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The effectiveness and cost-effectiveness of coloured filters for reading disability: A systematic review

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The effectiveness and cost-effectiveness of coloured filters for reading disability: A systematic review

A WEST MIDLANDS HEALTH TECHNOLOGY ASSESSMENT COLLABORATION REPORT

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WEST MIDLANDS HEALTH TECHNOLOGY ASSESSMENT COLLABORATION (WMHTAC)

The West Midlands Health Technology Assessment Collaboration (WMHTAC) produce rapid systematic reviews about the effectiveness of healthcare interventions and technologies, in response to requests from West Midlands Health Authorities or the HTA program. Reviews usually take 3-6 months and aim to give a timely and accurate analysis of the quality, strength and direction of the available evidence, generating an economic analysis (where possible a cost-utility analysis) of the intervention.

CONTRIBUTIONS OF AUTHORS:

Esther Albon (re)designed the protocol, identified included studies, undertook data extraction and quality assessment, identified included studies for the cost effectiveness section, and wrote the report. Yaser Adi designed the first draft of the protocol, and undertook study identification at the title and abstract stage. Chris Hyde advised on the protocol, wrote the section on cost effectiveness and advised on the general writing of the report.

CONFLICTS OF INTEREST:

None

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West Midlands Regional Evaluation Panel

Recommendation

Not proven and not supported. Given the potential size of the problem there is a need for more basic research in this area

Anticipated expiry date:

January 2011

GLOSSARY/ABBREVIATIONS AND ACRONYMS

Abbreviation/ Acronym	Definition
ARIF	Aggressive Research Intelligence Facility
CI	confidence interval
FRI	Formal Reading Inventory
ICER	incremental cost effectiveness ratio
IDPS	Irlen Differential Perceptual Schedule
ITT	intention to treat
LEA	Local Education Authority
m	month
MRC	Medical Research Council
MIS	Meares-Irlen Syndrome
Neale	Neale Analysis of Reading Ability
NLS	National Literacy Strategy (primary)
NR	not reported
pb	placebo
PCT	primary care trust
QoL	quality of life
RCT	randomised controlled trial
RD	reading disability
REP	Regional Evaluation Panel
SD	standard deviation
SE	standard error
SEN	special educational needs
SLD	specific learning difficulties
SMD	standardised mean difference
SRD	specific reading difficulties
SSS	scotopic sensitivity syndrome
tx	treatment
Viss	“Vision” software
WMHTAC	West Midlands Health Technology Assessment Collaboration
WRRT	Wilkins Rate of Reading Test
y	year

Note on terminology:

Please note that RD is used throughout the review for simplicity but some articles may have used different terminology such as dyslexia, specific reading difficulty, specific learning difficulty, developmental reading disorder, reading difficulty, reading problem, specific learning disability and specific reading disorder. These terms all refer to a reading deficit without an obvious cause.

EXECUTIVE SUMMARY

Background

Reading disability affects up to 18% of school-aged children in the UK. If left untreated it can adversely affect emotional, behavioural and socio-economic outcomes in adulthood. It has been hypothesised that coloured filters fitted as either glasses or contact lenses, or used as an overlay, may improve reading ability.

Aim

To use the process of systematic review to assess the effectiveness, and cost effectiveness, of coloured filters for reading disability.

Methods

Databases (MEDLINE, EMBASE, CINAHL, PsychINFO, Science Citation Index and the Cochrane Library) were searched from the database start date to September 2007 using appropriate terms and filters. Randomised controlled trials, quasi-randomised controlled trials and non-randomised controlled trials employing the relevant intervention (tinted or coloured lenses, glasses, or overlays) and comparator (no treatment, placebo or other current treatment) in subjects with reading disability were included. Subjects had to be aged 7 years or over. Studies were only included if outcomes of reading accuracy, speed and comprehension, or the symptoms, behaviour or quality of life associated with reading disability were assessed. Study inclusion, data abstraction and quality assessment were performed before quantitative and qualitative data analyses were carried out.

A systematic review of costs, and cost-effectiveness studies for the use of coloured filters for reading disability was conducted. Searches were undertaken during September to December 2007 using ERIC and OHE HEED in addition to the databases listed above. Any study relevant to the review question was included. It was not possible to develop an economic model to address the cost-effectiveness of coloured filters for reading disability.

Results

One quasi-systematic review was identified by the searches. Eight RCTs (four parallel studies and four crossover studies) were included in the review of effectiveness of coloured filters for reading disability. A number of different tests and scales were used to assess reading across the 8 studies. Study quality was generally poor. Threats to the validity of the results included small sample sizes, inadequate controls, lack of reporting of randomisation methods, difficulty in the maintenance of any blinding, and high levels of attrition. A further design flaw was identified in five studies, which used the intervention under evaluation to screen and enrol subjects showing some benefit with the intervention, prior to being randomised into the intervention or comparator groups (selection bias).

Meta-analysis for the outcome of reading accuracy (3 studies) showed no clear benefit to using coloured filters for reading accuracy compared to using the control. The two studies that could not be incorporated into meta-analysis reported a statistically significant improvement and no statistically significant improvement with preferred coloured filters compared to the control. Meta-analysis of reading speed and reading comprehension data (4 studies for each outcome) showed no clear benefit to using coloured filters for reading speed or comprehension compared to using the control. The two studies that could not be incorporated into meta-analysis for either outcome reported a statistically significant improvement and no statistically significant improvement with preferred coloured filters compared to the control. The results of the meta-analysis should be treated with caution since the trial design, patient characteristics and outcome tests varied considerably between studies. Based on the I^2 statistic, however, statistical heterogeneity between studies was low.

Two studies evaluated the outcome of symptoms of visual stress that can be associated with reading disability. Both studies used subjective measures to show that there was a statistically significant improvement in the level of symptoms when coloured filters were used compared to the control.

The long-term effects of using coloured filters were not evaluated as part of the randomised design by any of the included RCTs. None of the studies reported

behaviour, quality of life or adverse effects of using coloured filters for reading disability.

A further 15 non-randomised comparative studies were also identified that matched the review inclusion criteria. Methodological quality was very poor, with many threats to study validity.

A pre-existing economic evaluation of the use of coloured filters for reading disability was not identified by the searches. Only limited cost data on coloured filters and reading disability was available. In addition, there was little information on the long-term impact of reading disability. It was therefore not possible to provide an estimate of cost-effectiveness of coloured filters for reading disability.

Conclusions

Meta-analysis and qualitative assessment of eight included RCTs did not show that the use of coloured filters led to a clear improvement in reading ability in subjects with reading disability. It was not possible to comment on whether coloured filters can improve symptoms of visual stress that may be associated with reading disability due to a lack of available evidence.

Based on the evidence obtained from this systematic review there can be no major implications for current practice in the treatment of reading disability. It remains a possibility that there exists a subgroup of people who may experience an improvement in reading through the use of coloured filters, while others find that there is no beneficial effect. Further well-designed research may generate clearer results.

CONTENTS

APPENDICES

TABLES

FIGURES

AIM OF THE REVIEW

The aim of this review was to systematically evaluate the available evidence for the effectiveness of coloured filters for reading disability.

Two questions were considered:
-Does the use of coloured filters for reading disability lead to an improvement in reading performance compared to no treatment, placebo, or any other current treatment?
-Do coloured filters reduce the symptoms that can be associated with reading disability such as asthenopia, and headache?

1. BACKGROUND

1.1 Description of underlying health problem

1.1.1 Reading disability

Reading disability or disorder (ICD-10 code F81.0; DSM-IV code 315.00) is the most common of the learning disabilities. A reading disability (RD) is a specific and significant impairment in the development of reading skills that cannot be accounted for by mental age (intelligence), visual acuity problems, or inadequate opportunity. In the case of a child, RD may be suspected when there is difficulty in meeting reading milestones for a given age or grade. RD can be assessed in terms of IQ, in which reading is significantly lower than that predicted on the basis of age and IQ, or by using a non-IQ referenced measure of general low reading achievement when compared to population norms. Both group and individual tests can be used.

A child or adult can have difficulty with one or more aspects of the reading process including difficulty with accurate and/or fluent word recognition, word decoding, reading rate, oral reading, and reading comprehension. RD does not represent a transient developmental lag. There are three main groups of RD, known as dyseidetic, dysphonetic, or mixed (a combination of the two forms). Dyseidetic reading refers to a difficulty identifying patterns of letters when grouped together, even though individual letters can be sounded out. Dysphonetic readers find it

difficult to relate individual letters to sounds, so find it difficult to identify new words even though they are able to recognise memorised words. Emotional or behavioural disturbances are frequently associated with RD.[1,2]

A reading disability may also be referred to as a developmental reading disorder, reading difficulty, reading problem, specific learning disability, specific reading disorder or dyslexia. In the literature there is considerable variation in the use of terminology, with dyslexia, and specific reading disorder or disability being used interchangeably. In this review, the term reading disability (RD) is used but includes dyslexia and any other condition, which manifests itself primarily as a reading deficit with no other obvious cause.

1.1.2 Prevalence of RD

The office for National Statistics Study (ONS) assessed reading and IQ in a UK nationally representative sample of 5752 children (50% male, 90% white) aged 9 to 15 years in 1999, using the British Ability Scales II and British Picture Vocabulary Scales II. The study reported a prevalence of reading disability of 18% in boys and 13% in girls.[3,4] A second large study, The Environmental Risk Longitudinal Twin Study, involving twins born during 1994 and 1995 in England and Wales (2163 twin children, 49% male, 90% white) also reported a prevalence of 18% in boys and 13% in girls.[3,5] These two studies were well conducted, and used well-established tests with high reliability. Large samples were recruited with high participation rates that were not dependent on any form of service referral or exclusion based on possible causal factors (ONS accessed children through the Child Benefit register).

Group testing surveys conducted in inner London in 1970 (n=1689 10 year-olds) and the Isle of Wight in 1964 (n=1142 10 year-olds) showed a prevalence of specific reading retardation of 17% in boys and 7% in girls, and 9% in boys and 4% in girls respectively.

The prevalence rates identified by the above studies did not appear to be influenced by whether an IQ-referenced or non-IQ referenced definition of RD was used.[1]

Some sources state that RD has a lower prevalence of approximately 5-10% in school-age children. For example 3.9% of 1206 9 to 10 year-old children from 51 primary schools in the Lancashire Education Authority, had specific reading difficulties.[6] Differences in tests used to assess reading may account for some difference in prevalence.[7]

The prevalence of RD in 16-65 year-olds is less certain. Sixteen percent of the UK population in this age range do not have sufficient literacy skills to pass an English GCSE at any grade.[8]

Estimates of prevalence in children outside the UK are similar to those reported by the ONS and twin studies. The Dunedin Multidisciplinary Health and Development Study, conducted in New Zealand, followed up reading performance and IQ at age 7, 9 and 11 in a cohort born in 1972-3 (989 subjects, 52% male). The study reported rates of RD of 22% in boys and 8% in girls.[3] A second New Zealand study, The Christchurch Health and Development Study (895 subjects, 50% male) studied reading performance and IQ at ages 8 to 10 years in children born in 1977 and found a prevalence of RD of 21% in boys and 10% in girls.[3]

1.1.3 Symptoms associated with RD

Symptoms associated with RD include reversal of letters or other changes in letter position, failure to recognise words, omissions and additions of words, repetition of words, poor writing and spelling, hesitant oral reading, difficulty recalling or repeating particular types of words, word-by-word rather than contextual reading, a history of late speech development and general slowness in processing information.

1.1.4 Identification, diagnosis and prognosis of RD

First recognition of a reading difficulty usually takes place in the classroom when a child fails to reach a milestone predicted for their chronological age. Children may then be referred to a reading specialist, child psychologist or neuropsychologist for a formal clinical diagnosis.

There is no one single test that indicates the presence of RD. History, observation and an assessment of any difficulty in reading and linguistic ability are usually carried out. Diagnosis used to rely on the measurement of reading performance alongside intelligence testing, where a significant discrepancy between IQ and a reading achievement score was indicative of the presence of RD. This method was limited by the potential to misdiagnose children with below-average IQ scores. In 2004, the US passed a new set of criteria for diagnosis of RD that required a significant reading delay and poor response to reading intervention. With increasing doubts over the usefulness of IQ in diagnosing RD, any severe difficulty in learning to read, write or spell, is now identified as RD regardless of IQ in England and Wales.[9,10](www.bps.org.uk/publications/newsletters-and-periodicals/decp-dyslexia.cfm)

Other good predictors of poor reading ability relate to deficits in phonological processing. Phonological processing is the way in which words are broken into their corresponding letters and sounds, known as phonemes. Deficits include difficulty recognising phonemes, naming objects or letters quickly and poor memory when repeating sentences. Other indicators may be used such as a family history of RD, delayed spoken language development and attention difficulties.[11]

Early identification of RD is considered key to directing help to those who need it as soon as possible. Early intervention for children with a statement of educational needs (SEN), is part of a DfES strategy (Removing Barriers to Achievement), however children with a SEN are likely to have already been through several years of primary education with the potential to develop motivation problems or low self-esteem from repeated failure, frustration and discouragement. Strategies for the early identification of RD prior to reaching a SEN are gradually being put in place in schools in the UK although there are no formal screening programmes for identifying ‘at risk’ children on entry into primary school.[9]

For young adults, the most obvious indication of RD is that reading and writing is slow and laborious. Tests designed to assess word identification or accuracy of word identification, commonly used in younger children, are not likely to detect RD in adolescents or adults with a good attainment level of education. Tests measuring

reading speed compared with that of normally reading peers may be more reliable since they will identify a phonological deficit.[11]

Current educational policies relating to dyslexia state that the condition can be managed effectively with targeted teaching and support. Without intervention, literacy problems may persist into adulthood with many ramifications.[9](www.parliament.uk/post/home.htm)

1.1.5 Tests used to measure reading ability

A variety of tests have been used to measure reading ability. A description is given below for those tests used in the studies included in this review.

The *Neale Analysis of Reading Ability* (Neale) was developed in Australia to allow assessment of reading rate, accuracy and comprehension, for children aged 6-13 years. The three measures are interdependent as in the natural reading process. It consists of six passages of prose that form a continuous reading scale. Each passage is a complete narrative aimed at the interests of the age level to which it is assigned. There are three parallel forms of the test (Forms A, B and C), which allows re-testing without a significant learning or practice effect intervening. Form A is presented on yellow paper, B on white paper and C on blue paper.[12] Studies included in this review that used this test reprinted all three forms on white paper.

Children are required to read passages aloud at increasing levels of difficulty until they reach a ceiling level of errors before being asked a series of comprehension questions.[12]

One possible limitation of the Neale test is that short passages of double spaced text are clearly printed in a large typeface, which may not represent the text that has been causing reading difficulty. Reading comprehension also relies on memory.

The *Formal Reading Inventory* (FRI) (USA) provides a silent reading quotient and a classification of oral reading miscues. There are four parallel forms of the test (A, B, C, D). Form A may be read silently, whereas Form B is read aloud. Forms C and D

are used in the same way to allow re-testing to reduce the practice effect. Each form consists of 13 stories and five comprehension questions for each story, the answers to which are recorded on a sheet. Within each form the stories have been sequenced from the easiest to the most difficult relative to comprehension.[13]

The *Wilkins Rate of Reading Test* (WRRT) was developed by Arnold Wilkins as an objective way of assessing the effect of visual rather than linguistic factors on reading. The test assesses reading speed and errors by calculating the number of words read correctly aloud in a minute. The form consists of 10 closely spaced lines of nonsensical text. Each line is composed of 15 words that occur with a very high frequency in the English language, and which should be familiar to children aged 7 and older. Only basic word reading and comprehension skills are required. Four parallel versions of the test are available in small and large typeface. Wilkins claims that anxiety about being able to read is reduced because the text is nonsensical.[14]

The *Gates-MacGinitie Reading Test* (available in two forms, K and L) is a group administered, norm-referenced test measuring reading vocabulary (multiple choice) and comprehension. It consists of prose passages selected from published works.[15]

The *Woodcock Reading Mastery Test* comes in two forms (G and H). Each form assesses a different set of skills. Form G measures visual-auditory learning and letter identification. Form H assesses word identification and word attack. A further test assesses reading comprehension and passage comprehension.[16]

The *Gray Oral Reading Test* has two parallel forms containing 14 developmentally sequenced reading passages with five comprehension questions attached to each passage. Questions and answers are spoken aloud. Rate, accuracy comprehension, and an overall score can be measured.[17]

The *Stanford Diagnostic Reading Test* is a group administered norm-referenced (for a particular grade level) multiple-choice test assessing vocabulary, comprehension, and scanning skills.[18]

Some studies did not employ validated reading tests but selected passages from published texts, which were read under timed conditions with the number of errors noted.

