EVES for leisure reading, and those who were not. Although the numbers are small, and differences are not statistically significant, there appears to be no increase in reading speed relative to optical LVAs for those preferring p-EVES, but there is a decrease in reading speed with p-EVES for those who prefer optical LVAs. Group 1 shows a large difference in reading speed between the two sub-groups: those who preferred optical LVAs had much higher reading speeds than those who preferred p-EVES. There was a modest improvement in accuracy with p-EVES compared to optical devices for those participants who preferred p-EVES. The proportion of participants achieving at least 80% accuracy was 62% with optical LVAs and 70% with p-EVES, although this was not statistically significant.

To further explore the use of p-EVES for "survival" reading tasks, **Table 7** shows the magnifier used for the 5-TIADL tasks. As can be seen, there was a wide variation between the tasks in which LVA (if any) the participant chose to use. There was a strong tendency for p-EVES preference for Task 1 (telephone directory), and a tendency towards optical LVA preference for Task 3 (ingredients), Task 5 (medicine instructions) and (to a lesser extent) Task 4 (items on a shelf). Most participants chose to perform Task 2 (writing) without the use of any LVA. Despite these LVA preferences, there were no significant differences in time

taken, or graded accuracy of performance, on any task when comparing Interventions A and B.

The TIADL used only a limited number of practical tasks, but a wider range was explored with the NV-VFQ-15. This questionnaire asked participants to rate the difficulty experienced for a range of 15 near vision tasks, some of which had also been tested in the TIADL tasks. **Table 8** shows the Rasch-analysed scores, which indicate a highly statistically significant ($p<0.001$) decrease in the difficulty experienced during the period of Intervention A when p-EVES and optical LVAs were available, in comparison to the period of Intervention B with optical LVAs alone. A linear model was used to examine the influence of: Group allocation; test order (version sequence); age; distance and near VA; CS; CCVFT grade; finger-to-nose test; Brief Resilience Scale and ACE-III scores, on the "NV-VFQ-15 score in Intervention A". This analysis was not a model which had been planned, since NV-VFQ-15 was a secondary outcome, but as the NV-VFQ-15 showed a highly statistically significant effect of having p-EVES available, it was important to investigate whether any of the factors were predictive of this success. The model found no statistically significant participant factors to be predictive.

At the end of the study, 34% of participants decided to buy a p-EVES device: 14 participants from each Group.

Discussion

The p-EVES Study is unique in published studies of low vision rehabilitation in combining clinical effectiveness, cost effectiveness and qualitative evaluations of an intervention: cost effectiveness in particular has rarely been considered.[21] Virgili et al[22] noted the lack of rigorous trials of LVA use, and The p-EVES Study shows how such a trial can be delivered. A further strength of The p-EVES Study was the contribution of service users to both the study design and conduct. There were also useful interactions with manufacturers of the p-EVES devices, and the research will provide them with guidance on refining device design.

The participants recruited covered a wide range of ages, causes of VI, and prescribed optical LVAs: 57% used more than one near vision LVA, and 25% also had a distance LVA. The vast majority of participants used hand and stand magnifiers (either alone or in combination) as has been reported in other UK NHS low vision clinics [23] . Individuals with milder levels of VI were excluded from the current study, based on prior clinical experience with p-EVES, and the relatively high minimum magnification provided by these devices. The results do not suggest that a poorer VA, or poorer CS, cut-off would be more appropriate (i.e. worse than 0.7 logMAR (6/30) or log CS 1.2), since neither VA nor CS were predictive

factors in the model for p-EVES frequency of use. Based on these clinically-established visual criteria, it is likely that there are a significant number of patients in typical low vision clinics for whom p-EVES would not be considered. However there are some who would be likely to benefit who were not included in this study: some patients had unstable VA, and others had already purchased a p-EVES device for themselves. The decision not to restrict recruitment to the study on the basis of particular demographic and non-visual characteristics (e.g. age, resilience, manual dexterity) was also supported by the study results. Analysis showed that none of these characteristics were predictive of performance using p-EVES. This finding is important since it has been suggested in the past that, for example, younger employed individuals are more likely to be successful EVES users.[24,25] However it must be acknowledged that severe cognitive impairment and physical disability were used as exclusion criteria in this study, and these factors would be likely to impinge on successful use.

