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Optical reading aids for children and young people with low vision (Review)

Barker L, Thomas R, Rubin G, Dahlmann-Noor A

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[Intervention Review]

Optical reading aids for children and young people with low vision

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ABSTRACT

Background

Low vision in childhood is a significant barrier to learning and development, particularly for reading and education. Optical low vision aids may be used to maximise the child's functional vision. The World Health Organization (WHO) has previously highlighted the importance of the use of low vision aids in managing children with visual impairment across the world.

Objectives

To assess the effect of optical low vision aids on reading in children and young people with low vision.

Search methods

We searched CENTRAL (which contains the Cochrane Eyes and Vision Group Trials Register) (2014, Issue 12), Ovid MEDLINE, Ovid MEDLINE In-Process and Other Non-Indexed Citations, Ovid MEDLINE Daily, Ovid OLDMEDLINE (January 1946 to January 2015), EMBASE (January 1980 to January 2015), the Health Technology Assessment Programme (HTA) (www.hta.ac.uk/), the ISRCTN registry (www.isrctn.com/editAdvancedSearch), ClinicalTrials.gov (www.clinicaltrials.gov) and the World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) (www.who.int/ictrp/search/en). We did not use any date or language restrictions in the electronic searches for trials. We last searched the electronic databases on 8 January 2015.

We also used manual searching to check the references listed in retrieved articles. Manufacturers of low vision aids were contacted to request any information about studies or research regarding their products.

Selection criteria

We planned to include randomised controlled trials (RCTs) and quasi-RCTs where any optical low vision aid was compared to standard refractive correction in children and young people aged between 5 and 16 years of age with low vision as defined by the WHO. We planned to include within-person design studies where the order of presentation of devices was randomised.

Data collection and analysis

Two authors independently reviewed the search results for eligibility .

Main results

No studies met the inclusion criteria for this review.

Authors' conclusions

There is a lack of good quality evidence regarding the use of optical low vision aids in children and young people. As such, no implications for practice can be drawn. We believe future research should include functional outcome measures such as reading speed, accuracy and comprehension, as well as the effect of low vision aids on quality of life, in order to truly assess and compare the effect of these devices on a child's life and development.

PLAIN LANGUAGE SUMMARY

Magnifying reading aids for children and teenagers with low vision

Background
Low vision in children and teenagers not only affects reading, learning and education but is also thought to have a significant effect on a child's general development. Magnifying reading aids can assist a child or teenager to make the best use of the vision they have.

We reviewed the current evidence on the use of magnifying reading aids in children between the ages of 5 and 16 years of age with low vision, when compared to the use of glasses alone. We included magnifying aids such as hand- or stand-held magnifying glasses, telescopes or binoculars but we excluded electronic reading aids which will be the subject of a separate review.

Search date
The electronic databases were last searched on 8 January 2015.

We found no studies which met our criteria for inclusion in this review. We recommend that future studies in this area consider the effect of magnifying reading aids on reading speed and accuracy as well as simply the size of text correctly seen, in order to assess more fully the effect of the reading aid on a child's normal function. We also recommend that the effect of the reading aid on the child's quality of life is investigated as this may have significant implications on its regular and/or long-term use.

BACKGROUND

Description of the condition

In 2004, the World Health Organization (WHO) reported that more than 161 million people worldwide were visually impaired, with 124 million classified as having low vision and 37 million classified as blind (defined as visual acuity less than 3/60 in the better-seeing eye (World Health Organization 2004). In children, the prevalence of blindness varies from 0.3/1000 in high-income countries to over 1.0/1000 in low- and middle-income countries, equating to around 1.4 million blind children worldwide (Gilbert 2001; World Health Organization 2000). Low vision is about twice as common as childhood blindness, and might affect almost 3 million children worldwide (Gilbert 2008a; Gilbert 2008b).

The leading causes of low vision in children worldwide are retinal conditions, corneal scarring (caused by vitamin A deficiency, measles, harmful traditional practices), globe anomalies, cataract, optic nerve anomalies, glaucoma, and central nervous system disorders (Gilbert 2001). A recent study in Nepal identified corneal disease as the leading cause of visual impairment, followed by retinal disease and lens pathology. In 46% of children, however, the cause of visual loss could not be identified (Shrestha 2012). In high-income countries, brain damage sustained around the time of birth has become the leading cause of severe visual impairment (Bodeau-Livinec 2007; Mitry 2013; Rahi 2003). In England and Wales, the commonest conditions in children with impaired, but not severely impaired sight, are hereditary retinal conditions or congenital globe abnormalities (Mitry 2013).

In the United Kingdom (UK), there are an estimated 25,000 children with vision impairment (VI) or severe vision impairment/blindness (SVI/BL) (Morris 2008). The cumulative incidence of SVI/BL by 16 years of age is 5.9, and that of VI around 7 per 10,000 live births (Bodeau-Livinec 2007; Rahi 2003). About 950 new cases of VI or SVI/BL are diagnosed each year (Bodeau-Livinec 2007).

Children are considered to have 'low vision' when the corrected visual acuity (VA) is between less than 6/18 and light perception in their better eye, or their visual field is less than 10 degrees from the point of fixation, but they use, or are potentially able to use, vision for the planning or execution, or both, of a task (World Health Organization 1992). There is an overlap between the definitions of VI and SVI/BL. The exact definition of childhood blindness is variable, but usually ranges between a best-corrected visual acuity of less than 6/60 to 3/60 in the better-seeing eye in a young person under the age of 15 years (Gilbert 2001; World Health Organization 2004).