1.1.6 Issues associated with reading tests

Reading tests suffer from various limitations which may confound the results. These include the effect of re-testing and practice, the involvement of memory, and whether the test reflects changes in word recognition or contextual cues.

Test- re-test reliability was assessed for the WRRT.[14] The test was shown to be acceptably reliable when used in immediate succession and 8 weeks apart. A significant effect of practice was demonstrated at both immediate re-test and 8 weeks later, the second test being performed 3% faster than the first ($p=0.005$).[14] This should be taken into account when evaluating studies that use this test.

Deficits in memory may confound the results of reading comprehension tests if the test relies on recall to answer questions after reading the passage. A poor result may be obtained even though the reader has successfully read and understood the passage.

Reading tests used in a study investigating the effects of coloured filters, which aim to improve reading by increasing visual processing, may be limited by the fact that most test for word recognition or contextual cue skills. These skills develop over time and lead to better fluency and accuracy. Immediate retesting is unlikely to show benefit, whereas the same test used several weeks later following continued use of a filter may show some improvement when word recognition skills have had time to develop. Unfortunately, without good study design, this process will also be measuring the natural development of reading skills over time and not just any benefit from the use of the filter. Wilkins claims that the use of non-sensical text enables the WRRT to avoid this pitfall. Consideration is given to these issues in the quality assessment section.

1.1.7 Aetiology of RD

RD is likely to have a neurobiological origin. Historically, the cause of RD was considered to exist within the visual processing system because reading involves sight. More recent research, however, suggests that vision and eye co-ordination problems, although often present,[19] are not the primary cause. The fault may lie in the brain's ability to decipher the sound of spoken or written words or to process language information quickly (phonological processing).[11,20-22]

Phonological processing is necessary before words can be identified, understood, stored and remembered. For fluent reading this process must occur rapidly without awareness that it is taking place and with retention of the words long enough for the sentence (or paragraph) to have meaning. Slow processing of phonemes, whether in the breaking down of words (segmentation), reassembling, speed or memory, may be a major cause of reading difficulty. Neuroimaging has shown that there is decreased activity in specific areas of the brain in readers with phonological processing deficits while other areas are activated during reading tasks performed by skilled readers. Phonological and visual processing appear to be localised to different regions but early atypical phonological processing (at the pre-reading age) may disrupt development of the visual region.

RD is both a familial and heritable condition, as shown by clustering of reading difficulty in families. Genetic linkage analysis has identified possible loci on a number of different chromosomes. [23,24]

1.1.8 Comorbidity

Learning disabilities and behaviour problems have consistently been shown to coexist.[1,2] In the Isle of Wight studies, Rutter reported that a quarter of children with specific reading retardation demonstrated antisocial behaviour.[25] A longitudinal study of child development conducted in New Zealand investigating reading achievement and antisocial behaviour showed that RD at age 9 was a predictor of conduct disorder in boys at age 15.[26] A similar relationship was shown by a second New Zealand study.[27]

Attention deficits are highly correlated with RD[28,29] as are anxiety, poor social interaction and depression.[30-32]

Other forms of learning disability such as numeracy difficulties (dyscalculia), spelling, listening, writing and speaking, are also frequently associated with RD since they form part of the same neurological system.

1.1.9 Burden of disease (significance in terms of ill health)

RD in childhood is associated with adjustment problems and long-term adverse outcomes in multiple life domains.[33]

A significant relationship may exist between reading ability and health services knowledge or health outcomes, although the systematic review upon which this was based used largely observational, poor quality evidence.[34]

The review also found that young people who were more than 2 grades behind the expected reading level for their age were more likely to carry a weapon, miss school because it was unsafe or require medical attention following a physical fight. There is little information available on the economic burden of RD to either the individual or from a wider perspective.

1.2 Current service provision for RD

Children

In England and Wales, it is a legal requirement for all educational institutions and Local Education Authorities (LEAs) to comply with the Disability Discrimination Act 1995, with 2001 amendment, to ensure that there is equal access to the curriculum regardless of disability status. Schools and LEAs must currently adhere to the Education Act of 1996, which specifies the policy for identifying and supporting children with special educational needs, although the methods used vary with the individual school/ LEA.[9]

Primary schools follow the Primary National Literacy Strategy (NLS). Introduced in 1998, the strategy uses phonics teaching to help children recognise individual phonemes before combining them into words. There are two levels of support for

those children with reading difficulty in standard lessons (called wave 1). Initially, children enter wave 2 where small group teaching aims to repeat lessons at a slower pace with individual help when needed. How this is done is dependent on the school. One-to-one teaching (wave 3) is used for children who do not catch up with their peers following wave 2. This is funded by the school's SEN budget. Children with moderate to severe RD may not respond sufficiently to wave 3 interventions. In these cases, the school applies to the LEA for a statement of SEN, which comes with additional funding for teaching support for the individual child. Unfortunately this is rarely on a full-time basis.[9]

A child that is already identified as having a RD by the primary school will usually go on to be supported by the secondary school, using LEA funding. There is no secondary literacy strategy, which means the level of support can vary widely between schools. Often, young people with severe RD are likely to receive support, whereas those with less noticeable difficulties may struggle with poorer provision of specialist teaching.[9]

Parents of children with severe RD can apply to private institutions specialising in teaching pupils with learning difficulties. In rare cases funding, or an allowance, may be provided by the LEA, however in most cases the cost of attending such schools is met by the parents or carer.

Adults

Support for adults with RD attending institutes of further and higher education varies widely and depends on the institution. Funding is provided to support and retain those with disabilities, and some run specialised RD services. Students can apply for an allowance to help with the resources required to aid learning. Adults with RD who are not involved in further and higher education can seek help from basic skills teachers or other initiatives run by local authorities. Services, and the costs of accessing support, vary widely.[9]

Few interventions for RD have been evaluated using RCTs. Teaching programmes for those with less severe RD may aim to raise familiarity with phonemes in their written and spoken forms (phonological awareness training).

Other forms of treatment have been suggested to address the visual anomalies that can be associated with dyslexia. These include monocular occlusion,[35] saccadic (eye movement) training,[36] and orthoptic treatment. A further intervention is that of coloured filters as described in detail below.

1.3 Description of new interventions

1.3.1 Visual stress

In 1980, a New Zealand teacher, Olive Meares, described a set of symptoms that occurred when reading of eyestrain, fatigue, headaches and visual perceptual distortion, such as blurred or moving text, loss of place or skipping of words or lines, slow reading, poor comprehension and a resultant aversion to reading. A few years later, Helen Irlen, an American psychologist working at the California State University Adult Learning Disability Program, developed a treatment for the syndrome based on coloured transparencies, which were placed over the text. In recent years the collection of symptoms have been termed Meares-Irlen Syndrome (MIS) or visual stress,[37] although Irlen referred to them as scotopic sensitivity syndrome (SSS). The symptoms are non-specific, being associated with a number of other conditions or visual anomalies. Subjects with visual stress may not realise that they see the printed page differently from others who read without difficulty.

Much of Irlen's work has not been published in scientific journals. It is notable that our searches identified only one published article by Irlen.[38] In unpublished reports and newspaper articles Irlen claimed that SSS was prevalent among those with RD and was somehow related to light intensity and colour. Irlen's initial (unpublished) report was based on 37 learning disabled students and 70 subjects attending a private clinic. Each subject was tested using the Irlen Differential Perceptual Schedule (IDPS), a largely subjective test that is used routinely by Irlen practitioners.[39] The IDPS consists of three sections:

1. A questionnaire relating to reading and writing performance, light sensitivity, depth perception and symptoms of eye strain;
2. A series of visual tasks- counting number of squares in specific rows on grid patterns superimposed on pictures of cubes, answering questions on difficulty in performance and the nature of any visual distortion experienced. Observation of music lines and answering questions concerning their distortion;

3. An assessment of the extent to which performance on these visual tasks above and on reading tasks was improved by the use of coloured plastic overlays. A colour was chosen and used in a 20-30 minute reading session to identify differences in rate, accuracy, and endurance for oral reading as well as reported changes in symptoms of eye strain.

Irlen claimed that all 89 subjects demonstrating visual distortion that affected their reading, showed improvement with the use of coloured filters in reading rate, comprehension and symptoms. The study methodology was not reported in any detail so that replication studies could not be carried out. Irlen maintained that approximately 50% of the reading and learning disabled population have visual stress and that most of these will experience some degree of improvement in reading performance from the use of her coloured filters.[40]

Several theories have been put forward as a possible aetiology for visual stress: (i) hypersensitivity or hyperexcitability of the visual cortex (pattern glare), (ii) deficit in the magnocellular pathway, (iii) retinal sensitivity.

In hyperexcitability to pattern glare, certain patterns cause distortion to the text.[41-43] It has been hypothesised that hyperexcitability within certain areas of the visual cortex may be reduced by the redistribution of excitation by coloured filters.[44]

A deficit in the magnocellular pathway (or transient system) may arise from impaired development of the magnocellular neurones involved in eye movement. In this theory, sensory images, such as letters and words persist longer than the physical duration of the image. As the eyes fix on subsequent words the images become superimposed and appear jumbled on the page. In normal reading, the transient system directs the eye to a particular location or set of words. Once the location has been fixed, the parvocellular pathway (or sustained system) extracts the visual detail or letters and words. The transient system prevents the visual detail persisting until the next location has been fixed. Studies indicate that the rate of transient activity increases as the wavelength of light decreases from red to blue. Children with RD have been shown to have decreased transient channel processing rates, which coloured filters appear to change.[45-49]

The theory of retinal sensitivity is based on there being a greater sensitivity to light in the peripheral vision. This may be due to a higher number of peripheral cones in the retina, which was found in subjects with dyslexia. This may cause images of letters in the peripheral vision to compete with letter images in the central vision, which would be worse in tasks requiring rapid eye movement such as reading.[50,51]

Visual stress still cannot be detected by standard optometric, educational or medical tests but only by testing for a subjective improvement in symptoms and reading ability with the coloured filters that are used to treat it. The existence of visual stress and its relationship to RD is still uncertain. For the purpose of this review, the use of coloured filters for the treatment of RD, and not visual stress, will be assessed.

1.3.2 Coloured filters

Coloured filters come as overlays, glasses or contact lenses. Contact lenses have a small dot of colour over the pupil. For glasses and contact lenses, the tint can be combined with any existing optometric prescription. Coloured filters are usually fitted by optometrists, or opticians trained in the system being prescribed and working in private practice or specialist eye care units. Treatment and prescription of coloured filters may take place over two to three visits. An initial screening visit is conducted to establish the colour providing the most (if any) improvement in reading or symptoms. Tinted glasses or contact lenses would be supplied and fitted at a subsequent visit. A follow-up check up may also take place (F. Eperjesi, personal communication, November 2007). The individual is encouraged to wear the filters for all reading tasks. The main aim of coloured filters is to improve reading performance. A secondary aim is to reduce symptoms that may be associated with RD such as headache and asthenopia.

The process of colour selection has involved placing overlays over text (often non-sensical) until the individual has found the colour, or combination of colours, that (usually subjectively) provide the greatest improvement in reading or symptoms. Once an overlay has been selected, an objective test for changes in reading speed may be used. An increase in speed of 10% or more compared to reading without the overlay is normally considered necessary before an overlay is supplied (F. Eperjesi, personal communication, January 2008). It should be noted that an increase in

reading speed without a corresponding increase in accuracy or comprehension is meaningless. In the literature the colour showing the greatest improvement has been termed the selected, chosen, optimal or preferred colour. Throughout this report this is referred to as the 'preferred' colour.

It has been shown that the colour of an overlay chosen as giving the greatest benefit to reading is not a good predictor of the colour that will be optimal for glasses lenses.[52-54] An overlay can only provide one coloured surface in a visual field containing many different coloured surfaces. When an overlay is used the eyes are adapted to white light. When coloured glasses or contact lenses are worn the entire visual field is coloured. The brain and eyes are able to adapt to the colour, and the colour is then discounted so that white surfaces are seen as white despite the colour of the lens.[55-59] Tints for glasses lenses can be prescribed more accurately than the colours available for overlays.

1.3.3 The Irlen system

Irlen markets her filters and lenses (10 coloured overlays) through the Irlen Institutes or Centres, of which there are ten across the UK. Technical data for Irlen's coloured filters and colour selection has not been published. The primary purpose of these filters is to improve reading performance. A secondary purpose is to reduce the symptoms of visual stress. Irlen claimed that the coloured filters needed to be prescribed with great precision and that different people required different colours.[60]

1.3.4 The Intuitive system

Arnold Wilkins developed Intuitive Overlays and glasses tinting in 1993 in conjunction with the Medical Research Council, UK. There are 9 coloured overlays and one grey overlay, which can be used alone or in combination. Colours used in pairs are of a neighbouring chromaticity. The overlays are placed over a passage of jumbled text until the 'preferred' colour is found. Wilkins also developed the Intuitive Colorimeter, which helps to determine the exact colour of filter able to produce the greatest improvement in reading by illuminating the text with light. The system allows colours (from the CIE 1976 UCS chromaticity) to be sampled systematically and comprehensively by varying hue (colour), saturation (strength of colour) and

brightness (luminance) independently of each other and therefore intuitively.[52] The MRC owns rights to the Intuitive Colorimeter and associated tinting system, which is marketed under licence by Cerium Visual Technologies, Tenterden, Kent, UK (1993).[61]

1.3.5 The ChromaGen system

ChromaGen lenses (ChromaGen Ltd, Chester, UK) developed by David Harris, are a series of precision tinted lenses, worn either as contact lenses or glasses. These filters were originally developed to improve the shade discrimination of colour-defective subjects.[62] The correct colour is determined by 25 hues for contact lenses or eight hues for glasses. There has been no technical data published.

1.3.6 Other filters

Prior to the development of filters that aim to comprehensively sample the full range of chromaticities, blue tinted lenses were also hypothesized to aid reading.[63] Some studies included in this review employed filters, such as overhead transparencies that were not part of a system.

1.3.7 Costs of coloured filters

An initial screening visit for Irlen filters costs £58. A report and overlays to last one year are provided. The second visit for the fitting of coloured glasses costs £300-400, which includes frames, and prescription lenses in the preferred colour. Pre-existing prescription glasses could also be tinted and tested in time for this visit. Re-tinting of glasses is provided free of charge anytime during the first two years (www.irlencentralengland.co.uk/).

The cost for an initial visit for alternative systems range from £15 (for under 16 year olds and those receiving state benefit) or £50 (for all other individuals) to £120, with the lower cost being charged by specialist eye care units, and the higher cost charged by private clinics. The fitting of prescription coloured glasses at a subsequent visit costs approximately £100 to £150 for the tinted lenses with an additional cost for the frames.