MRS was chosen as a primary outcome measure because difficulty with reading is a primary concern of those with VI, and it is relatively easy to measure using standardised and validated tests. In addition, it has been used previously to evaluate the effect of LVAs[21,26] , and had been shown in earlier studies to be increased with electronic compared to optical LVAs.[27,28] In the current study, however, there was no statistically significant benefit with p-EVES for the overall group. There were more drop-outs among the participants than had been expected (18% compared to 10%), and some missing data, but there was no indication that the lack of significance for MRS was due to an under-powered analysis. In fact some participants read faster with optical LVAs than they did with p-EVES. An improved performance with optical LVAs in comparison to head-mounted EVES was reported by Culham et al.[25] The apparent disagreement in the literature, as to whether electronic or optical LVAs allow faster reading, may well be explained by the different characteristics of the devices in the different studies. The most obvious difference is that the EVES used in some earlier studies had a desk-top screen which therefore has a larger field of view than a p-EVES; an advantage over a high-powered optical magnifier would therefore be more likely in this case.

When an individual reads with a magnifying device, their CPS and TPS depend on the capabilities of the device, and the ability of the user to employ these appropriately, in addition to the user's visual status. It was therefore not surprising that CPS and TPS were statistically significantly smaller ("better") with the p-EVES than with optical LVAs, in view of the higher magnification available (although there is no guarantee that the user will always exploit this facility to the full). The question arises whether this statistical improvement has

functional significance: if it allows the user to access a size of print which they rarely encounter in everyday life, then this improvement is not helpful. The improvement in CPS (the size of print accessible for leisure reading) was from 8 point with the preferred optical LVA to 3.5 point with p-EVES for Group 1, and from 10 point to 6 point for Group 2; the change in TPS (the size of print accessible for survival reading) was from 5 point to 2.5 point for Group 1 and from 6 point to 4 point for Group 2. These values suggest that although the extended magnification range was used by most participants during the test, the functional advantage for the majority of everyday activities is likely to be limited.
Only TPS for users who preferred optical LVAs (i.e. "p-EVES not preferred" in Table 5) did not show a statistically significant improvement with the electronic magnifier. This finding may have been because these participants were less likely to fully exploit the full magnification range of the device, due to less familiarity/expertise with the device.

One of the unique features of p-EVES in comparison to optical LVAs is the ability to change/enhance the contrast of the display. This design feature has the potential to give p-EVES a significant advantage over optical LVAs when being used to read reduced contrast text. In fact, the results suggest reduced contrast MRS was higher with optical LVAs. There are two possible reasons for this finding. Firstly, it may be that the contrast chosen for the test (50%) was unrealistically low, and beyond the operating range of the electronic device. Culham et al report this phenomenon (described as "saturation" of the display) for low contrast targets in the EVES devices they tested.[25] Secondly, in order to replicate "real life" usage by patients, participants were not guided as to which contrast setting to use for the individual tests during the study: they may therefore be making a non-optimal choice. There are several reasons why the set-up may be sub-optimal: users may require training to systematically explore the contrast settings, since these are likely to be much less intuitive than magnification settings. In addition, the contrast settings are not particularly user-friendly: if the user accidentally goes one setting too far in the sequence, they have to scroll through them all again, and cannot simply "go back one".

The second primary outcome measure was "frequency of use" of the p-EVES device in comparison to optical LVAs. The hypothesis was that usage would be increased, since the features of the p-EVES device would make it more versatile, and enable use for a wider range of tasks. This hypothesis was not supported by the data, which showed that the most used optical LVA was used more frequently than the p-EVES. Further consideration suggested that the reason for this finding was that whilst the p-EVES was (slightly) preferred for leisure reading, optical LVAs were significantly preferred for survival reading, and were used for a wider range of tasks. Therefore, contrary to expectation, the optical LVA proved to

be more versatile. Although a p-EVES is less versatile than an optical LVA in the range of tasks it permits, the addition of a p-EVES device appears to have allowed a different range of tasks to be performed, because there was a reduction in the number of those that could either not be undertaken, or required help to perform, when using optical LVAs alone. This finding suggests that adding a p-EVES gives the optical aid user the opportunity to be more independent, which is likely to improve quality of life, and save on carer time.