Visual impairment can result in developmental delay by reducing the range of experiences to which the child is exposed. Early assessment with provision and training of low vision aids (LVAs) is essential to improve functional vision and adaptation to visual impairment, so allowing most children to enter and remain in mainstream schools (Ducrey 1998; Massof 1998; Silver 1976). In the UK, approximately 70% of children with VI are educated in mainstream schools where the use of LVAs to enable use of printed educational materials is essential (Morris 2008). In the developing world, access to enlarged print, or methods to enlarge text (i.e. computers or photocopiers) is more spartan, and magnifiers can be provided as a cheaper and more transportable option for children with low vision. Epidemiological studies in Pakistan have demonstrated that the provision of basic magnification aids would permit at least 11% of children currently educated in schools for the blind to be moved to mainstream schooling (Sight Savers International 2003). This estimate, however, was based on a sample of 1000 children in schools for the blind and was subject to selection bias due to the small percentage of children with low vision currently being educated in special schools in low- and middle-income countries; the overall potential for improvement is significantly higher. In Nepal, optical intervention provided a significant improvement to the vision of 48.2% of children in schools for the blind, enabling those learning braille to learn to read visually, or visually in conjunction with braille (Gnyawali 2012). Despite this improvement however, only 34.8% of children were still using their LVA one year later. Damage or loss was the most common reason reported for cessation of use; however, inadequate instruction and inappropriate setting/lighting were also reported, both of which highlight the vital importance of maintenance of equipment - however basic - and instruction to enable its use (Gnyawali 2012).

Description of the intervention

An LVA can be defined as any device that enables a person with low vision to improve visual performance. LVAs can be classified into optical aids (magnifiers) and electronic 'assistive technologies' (AT). Non-optical aids (filters, tinted lenses and coloured overlays) are also sometimes used to enhance vision, but are less frequently used in children with VI and will, therefore, not be included in this review.

Commonly used optical aids include:

- magnifiers: hand and stand magnifiers, with and without illumination; in general, the higher the magnification the greater the restriction of visual field
- high dioptric power reading glasses or near adds in bifocal glasses (above +4.00 DS and up to +20.00 DS)
- distance telescopes or binoculars: a hand-held or spectacle-mounted lens system that provides magnification at greater distance
- electronic magnification: the longest established form of electronic magnification uses closed-circuit television (CCTV).

Other devices increasingly used in educational settings include screen-magnifying and screen-reading software operated on computers (desktops, laptops, tablets). For the purpose of this review, we will exclude devices that include monitors to display enlarged text. The present review will focus on optical LVAs; assistive technologies including CCTV will be the topic of a second review. No review is planned on non-optical visual aids.

A different magnification strategy used in educational settings is the enlargement of hardcopy printed material. Decisions about which strategy is superior, i.e. LVAs or text modification, depend on the outcomes selected for evaluation. Any form of visual support, i.e. LVAs or enlarged print, can be expected to facilitate access to the educational curriculum and to enable a child to develop better reading and literacy skills. Compared with text enlargement, LVAs may have the additional advantage of providing children and young people with greater independence of access to printed material (Corn 2002; Douglas 2011). However, peer pressure and the fear of 'standing out' may reduce usage of LVAs by children and young people (Mason 1999).

Why it is important to do this review

Improving functional vision in children with VI is important for enabling education and personal development, and for improving vision-related quality of life. The previously held belief that children with low vision should be treated as children with no vision may, in the past, have hampered the study and use of LVAs. The WHO identified and highlighted the provision, education and use of LVAs in children as a priority in managing children with VI (World Health Organization 1992).

The use and benefit of LVAs in adults is well documented, although the need for further research into the comparative benefits of different types of visual aids was highlighted by a previous Cochrane review (Margrain 2000; Virgili 2013). Multiple studies document the use and subjective benefit of LVAs in children (de Carvalho 1998; Haddad 2006; Haddad 2009), and training in the use of magnifiers has been shown to improve the beneficial effects of their use (Cox 2009). There appears to be, however, a lack of agreement and comparative data on relevant outcomes and benefits of LVAs in children and young people.

LVA users, i.e. children, their families and carers, as well as healthcare providers or commissioners, require high-quality evidence to make informed choices about allocation of personal, institutional and public resources. Facilitating reading and literacy in children and young people not only optimises individuals' access to education and employment, but also benefits society. The rationale for this review is, therefore, to provide critical evaluation of information that is already available from high-quality trials, and to delineate a framework for future research and practice policies in low-income, middle-income, and high-income countries.

OBJECTIVES

To assess the effect of optical low vision aids on reading in children and young people with low vision.

METHODS

Criteria for considering studies for this review

Types of studies

We planned to include randomised controlled trials (RCTs) and quasi-RCTs in this review. We considered within-person design studies, in which the order of presentation of devices was randomised, as quasi-RCTs. Within-person studies are similar in design to conventional cross-over studies, but instead of offering interventions sequentially, LVA studies frequently offer these simultaneously and measure outcomes sequentially, in the same session.

Non-randomised studies were excluded from the review, although if sufficient relevant studies are identified in future updates of this review, they might be included in the discussion.

Types of participants

We planned to include trials involving children between the ages of 5 and 16 years with low vision as defined by, or equivalent to, the WHO 1992 definition (World Health Organization 1992):

"A person with low vision is one who has impairment of visual functioning even after treatment and/or standard refractive correction, and has a visual acuity of less than 6/18 to light perception, or a visual field of less than 10° from the point of fixation, but who uses, or is potentially able to use, vision for the planning and/or execution of a task".

We excluded children of pre-school age, as young children tend to hold objects close to their face to achieve magnification, and LVAs are not usually prescribed for this age group. When LVAs are issued to children under the age of five years, the aim is to introduce children to the concept of magnifying devices in a playful manner, and not actually to improve access to visual information.

Types of interventions

We planned to include studies that assess optical visual aids. These included non-electronic magnifiers of all types. We did not include CCTV, which, although it magnifies, is an electronic device. A separate Cochrane review will explore the effects of assistive technologies in the same population. The motivation for splitting the topic into two reviews has its basis in the different objectives of these technologies. Optical aids are prescribed to facilitate reading and access to printed material by providing magnification. Electronic assistive technologies have a broader aim: facilitating access to education, but also to social media and real-time information available via the internet, for example maps/directions, educational or leisure activities offered in the vicinity etc. As such, a comparison of optical aids with assistive technologies would be difficult, as trial outcomes would be limited to the smallest common denominator, i.e. reading-related outcomes. We planned to include studies in which both mediums were used, however, if it was possible to isolate the data relating to the use of optical aids alone.