2. EFFECTIVENESS

2.1 Methods for reviewing effectiveness

2.1.1 Search strategy

The following sources were searched for pre-existing systematic reviews and primary studies:

- Cochrane Library (Wiley internet version) 2007 Issue 3 (CENTRAL)
- MEDLINE (Ovid) 1950 to September Week 2 2007
- MEDLINE (Ovid) In-Process and Other Non-Indexed Citations 25 September 2007
- EMBASE (Ovid) 1980 to 2007 Week 38
- CINAHL (Ovid) 1982 to September 2007
- PsycINFO (Ovid) 1967 to September Week 4 2007
- Science Citation Index (Web of Science) 1900 to September 2007
- Social Science Citation Index (Web of Science) 1900 to September 2007
- Citations of relevant studies
- Relevant internet resources
- Further information from contact with relevant experts.

Searches included text words and index terms covering reading, learning, dyslexia, irlen, scotopic sensitivity, visual stress, visual perceptual, colour, tint, overlay, glass, lens and filter. The search strategies are shown in Appendices 1 and 2. No language or date restrictions were applied. All citations were exported, or entered by hand, into Reference Manager version 11 (ISI, Carlsband, CA, USA).

2.1.2 Inclusion and exclusion criteria

Studies were included if they met all of the following criteria:

- *Study design*: Systematic reviews, or randomised or quasi-randomised controlled trials (RCTs), or non-randomised comparative studies.

- *Population*: Children aged 7 years old and over, or adults, with reading disorder, disability, difficulty or dyslexia. Age 7 was chosen as the suggested age by which basic word recognition skills have been mastered,) which may reduce the involvement of this as a confounding factor in any change in reading ability.[64]
- *Intervention*: Tinted or coloured overlays, or lenses, or glasses or filters.
- *Comparator*: Placebo, or no treatment, or other current treatment.
- *Outcomes*: Any single outcome or combination of reading speed, accuracy, comprehension, symptoms, behaviour, or quality of life.

Study selection was carried out by a single reviewer (EA) and checked by a second (YA). Following scanning of titles and abstracts, full text was obtained for potentially relevant articles.

2.1.3 Data extraction strategy

Data extraction was undertaken by a single reviewer (EA) and checked by a second (BL) in the case of the RCTs. Study characteristics, outcome results and aspects of study quality were collected using a pre-designed extraction form. Any discrepancies were resolved by discussion.

2.1.4 Quality assessment strategy

Quality assessment was undertaken by a single reviewer (EA) and for RCTs, was checked by a second reviewer (BL). Quality of trial methodology was assessed on the basis of method of allocation to intervention or comparator groups, concealment of allocation, blinding, analysis and loss to follow up. Where appropriate, an overall quality score (Jadad) was assigned to RCTs (Appendix 4).[65]

In addition to the criteria above, crossover studies were assessed for the presence of a wash out period, period effect test, and evidence of control for the effect of practice on reading test outcome.

A study was judged to be of ‘inadequate’ quality if there were two or more major threats to validity.

2.1.5 Data handling and analysis

Study characteristics (population, interventions, comparators and outcomes), quality and results were tabulated. Analysis was both quantitative and qualitative. Qualitative analysis relied on conclusions being drawn from patterns revealed in the tables of included studies. Data was entered into Stata version 10 (Stata Corporation, College Station, TX, USA) and pooled across some studies using a random effects method by Hedges.[66] Random effects methods were used due to the high level of statistical heterogeneity between studies. The Hedges method makes an adjustment to correct for bias introduced by the use of small sample sizes.

2.2 Results

2.2.1 Quantity and quality of research available

The number of potentially relevant studies identified and screened for retrieval was 234. Of these, 143 were excluded on the basis of title and abstract. A full copy of the article was retrieved where there was any doubt about its relevance. The full text of 91 articles was retrieved for scrutiny against the inclusion and exclusion criteria. 67 articles were subsequently excluded.

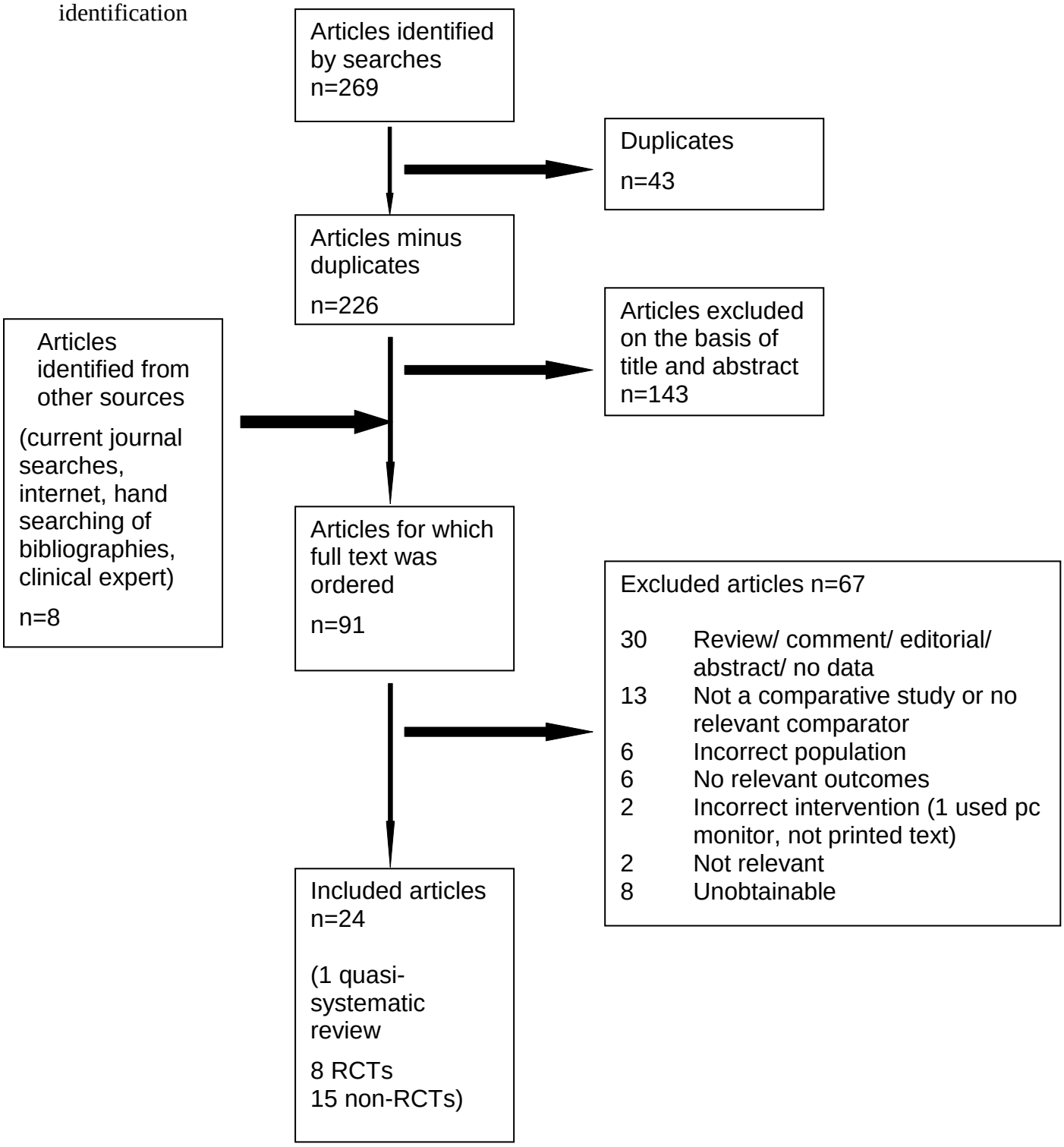
The main reasons for exclusion were a lack of relevant data (e.g. review article), or that the study was not comparative or employed an improper comparator. Studies that were regularly featured in other reviews or bibliographies and those that were excluded from this review are shown, with reasons in Appendix 3. The list also shows the articles that were unobtainable (could not be located or were not available through the British Library).

One review evaluating effectiveness of coloured filters for the treatment of reading problems was identified by the searches, but this was not fully systematic.[67] Eight RCTs (described by nine articles) evaluating the effectiveness of coloured filters for improving reading performance in children and adults with reading difficulty were identified.[40,52,68-74]

A further 15 non-randomised comparative studies were also identified.[54,63,75-87] In 5 of these studies, the primary objective was not the evaluation of the effectiveness of coloured filters on reading ability in subjects with reading difficulty.[75,77,78,81,86]

A summary of the search process, reasons for exclusion, and results can be seen in Figure 1.

Figure 1. PRISMA (previously QUOROM) flow diagram for clinical effectiveness study identification



2.3 Existing systematic reviews

The quasi-systematic review by Dohnert and Englert[67] aimed to identify reviews and primary studies investigating the effectiveness of coloured filters for reading problems using a search of MEDLINE from 2002 (the article was published in 2004) for “Irlen Syndrome”. The authors also contacted Irlen organisations and centres, and followed up bibliographies from Irlen brochures. The authors identified 43 relevant articles. Study characteristics of 10 articles describing 9 primary studies[40,43,52,72-74,78,82,83,88] were tabulated. Although the review used a published evidence-grading checklist (The Canadian Task Force on Periodic Health Examination, 1994), the quality of the studies did not appear to have been adequately assessed and at least five studies were incorrectly graded. Overall, the review concluded that there did not appear to be conclusive evidence of the effectiveness of coloured lenses in the treatment of dyslexia and suggested that there may be a placebo effect.

Of the nine studies described by Dohnert, seven are also included in this review. The studies by Blaskey,[40] O’Connor,[72] Wilkins,[52] and Robinson and Foreman(2 articles describing one study)[73,74] are shown in the RCT list below and are described in detail. The two studies by Robinson and Conway,[82,83] and one study by Kyd[78] are included in the list of non-RCTs. The two studies included by Dohnert were excluded from this review (see Appendix 3) because they had no included outcomes[43] or had no comparative intervention.[88]

2.4 RCTs

2.4.1 Study characteristics

The eight RCTs were published between 1989 and 2002. Three were carried out in the UK,[52,68,71] three in Australia[70,72-74] and two in the US.[40,69] The underlying aetiology of RD is unlikely to be different between these western populations, although identification, and definition of RD, and testing of reading outcomes may be specific to the country in which the study was conducted.

All eight RCTs were prospective in nature. Three studies were of a standard RCT design,[40,70,72] four were crossover RCTs,[52,68,69,71] and one was described as a

crossover study but for the purposes of this review will be treated as a standard RCT since one of the three study arms did not crossover to any other intervention (arm one), and the other two arms started the study using two other alternative interventions but then crossed over to the same intervention as used in arm one.[73,74] The first few months of the study therefore constitute a standard parallel RCT design, with the remainder of the study duration (20 months) being used to assess the long-term effects of using the preferred colour filter without comparison to any other intervention.

Sample sizes were generally small. The study by Christenson recruited only 16 subjects, while Robinson and Foreman was the largest study with 148 children. Table 1 provides the details of sample size for all studies.

The Intuitive colour system was used by the Bouldoukian[68] (overlay), and Wilkins[52] (glasses) studies. Only Blaskey[40] employed Irlen glasses and only Harris and MacRow-Hill[71] used the ChromaGen system, which in this case was in the form of contact lenses. Various other systems were used by the remaining four studies[69,70,72-74], of which all used glasses except O'Connor, who used overlays. With the exception of Christenson, all other studies used the preferred colour for the intervention. Christenson specifically investigated the effect of blue tinted glasses. In the study by Blaskey, subjects in the intervention group were given the preferred colour and a pair of placebo glasses with a randomly selected tint. After trying each for two weeks the subjects were asked to carry on using the glasses they preferred for a further two weeks. Similarly in the study by Gole, subjects were given either the preferred colour glasses or clear glasses when giving a positive or negative response respectively, to questioning about reading through the lenses. These details are shown in Table 1.

The comparator(s) used in each of the studies are shown in Table 1. Some studies attempted to employ a placebo control. O'Connor, Robinson and Foreman, and Wilkins all employed placebo control filters with a colour similar to, but outside the chromaticity known to show some benefit.
'No treatment' controls were used by Blaskey, and Harris and MacRow-Hill. Robinson and Foreman used a no treatment control but these subjects were not

identical to those in the intervention groups since they had reading difficulty in the absence of SSS/ visual stress. Clear glasses,[70] contact lenses[71] or overlay,[72] pale yellow UV blocking,[68] and glasses frames without lenses[69] were also used as controls. Other comparators were a vision therapy program in which subjects were given eye exercises,[40] and blue tinted glasses.[73,74]

The duration of use of coloured filters was assessed after one week by O'Connor,[72] for one month by Blaskey,[40] and Wilkins,[52] for 1-2 terms (approximately 3-6 months) by Gole,[70] up to 20 months by Robinson and Foreman,[73] and was not reported by Bouldoukian,[68] and Christenson.[69] In these last two studies it is likely that the immediate effects of filters were assessed. Harris and MacRow-Hill carried out all use and testing on a single day.[71]

Reading outcomes were assessed using a variety of measures. These were discussed in detail in section 2.1.4. Gole,[70] O'Connor,[72] Robinson and Foreman,[73] and Wilkins[52] all employed the Neale Analysis of Reading Ability (Neale). Bouldoukian,[68] and Harris and MacRow-Hill[71] used the Wilkins rate of Reading Test (WRRT). Blaskey[40] employed the less well-known Woodcock Reading Test, Gray Oral Reading Test and the Stanford Reading test. Christenson[69] measured reading comprehension alone, using the Gates MacGinitie Reading Test. O'Connor also used the Formal Reading Inventory. The Gole study excluded subjects who had used the Neale test in the six months prior to enrolment in an effort to rule out the possible confounding effects of reading test practice. This was not mentioned by the other seven studies. Five studies used the change from the baseline, or pre-intervention reading measurement, to the post-intervention reading measurement, which seems appropriate for this type of study.[40,70-74]

Blaskey and Wilkins, used questionnaires and diaries respectively, to assess changes in the level of symptoms in intervention and comparator groups. No other studies assessed symptoms.

All basic study characteristics are shown in Table 1.

Table 1 Study characteristics of included RCTs (8) (spilt by parallel RCT and crossover RCT)

Reference	Study design	Population	N	Intervention	Comparator(s)	Relevant outcomes	Study objective
Blaskey et al., 1990 USA[40]	Parallel RCT Random allocation to (i)Irlen filter group or (ii) vision therapy group or (iii) no intervention control group. Mean pre- vs. post-intervention test comparisons between groups. 1month between pre-and post-testing?	Children and adults (37%) with reading difficulties and symptomatic SSS (used Irlen Screening Manual). All had significant vision problems, which were not corrected unless in the vision therapy group.	30	Irlen coloured glasses (preferred) OR a placebo (randomly selected tint) (n=11)	Vision therapy (n=11) N.B. These subjects were given prescription glasses. No treatment control (n=8)	Word recognition in isolation (Woodcock Reading Mastery Test) Word recognition in context, speed (Gray Oral Reading Test) Reading comprehension (Stanford Reading Test) Symptom (questionnaire).	To investigate the effectiveness of Irlen filters for improving reading performance in subjects with reading difficulty.
Gole et al., (SPELD study) 1989 Australia[70]	Parallel RCT Random allocation to (i) tinted glasses or clear control glasses or (ii) no treatment then tinted glasses after 1 term. Mean pre- vs. post-intervention test comparisons between groups. 1 term between pre- and post-testing.	Children with dyslexia (non-asthmatic)	24	SOLA tinted glasses (red, green, yellow or blue) of varying densities (preferred) OR clear glasses (negative response to questioning about reading through lenses) (n=13)	No treatment control for 1 term then fitted with tinted glasses for 2 terms (n=11)	Reading speed, accuracy and comprehension (Neale)	To investigate the effectiveness of tinted lenses on the reading ability of non-asthmatic dyslexic children.