Measuring “duration of use” of a device can be somewhat equivocal. If the task is survival/spot reading, short duration is considered positive, since it suggests that the user is able to accomplish a task more quickly/efficiently. In contrast, if the task is leisure reading a long duration of use is considered beneficial, since it suggests that the experience is comfortable and relaxing. Therefore interpretation of the “duration of use” results is dependent on the task being performed with the LVA. In the current study “duration of use” was compared with p-EVES and optical LVAs, only for those who specifically reported doing leisure reading (“reading books/newspapers” on MLVQ). The results showed that p-EVES were used for significantly longer periods in this group, suggesting that p-EVES did allow more comfortable leisure reading. It might be expected therefore that p-EVES would show an advantage over optical LVAs with the IReST test. However, as with MNRead, there was no overall improvement in reading speed with p-EVES in comparison to the preferred optical LVA.

In tests of extended reading, such as IReST, it has been argued that accuracy is an important parameter as well as speed[15], since this is necessary to support comprehension, and enable someone to enjoy leisure reading. It therefore follows that any significant improvements in accuracy could be a valid reason for LVA preference. In this study, 80% accuracy was chosen as an appropriate minimum requirement. However, improvements in accuracy were found to be small, and not sufficient to move statistically significant numbers of individuals over the critical 80% boundary. Therefore, whilst 70% of participants chose to use p-EVES for leisure reading, it appears that this choice is not based on reading performance. It may be related to ergonomic factors such as comfort, posture and being able to use both eyes (even if there is no true binocular vision), which may enable individuals to use p-EVES for longer durations.

The results of the 5-TIADL suggest that p-EVES were not perceived by participants to be equally useful for each task. Participants were most likely to choose to use the p-EVES for Task 1 (telephone directory: small black and white text on a flat surface), and there was a tendency for optical LVAs to be preferred for Tasks 3 (ingredients) and Task 5 (pill bottle). However, use of the p-EVES for Task 1 did not improve accuracy or speed (both of which were also poor with optical LVAs). Interestingly, the nature of the inaccuracy in Task 1 was

very different in the two cases. With optical LVAs, participants found the print too small to read, whereas with the p-EVES device they often read a number very easily, but they had not accurately navigated the columns and it was the incorrect number. The p-EVES device was found to be less popular than optical LVAs for certain tasks despite having specific design features that could be seen as advantageous for that task. For example, the ingredients on the can were in coloured text (when altering the contrast may have helped); or the items on a shelf where the camera would have allowed these to be examined without having to pick them up. Manufacturers usually design p-EVES in a way that will allow use for writing. However, the results show that very few participants used any sort of magnifier for writing. If they did, it was often just to see where to begin (the line they needed to write on), or to provide some increased lighting (using the magnifying device as a torch).

Culham et al found that performance of everyday tasks was slower with EVES in comparison to optical LVAs, but there was some question in that study whether it was due to user unfamiliarity with the devices.[25] In the current study there was no significant difference in time or accuracy of performance for any TIADL task using p-EVES compared to optical LVAs. Timings in the current study may in fact favour the p-EVES because in the 5-TIADL, the p-EVES devices were switched on ready on the table (although not necessarily optimally adjusted). Therefore in reality p-EVES devices may be slower, and less preferred, than optical LVAs in real everyday usage. The performance of these everyday tasks was often slow and inaccurate, regardless of the device used. This outcome is also apparent in the MLVQ, in the range of tasks for which participants report needing help from others. There is therefore certainly room for improvement in performance of certain IADL and it is not surprising that this poor performance would have an effect on quality of life. However, the addition of a p-EVES device had a relatively small effect on total functional ability even though this difference was highly statistically significant (as measured by the NV-VFQ-15).