We aimed to compare the use of optical aids with standard practice, which consists of standard refractive correction including any required near add up to +4.00 DS in aphakic (lacking a lens) or pseudophakic patients. We also would have included studies that compared different types of optical aids with each other, as we aimed to compare optical aids provided with, or without, instructions for use.

Types of outcome measures

Outcome measures for objective outcomes include near visual acuity, distance visual acuity, and reading accuracy, comprehension and speed (Binns 2012). A range of questionnaires is available to measure functional outcomes relating to activities of daily living (ADL), psychological status, and quality of life (both voice-related (VRQoL) and health-related (HRQoL)), such as the Manchester Low Vision Questionnaire (MLVQ) (Harper 1999), the Low Vision Quality of Life Questionnaire (LVQoL) (Wolffsohn 2000), the National Eye Institute Visual Function Questionnaire (NEI-VFQ) (Mangione 1998; Mangione 2001), and the Impact of Vision Impairment profile (IVI) (Hassell 2000; Weih 2002). Only a few tools have been developed and validated for use in children and young people, and even fewer have been developed with focus groups of children and young people. Examples include the Impact of Vision Impairment Profile for Children (IVI_C) (Cochrane 2011), the Cardiff Visual Ability Questionnaire for Children (CVAQL) to assess VRQoL (Khadka 2010), the Functional Vision Questionnaire for Children and Young People with Visual Impairment (FVQ CYP) (Tadic 2013), and the general health-related Pediatric Quality of Life Inventory (Varni 2001; Varni 2002). Some tools gather the views of parents/

carers about their own as well as the child's quality of life (Gothwal 2015; Varni 2001; Varni 2002).

Usage of LVAs is an additional important outcome measure, as it may reflect pragmatic and emotional difficulties with using devices. Peer pressure and the fear of 'standing out' may lead to optical aids being used infrequently or abandoned (Mason 1999). Usage of the LVA is likely to be a more specific outcome measure than VRQoL and HRQoL tools.

Whilst the main aim of LVAs is to magnify visual information, near visual acuity, reflecting successful enlargement of text, is of limited value as a main outcome measure. Reading speed may be the most appropriate primary outcome, as it evaluates the functional visual effect of the aid. Reading performance has been found to be one of the best predictors of patient-reported visual ability and VRQoL (Hazel 2000; McClure 2000). Reading is an important function in daily life. It is a standard outcome in studies monitoring conditions causing VI and in clinical trials evaluating the effectiveness of interventions (Rubin 2013). Maximum reading speed may be the most commonly used outcome in assessing the effect of reading aids, and is the primary outcome explored in a Cochrane review on reading aids for adults with low vision (Virgili 2013). It is typically stable across a range of print sizes over a certain threshold (critical print size), whereas at smaller print sizes, below the critical print size, the reading speed slows and the reading acuity limit is reached (Ahn 1995a; Ahn 1995b; Bailey 2003). Using standardised reading charts such as those in the Minnesota Low-Vision Reading test (MNREAD), a plot of reading speed against font size (adjusted for reading distance and expressed in logMar) can be obtained (Legge 2007). Typically, reading speed also slows above a certain magnification due to the restricted field of view and a lack of a proportional increase in the size of saccades (fast movements of the eyes) (Dickinson 2000).

The use of different font sizes in various studies is a methodological problem for meta-analysis. The most recent update of the Cochrane review on reading aids for adults with low vision included only studies assessing reading speed "when reading ordinary print size", i.e. 10 to 14 points (Virgili 2013). However, there is no universal agreement on ordinary print size for children. Books for young readers frequently use a large font size, i.e. 14 points or larger. School textbooks frequently reduce font size as their target audience matures, but there are no standards, and no recommendations as to when 'standard adult font size' (usually 9 to 14 points) should be used.

The type of reading material also influences reading speed. Research studies often use standardised reading charts such as the MNREAD and, more recently, the International Reading Speed Texts (IReST). Repeated, standardised assessment of reading performance requires a collection of texts of similar difficulty. Whilst the MNREAD chart contains single short sentences, IReST consists of 10 paragraphs of texts (around 130 words each) and offers the advantage of a longer paragraph, which facilitates more accurate measurement of reading speed and judgement of fluency and mistakes (Trauzettel-Klosinski 2012). IReST has been evaluated in a cohort of normal sighted young adults and in patients with age-related macular degeneration, but has not been validated in children and young people.

In addition to reading performance, literacy outcomes such as reading accuracy and comprehension can give additional functional information. A measure of reading ability used in children with VI is the Neale Analysis of Reading Ability (NARA), currently available in its second edition (NARA II) (Neale 1997). This is a comprehensive assessment of reading ability aimed for use with pupils aged 6 to 12 years, and is also recommended for use beyond the age of 12 years in children with sensory impairment. The test material consists of 6 paragraphs that increase in length from 26 to 140 words, and increase in difficulty.The test is designed to assess oral reading ability in terms of reading rate, accuracy and comprehension. Validation data are available for normally sighted individuals, and also for children and young people with visual impairment (Douglas 2002; Hill 2005). There are two parallel versions of the test, which permits the same child to be re-tested without remembering a previous test and thereby altering the score. The child's scores are converted into reading ages for accuracy, comprehension and speed. Accuracy is determined by noting reading errors such as mispronunciations, substitutions, refusals, additions, omissions and reversals. Comprehension is measured by asking the child a number of set questions concerning the passage he/she has just read. Reading speed is measured by timing the passages read and converting this into words per minute over the total number of passages read. Results can be plotted as graphs comparing the performance of VI-students with normal-sighted age-matched peers (Douglas 2002; Hill 2005).

All literacy evaluations need to take into account that children are learning to read, i.e. are developing a skill. Children with low vision often read print more slowly and less accurately than normally sighted peers (Douglas 2004; Gompel 2004). Comprehension may also be delayed; this may be linked to general delay in reading development (Douglas 2002). Other literacy tests used in educational settings, such as the National Foundation for Educational Research (NFER) and Access Reading Test (ART), include access features for children with low vision (enlarged print, braille, extended time), but no data from children with low vision are available.

Primary outcomes

- Maximum reading speed in words per minute using MNREAD, IRest, NARA, NARA II or equivalent test in another language.