Reference	Study design	Population	N	Intervention	Comparator(s)	Relevant outcomes	Study objective
O'Connor et al., 1990 Australia[72]	Parallel RCT Random allocation of SSS subjects to (i) preferred colour or (ii) clear overlay or (iii) non-preferred colour or (iv) clear overlay (post-test only) Non-SSS subjects to (i) clear overlay or (ii) random colour. Mean pre-vs. post intervention test comparisons between groups. 1 week between pre- and post-testing.	Children with reading disability and SSS (IDPS) (n=67) or RD and non-SSS (n=25)	92	Coloured overlays (preferred) (n=17)	Clear overlay (n=17) Non-optimal coloured overlay (n=17) Clear overlay (post-test only) (n=16)	Reading speed, accuracy and comprehension (Neale), Formal Reading Inventory	To investigate the effectiveness of coloured overlays on the reading performance of children with reading disability.

Reference	Study design	Population	N	Intervention	Comparator(s)	Relevant outcomes	Study objective
Robinson and Foreman, 1999a[74] 1999b[73] Australia	Quasi crossover RCT Subjects with moderate to high symptoms of SSS randomly allocated to (i) preferred colour for full study duration or (ii) blue colour 4m then cross to preferred colour for rest of study or (iii) placebo colour 4m then cross to preferred colour for rest of study. Tested pre-intervention, then post at 4m, 8m, 20m. Few or no symptoms of SSS used as the no treatment control group.	Children with reading difficulties and SSS (Irlen Screening Manual) (n=113) or RD and non-SSS used as a no treatment control group (not part of the RCT) (n=35)	148	Coloured glasses (preferred) (n=38)	Blue glasses (n=41) Placebo glasses (colour similar to preferred) (n=34) No treatment control (non-SSS) (n=35)	Reading speed, accuracy and comprehension (Neale)	To investigate the effectiveness of coloured filters on the reading performance of children with reading difficulty.

Reference	Study design	Population	N	**Intervention**	Comparator(s)	Relevant outcomes	Study objective
Bouldoukian et al., 2002 UK[68]	Crossover RCT Random allocation to either (i) Intuitive overlay cross to control overlay or (ii) control overlay cross to Intuitive overlay. No baseline comparison. All testing carried out on same day?	Children and adults (12%) attending the Institute of Optometry with suspected or diagnosed specific learning difficulties, reporting symptomatic relief from coloured filters.	33	**Intuitive** coloured overlay (preferred) (n=33)	Pale yellow UV blocking control overlay (n=33)	Reading speed (WRRT)	To investigate the effectiveness of individually prescribed coloured filters for improving reading performance in subjects with learning difficulty.
Christenson et al., 2001 USA[69]	Crossover RCT Random allocation to either (i) blue filter cross to no filter or (ii) no filter cross to blue filter. No baseline comparison. Testing carried out on same day? 2-5 weeks between crossover.	Children with dyslexia (diagnosed using Dyslexia Determination Test)	16	Blue tinted glasses (Lee filters, C.A.) (n=16)	Black glasses frames without filter (n=16)	Reading comprehension (Gates MacGinitie Reading test)	To investigate the effectiveness of blue tinted lenses for improving reading performance in children with dyslexia.

Reference	Study design	Population	N	Intervention	Comparator(s)	Relevant outcomes	Study objective
Harris and MacRow-Hill, 1999 UK[71]	Crossover RCT Random allocation to (i) tinted lenses cross to placebo lenses or (ii) placebo lenses cross to tinted lenses. No treatment control testing also carried out for both groups. Mean pre- vs. post intervention test comparisons between groups. All testing carried out on same day.	Children and adults (%NR)with dyslexia 41/47 also had visual distortion	47	**ChromaGen** tinted contact lenses (preferred) (n=47)	Clear placebo contact lenses (n=47)	Reading speed (WRRT)	To investigate the effectiveness of ChromaGen tinted lenses on the reading performance of subjects with dyslexia.
Wilkins et al., 1994 UK[52]	Crossover RCT Random selection of preferred or placebo glasses given for 1m followed by alternative glasses for a second month. 2 week wash out in between. No baseline comparison.	Children with reading difficulty, suffering from headaches and asthenopia, and reporting benefit from overlay usage.	68	**Intuitive** coloured glasses (preferred) (n=68)	Placebo glasses (colour similar to preferred) (n=68)	Reading speed, accuracy and comprehension (Neale), Symptoms (diaries)	To investigate the effectiveness of Intuitive coloured filters on the reading performance of children with reading difficulty.

2.4.2 Patient characteristics

A clearly defined population sample, with attempts made to rule out possible confounding factors, was an important criterion for a study to reliably establish whether coloured filters were effective for reading disability. The following section discusses subject age, definition of reading disability, the presence of symptoms and SSS/ visual stress, other important inclusion criteria, visual history, and recruitment strategy and tests, as a comparison across studies. These characteristics are also summarised in Table 2.

Adults, as well as children, were included in the studies by Blaskey (37%), Bouldoukian (12%), and Harris and MacRow-Hill (% not reported). The remaining five studies recruited only children, in the age range 8 to 15 years.[52,69,70,72-74]

The definition of reading disorder varied between studies. Christenson, Gole, and, Harris and MacRow-Hill recruited subjects with a specific diagnosis of dyslexia. Christenson used the Dyslexia Determination Test,(DDT)[89] to enrol subjects. The dyslexic subjects in the Gole study were non-asthmatic due to concerns over effects of medication on attention. These children were also required to have a reading age at least 2 years behind their chronological age. The subjects recruited by Harris and MacRow-Hill were required to have a formal diagnosis of dyslexia accompanied by a SEN or some other evidence of the diagnosis.

Blaskey, and Robinson and Foreman recruited subjects with “reading difficulty”. No other information was provided on how this was defined by either study. The children recruited by Wilkins were described as generally suffering from “reading difficulty”. Bouldoukian enrolled subjects with “suspected or diagnosed specific learning difficulties” but this was not defined further. Children with “reading disability” defined as a reading age at least 18 months below the chronological age were recruited by O’Connor (sample mean 2.1 years).

Bouldoukian recruited subjects attending the UK Institute of Optometry for suspected or diagnosed specific learning difficulties, while Christenson recruited from a reading disabled school in the US. Gole *et al*, recruited subjects referred to SPELD (an Australian non-profit organisation providing assessment and advice for dyslexic children and adults), and Robinson and Foreman enrolled subjects referred to an Australian University-based special education centre. O'Connor and Wilkins recruited subjects from non-specialist schools[52,72] and a Dyslexia Institute.[52] Blaskey, and Harris and MacRow-Hill recruited volunteers via the media. Studies relied on self-reported poor reading performance,[40] or the judgement of teachers[52,72,73] or psychologists for nomination or referral of subjects.[73]

SSS/ visual stress, or symptoms of perceptual distortion were inclusion criteria for five studies (Blaskey, Bouldoukian, O'Connor, Robinson and Foreman, and Wilkins). The Irlen Screening Manual, or the more recent version called the Irlen Differential Perceptual Schedule (IDPS), was used to determine the presence of SSS, by showing an improvement in reading, by Blaskey, O'Connor, and Robinson and Foreman. Bouldoukian used coloured overlays in the screening process and reported that some subjects were new to filters but showed immediate benefit (n=17), while others had used them over a period of weeks and demonstrated sustained voluntary use (n=16). Wilkins required subjects to have used coloured overlays regularly without prompting for at least three weeks prior to enrolment, to ensure only those subjects likely to be experiencing a benefit took part in the study.

In the Blaskey, Robinson and Foreman, and Wilkins studies the sample selection process used coloured overlays, while the intervention was coloured glasses. Bouldoukian and O'Connor used overlays in the selection process and for the intervention. It was argued by Wilkins *et al*, that since the population likely to benefit from tinted filters has not yet been identified and was thought to come from many different diagnostic groups, the statistical power could be improved by selecting children who show benefit from the use of coloured filters.

Previous exposure to tinted overlays or glasses was used as an exclusion criteria by Gole *et al*. Previous exposure was not reported by Christenson, or Harris and MacRow-Hill. All studies, except Christenson, have used filters during the initial phase of the study (post-sample selection) to determine the subject-specific preferred filter colour to be used.

O'Connor, and Robinson and Foreman both recruited a second group of subjects with reading disability or difficulty but without SSS. These children showed no signs of SSS and no improvement with a coloured overlay. O'Connor randomised these subjects into two arms (randomly coloured overlay or clear overlay), which needed to be treated as a separate trial conducted alongside the main trial with four arms. The non-SSS subjects in the Robinson and Foreman study cannot be compared to the other three treatment arms since they were not included in the randomisation.

Other inclusion criteria relevant to the introduction of confounding factors were a measure of intelligence, the presence of attention deficits, and the presence of visual anomalies. Five studies recruited subjects with average or higher intelligence, which aimed to reduce the likelihood of confounding poor reading performance due to cognitive deficits.[40,69,70,72-74] Bouldoukian, Harris and MacRow-Hill, and Wilkins made no mention of the level of intelligence of enrolled subjects. None of the studies attempted to determine whether subjects had any form of attention deficit prior to enrolment in the study, however, Gole *et al* excluded subjects on treatment known to have an effect on cognitive and higher cerebral functions (asthmatics).

All studies, with the exception of Blaskey, aimed to exclude subjects who had uncorrected optometric anomalies such as refractive, binocular or accommodative problems. Blaskey recruited subjects with significant vision problems and made no attempt to correct these unless subjects were part of the vision therapy group. A complete vision examination was carried out in four studies.[40,52,68,69] Children in the Gole study were given a visual acuity test. Harris and MacRow-Hill used the reports from the subject's own optometrist. Not all children had a formal optometric assessment in the study by O'Connor

but all had been assessed during the visual screening process conducted on all school children in grade 1. Robinson and Foreman stated that subjects in the treatment groups received an optical examination within the year prior to being screened. It is therefore possible that visual anomalies were missed in subjects recruited by O'Connor, and Robinson and Foreman.

Colour deficiency was not reported by five studies.[40,68-70,73,74] Harris and MacRow-Hill reported that 9 of 38 male subjects were colour deficient. 13/92 subjects were colour defective in the O'Connor study. Data from colour vision testing by a variety of methods appears to have been available to Wilkins *et al*, but it was not clear how may subjects were colour defective.

Table 2 Patient characteristics of included RCTs (spilt by parallel RCT and crossover RCT)

Reference	Definition of reading disorder	Other criteria/ Place of recruitment	N Mean age [range] Proportion female	Refractive/ binocular/ accommodative correction	Colour deficiency	Symptoms/ Presence of SSS/ visual stress	Visual tests/ Previous use of filters
Blaskey et al., 1990 USA[40]	Reading difficulties Self-reported poor reading performance.	Positive test for SSS, vision problems, average or higher IQ. Advertisement/ media coverage.	N=30 23.6y [9-51y] 60%	All had significant vision problems, which were not corrected unless in the vision therapy group.	NR	Symptomatic SSS (used Irlen Screening Manual) including headache, eye-strain, intermittent blurring when reading, words moving, loss of place etc.	Complete vision exam carried out by licensed optometrists. Positive test for Irlen filters.

Reference	Definition of reading disorder	Other criteria/ Place of recruitment	N Mean age [range] Proportion female	Refractive/ binocular/ accommodative correction	Colour deficiency	Symptoms/ Presence of SSS/ visual stress	Visual tests/ Previous use of filters
Gole et al., (SPELD study) 1989 Australia[70]	Dyslexia Reading age >2y behind chronological age.	Non-asthmatic, IQ over 85, at least one term at current school, no major emotional/ physical problems, no exposure to Neale in last 6m. Referral to SPELD organisation (non-profit organisation providing assessment and advice for dyslexic children and adults).	N=24 Mean NR [9-12y] 8%?	Reading vision normal.	NR	NR	Visual acuity test. No previous exposure to tinted filters.

Reference	Definition of reading disorder	Other criteria/ Place of recruitment	N Mean age [range] Proportion female	Refractive/ binocular/ accommodative correction	Colour deficiency	Symptoms/ Presence of SSS/ visual stress	Visual tests/ Previous use of filters
O'Connor et al., 1990 Australia[72]	Reading disability with an average reading ability 2.1y below grade level.	Average or higher IQ. Nominated by teachers if had reading ability at least 18m below chronological age.	N=92 Mean NR [8-12y] 33% SSS 44% non-SSS	All corrected.	12/67 SSS 1/25 non-SSS	With SSS (IDPS) (n=67) Without SSS (n=25)	Some did not have formal optometric assessment, but all had been assessed during routine school visual screening during grade 1. IDPS testing for improvement in reading with coloured overlay for signs of SSS.
Robinson and Foreman, 1999a[74] 1999b[73] Australia	Reading difficulties with average discrepancy between reading age and chronological age of 1.9y SSS, 2.2y non-SSS.	Average IQ. Referred to special education centre for reading or study problem. Controls from 2 local public schools.	N=148 Mean NR [9.2- 13.1y] SSS [9.4- 12.9y] non-SSS 41%	The experimental group had prescription lenses fitted when required.	NR	With SSS (n=113) Without SSS (n=35)	All subjects in the experimental group had received an optical or ophthalmological exam within the year prior to be screened. The control children and parents claimed to have had an optometric exam in the last year. Irlen Screening Manual involved use of coloured overlays.

Reference	Definition of reading disorder	Other criteria/ Place of recruitment	N Mean age [range] Proportion female	Refractive/ binocular/ accommodative correction	Colour deficiency	Symptoms/ Presence of SSS/ visual stress	Visual tests/ Previous use of filters
Bouldoukian et al., 2002 UK[68]	Suspected or diagnosed specific learning difficulties, reporting symptomatic relief from coloured filters. Diagnosis of dyslexia (n=20) Diagnosis of specific learning difficulties (n=3)	Institute of Optometry.	N=33 4 adults 29 children children 11y4m [7y10m-14y11m] 30%	All corrected.	NR	Symptoms of asthenopia and/or perceptual distortions.	Detailed optometric assessment. All subjects reported symptomatic relief from coloured filters. Some new to overlays but shown immediate benefit (n=17). Others used overlays over previous weeks, showing sustained voluntary use (n=16).
Christenson et al., 2001 USA[69]	Dyslexia diagnosed using Dyslexia Determination Test	Not cognitively disabled. Reading disabled school.	N=16 Mean NR [10y6m-13y11m] 50%	Corrected visual acuity, no binocular dysfunction or eye health anomaly.	NR	NR	Comprehensive eye examination.
Harris and MacRow-Hill, 1999 UK[71]	Formal diagnosis of dyslexia (statement of Special Educational Needs or other evidence of diagnosis).	Able to wear contact lenses. Media interest.	N=47 14.7y (SD 5.2) [9-40y] 19%	All corrected.	9/38 males	41/47 (87%) also had visual distortion	Report from subject's own optometrist. Subjects received the ChromaGen colour assessment just before receiving the ChromaGen lenses.

Reference	Definition of reading disorder	Other criteria/ Place of recruitment	N Mean age [range] Proportion female	Refractive/ binocular/ accommodative correction	Colour deficiency	Symptoms/ Presence of SSS/ visual stress	Visual tests/ Previous use of filters
Wilkins et al., 1994 UK[52]	Reading difficulty, reporting benefit from overlay usage.	3 schools selected by failing in reading, 4th school selected from those reporting eye strain, headaches, perceptual distortion. Recruited by teachers from 3 state schools, one private school, and Dyslexia Institute.	N=68 12y2m (SD 1y9m) [9y9m-15y5m] 38%	All corrected.	Unclear.	Suffering from headaches and asthenopia.	Full optometric assessment. Use of overlays without prompting for at least 3 weeks.

2.4.3 Quality assessment and threats to validity

A study was judged to be of 'inadequate' quality if there was evidence of two or more major threats to validity. It should be noted that poor quality may be a reflection of poor reporting of a well conducted study.

Parallel studies

Table 3 shows the results of quality assessment of the parallel RCTs.[40,70,72,73] All of the parallel RCTs were of inadequate quality.