Limitations of this study

This study has many of the characteristics of a pragmatic rather than explanatory RCT.[29] It was designed specifically to be able to inform policy decisions on the delivery of healthcare,[30] and with the aim of being able to translate the findings into clinical prescribing guidelines with little delay. Along with its strengths, the pragmatic trial design has some disadvantages relative to a narrower explanatory trial, in that the interventions are less rigidly specified, though arguably more realistic. Therefore participants already had experience with optical devices, and continued to use these alongside the p-EVES device. They also had minimal training, and were allowed to use either device in whatever way they chose: it was

deliberately not adjusted optimally for them if they had not achieved this themselves. This study therefore did not seek to determine the best possible performance with the p-EVES (efficacy), but instead the average performance achieved by a representative and heterogeneous group of users (effectiveness).[31]

The design of the current study inevitably meant that participants were more familiar with optical aids than with p-EVES devices. The time allowed to integrate p-EVES within their daily routine was only 2 months, but this was based on the fact that previous focus groups suggested it only took a few days to become accustomed to p-EVES devices.[6] There was also no formal training, although participants had 5-30 minutes (mean 15 (SD 6)) of task-based practice. We feel that this was sufficient since only two participants identified difficulties with the p-EVES device when contacted by the clinician researcher after 1 week: one was due to a faulty charger (replaced), and the other to difficulty with the on/off switch (an additional appointment was conducted for re-instruction). A recent RCT also showed that whilst improvements in reading performance[32] and in some dimensions of the LVQOL quality of life questionnaire[33] were found as a result of receiving a CCTV, comprehensive training in use of the device did not provide any additional benefit.

Recruitment was only from a single site, although this site was a typical NHS low vision clinic, albeit one based in a large eye hospital. The range of participants was broadly similar to that in other reported low vision populations[23, 34] suggesting that these results would be generalisable to other clinics. The participants in the current study were almost exclusively of white British ethnicity. Unfortunately some participants of other ethnicities were excluded because English was not their habitual language. That population is likely to be excluded from any trial that uses standardised reading tests.

Participants were able to choose a preferred p-EVES device from a limited range (n=4) which had been pre-selected by a (different) group of individuals with VI. Within the context of potential future supply of (possibly a single) p-EVES through the NHS, the focus group brief was to identify a device which had the potential to be used for all types of reading. This selection may have influenced the results of this study: a smaller, simpler device may have gained more usage for survival tasks, and a device with a larger screen may have been even more popular/successful for leisure reading. It is probable, however, that newer designs of p-EVES would give similar results to these models, if the range of features, and the overall quality of the devices, is similar.

The difficulty in masking in a study of this type means that there is some possibility of bias. The study researcher was masked to the group allocation of the participant when the

baseline assessment was carried out, but not at any subsequent study visits. Obviously the participants were also not masked, but this limitation may have caused a bias either way: towards the p-EVES as the novel technology; or towards optical LVAs due to the participants' satisfaction and familiarity with them (an inclusion criterion was that they were already optical LVA users). It was unavoidable that participants would already be familiar with optical LVAs, since electronic devices provide too high a level of magnification to be acceptable to those with mild impairment.

Conclusions

This study suggests that p-EVES do not replace optical LVAs, among those who already use optical devices, but can serve a useful purpose if prescribed in conjunction with them. A total of 34% of participants found the p-EVES so useful that they decided to purchase it at the end of the study, despite the fact that they were accustomed to having their LVAs provided free of charge by the NHS. The p-EVES devices are most useful for extended reading tasks, and may be a helpful addition for participants who find that their optical LVAs are unsatisfactory; and/or for users who find there are several tasks they cannot do, or with which they need help, when using their optical LVAs. A significant minority of patients being seen in NHS Low Vision Clinics could benefit from p-EVES being added to the possible devices available for supply. There were no participant factors which were predictive of the person's visual ability whilst using p-EVES, suggesting that these devices are potentially useful for a wide range of individuals with moderate/severe VI. The findings of the study are sufficient to support a bid to commissioners of services to extend p-EVES supply into NHS clinics across the UK.

The successful combination of user performance, user opinion, and cost-effectiveness used in The p-EVES Study, could offer a template for other pragmatic evaluations of rehabilitation interventions. Whilst some highly significant benefits to p-EVES users were found in this study, these benefits were not universal: some findings were counter-intuitive, and several contradicted the original hypotheses of the study. Such outcomes show the importance of robust investigation of new technologies, which might (incorrectly) be assumed to always be "better". The study illustrates the importance of the use of a range of outcome measures in studies of low vision rehabilitation, since the disability, and the intervention, can affect so many aspects of life.