Secondary outcomes

Any of the following outcomes assessed using a standardised chart such as MNRead or IReST, or a standardised literacy test such as NARA.

- Reading accuracy as errors per words read.
- Reading comprehension as number of correctly answered set questions concerning the text read.
- Reading acuity in logMar, defined as the smallest print that the child/young person can read without making significant errors.
- Critical print size, defined as the smallest print that the child/young person can read with maximum speed.
- Fatigue-free reading duration in minutes.

Secondary outcomes with different means of assessment (i.e. not standardised chart or literacy test).

- Acceptance of the LVA, as reflected in usage (days per week, hours per day, at home and at school).

- Independent learning, i.e. ability to access the curriculum independently, as assessed by questionnaires.
- VRQoL, evaluated using any validated VRQoL scale for children.
- HRQoL evaluated using any validated HRQoL scale for children.
- Cost effectiveness.
- Adverse outcomes, for example loss of motivation to use the device.

With regard to the time points of evaluation, general child development and, particularly, the development of reading and literacy skills will affect the effect size of interventions at given time points. One would expect an increase in reading speed with time as a younger child learns to read, regardless of LVA use, but using an aid may allow faster development of reading skills. On the other hand, a child's ability may have improved to a degree over that period of time, just as his/her general development has progressed.

For this review, we considered the following time points: Primary outcome: 3 and 12 months (+/- 3 months) after the intervention and relevant instructions, if any, have been issued, where 3 months was a proof of concept. Secondary outcomes: 12 months (+/- 3 months). Ultimate outcomes such as educational attainment, as measured in educational progress, would be desirable, but due to the length of follow-up required, these are unlikely to be captured in research studies.

Search methods for identification of studies

Electronic searches

We searched CENTRAL (which contains the Cochrane Eyes and Vision Group Trials Register) (2014, Issue 12), Ovid MEDLINE, Ovid MEDLINE In-Process and Other Non-Indexed Citations, Ovid MEDLINE Daily, Ovid OLDMEDLINE (January 1946 to January 2015), EMBASE (January 1980 to January 2015), the Health Technology Assessment Programme (HTA) (www.hta.ac.uk/), the ISRCTN registry (www.isrctn.com/editAdvancedSearch), ClinicalTrials.gov (www.clinicaltrials.gov) and the World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) (www.who.int/ictrp/search/en). We did not use any date or language restrictions in the electronic searches for trials. We last searched the electronic databases on 8 January 2015.

See: Appendices for details of search strategies for CENTRAL (Appendix 1), MEDLINE (Appendix 2), EMBASE (Appendix 3), HTA (Appendix 4), ISRCTN (Appendix 5), ClinicalTrials.gov (Appendix 6) and the ICTRP (Appendix 7).

Searching other resources

We also used manual searching to check the references listed in retrieved articles. Manufacturers of LVAs were contacted to request any information of which they are aware about studies or research regarding their products.

Data collection and analysis

Selection of studies

Independently, two review authors (LB and AHDN) assessed titles and abstracts for eligibility. Studies were divided into categories to 'definitely include', 'definitely exclude' and 'possibly include', and final judgements about inclusion/exclusion were made by obtaining full-text copies of the studies in the 'possibly include' category. Abstracts and, where necessary, full-text articles were translated into English before a final decision was made regarding inclusion/exclusion. Disagreements between the two review authors was to be resolved by discussion or a designated third author, or both, but no disagreement occurred.

Data extraction and management

We had planned for two authors to independently extract data using the data extraction form (Appendix 8) developed in conjunction with the Cochrane Eyes and Vision Group using Chapter 7 of the *Cochrane Handbook for Systematic Reviews of Interventions* for guidance (Higgins 2011a). Data were to be entered into Review Manager (RevMan 2014) software by one author and to be independently reviewed and cross-checked by a second.

For continuous data, data on the mean and standard deviation (SD) in each group were to be extracted. RevMan was to be used to calculate the mean difference and 95% confidence intervals (CI). When dealing with cross-over studies we planned to use the generic inverse variance method as described in Chapter 16 of the *Cochrane Handbook for Systematic Reviews of Interventions* for guidance (Higgins 2011b).

Assessment of risk of bias in included studies

Two authors were to work independently to review the risk of bias of included studies using the Cochrane Collaboration's 'Risk of Bias' assessment tool, detailed in Chapter 8 of the *Cochrane Handbook for Systematic Review of Interventions* (Higgins 2011c), as guidance. The five main domains of the tool include:

Selection bias

Studies were to be graded by review authors as 'high risk', 'low risk' or 'unclear risk' based on the method of randomisation (sequence generation) and allocation concealment. If an 'unclear risk' assessment is made, study authors are contacted to provide further information to enable a more detailed risk assessment to be made.

Performance bias

Masking of participants is not possible given the nature of the intervention in question. We did not, therefore, plan to grade studies on the basis of masking alone. A judgement regarding performance bias was to be made by the review authors, taking into consideration the instruction and education given to participants for each visual aid and the 'learning-effect' time allocated before the final assessment was made.

Attrition bias

Incomplete outcome data was to be recorded and attempts were to be made to contact the study authors in order to obtain complete data. A judgement of 'high risk', 'low risk' or 'unclear risk' of attrition bias was to be made by review authors with regard to the completeness of the data and the handling of incomplete data in the studies.

Detection bias

Masking of study investigators and personnel is not possible due to the nature of the intervention in question. Detection bias would occur if the allocated intervention, i.e. use of the optical aid, was visible to the outcome assessor. One way of reducing this risk would

be to record reading on audiotape, or as audiofile, and later to have masked evaluation by a masked observer. We planned to judge studies on use of masking strategies. Detection bias may, in turn, affect reporting, if assessors then chose to exclude some participants or type of devices based on performance, thereby introducing reporting bias.

Reporting bias

Where a study protocol was available, the review authors were to compare the published protocol with the final outcomes reported to assess the risk of selective outcome reporting as 'high risk', 'low risk' or 'unclear risk'. Where no protocol was available, the full-text article was to be studied to make this judgement.