The randomisation method was only stated by Gole and O'Connor. The method used by Gole can be considered only just adequate, with additional concern over the mention of use of matched controls as this is unnecessary in a randomised study. The adequacy of the method used by O'Connor is uncertain. None of the four studies described concealment.

O'Connor, and Robinson and Foreman were both described as double-blind with statements regarding subject and assessor blinding to support this. The study by O'Connor used a clear overlay in addition to coloured overlays, which may have lead to unblinding by some subjects and assessors. The studies by Blaskey, and Gole, could be considered single-blind since attempts were made to prevent the assessors being aware of group allocation but in both cases the intervention group would be obvious.

Loss to follow-up or lack of compliance was noted by Blaskey (27%), Gole (54% not complying with study requirements), and Robinson and Foreman (18%), although the latter did not provide a breakdown per group or time point at which the subject withdrew. Numbers withdrawn or not wearing the filters was high in all three studies and likely to threaten the validity. There were no statements regarding intention to treat analysis but it was clear that Blaskey and O'Connor have carried out analysis in this way. Gole carried out some analysis as if subjects remained in the groups they were randomised to, however they also analysed subjects based on whether they had worn the lenses provided or not, regardless of the group allocation. In the study by Robinson and Foreman it was not clear how some figures had been

calculated. Unscheduled crossover into another study arm was not reported by any of the four studies, although Blaskey noted that two subjects were given Irlen filters following vision therapy.

A statement regarding equivalence of study groups after randomisation was given by Blaskey, who considered vision anomalies, IQ and positive response to filters, to be important but age, race, and gender were not. Age and gender were similar in the study arms of the other three studies. Gole also matched IQ, and O'Connor, and Robinson and Foreman presented evidence, or stated, that the reading ages were similar between groups at study start. The subjects in the study arms in each of the four studies were treated the same, except for the vision therapy arm in the Blaskey study who were given correction for optometric anomalies, whereas the other two arms had significant vision problems that were not corrected. Jadad scores for all four studies were fairly low at either 2 or 3.

Table 3 Study quality- parallel RCTs

Reference	Trial described as randomised?	Randomisation method stated?	Adequate concealment described?	Trial described as double-blind?	Blinding of subjects stated?	Blinding of outcome assessors stated?	Withdrawals stated?	Analysis by intention to treat?	Jadad score	Unscheduled crossover?	Study arms comparable at entry?	All study arms treated identically?
Blaskey et al., 1990 USA[40]	Y	N	N	N	N blinding possible only if in filter group (given preferred AND random tint for placebo), but group allocation would be obvious.	Y no access to subject records, but obvious group allocation. Filter group could have placebo or preferred tint-blinded.	Y 0/11 for filter group, 3/11 vision therapy group, 5/8 control group.	Y	2	? during study. 2 given Irlen filters after vision therapy.	Y vision anomaly, positive for filters, IQ N age, race, sex	N vision therapy had corrected vision anomalies.
Gole et al., (SPELD study) 1989 Australia[70]	Y	Y by draw of a random number (odd-experimental group, even-control)- just about adequate but text mentions use of matched controls.	N	N	N not possible, group allocation would be obvious.	Y optometrist unaware of preferred colour, but group allocation to clear glasses or no treatment control would be obvious.	Y Compliance: 6/13 in filter group didn't wear glasses at all, 7/11 controls didn't wear glasses for study duration- appear as withdrawn after 1 term.	U split filter group and control group into lens wearers and non-wearers.	3	NR	Y? stated age, IQ and sex matched controls.	Y

Reference	Trial described as randomised?	Randomisation method stated?	Adequate concealment described?	Trial described as double-blind?	Blinding of subjects stated?	Blinding of outcome assessors stated?	Withdrawals stated?	Analysis by intention to treat?	Jadad score	Unscheduled crossover?	Study arms comparable at entry?	All study arms treated identically?
O'Connor et al., 1990 Australia[72]	Y	Y but unsure whether adequate "expanded Soloman Four design. Stratified to ensure equal grade distribution."	N	Y	Y some blinding possible? Preferred colour vs. clear vs. placebo (non-preferred colour). Allocation to colour vs. clear overlay would be obvious.	Y unaware of group allocation or research design but allocation to colour vs. clear overlay would be obvious.	N	Y	2 or 3	NR	Y reading age, age, gender, were similar between groups.	Y

Reference	Trial described as randomised?	Randomisation method stated?	Adequate concealment described?	Trial described as double-blind?	Blinding of subjects stated?	Blinding of outcome assessors stated?	Withdrawals stated?	Analysis by intention to treat?	Jadad score	Unscheduled crossover?	Study arms comparable at entry?	All study arms treated identically?
Robinson and Foreman, 1999a[74] 1999b[73] Australia	Y	N	N	Y	Y blinding possible. Preferred colour vs. blue vs. placebo (similar colour to preferred).	Y used independent blinded outcome assessors.	U not described for each group but 26 lost overall from treatment groups (16 change of address outside area, 2 lack of response to placebo, 8 reluctance to wear glasses) 7 lost from control group (mostly address changes).	U	3	NR	Y reading age, age, gender, were similar between groups. Preferred colour, blue, and placebo groups were comparable (all had SSS). No treatment control group were non-SSS subjects so cannot be compared to the treatment groups.	Y up to 4m follow up.

Y- yes, N- no, U- unclear

Crossover studies

All crossover studies were judged to be of 'inadequate' quality.[52,68,69,71] All four studies gave an indication of randomisation but none stated how this had been done. No studies reported concealment of allocation.

Bouldoukian and Christenson made no attempt to blind subjects or assessors. Harris and MacRow-Hill, and Wilkins were described as double-blind and provided statements to support this. Wilkins assessed the effectiveness of the placebo by questioning the children at the end of the study and showed that they were unable to reliably distinguish between the experimental and control glasses.

Loss to follow up was not reported by Bouldoukian. Christenson, and Harris and MacRow-Hill made no statement about loss to follow up but Christenson provided data for all subjects for both crossover periods, and analysis by Harris and MacRow appeared to show that there were no losses. Wilkins reported losses of over 10% but not the period in which subjects withdrew. It was difficult to determine whether analysis had been carried out by intention to treat in all studies except that by Harris and MacRow-Hill.

All four studies appeared to attempt to control for the effect of practice on the outcome assessment by using multiple versions of the same test and/or by including a gap between reading tests (a wash out period). Administering the reading test at baseline and in between crossover can also give an indication as to whether reading test practice is leading to an improvement in reading that may confound any true effect of the intervention. Harris and MacRow-Hill included an outcome assessment at baseline, whereas the other three studies only tested at the end of each crossover period. Bouldoukian did not include a wash out period, Harris and MacRow-Hill used only 30 minutes rest between testing, and Harris and MacRow-Hill, and Wilkins used a wash out of 2-5 weeks, and at least 2 weeks respectively. Table 4 summarises the quality assessment for crossover RCTs..

Table 4 Study quality- crossover RCTs

Reference	Trial described as randomised?	Randomisation method stated?	Adequate concealment described?	Trial described as double-blind?	Blinding of subjects stated?	Blinding of outcome assessors stated?	Withdrawals stated and in which period?	Analysis by intention to treat?	Temporal effect test carried out?	Control for practice/ order effects?	Outcome assessment at baseline and end of each period?	Washout period?
Bouldoukian et al., 2002 UK[68]	Y	N	N	N	N	N	N	U	N ?all carried out on same day.	Y 4 versions of the reading test used. Half the subjects read first with the control, then overlay, overlay, control. The other half read first with the overlay, then the control, control, overlay. Practice improved performance but order effect should be accounted for.	N test carried out after each intervention but not at baseline.	N

Reference	Trial described as randomised?	Randomisation method stated?	Adequate concealment described?	Trial described as double-blind?	Blinding of subjects stated?	Blinding of outcome assessors stated?	Withdrawals stated and in which period?	Analysis by intention to treat?	Temporal effect test carried out?	Control for practice/ order effects?	Outcome assessment at baseline and end of each period?	Washout period?
Christenson et al., 2001 USA[69]	Y	N	N	N	N	N	N but data for all subjects provided for both periods so appears no withdrawals.	U?	N would have been useful as up to 5 wks between re-tests.	Y 2 versions of the reading test used: form L for blue filter then form K for no filter, or form L with no filter then form K with blue. Order effect tested for and none found.	N test carried out after each intervention but not at baseline.	Y 2-5 weeks.
Harris and MacRow-Hill, 1999 UK[71]	Y	N	N	Y	Y placebo contact lenses were clear	Y independent from filter provider and nurse inserting/ removing contact lenses.	N but appeared to have no withdrawals.	Y	N all carried out on same day.	Y but not reported whether different versions of WRRT were used. Control reading test (no lenses) carried out twice after each intervention, to check for carryover and practice effects- no practice effect seen but order effect was significant.	Y	U only 30 minutes rest.

Reference	Trial described as randomised?	Randomisation method stated?	Adequate concealment described?	Trial described as double-blind?	Blinding of subjects stated?	Blinding of outcome assessors stated?	Withdrawals stated and in which period?	Analysis by intention to treat?	Temporal effect test carried out?	Control for practice/ order effects?	Outcome assessment at baseline and end of each period?	Washout period?
Wilkins et al., 1994 UK[52]	Y	N	U selection of preferred tint or placebo tint carried out by tinting lab.	Y	Y children unable to reliably distinguish experimental glasses from control glasses.	Y assessors unable to reliably distinguish experimental glasses from control glasses.	Y 15/68 withdrew. A further 16 failed to complete diary. 23 failed to complete the NARA test. Period in which subjects withdrew was not stated.	U	N would have been useful as up to 2 m between tests.	U 2 versions of the reading test used. Order effect: showed non-significant effect of using placebo first.	N test carried out after each intervention and an initial examination of reading before the first pair of glasses but these results were not used.	Y at least 2 weeks.

Y- yes, N- no, U- unclear

2.4.4 Outcomes

Table 5 summarises the characteristics of the outcomes. Qualitative and quantitative analysis is presented below for each outcome. Sample numbers were small with incomplete data sets being a problem for some studies. In particular, the 'no treatment' arm for the Blaskey study was based on outcome data from only three subjects.

For meta-analysis, if missing data was under 10% of the original sample, simple assumptions can be adopted (i.e. missing values have the same properties as known values). When missing data exceeds 10%, complex modelling is required, which was beyond the scope of this review. Where reported, missing data was above 10%. A number of different scales were used to measure the same outcome so standardised mean differences (units of standard deviation) were used to express the size of the treatment effect in the meta-analysis. This method assumes that differences in variability (standard deviations) between studies are due to differences in the scales used to measure the outcome and not due to real differences between the study populations. As noted above this may not be the case.

In some cases, meta-analysis combined data from parallel and crossover studies. Crossover studies were treated as if conducted as a parallel study. The number of studies being pooled was too few to conduct analysis separately based on study design or definition of RD. All forest plots (Figures 2, 3, and 4) showed very little statistical heterogeneity, based on the I^2 statistic, between studies. Clinical heterogeneity, however, based on differences in study sample, study design, and tests for outcome measures were likely to be considerable. This should be taken into account when interpreting the results of pooled data.

Outcome 1: reading accuracy

Reading accuracy was measured by five studies.[40,52,70,72,73] The studies by Blaskey, Gole and Wilkins reported no improvement in reading accuracy with preferred filters compared to control groups. O'Connor reported an

improvement in reading accuracy with preferred filters compared to clear or other coloured filters. Robinson and Foreman reported a significant improvement for all treatment arms but all results were compared to the control group, which was not a randomised comparator. Table 6 summarises the results taken from the study reports.

Table 5 Characteristics of outcomes

Reference	Design	Reading accuracy measure	Reading rate measure	Reading comprehension measure	Symptoms
Blaskey et al., 1990 USA[40]	Parallel 3 arms: preferred irlen/pb colour (n=11) vision tx (n=11) n=8 used in analysis no treatment (n=8) n=3 used in analysis	Woodcock Reading Test Standard scores (used as a proxy for accuracy by EA in meta analysis) Gray Oral Reading Test Standard scores	Gray Oral Reading Test Standard scores	Stanford Reading Test, Passage Comprehension Subtest Scaled scores	Questionnaire
Gole et al., (SPELD study) 1989 Australia[70]	Parallel 2 arms: preferred sola/clear (n=13) no treatment (n=11)	Neale Reading age (y,m)	NR	Neale Reading age (y,m)	ND
O'Connor et al., 1990 Australia[72]	Parallel 4 arms (sss): preferred colour (n=17) clear (n=17) non-preferred colour (n=17) clear post-test (n=16) 2 arms (non-sss): random colour (n=13) clear (n=12)	Neale Reading age	Neale Reading age	Neale Reading age FRI Reading age	ND
Robinson and Foreman, 1999a[74] 1999b[73] Australia	Parallel 3 arms: preferred colour (n=38) blue (n=41) placebo colour (n=34) 1 arm (non-sss): no treatment control (n=35)	Neale Reading age mean (y) (SD)	Neale Reading age (y) mean (SD)	Neale Reading age mean (y) (SD)	ND

Reference	Design	Reading accuracy measure	Reading rate measure	Reading comprehension measure	Symptoms
Bouldoukian et al., 2002 UK[68]	Crossover (n=33) 2 arms: preferred intuitive-UV control UV control-preferred intuitive	ND	WRRT Mean number words per min (SE)	ND	ND
Christenson et al., 2001 USA[69]	Crossover (n=16) 2 arms: blue-no filter no filter-blue	ND	ND	Gates-MacGinitie Test Grade equivalent, Raw scores	ND
Harris and MacRow-Hill, 1999 UK[71]	Crossover (n=47) 2 arms: preferred chromagen-placebo clear placebo clear -preferred chromagen no treatment control also for both groups	ND	WRRT Mean number words per min (SD)	ND	ND
Wilkins et al., 1994 UK[52]	Crossover (n=68) 2 arms: preferred intuitive-placebo colour placebo-preferred intuitive	Neale Reading age	Neale Reading age	Neale Reading age	Diaries