References

1. Watson GR, de l'AuneW, Stelmack J et al. National survey of the impact of low vision device use among veterans. Optom Vis Sci 1997; 74: 249-259

2. McIlwaine GG, Bell JA, Dutton GN. Low vision aids – is our service cost effective? Eye 1991; 5: 607-611

3. Charlton M, Jenkins DR, Rhodes C et al. The Welsh Low Vision Service- a summary. Optometry in Practice. 2011; 12(1): 29-38.

4.. Bray N, Brand A, Taylor J, Hoare Z, Dickinson C, Tudor Edwards R. Portable-electronic vision enhancement systems (p-EVES) in comparison to optical magnifiers for near vision activities in visual impairment: Economic evaluation alongside a randomised crossover trial Acta Ophthalmologica doi/10.1111/aos.13255

5. Reischies FM, Geiselmann B. Age-related cognitive decline and vision impairment affecting the detection of dementia syndrome in old age. British J. Psych. 1997; 171: 449-451.

6. Taylor J, Bambrick R, Dutton M et al. The p-EVES study design and methodology: a randomised controlled trial to compare portable electronic vision enhancement systems (p-EVES) to optical magnifiers for near vision activities in visual impairment. Ophthalmic Physiol. Opt. 2014; 34: 558–572.

7. Cole RJ. Modifications to the Fletcher Central Field Test for patients with low vision. J. Visual Impairment & Blindness. 2008; 102(10): 659

8. Harper R, Doordyun K, Reeves B, Slater L. Evaluating the outcomes of low vision rehabilitation. Ophthal. Physiol. Opt. 1999; 19 (1): 3-11.

9. Smith BW, Dalen J, Wiggins K et al. The Brief Resilience Scale: Assessing the Ability to Bounce Back. Int. J. Behav. Med. 2008; **15**: 194-200.

10. Dickinson CM, Shim M. The influence of manual dexterity on reading speed with a hand-held magnifier. Invest. Ophthalmol. Vis. Sci. 2007; 48: 4368-4374

11. Addenbrooke's Cognitive Examination (ACE) III (2012) Available at: http://neura.edu.au/sites/neura.edu.au/files/page-downloads/ACE-III%20Administration%20%28UK%29.pdf *Accessed 14-04-2014*

12. Taylor J, Dickinson CM. The use of MNRead acuity charts in low vision rehabilitation. *European Society for Low Vision Research & Rehabilitation (ESLRR) conference, Oxford, September 2015.*

13. Hahn GA, Penka D, Gehrlich C et al. New standardised tests for assessing reading performance in four European languages. Br.J. Ophthalmol. 2006; 90: 480-484.

14. Trauzettel-Klosinski S, Dietz K, and the IReST Study Group. Standardized assessment of reading performance: The new International Reading Speed Texts IReST. Invest. Ophthalmol. Vis. Sci. 2012; 53: 5452-5461.

15. Taylor J, Dickinson CM. The use of International Reading Speed Texts (IReST) in low vision rehabilitation. *European Society for Low Vision Research & Rehabilitation (ESLRR) conference, Oxford, September 2015*

16. Stelmack JA, Massof RW. Using the VA LV VFQ-48 and LV VFQ-20 in Low Vision Rehabilitation. Optom. Vis. Sci. 2007: 84: 705-709

17. Patel PJ, Chen FK, Da Cruz L et al. Test-retest variability of reading performance metrics using MNREAD in patients with age-related macular degeneration. Invest Ophthalmol Vis Sci. 2011; 52: 3854-3859

18. Senn S Cross-Over Trials in Clinical Research. 2nd Edition, New York: Wiley, 2002.

19,. Senn SJ. The AB/BA crossover: how to perform the two-stage analysis if you can't be persuaded that you shouldn't. *In* Liber Amicorum Roel van Strik, pp93-100. Edited by B Hansen and M De Ridder, Rotterdam, Netherlands: Erasmus University. 1996.