Other bias

The review authors planned to judge whether each study design was subject to any other risks for the introduction of bias that are not detailed above. In particular, we expected studies with within-person design to be commonly used in assessing the effects of LVAs, as a previous Cochrane review found this to be the case in studies investigating the use of LVAs in adults (Virgili 2013). A particular problem with this design in paediatric studies is that by the time participants start using a second intervention they may have matured and acquired more skills, which may influence the effect size of the second intervention. Chapter 16 of the *Cochrane Handbook for Systematic Reviews of Interventions* recommends that when cross-over studies are evaluated, review authors should take into account whether the condition is chronic and stable, whether the intervention provides temporary relief and not permanent change, whether the outcome can be repeated in the second period if it occurs in the first, whether the effect of the first intervention lasts into the second treatment period, and whether trial length is sufficient to allow appropriate use of the intervention (Higgins 2011b).

Within-person studies can provide randomisation by including independent sequence generation and allocation concealment. We planned to grade both sequence generation and allocation concealment as factors carrying a 'low risk' of bias in these studies, as in a previous review focussing on LVA use in adults (Virgili 2013). We planned to ask two questions to rate the quality of randomisation and allocation in this type of study: 1. Does knowledge of the first LVA selected affect recruitment into the trial, and 2. Does the order in which the LVAs are used affect the results?

For within-subject studies testing several devices within the same research session, knowledge of the first LVA should not affect recruitment. In such situations we planned to consider two additional items for question 2: 1) period effect, that is, whether the condition might change during subsequent phases of testing of each device; and 2) carry-over effect and period-by-treatment interaction, that is, whether the effect on performance of using a specific device affects the performance of the devices assessed afterwards (Virgili 2013).

Review authors were not masked to any aspect of the study design and any disagreement was to be settled by discussion or a third designated author, or both.

Measures of treatment effect

The primary outcome (reading speed) is a continuous variable, as are reading accuracy, comprehension, acuity, print size, duration, acceptance/usage. Validated VRQoL and HRQoL tools also deliver continuous scores.

Non-continuous variables were not to be included in the meta-analysis. These might have included data assessed by non-validated questionnaires, such as 'independent learning', and data such as 'cost-effectiveness' and 'adverse outcomes'.

Unit of analysis issues

Individual participants/children, rather than individual eyes were to be used as the unit of randomisation, as the use of LVAs is most commonly binocular.

Although near and distance visual acuity is commonly measured for individual eyes in a clinical setting, reading speeds and educational assessments are routinely obtained with both eyes open. This allows a more functional assessment, based on the better seeing eye and excluding artefacts such as, for example, an increase in nystagmus amplitude by covering one eye. Studies that measured outcome in the better eye were to be included.

As the main outcome is measured at the person level, we did not expect any unit of analysis issues.

Dealing with missing data

Study authors were to be contacted to obtain missing data where necessary. Where not available or forthcoming, the details of the missing data and the handling of this in the outcome reporting was investigated and reported in detail.

Assessment of heterogeneity

We planned to examine the characteristics of the included studies to identify clinical, methodological and statistical heterogeneity. Methodological heterogeneity may arise from differences in interventions, masking, allocation concealment, outcomes and their measurement.

If sufficient studies are identified in future updates of this review, we will use the I^2 statistic with CIs along with inspection of forest plots (poor overlap of CIs) to assess heterogeneity as detailed in Chapter 9 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2011). The interpretation of this statistic would be in line with the guidance in the *Handbook*, where an I^2 value of over 50% was considered to represent 'substantial' (50% to 90%), or 'considerable' (75% to 100%) heterogeneity.

Assessment of reporting biases

Assessment of reporting bias was to be carried out as detailed in the Assessment of risk of bias in included studies section above. In future updates of this review, if 10 or more studies are included in analysis, we plan on constructing a funnel plot and examining it for asymmetry in order to assess reporting bias.

Data synthesis

Meta-analysis would have been carried out if more than one RCT had been identified and there had been sufficient homogeneity in study design to yield a meaningful analysis. In future updates of

this review, if sufficient studies are included, a meta-analysis will be conducted according to Chapter 9 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2011).

Since a within-person design is common in research on the effectiveness of LVAs (Virgili 2013), these studies were to be included if the devices were presented in randomised or quasi-randomised order. This study design leads to specific issues, such as within-subject correlation and multiplicity of testing. We proposed to deal with these issues using methods suggested in Elbourne 2002 and in Chapter 16 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011b).

Subgroup analysis and investigation of heterogeneity

No subgroup analysis was planned.

Sensitivity analysis

If sufficient studies are identified in subsequent updates of this review, sensitivity analysis will be conducted to establish the effect of:

- assumptions made when dealing with missing data;
- excluding studies at 'high risk' of bias.

'Summary of findings' table

We planned to summarise the results in a 'Summary of findings' table using relative and absolute measures of effect. The overall quality of the evidence will be assessed using GRADE (GRADEpro 2014).