ND- not done

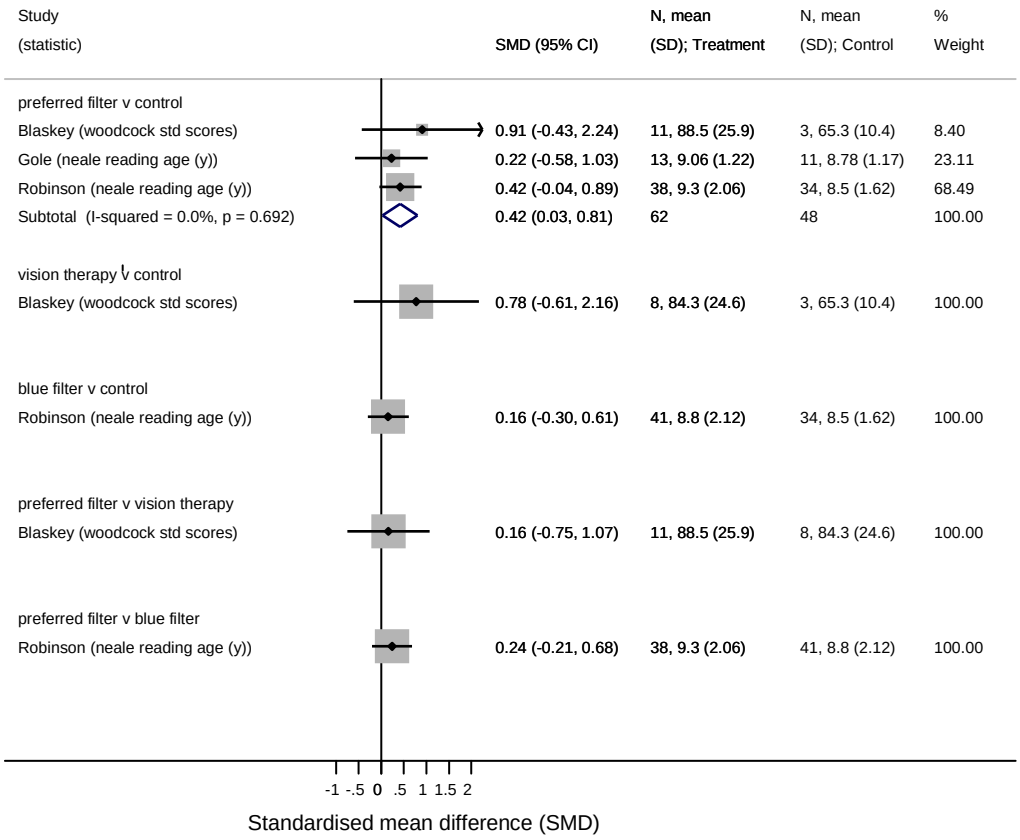
Table 6 Reading accuracy

Reference	Results				Findings reported by authors	Included in meta-analysis?
Blaskey et al., 1990 USA[40]	Woodcock reading test standard scores				No statistically significant improvement in reading accuracy with Irlen filters.	Yes
		N	Mean (SD)	p		
	Preferred colour filter:					
	Pre-treatment	11	81.36 (24.58)			
	Post-treatment	11	88.54 (25.86)	0.05		
	Vision therapy:					
	Pre-treatment	11	69.8 (32.37)			
	Post-treatment	8	84.25 (24.63)	0.12		
	No treatment:					
	Pre-treatment	8	63.33 (7.57)			
	Post-treatment	3	65.33 (10.4)	0.25		
Gole et al., (SPELD study) 1989 Australia[70]	Neale reading test reading age (y)				No statistically significant difference in the absolute value or change in reading age for accuracy between treatment and control groups.	Yes
		N	Mean (SD)	p		
	Preferred colour filter:					
	Pre-treatment	13	9.15 (0.96)			
	Post-treatment	13	9.06 (1.22)	NR		
	No treatment:					
	Pre-treatment	11	8.79 (0.98)			
	Post-treatment	11	8.78 (1.17)	NR		

Reference	Results	Findings reported by authors	Included in meta-analysis?
O'Connor et al., 1990 Australia[72]	*Group mean change in reading age (m) between pre- and post-testing* *Neale* Preferred colour: +6.9 Clear: -3.18 Non-preferred colour: -0.18 Non-SSS Clear: -0.18 Non-SSS Random colour: +0.88 Kruskel-Wallis one-way ANOVA differences among groups p≤0.001.	Statistically significant improvement in reading accuracy with preferred colour filters for sss children compared to clear or other colour filters.	No (no p values, SD or variance reported)
Robinson and Foreman, 1999a[74] 1999b[73] Australia	Neale reading test reading age (years) N / Mean (SD) / p *Preferred colour filter:* Pre-treatment 38 8.2 (1.53) Post-treatment 38 9.3 (2.06) NR *Blue filter:* Pre-treatment 41 8.4 (1.52) Post-treatment 41 8.8 (2.12) *Placebo:* Pre-treatment 34 8.3 (1.26) Post-treatment 34 8.5 (1.62) NR	Statistically significant improvement in accuracy for all 3 arms after 4m.	Yes
Wilkins et al., 1994 UK[52]	*Group mean reading age (y)* *Neale* Preferred colour: 9.57 Placebo colour: 9.42 Difference not statistically significant (p>0.05).	No statistically significant improvement in reading accuracy with Intuitive filters compared to placebo.	No (no p values, SD or variance reported)

Data from the Blaskey, Gole, and Robinson and Foreman studies were entered into a meta-analysis. O'Connor and Wilkins did not provide the data necessary for meta-analysis. Figure 2 shows the forest plot for the outcome of reading accuracy.

Figure 2 Meta-analysis: reading accuracy



The control comparator in the plot above was 'no treatment' for the Blaskey and Gole studies and was 'placebo colour' for the Robinson and Foreman study. In all pairwise comparisons shown in Figure 2, the 95% confidence intervals cross zero indicating that the intervention was no better than the control at improving reading accuracy, and that preferred filters were no better than vision therapy or blue filters. The plot showed that there may be a non-significant trend towards a benefit with the preferred filter compared to the controls.

Vision therapy versus control and the preferred filter versus vision therapy are shown for completeness, however the vision therapy group was not comparable to the preferred filter and control arms since vision therapy subjects were given correction for standard optometric anomalies, whereas those subjects in the other two arms were left with significant refractive, accommodative and binocular problems.

Outcome 2: reading speed

Reading speed was measured by six studies.[40,52,68,71-73] The studies by Blaskey, Robinson and Foreman, and Wilkins reported no improvement in reading rate with preferred filters compared to control groups. O'Connor, Bouldoukian, and Harris and MacRow-Hill reported an improvement in reading rate with preferred filters compared to clear or other coloured filters, UV control or placebo clear filters. Table 7 summarises the reported results.

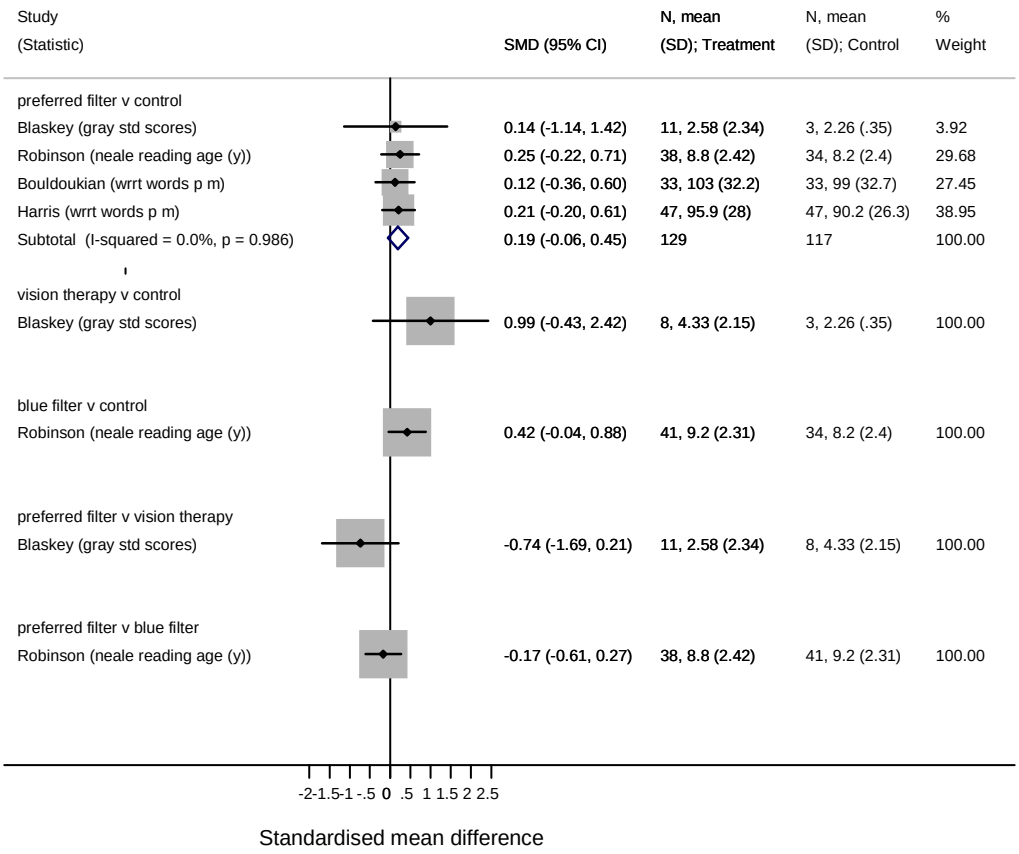
Data from the Blaskey, Robinson and Foreman, Bouldoukian, and Harris and MacRow-Hill studies were entered into a meta-analysis. O'Connor and Wilkins did not provide the data necessary for meta-analysis. Figure 3 shows the forest plot for the outcome of reading speed.

Table 7 Reading speed

Reference	Results	Findings reported by authors	Included in meta-analysis?
Blaskey et al., 1990 USA[40]	Gray oral reading test standard scores N Mean (SD) p *Preferred colour filter:* Pre-treatment 11 2.07 (3.03) Post-treatment 11 2.58 (2.34) 0.19 *Vision therapy:* Pre-treatment 11 1.72 (0.95) Post-treatment 8 4.33 (2.15) 0.006 *No treatment:* Pre-treatment 8 2.76 (1.55) Post-treatment 3 2.26 (0.35) 0.3	No statistically significant improvement in reading rate with Irlen filters.	Yes
O'Connor et al., 1990 Australia[72]	Neale group mean change (m) between pre- and post-testing *Preferred colour*: +6.6 *Clear:* -3.76 *Non-preferred colour*: -1.7 *Non-SSS Clear*: -1.0 *Non-SSS Random colour*: -2.0 Kruskel-Wallis one-way ANOVA differences among groups $p \leq 0.001$.	Statistically significant improvement in reading rate with preferred colour filters for sss children compared to clear or other colour filters.	No (no p values, SD or variance reported)
Robinson and Foreman, 1999a[74] 1999b[73] Australia	Neale reading test reading age (years) N Mean (SD) p *Preferred colour filter:* Pre-treatment 38 8.7 (2.37) Post-treatment 38 8.8 (2.42) NR *Blue filter:* Pre-treatment 41 9.1 (2.38) Post-treatment 41 9.2 (2.31) *Placebo:* Pre-treatment 34 9.0 (2.7) Post-treatment 34 8.2 (2.4) NR	No improvement in reading speed for any of the 3 arms.	Yes

Reference	Results	Findings reported by authors	Included in meta-analysis?
Bouldoukian et al., 2002 UK[68]	Wilkins rate of reading test words per min N mean (SD) p Preferred colour: 33 103 (32.17) UV control: 33 99 32.74) 0.002	Statistically significant increase in rate of reading with coloured overlay compared to control.	Yes
Harris and MacRow-Hill, 1999 UK[71]	Wilkins rate of reading test words per min for 'all subjects' N Mean (SD) p *Preferred colour filter:* Pre-treatment 47 83.7 (26.4) Post-treatment 47 95.9 (28.0) NR *Placebo colour:* Pre-treatment 47 83.7 (26.4) Post-treatment 47 90.2 (26.3) NR	Statistically significant improvement in reading rate with chromagen filters compared to placebo for subjects with distortion (n=41), and distortion with no colour deficiency but not in 'all subjects'.	Yes
Wilkins et al., 1994 UK[52]	Neale Group mean reading age (y) Preferred colour: 9.37 Placebo colour: 9.22 Difference not statistically significant (p>0.05).	No statistically significant improvement in reading rate with Intuitive filters compared to placebo.	No (no p values, SD or variance reported)

Figure 3 Meta-analysis: reading speed



The control comparator in the plot above was no treatment for the Blaskey study, placebo colour for the Robinson and Foreman study, a pale yellow UV control in the Bouldoukian comparison and a clear placebo in the Harris and MacRow-Hill study. The plot suggests that the intervention was no better than the control, and that preferred filters were no better than vision therapy, or blue filters, at improving reading speed since all 95% CI's cross zero. As with reading accuracy, the plot showed that there may be a trend towards a benefit with the preferred filter compared to the controls employed.

Outcome 3: reading comprehension

Reading comprehension was measured by six studies.[40,52,69,70,72,73] The studies by Blaskey, Gole, Christenson, and Wilkins showed no improvement in reading comprehension with preferred filters compared to control groups. O'Connor, and Robinson and Foreman reported an improvement in reading comprehension with preferred filters compared to clear or other coloured filters (including placebo colour). Table 8 summarises the reported results.

Data from the Blaskey, Gole, Robinson and Foreman, and Christenson studies were entered into a meta-analysis. O'Connor and Wilkins did not provide the data necessary for meta-analysis. Figure 4 shows the forest plot for the outcome of reading comprehension.

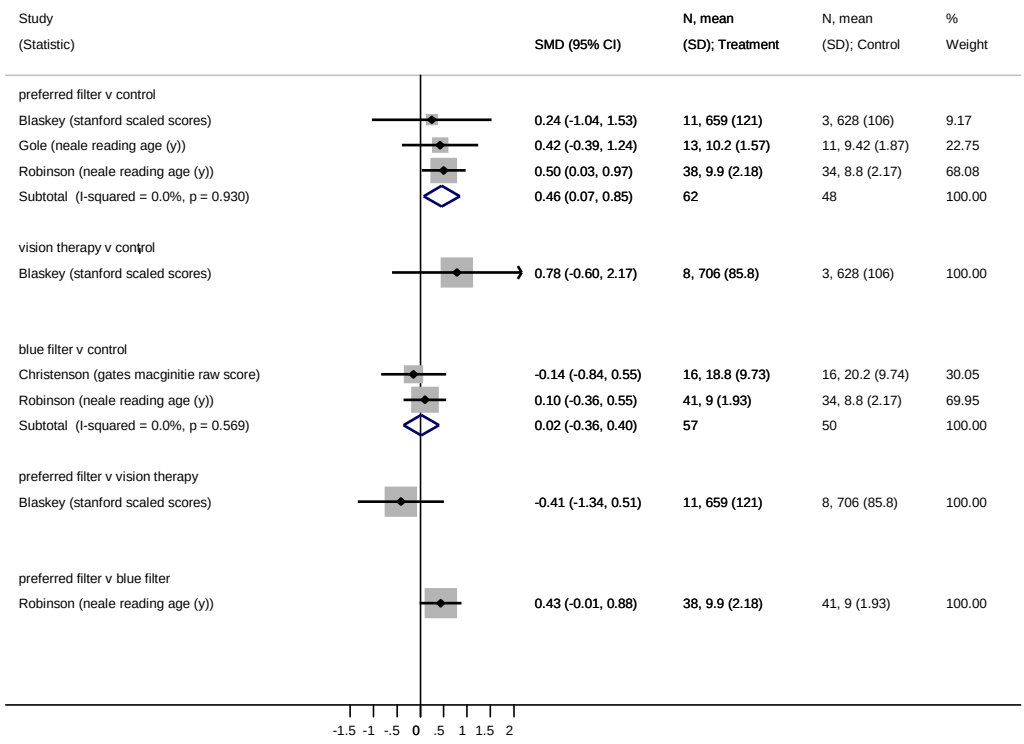
Table 8 Reading comprehension

Reference	Results				Findings reported by authors	Included in meta-analysis?
Blaskey et al., 1990 USA[40]	Stanford reading test scaled scores				No statistically significant improvement in reading comprehension with Irlen filters.	Yes
		N	Mean (SD)	p		
	Preferred colour filter:					
	Pre-treatment	11	648.73 (114.65)			
	Post-treatment	11	659.36 (121.04)	0.14		
	Vision therapy:					
	Pre-treatment	11	704.5 (69.39)			
	Post-treatment	8	706.12 (85.76)	0.46		
	No treatment:					
	Pre-treatment	8	633.67 (111.38)			
	Post-treatment	3	628.33 (106.29)	0.18		
Gole et al., (SPELD study) 1989 Australia[70]	Neale reading test reading age (years)				No statistically significant difference in the absolute value or change in reading age for comprehension between treatment and control groups.	Yes
		N	Mean (SD)	p		
	Preferred colour filter:					
	Pre-treatment	13	9.81 (1.57)			
	Post-treatment	13	10.17 (1.57)	NR		
	No treatment:					
	Pre-treatment	11	9.21 (1.32)			
	Post-treatment	11	9.42 (1.87)	NR		

Reference	Results	Findings reported by authors	Included in meta-analysis?
O'Connor et al., 1990 Australia[72]	*Group mean change (m) between pre- and post-testing* *Neale* SSS Preferred colour: +19.35 SSS Clear: -5.94 SSS Non-preferred colour: -0.29 Non-SSS Clear: -0.77 Non-SSS Random colour: +2.58 Kruskel-Wallis one-way ANOVA differences among groups p≤0.001. *FRI* SSS Preferred colour: +16.35 SSS Clear: -5.35 SSS Non-preferred colour: +0.53 Non-SSS Clear: -1.38 Non-SSS Random colour: +0.08 Kruskel-Wallis one-way ANOVA differences among groups p≤0.001.	Statistically significant improvement in reading comprehension with preferred colour filters for sss children compared to clear or other colour filters.	No (no p values, SD or variance reported)

Reference	Results	Findings reported by authors	Included in meta-analysis?
Robinson and Foreman, 1999a[74] 1999b[73] Australia	Neale reading test reading age (years) N Mean (SD) p *Preferred colour filter:* Pre-treatment 38 8.4 (1.44) Post-treatment 38 9.9 (2.18) NR *Blue filter:* Pre-treatment 41 9.1 (1.81) Post-treatment 41 9.0 (1.93) NR *Placebo:* Pre-treatment 34 8.7 (1.79) Post-treatment 34 8.8 (2.17) NR	Statistically significant improvement in comprehension for all 3 arms after 4m.	Yes
Christenson et al., 2001 USA[69]	Gates MacGinitie reading test raw score N Mean (SD) p *Blue filter:* 16 18.75 (9.73) *No filter:* 16 20.19 (9.74) NR	No statistically significant difference in reading comprehension for blue filter compared to no filter.	Yes
Wilkins et al., 1994 UK[52]	Neale group mean reading age (y) Preferred colour: 10.28 Placebo colour: 10.12 Difference not statistically significant (p>0.05).	No statistically significant improvement in reading comprehension with Intuitive filters compared to placebo.	No (no p values, SD or variance reported)

Figure 4 Meta-analysis reading comprehension



The control comparator in the plot above was no treatment for the Blaskey and Gole studies, and placebo colour for the Robinson and Foreman study. The plot suggests that the preferred filters may be marginally better than the control, since the pooled estimate 95% CI's do not cross zero. All other comparisons, including blue filters versus no filter (Christenson study) and placebo colour (Robinson and Foreman), show 95% CI's that cross zero suggesting that the intervention was no better than the comparator at improving reading comprehension. As mentioned above, comparisons involving vision therapy (Blaskey study) should be treated with caution.