20. Christensen RHB A Tutorial on fitting Cumulative Link Mixed Models with clmm2 from the ordinal Package. Available at https://cran.r-project.org/web/packages/ordinal/vignettes/clmm2_tutorial.pdf Accessed 20 02 2016

21. Binns AM, Bunce C, Dickinson C et al. How Effective is Low Vision Service Provision? A Systematic Review. Surv. Ophthalmol. 2012; 57(1): 34-65.

22. Virgili G, Acosta R, Grover LL et al. Reading aids for adults with low vision. Cochrane Database of Systematic Reviews 2013, Issue 10. Art. No.: CD003303. DOI: 10.1002/14651858.CD003303.pub3.

23. Crossland MD and Silver JH. Thirty years in an urban low vision clinic: changes in prescribing habits of low vision practitioners. Optom Vis Sci 2005; 82: 617-622

24. Wolffsohn JS and Peterson RC. A review of current knowledge on Electronic Vision Enhancement Systems for the visually impaired. Ophthal. Physiol Opt 2003; 23: 35-42

25. Culham LE, Chabra A and Rubin GS Clinical performance of electronic, head-mounted, low vision devices Ophthal Physiol Opt 2004; 24: 281-290

26. Nguyen NX, Weismann M, Trauzettel-Klosinski S Improvement of reading speed after providing of low vision aids in patients with age-related macular degeneration Acta Ophthalmol 2009; 87: 849-853

27. Goodrich GL, Kirby J A comparison of patient performance and preference: optical devices, handheld CCTV (Innovations Magni-Cam) or stand-mounted CCTV (Optelec Clearview or TS ! Genie) Optometry 2001; 72: 519-528

28. Peterson RC, Wolffsohn JS, Rubinstein M et al Benefits of electronic vision enhancement systems (EVES) for the visually impaired. Am J Ophthalmol 2003; 136: 1129-1135

29. Schwartz D, Lellouch J. Explanatory and pragmatic attitudes in therapeutic trials. J Chronic Dis. 1967; 20: 637-648.

30. Thorpe KE, Zwarenstein M, Oxman AD, et al. A pragmatic-explanatory continuum indicator summary (PRECIS): a tool to help trial designers. J Clin Epidemiol 2009;62:464-75.

31. Patsopoulus NA A pragmatic view on pragmatic trials Dialogues Clin Neurosci. 2011;13:217-224

32. Burggraaff MC, van Nispen RMA, Hoeben FP et al Randomized controlled trial on the effects of training in the use of closed-circuit television on reading performance Invest Ophthalmol Vis Sci 2012; 53: 2142-2150

33. Burggraaff MC, van Nispen RMA, Knol DL et al Randomized controlled trial on the effects of CCTV training on quality of life, depression, and adaptation to vision loss Invest Ophthalmol Vis Sci 2012; 53: 3645-3652

34. Court H, Ryan B, Bunce C and Margrain TH. How effective is the new community-based Welsh low vision service? Br J Ophthalmol 2011; 95: 178-184

Figure Captions

Figure 1 Details of the participants involved at each stage of the study

Table Captions

Table 1: Demographic and visual characteristics of participants recruited to the study**.**

Table 2 The breakdown of primary ocular pathologies amongst the study participants who completed the study (n = 82).

Table 3 The range of optical low vision aids used by participants who completed the study (n=82). The number and percentage of participants owning each combination of devices for near vision are shown.

Table 4 The details of the devices used in Intervention A and the time spent in each study arm, for participants in each group. .

Table 5: The mean (SD) maximum reading speed (MRS), critical print size (CPS), and threshold print size (TPS), as measured using the MNRead high contrast (a) and MNRead reduced contrast (b) charts, for each intervention in both groups. ES is unstandardised effect size estimate.

Table 6 Selected responses (mean (SD)) from the MLVQ (a), and the IReST (b) reading performance, for each Intervention in both groups. ES is unstandardised effect size estimate.

Table 7 The number of participants (n (%)) who used each type of LVA in each TIADL task is shown. *one participant missed Task 2 due to a broken arm; # one participant missed Task 4 because equipment not available.

Table 8 The mean (SD) visual ability from Rasch analysis of the responses to the NV-VFQ-15 questionnaire made up of selected “near vision” items from the VFQ-48 instrument. ES is unstandardized effect size estimate, CI is confidence interval.