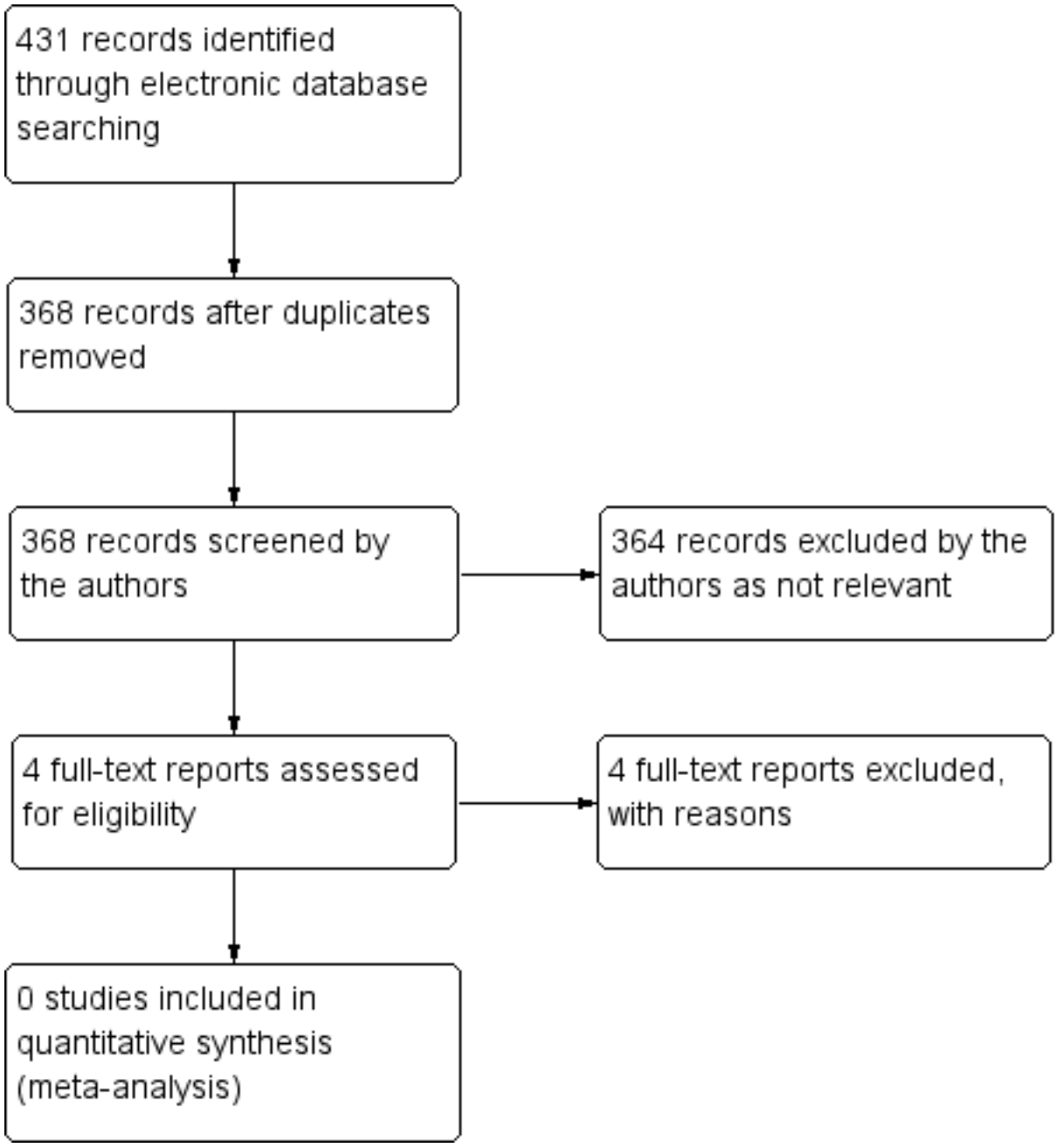
RESULTS

Description of studies

Results of the search

The electronic searches yielded a total of 431 references (Figure 1). After duplicates were removed we assessed 368 references for potential inclusion in the review. We discarded 364 reports as they were not relevant to the scope of the review. We assessed the full-text reports of four studies (Greene 1993; Huurneman 2013; John 2006; NCT00366392) as they potentially met the inclusion criteria; two were reviewed in full, while for the third, only the abstract was available. None of the four studies met the inclusion criteria for this review.

Figure 1. Results of searching for studies for inclusion in the review



Contacting device manufacturers did not yield any ongoing or recent studies.

Included studies

No studies met the inclusion criteria for this review.

Excluded studies

Four studies (Greene 1993; Huurneman 2013; John 2006; NCT00366392) were initially placed in the 'possibly include' category but ultimately excluded as they did not meet the inclusion criteria:

Risk of bias in included studies

No studies met the inclusion criteria for this review and therefore no comment on risk of bias in included studies can be made.

Effects of interventions

No studies met the inclusion criteria for this review and therefore no comment on the effects of interventions can be made.

DISCUSSION

Summary of main results

The main question posed by this review is whether optical low vision aids (LVAs) have a beneficial effect on reading in children and young people with low vision. No studies were identified which could be included in this review, due to a lack of randomisation and/or a variability of outcome measures, and therefore our main conclusions in this review must be that:

1. High-quality evidence on the use of LVAs by children and young people is lacking.
2. For future studies, greater uniformity of outcome measures is important to facilitate comparison and meta-analysis of findings.

Overall completeness and applicability of evidence

We identified only two studies and one non-randomised clinical trial which recruited children. The difficulty in assessing LVA use in young children has already been discussed with regard to the additional confounding factor that these children are learning to read at the same time. This may contribute to the paucity of studies on LVA use in children. A similar review performed in adult participants however, also identified a lack of high-quality evidence from which to draw conclusions (Virgili 2013).

The variability of outcome measures should also be mentioned. In the three studies detailed above on which we have sufficient information, Greene 1993 used a subjective questionnaire to assess patient use and acceptance of LVAs, Huurneman 2013 used near visual acuity and response time and John 2006 used distance acuity, reading speed and comprehension assessments as outcome measures. The disparity in reported outcomes prohibits comparison, even if the study designs had been more favourable. A standardised approach to assessing the effect of LVA interventions would allow more accurate and evidence-based comparison in future studies.

Quality of the evidence

The lack of randomisation and the favoured use of cross-over or within-person design studies in this subject has also been discussed above and in a previous review on LVA use in adults (Virgili 2013). Whilst we elected to include within-person design studies where the order in which the devices were presented was randomised, the limitations of this type of methodology remain, particularly when used in developing children (period effect) or progressive pathology (worsening of baseline condition). Ideally, parallel-armed studies at multiple age groups would provide comparable and extrapolatable evidence, however the large numbers required for this type of design, particularly if it was to include all age groups, likely make this type of study design prohibitive.

AUTHORS' CONCLUSIONS

Implications for practice

Due to the lack of high-quality evidence from randomised controlled trials (RCTs), we cannot discuss the implications for practice.

Implications for research

Low vision aids (LVAs) can allow children and young people with sight impairment independent access to learning. Education, and particularly the ability to read, is an important component of children's life and development. Educational success can have a major economic and social impact, as it may help a sight-impaired person to lead an independent life. As such, research on low vision and its treatment and management in children and young people is vital. High-quality evidence is needed to assess the efficacy and cost-effectiveness of LVAs and the training in their use.