Outcome 4: symptoms

Only two studies, Blaskey by questionnaire, and Wilkins by completion of a diary, carried out an assessment of the effect of coloured filters on symptoms of visual stress. Both studies reported a statistically significant improvement in a subjective measure of symptoms for Irlen filters (and vision therapy)[40] and preferred filters[52] compared to no treatment and placebo colour filters respectively.

Table 9 Symptoms

Reference	Results	Reported findings
Blaskey et al., 1990 USA[40]	Symptom questionnaire score N Mean (SD) p *Preferred colour filter:* Pre-treatment 11 26.45 (7.02) Post-treatment 11 12.64 (5.43) <0.0001 *Vision therapy:* Pre-treatment 11 27.25 (4.75) Post-treatment 8 15.94 (5.19) 0.0002 *No treatment:* Pre-treatment 8 29.0 (6.38) Post-treatment 3 27.0 (2.16) 0.25	Statistically significant improvement in symptoms with Irlen filters.
Wilkins et al., 1994 UK[52]	Mean no. symptom free days/ mean no. days glasses worn (Number completed diaries =36) *Preferred colour filter:* 13.9/ 18.4 (71%) *Placebo colour:* 11.9/ 17.9 (66%)	Statistically significant less frequent symptoms with experimental glasses compared to placebo.

2.5 Non-RCTs

Fifteen relevant comparative studies were also identified and have been summarised for completeness. The non-RCT studies were of very poor quality, occupying level 4 in the hierarchy of evidence.[90] Most of these studies were of a before-after design, where the reading outcome was measured pre-intervention and compared to the reading outcome when the coloured filter was employed. Where used, the control group was a different population, usually subjects without reading difficulty. Table 10 summarises the study characteristics. The reported results are summarised in Table 11. Six studies reported some improvement in reading rate with the use of a coloured filter. An improvement in reading comprehension was also reported by three studies when a coloured filter was used. Three studies reported that there was no change in reading performance with the use of the filter. These results should not be taken as evidence of an effect since there are many threats to study validity.

Table 10 Study characteristics- non-RCTs (15)

Reference	Study design	Population	N*	Intervention	Comparator(s)	Relevant outcomes	Study objective
Cotton and Evans, 1990 Australia[75]	Before-after study. All subjects were tested with all 4 intervention conditions presented in random order.	Children with reading difficulties with mild to severe SSS (IDPS)	22	**Irlen** coloured lenses (glasses?) (preferred)	Random colour Plain lenses No lens control	Neale, Reading performance	To compare the personality differences, hand-eye coordination and depth perception in children with specific reading difficulties with SSS and those with SRD but no SSS. To investigate the effectiveness of Irlen lenses on the reading performance of children with SSS.
Iovino et al., 1998 USA[76]	All subjects were tested with all 3 intervention conditions in non-random order.	Children with reading disability and comorbid conditions	45 ?	Blue overhead transparencies (3M) Red overhead transparencies (3M)	No overlay	FRI (reading accuracy, rate, and comprehension)	To investigate the effectiveness of blue overlays on the reading ability of children with RD with and without other deficits.
Kriss and Evans, 2005 UK[77]	Before-after study. Used normal control group comparison. All subjects were tested with and without overlay.	Children with dyslexia	32	**Intuitive** coloured overlay (preferred)	No overlay	WRRT	To compare the prevalence of MIS in a cross-sectional sample of dyslexic and control children.
Kyd et al., 1992 UK[78]	Before-after study. Used non-SSS control group comparison. All subjects were tested with and without overlay.	Children with specific learning difficulties with SSS (IDPS)	14	**Irlen** overlays (preferred)	No overlay	Neale	To evaluate the Irlen screening method in identifying SSS in subjects with SLD, and to assess effectiveness of coloured overlays in relieving symptoms of SSS and improving reading skills.

Reference	Study design	Population	N*	Intervention	Comparator(s)	Relevant outcomes	Study objective
Lightstone et al., 1999 UK[54] Study II	All subjects were tested with all intervention conditions, presented in random order. No other control group.	Children and adults attending the Specific Learning Difficulties clinic	17	**Intuitive** overlay (preferred)	Lenses matching the preferred overlay Lenses matching the colorimeter setting No colour	WRRT	To compare reading rate of SLD subjects using coloured overlays for more than 2m with no colour, a chosen overlay, lenses matching the chosen overlay and lenses matching the colorimeter setting.
Martin and MacKenzie et al., 1993 Australia[79]	Compared SRDs with lenses to SRDs without lenses over time. Non-randomly divided into 2 groups. Used normal control comparison.	Children with reading disability With SSS (n=20) without SSS (n=20)	40	**Irlen** lenses	No lenses	Neale	To compare RD and normally reading children on measures of reading performance and to see what effect the Irlen lenses have on these measures.
Menacker et al., 1993 USA[80]	All subjects were tested with all 6 intervention conditions. Rotated order of presentation. No baseline.	Children with dyslexia	24	SOLA coloured glasses (red, blue, yellow, green)	Neutral density glasses Empty glasses frames	Arnold and Smith text books	To determine if tinted lenses cause a measurable improvement in the reading performance of dyslexic children.
Northway, 2003 UK[81]	Before-after study. No control group.	Children with dyslexia	64	**Intuitive** overlays (preferred)	No overlay	WRRT	To use WRRT to determine whether coloured overlays could enhance reading performance.
Robinson and Conway, 1990 Australia[82]	Before-after study. Comparison of pre- and post-preferred lens scores over 12m. No control group.	Children with reading disabilities	44	**Irlen** lenses	No overlay	Neale	To assess the effects of Irlen lenses over 12m and to assess changes in attitude towards reading.

Reference	Study design	Population	N*	Intervention	Comparator(s)	Relevant outcomes	Study objective
Robinson and Conway, 1994 Australia[83]	Before-after study. Mean pre-post test comparison. No other control group.	Children with reading problems with SSS (IDPS) (n=29) without SSS (n=31)	60	**Irlen** lenses	No overlay	Neale	To investigate the effect of tinted non-optical (Irlen) lenses in 29 lens using subjects and a control group of 31 subjects on reading performance.
Saint-John and White, 1988 Australia[84]	Used normal control group. Mean pre-post test comparison.	Specific reading-disabled children	11	Coloured plastic transparencies	Coloured glasses Polaroid lenses in spectacle frames Empty glasses frames	Reading selected passages from a book.	To investigate effects of coloured transparencies on the reading ability of SRD children.
Sawyer et al., 1994 UK[85]	Before-after study. Compared pre-post differences between groups. One group got the overlay (n=110), one group didn't (n=185).	Children with specific learning difficulties	295	Coloured overlays (preferred) (blue, green, red, yellow)	No overlay	Salford Reading Test	To investigate effects of coloured overlays equivalent to Irlen tints for improving reading ability, confidence and interest in reading in children with SLD and a control group.
Singleton and Henderson, 2007 UK[86]	Before-after study. Used other non-dyslexic and reading-age control groups.	Children with dyslexia	22	**Intuitive** overlays	No overlay	WRRT	To evaluate predictive validity of ViSS in a dyslexic sample by comparing with current technology to measure visual stress and symptoms and compared to normal readers.

Reference	Study design	Population	N*	Intervention	Comparator(s)	Relevant outcomes	Study objective
Solan et al., 1997 USA[63]	Before-after study. Compared pre-post differences between groups. Used normal control group.	Children with reading disability	31	Blue coloured glasses (Lee filters)	No filter (empty glasses frames) Light grey filter Dark grey filter	Timed reading (Specific Skills Series) and reading comprehension	To investigate whether reading comprehension skills of children with RD improve as wavelength and contrast of light are altered.
Tyrrell et al., 1995 UK[87]	Before-after study. Used other control groups.	Children with well-below average reading (3-5yrs below chronological age) with SSS (IDPS)	6	**Irlen** overlays	No overlay	15 min reading from selected book passages	To investigate the effect of selected coloured overlays on reading skills and general reading behaviour in school children (small number with RD).

* number shown is for children with RD only.

Table 11 Results of non-RCTs

Reference	Summary of reported results
Cotton and Evans, 1990 Australia[75]	No significant improvement in reading with use of Irlen lenses by children diagnosed as SSS. Minimum improvement (months) seems to reflect passage of time between testing. Subjective measure (no distortion to music lines) leads to higher % of reported beneficial effects of the Irlen lenses than a more objective, quantifiable task (cube counting) which leads to a very small difference in performance between lens conditions. No quantifiable effect of the lenses, although some subjective effect.
Iovino et al., 1998 USA[76]	Blue overlays significantly improved reading comprehension accuracy relative to reading without an overlay for all groups, but reduced reading rate. The small effect size did not normalise reading skills in those with RD.
Kriss and Evans, 2005 UK[77]	In subjects who chose an overlay there was a significant improvement in rate of reading with the preferred overlay. Effect of overlay on WRRT results reached significance in the dyslexic group.
Kyd et al., 1992 UK[78]	Unexpected worsening of reading accuracy and comprehension. Significant increased rate of reading with overlay. Subjects whose results went off the end of scale were ignored.

Reference	Summary of reported results
Lightstone et al., 1999 UK[54] Study II	Significant comparisons between the no lens condition and the chosen overlay and the no colour condition and the lens matching the colorimeter. Increase in reading speed with the lens matching the colorimeter.
Martin and MacKenzie et al., 1993 Australia[79]	Both groups (Irlen lenses and no lenses) improved from pretest to post test but declined at follow up (still better than at pre-test). No differences emerge from pre-test to post-test or to follow up. No differences between SRDs with lenses and SRDs without lenses for accuracy or comprehension. No indication that Irlen lenses lead to long-term improvement in either Neale accuracy or comprehension scores. Decrease in accuracy and comprehension performance at follow up was greater for SRDs with lenses than SRDs without, but did not approach significance.
Menacker et al., 1993 USA[80]	Neither improvement nor deterioration attributable to lens colour or density. Non-significant effect for any condition for accuracy or speed.
Northway, 2003 UK[81]	Children who did not chose an overlay and those who stopped using their chosen overlay performed better on all tests than those who continued to use the overlays for 12 weeks but this was not statistically significant. Children who did not chose an overlay and those who stopped using their chosen overlay performed worse when using the overlays than without. Children who continued to use the overlays for 12 weeks performed better with the overlays than without.
Robinson and Conway, 1990 Australia[82]	Significant improvement in reading comprehension and reading accuracy, but not in rate of reading at 3, 6 and 12m after lens fitting. Results section shows increase in rate though minor.
Robinson and Conway, 1994 Australia[83]	Assessment of reading 4m after the initial screening showed a significant improvement in reading rate and comprehension but not accuracy for lens users. Doesn't state whether this was over time or compared to controls.
Saint-John and White, 1988 Australia[84]	Improved reading speed for SRDs during post testing reflected the effect of practice, not the wearing of coloured overlays or Polaroid lenses.
Sawyer et al., 1994 UK[85]	Significant improvement in reading age using overlays for 1.5 terms. No improvement in confidence, interest or amount of reading by lens using group compared to the group without lenses.
Singleton and Henderson, 2007 UK[86]	Significant gains in speed seen with use of the overlay compared to without.
Solan et al., 1997 USA[63]	Blue filters significantly improved reading comprehension in RD subjects. Dark grey and light grey filters also improved comprehension but this was not statistically significant.
Tyrrell et al., 1995 UK[87]	No separate data were given for the well-below average readers.

2.6 ummary of effectiveness results

- One quasi-systematic review, eight RCTs and 15 non-RCTs were identified by the searches.
- Of the eight RCTs, four were of a parallel design, four were crossover studies.
- Seven RCTs studied the effectiveness of a 'preferred' colour filter, which was selected from a series of coloured filters as the colour providing the greatest perceived benefit in reading.
- Comparators were UV blocking,[68] no treatment,[40,71] placebo colour[52,72-74] or clear filters.[70,71] The eighth RCT investigated the effectiveness of blue filters compared to no filters.[69]
- Blaskey, Bouldoukian, O'Connor and Wilkins all reported that there was no placebo effect. Some subjects in the Harris and MacRow-Hill study reported a large response to the placebo. The authors argue that the placebo wasn't unmasked.
- Children and adults with dyslexia (3 studies)[69-71] or reading disability with symptoms of visual stress (5 studies)[40,52,68,72-74] were enrolled.
- Five RCTs included a pre-study measure of IQ and only enrolled subjects with an average or higher intelligence.[40,69,70,72,73] Vision problems were corrected in all but one study.[40]
- No RCT examined the long-term effects of using coloured filters as part of the randomised design, although one study transferred all subjects to the preferred filter for an additional 16 months.
- Clinical heterogeneity between studies was likely to be significant, although statistical heterogeneity, based on the I^2 statistic, was low.
- A variety of scales or tests were used to measure outcomes of reading ability.
- Reading accuracy was measured by five RCTs. Meta-analysis involving three studies showed no clear benefit to using coloured filters for reading accuracy compared to using the control. The two studies that could not be incorporated into meta-analysis reported a statistically significant improvement and no statistically significant improvement with preferred coloured filters compared to the control.