Stringent inclusion criteria may mean that not all children and young people with low vision can be included in an RCT, as all participants would need to be able to use the devices to which they are randomised, and to carry out the outcome assessments. However, data from such trials would allow comparison of devices and techniques. Trials have to ensure that adequate training in the use of each device is included in the study design.

This review details outcomes deemed relevant not only by researchers, but also by children and young people with low vision, their families and teachers. It is important to move away from visual acuity as a principal outcome measure, as it merely reflects the optical/geometrical relationship between angle of resolution and magnification. Functional outcomes such as reading speed, accuracy and comprehension are more informative and relevant to users and providers. In addition, assessing the wider impact of devices on quality of life is increasingly important for decisions about allocation of resources. Several tools to measure the impact of interventions on the vision-related and general health-related quality of life and functional vision of sight-impaired children/young people as well as the quality of life of their families are now available for use (Cochrane 2011; Gothwal 2015; Khadka 2010; Tadic 2013; Varni 2001; Varni 2002).

As device usage may be adversely affected by practicalities such as device weight and transportability, comfort, fit and cosmesis, future studies should assess and record these factors, possibly as adverse events.

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CHARACTERISTICS OF STUDIES

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Greene 1993	Described a randomised cross-over trial of spectacle-mounted telescope low vision aids (new technology versus older models), but all participants were adults. In addition, the outcome measures were subjectively reported based on the type (when the telescopes were used in day-to-day life) and amount (how often the telescopes were used) of usage.
Huurneman 2013	Compared magnifiers versus large print in children aged 4 to 8 years. The article did not specify whether children were allocated to treatment groups by randomisation. The first author was contacted and confirmed that allocation was not randomised but carried out by an independent observer who allocated children to either study arm based on age and near visual acuity to ensure matching.
John 2006	Presented a comparison of low vision telescopes (LVT) and standard-correction glasses (SCG) in paediatric glaucoma patients as a conference proceeding. The abstract did not give details regarding how many children had low vision and whether children were randomly allocated to interventions. We contacted the senior and first authors for further details of the study, but did not receive a reply.
NCT00366392	This clinical trial compared large print versus optical aids for visually impaired students aged 5 to 17 years. The study was closed in 2007. It did not meet the inclusion criteria for this review, as allocation was not randomised and no masking took place.

APPENDICES

Appendix 1. CENTRAL search strategy

#1 MeSH descriptor: [Vision, Low] explode all trees
#2 low near/2 vision*
#3 MeSH descriptor: [Visually Impaired Persons] explode all trees
#4 (vision* or visual*) near/2 impair*
#5 MeSH descriptor: [Blindness] explode all trees
#6 MeSH descriptor: [Hemianopsia] explode all trees
#7 hemianop*
#8 quadrantanop*
#9 amauros*
#10 (handicap* or disabil* or disabl*) near/3 (visual*)
#11 (handicap* or disabil* or disabl*) near/3 (vision)
#12 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11

#13 MeSH descriptor: [Sensory Aids] explode all trees
#14 MeSH descriptor: [Lenses] this term only
#15 MeSH descriptor: [Optics and Photonics] this term only
#16 MeSH descriptor: [Optical Devices] this term only
#17 "low vision aid"
#18 MeSH descriptor: [Reading] explode all trees
#19 (aid* or device* or instrument* or equipment or apparatus) near (read*)
#20 (aid* or device* or instrument* or equipment or apparatus) near (optic*)
#21 telescop* or magnifi* or binocular*
#22 #13 or #18 or #20 or #21
#23 MeSH descriptor: [Child] explode all trees
#24 MeSH descriptor: [Infant] explode all trees
#25 MeSH descriptor: [Adolescent] explode all trees
#26 MeSH descriptor: [Pediatrics] explode all trees
#27 boy* or girl* or child* or minor* or offspring or prepubescen* or pubescen*
#28 adolescen* or juvenile* or teen or teens or teenage* or youth or youths or underage
#29 paediatric* or pediatric*
#30 (primary or elementary or high or secondary) near/1 school*
#31 nurser* or kindergarten* or preschool* or pre school* or school*
#32 schoolchild* or schoolage or highschool* or daycare
#33 #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32
#34 #12 and #22 and #33

Appendix 2. MEDLINE (OvidSP) search strategy

1. randomized controlled trial.pt.
2. (randomized or randomised).ab,ti.
3. placebo.ab,ti.
4. dt.fs.
5. randomly.ab,ti.
6. trial.ab,ti.
7. groups.ab,ti.
8. or/1-7
9. exp animals/
10. exp humans/
11. 9 not (9 and 10)
12. 8 not 11
13. exp vision low/
14. (low adj2 vision$).tw.
15. exp visually impaired persons/
16. ((visual$ or vision$) adj3 impair$).tw.
17. exp blindness/
18. exp hemianopsia/
19. hemianop$.tw.
20. exp quadrantanopsia/
21. quadrantanop$.tw.
22. amauros$.tw.
23. ((handicap$ or disabil$ or disabl$) adj3 vision$).tw.
24. ((handicap$ or disabil$ or disabl$) adj3 visual$).tw.
25. or/13-24
26. sensory aids/
27. Lenses/
28. "Optics and Photonics"/
29. Optical Devices/
30. "low vision aid$".tw.
31. exp reading/
32. ((aid$ or device$ or instrument$ or equipment or apparatus) adj3 read$).tw.
33. ((aid$ or device$ or instrument$ or equipment or apparatus) adj3 optic$).tw.
34. (telescop$ or magnifi$ or binocular$).tw.
35. or/26-34
36. exp child/
37. exp adolescent/

38. exp pediatrics/
39. (boy$ or girl$ or child$ or minor$ or offspring or prepubescen$ or pubescen$).tw.
40. (adolescen$ or juvenile$ or teen or teens or teenage$ or youth or youths or underage).tw.
41. (paediatric$ or pediatric$).tw.
42. ((primary or elementary or high or secondary) adj1 school$).tw.
43. (schoolchild$ or schoolage or highschool$ or daycare).tw.
44. or/36-43
45. 25 and 35 and 44
46. 12 and 45

The search filter for trials at the beginning of the MEDLINE strategy is from the published paper by Glanville et al (Glanville 2006).

Appendix 3. EMBASE (OvidSP) search strategy

1. exp randomized controlled trial/
2. exp randomization/
3. exp double blind procedure/
4. exp single blind procedure/
5. random$.tw.
6. or/1-5
7. (animal or animal experiment).sh.
8. human.sh.
9. 7 and 8
10. 7 not 9
11. 6 not 10
12. exp clinical trial/
13. (clin$ adj3 trial$).tw.
14. ((singl$ or doubl$ or trebl$ or tripl$) adj3 (blind$ or mask$)).tw.
15. exp placebo/
16. placebo$.tw.
17. random$.tw.
18. exp experimental design/
19. exp crossover procedure/
20. exp control group/
21. exp latin square design/
22. or/12-21
23. 22 not 10
24. 23 not 11
25. exp comparative study/
26. exp evaluation/
27. exp prospective study/
28. (control$ or prospectiv$ or volunteer$).tw.
29. or/25-28
30. 29 not 10
31. 30 not (11 or 23)
32. 11 or 24 or 31
33. exp visual disorder/
34. exp visual impairment/
35. exp blindness/
36. (low adj2 vision$).tw.
37. ((visual$ or vision$) adj3 impair$).tw.
38. exp hemianopia/
39. hemianop$.tw.
40. quadrantanop$.tw.
41. amauros$.tw.
42. ((handicap$ or disabil$ or disabl$) adj3 vision$).tw.
43. ((handicap$ or disabil$ or disabl$) adj3 visual$).tw.
44. or/33-43
45. exp visual aid/
46. exp general medical aids/
47. optical instrumentation/
48. exp reading/

49. ((aid$ or device$ or instrument$ or equipment or apparatus) adj3 read$).tw.
50. ((aid$ or device$ or instrument$ or equipment or apparatus) adj3 optic$).tw.
51. (telescop$ or magnifi$ or binocular$).tw.
52. or/45-51
53. exp child/
54. exp adolescent/
55. exp pediatrics/
56. (boy$ or girl$ or child$ or minor$ or offspring or prepubescen$ or pubescen$).tw.
57. (adolescen$ or juvenile$ or teen or teens or teenage$ or youth or youths or underage).tw.
58. (paediatric$ or pediatric$).tw.
59. ((primary or elementary or high or secondary) adj1 school$).tw.
60. (schoolchild$ or schoolage or highschool$ or daycare).tw.
61. or/53-60
62. 44 and 52 and 61
63. 32 and 62

Appendix 4. HTA Programme search strategy

low vision

Appendix 5. ISRCTN search strategy

low vision

Appendix 6. ClinicalTrials.gov search strategy

Reading Aids AND Low Vision

Appendix 7. ICTRP search strategy

Low Vision = Condition AND Reading Aids = Intervention

Appendix 8. Data extraction form

Review author	
Study ID	
Dates when study was conducted	If not available, comment "dates not available"
Funding source(s)	
Declarations of interest by researchers	
Methods	Study design, e.g. parallel group randomised trial, cluster-randomised trial, controlled before and after study, within-person Duration Within-person design: method of intervention allocation
Participants	Total number, number in each group (sample size) Comparability Setting
Risk of bias	Assessed using 'Risk of bias' tool (see *Handbook*)

(Continued)

Outcomes (as defined in study) **Please specify which**	**Primary outcome** • Maximum reading speed in words per minute using MNREAD, IRest, NARA or NARA II **Secondary outcomes** • Reading accuracy as errors per words read • Reading comprehension as number of correctly answered set questions concerning the text read • Reading acuity in logMar, defined as the smallest print that the child/young person can read without making significant errors • Critical print size, defined as the smallest print that the child/young person can read with maximum speed • Fatigue-free reading duration in minutes, all assessed using a standardised chart such as MNRead or IReST or a standardised literacy test such as NARA. • Acceptance of the LVA, as reflected in usage (days per week, hours per day, at home and at school) • Independent learning, i.e. ability to independently access the curriculum, as assessed by questionnaires • VRQoL, evaluated using any validated VRQoL scale for children • HRQoL evaluated using any validated HRQoL scale for children • Cost effectiveness • Adverse outcomes, for example loss of motivation to use the device
Interventions compared	Intervention 1 = Standard care (baseline refractive correction), or LVA (specify type) Intervention 2 = LVA (specify type) additional interventions: LVA - specify type

PRIMARY OUTCOME: Maximum reading speed	**Intervention 1**			**Intervention 2**		
Time point	**Total number of participants**	**Mean**	**Standard deviation***	**Total number of participants**	**Mean**	**Standard deviation***
Baseline						
Immediately after intervention issued						
3 months						
6 months						
12 months						
	Intervention 3			**Intervention 4**		
Time point	**Total number of participants**	**Mean**	**Standard deviation***	**Total number of participants**	**Mean**	**Standard deviation***
Baseline						
Immediately after intervention issued						

(Continued)

3 months						
6 months						
12 months						

SECONDARY OUTCOMES: Copy table for each secondary outcome	**Intervention 1**			**Intervention 2**		
Time point	**Total number of participants**	**Mean**	**Standard deviation***	**Total number of participants**	**Mean**	**Standard deviation***
Baseline						
Immediately after intervention issued						
3 months						
6 months						
12 months						
	Intervention 3			**Intervention 4**		
Time point	**Total number of participants**	**Mean**	**Standard deviation***	**Total number of participants**	**Mean**	**Standard deviation***
Baseline						
Immediately after intervention issued						
3 months						
6 months						
12 months						

CONTRIBUTIONS OF AUTHORS

Lucy Barker: design and co-ordination of review, writing of protocol and review.
Annegret Dahlmann-Noor: guarantor of review; design and writing of protocol and review.
Rachel Thomas, Gary Rubin: design and writing of protocol and review.

DECLARATIONS OF INTEREST

Lucy Barker: No commercial or proprietary interests to declare.
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Gary Rubin: No commercial or proprietary interests to declare.
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INDEX TERMS

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*Reading; Optical Devices; Vision, Low [*rehabilitation]

MeSH check words

Humans