- Reading speed was measured by six RCTs. Meta-analysis involving four studies showed no clear benefit to using coloured filters for reading speed compared to using the control. The two studies that could not be incorporated into meta-analysis reported a statistically significant improvement and no statistically significant improvement with preferred coloured filters compared to the control.
- Reading comprehension was measured by six RCTs. Meta-analysis involving four studies showed no clear benefit to using coloured filters for reading comprehension compared to using the control. The two studies that could not be incorporated into meta-analysis reported a statistically significant improvement and no statistically significant improvement with preferred coloured filters compared to the control.
- Two RCTs evaluated symptoms of visual stress that can be associated with reading disability. Both studies used subjective measures to show that there was a statistically significant improvement in level of symptoms with use of preferred coloured filters compared to the control.
- No RCTs reported behaviour, quality of life or adverse effects of using coloured filters for reading disability.
- There was no difference in outcome results demonstrated by the studies employing dyslexic subjects compared to those defined as having reading disability.
- All RCTs were likely to be underpowered, including the four crossover studies, since the sample sizes were small. No power calculations were reported by any of the studies.
- All RCTs were of less than adequate quality. Only two studies could be considered truly double-blind.[52,73] In all studies randomisation was unclear or not stated. All studies were threatened by high loss to follow up, poor compliance, and lack of reporting of subject withdrawals. High rates of attrition may be an indicator of lack of benefit to the use of coloured filters. Group equivalence at the study start was not certain for the study by Blaskey.
- External validity would be hampered by the lack of a clear definition of RD. The severity of RD was likely to cover a broad spectrum.

- There were 15 non-RCTs of poor quality with variable results that should not be used as evidence for or against the review question.
- In summary, there does not appear to be evidence to support the hypothesis that individually prescribed coloured filters can be effective in improving reading performance or symptoms in subjects with reading disability.

2.7 Discussion of effectiveness results

The results may be influenced by several important aspects of study design such as the use of a parallel or crossover design, sample selection, selection of an appropriate comparator, pre-study filter use and duration of use of filter, and presence of undetected visual anomalies.

Crossover studies have an advantage over parallel designs in that each subject acts as their own control, which removes the variability between subjects, and that a smaller sample number is needed to obtain the same power. The crossover design, however, may be a poor choice for some trials since they generally require the subject to be part of a study for a longer period than that required by parallel trials. The longer the study, the more likely subjects are to drop out, which can confound any treatment effect seen in the second treatment period. Since loss to follow up was not clearly reported by any of the four crossover studies, it was difficult to determine how much this may have affected the results.

Further disadvantages of the crossover design are the potential for the underlying condition to improve naturally over time (a temporal effect), and to carry over effects of the first treatment period into the subsequent trial period (carry-over effect). In these cases any difference in the effects of two treatments would depend upon the order in which the treatment was given. In the included crossover studies, the effect of practice, subjects getting tired, or changes in motivation on the outcome of the reading test could be important carry-over effects. All four crossover studies made some attempt to control for this.

An appropriate comparator in RCTs of new interventions is often a placebo. An effective placebo must mimic the experimental intervention as closely as possible to avoid detection by the subject (and ideally the outcome assessor) with the aim of limiting bias in the results. The placebo must also remain inert, so that it does not produce either a positive effect, or a negative effect that may erroneously inflate the effects of the intervention. The design of an effective placebo control in studies assessing the effectiveness of coloured filters has not been easy. A tint designed to be similar to the preferred colour, but lying outside the chromaticity shown to be effective in an earlier test of the intervention appears to be the most effective placebo control used to date. The placebo colour is specific to the individual. Maintenance of the mask and uncertainty over whether the placebo was inert may introduce a confounding factor.[52] Three studies[52,72-74] all employed placebo controls designed in this way.

No treatment control comparators were used by two studies.[40,71] This type of study design does not allow for the blinding of subjects, which may introduce some bias.

The duration of use of filter may also affect the results. Studies that assess the immediate effects of filters can measure the change in print clarity but in many cases this is unlikely to translate into an immediate improvement in reading ability. The word recognition skills that contribute to reading performance take time to develop. It is possible that several months of use of the coloured filter would be required to truly measure any potential effect on reading ability. In studies with longer follow up, however, good controls for period or temporal effects are necessary since reading skills will develop naturally over time. This could confound any benefit seen when using a filter. One study assessed the immediate effects of the filter,[71] two others did not state duration of use, but were likely to have been assessing immediate effects.[68,69] One study assessed effects of the filter following one weeks' use.[72]

The paucity of information on the definition of RD is a weakness in the reporting of the majority of the included studies. In addition, some studies relied on self-reports of RD, while others used professionals. This uncertainty in the diagnosis is further borne out by the range of recruitment settings used across the eight studies. Subjects recruited via specialist centres may exhibit a greater degree of reading deficit or symptoms to those recruited from ordinary schools or the media. In addition, the rate of reading development may vary with age making the spread of ages an important criteria on which to base group equivalence at the start of a study and for comparison between studies. This made it difficult to assess the level of heterogeneity between samples. As a worst case, it should be assumed that the populations represent a spectrum of severity of RD.

There are serious limitations in using the intervention under investigation to screen and include subjects for a study of effectiveness of that same intervention, since the study population has then been pre-sampled to show benefit from the intervention, which is likely to bias the results towards a positive effect. Five of the eight included RCTs were flawed in this way.[40,52,68,72-74] Even with the use of a different format for the filter between selection and actual study, this element of study design could bias the results towards a benefit that does not truly exist.

In addition to the above concerns over sample selection based on the use of the intervention, previous exposure to coloured filters prior to the actual tests for effectiveness may influence the degree of change in reading performance between pre- and post-testing. If previous exposure to filters is over several weeks prior to enrolment in the study, word recognition skills may develop altering the true difference in reading performance. Comparison, as in the meta-analysis, between studies of immediate vs. long-term effects, or of previous exposure to filters vs. no exposure must therefore be treated with caution.

Reports of benefit by those with a commercial interest must be treated with caution. The Bouldoukian study was co-authored by Wilkins, and the Wilkins

study was authored by Wilkins, who developed the Intuitive Colorimeter and filter system in conjunction with the MRC. The article makes a declaration of interest since Wilkins receives an “Award to Inventors” from the MRC. The Harris and MacRow-Hill study also reports a disclaimer stating that Harris is the inventor of the ChromaGen system and therefore has an interest in the product. No other statements were made regarding financial or other interest.

3. ECONOMIC ANALYSIS

3.1 Aim

To use systematic review to identify and appraise pre-existing economic evaluations of coloured filters for reading disability.

To identify cost data relevant to the West Midlands.

3.2 Methods for economic analysis

3.2.1 Search strategy

A systematic review of the literature relating to cost-effectiveness and costs of Irlen's lenses was conducted. A search for published economic evaluations and cost data was carried out using the search terms employed in the review of effectiveness. The following databases were searched:

- MEDLINE (Ovid) 1950 – September week 3 2007
- EMBASE (Ovid) 1980 – 2007 week 38
- CINAHL (Ovid) 1982 – September 2007
- NHS EED on the Cochrane Library (Wiley) 2007 Issue 3
- OHE HEED September 2007 issue.

Citation lists from included relevant reviews and primary studies were also examined. The full search strategies are shown in Appendix 2.

3.2.2 Inclusion and exclusion criteria for the economic evaluation

Studies were included if they met the following criteria:

- *Study design*: any type of economic evaluation (cost minimisation, cost effectiveness analysis, cost utility analysis and cost benefit analysis); any primary study that had measured costs associated with reading disability in children or adults, or associated with the provision of precision coloured filters (glasses, contact lenses or overlays). Studies evaluating costs in countries where practice is not comparable to the UK were excluded. Study designs with no comparator were excluded.

- *Population*: children or adults, with reading disorder, disability, difficulty or dyslexia
- *Intervention*: tinted or coloured overlays, lenses, glasses or filters
- *Comparator*: placebo, no treatment, or other current treatment
- *Outcomes*: cost effectiveness of coloured filters, or quality of life or costs associated with reading disability or provision of coloured filters.

Citations were scanned for inclusion by one reviewer (EA) and checked and appraised by a second reviewer (CH). The quality of economic evaluations was assessed using the checklist by Drummond.[91] Results were tabulated and discussed.

The information on costs in particular was supplemented by the clinical advisor on the report (FE).

Following the initial review the scope of the search was extended to explore research examining the association between reading ability, or illiteracy with health, social or economic outcomes in later life. The following sources were interrogated in this additional search : MEDLINE (Ovid) 1950 – December week 1 2007, PsycINFO (Ovid) 1967 – December week 1 2007 and ERIC (CSA) 1967 – 12 December 2007. As for the initial review, citations were scanned for inclusion by one reviewer (EA) and checked and assessed by a second reviewer (CH). This additional search was not a full systematic review. There was no formal appraisal or synthesis process. Included studies were described narratively and their general implications for cost-effectiveness and conduct of a health economic model considered.

The original intention if a suitable existing economic model was not identified in the systematic review of economic evaluations was to proceed to developing a simple illustrative economic model. In the event, for reasons elaborated in the discussion section, this was not pursued.

3.3 Results

3.3.1 Quantity and quality of existing research

Following removal of duplicates, 146 articles were identified from the initial systematic search for articles reporting costs, quality of life, and cost-effectiveness. A full copy was retrieved for seven articles. There were no studies that met the inclusion criteria described above. Reasons for exclusion were failure to address costs or cost-effectiveness in any systematic manner.

The additional search for long-term outcomes of reading disability or illiteracy (Appendix 2) identified 857 articles. These were checked for potential relevance by one reviewer (EA). 14 articles were obtained for further reading. Of these 7 informative studies, including one previous systematic review was identified. There were also 3 studies from the initial review that provided information on the longer-term consequences of reading difficulties without addressing the cost-effectiveness of Irlen's lenses.

3.3.2 Costs and cost-effectiveness of coloured filters

As already indicated there were no relevant included studies of any type. Costs associated with assessment and prescription of Irlen's/coloured filters in private practice range between: £90-120 for assessment and £100-150 for lenses/frames but can be considerably lower.

3.3.3 Association between reading impairment and long term outcomes

Summaries of the studies examining the cost impact of illiteracy, or the link between literacy, health and societal outcomes are shown in Appendix 5.

The information available was highly variable in methodological quality. The best evidence was a systematic review of observational studies (DeWalt et al., 2004). This concluded that "Low literacy is associated with several adverse health outcomes". This conclusion seems reasonable but the attempt to quantify this as 1.5 to 3 times more likely to have adverse health outcomes where literacy is impaired is highly speculative given the nature of the evidence reviewed (all 44 directly relevant included studies highly susceptible

to confounding) and data actually abstracted and presented (many included studies showed no relationship at all).

The other included studies reinforce the likelihood and extend the plausibility that illiteracy could have a major impact on health, social and economic outcomes. A number of studies provide estimates of the economic costs, but in all cases the methods are not clearly described and must again be regarded speculatively. These studies and all the included studies do however indicate that attention is beginning to seriously focus on adverse consequences of illiteracy at a societal level, which would in turn highlight the potential of any intervention, which successfully improved literacy as being highly valued and potentially cost-effective even if those costs were substantial.

3.3.4 Economic model

In the absence of any previous assessment of the cost-effectiveness of coloured filters, the intention was to develop an illustrative model that explored the potential cost-effectiveness of coloured filters. In the event, this was abandoned because although we had some indication of the size of effect of coloured filters on reading levels, we had no direct information on impact on the longer term, wider outcomes, which would exert real influence on the ratio between costs and benefits. Although there was separate evidence about the relationship between illiteracy and health, social and economic outcomes this too could not be incorporated because:

a) the relationships were not accurately quantified
b) the observational evidence does not confirm that reversal of illiteracy would necessarily lead to complete avoidance of any adverse outcomes
c) the measures of reading ability in the observational studies are different from those used on the RCTs and crossover trials of coloured filters systematically reviewed earlier

d) it is difficult to gauge whether even the most optimistic estimates of the impact of Irlens' lenses or equivalent systems on reading would constitute reversal of illiteracy.

Thus, we did not proceed with model development because the parameters influencing the key driver of the modelled ICER would be essentially hypothetical with little or no empirical bases. Although this may have been overcome to some degree with further review of the literature and other data sources, this was beyond the limited resources available for the economic component of this report.

3.4 Discussion

Despite extensive searches we were unable to identify any literature which substantively addressed the cost-effectiveness of coloured filters. Although other data and research literature point to the modest costs associated with the intervention and the huge potential for interventions that improve reading skills/ameliorate illiteracy to have a major impact, it remains wholly conjecture on whether coloured filters would indeed be cost-effective. Inevitably the priority for improving understanding of whether coloured filters are cost-effective must rest on further research. Although further interrogation of the literature and other data sources might yield sufficient additional information to develop an illustrative economic model as had been originally envisaged in this project, original research quantifying the relationship between improvements in reading levels and longer term outcomes is, we believe, more likely to improve understanding. The difficulty of such primary research should not however be underestimated.

4. DISCUSSION

4.1 Principle findings

One quasi-systematic review was identified by the searches. Eight RCTs (four parallel studies and four crossover studies) were included in the review of effectiveness of coloured filters for reading disability. Different tests and scales were used to assess reading across the eight studies. Study quality was generally poor. Threats to the validity of the results included small sample sizes, inadequate controls, lack of reporting of randomisation methods, difficulty in the maintenance of any blinding, high levels of attrition, possible financial involvement of the investigators and ophthalmic status of the subjects. A further design flaw was identified in five studies, which used the intervention under evaluation to screen and enrol subjects showing some benefit with the intervention, prior to being randomised into the intervention or comparator groups (selection bias).

Meta-analysis for the outcome of reading accuracy (three studies) showed no clear benefit to using coloured filters for reading accuracy compared to using the control. The two studies that could not be incorporated into meta-analysis reported a statistically significant improvement and no statistically significant improvement with preferred coloured filters compared to the control. Meta-analysis of reading speed and reading comprehension data (four studies for each outcome) showed no clear benefit to using coloured filters for reading speed or comprehension compared to using the control. The two studies that could not be incorporated into meta-analysis for either outcome reported a statistically significant improvement and no statistically significant improvement with preferred coloured filters compared to the control.

Two studies evaluated symptoms of visual stress that can be associated with reading disability. Both studies used subjective measures to show that there was a statistically significant improvement in the level of symptoms when coloured filters were used compared to the control.

The long-term effects of using coloured filters were not evaluated as part of the randomised design by any of the included RCTs. None of the studies reported behaviour, quality of life or adverse effects of using coloured filters for reading disability.

The disparity in the results of the eight RCTs could be attributable to a number of factors including varying design, sample selection and filter use. Confounding factors such as colour deficiency, presence/ absence of visual stress, additional medication, undetected vision anomalies, type of coloured filter (prescribed or not), length of use of filter, average age of sample, outcome test/ scale used, and improvement data coming from a small number of individuals with the majority reporting no benefit may have influenced the results.

A further 15 non-randomised comparative studies were also identified that matched the review inclusion criteria and were presented for completeness. Methodological quality was very poor, with many threats to study validity.

A pre-existing economic evaluation of the use of coloured filters for reading disability was not identified by the searches. There was limited data on costs of coloured filters, and the long-term consequences of reading disability, which made the development of an economic model inappropriate.

4.2 Strengths and limitations of the review

The identification of studies meeting the inclusion criteria is key to the success of the process of systematic review. Although not formally tested in this review, there may be a publication bias towards printing reports of benefit from use of coloured filters over those that show no benefit. Some non-mainstream journals may have been missed even though psychological and educational databases were searched in addition to those routinely used. Discussion with a clinical expert may have limited this bias.

Ideally, data extraction should be performed independently by two reviewers. For this review, however, data was extracted and checked by a second reviewer. Assessment of study quality relied on the published reports alone, so that study quality is a reflection of reporting and not simply the study design and conduct. The review would have benefited from an assessment of the validity of some of the reading ability outcome measures.

Meta-analysis of studies with heterogeneity in sample selection, intervention system and measurement of outcomes should be treated with caution and used as a guide to interpretation only.

This review was limited by the lack of pre-existing economic evaluations and available data to inform and populate an economic model.

4.3 Recommendations for future research

Long term RCTs are certainly needed, with pre and post testing to limit any differences between the groups with respect to pre-intervention reading levels and to take into account natural reading development over time. Collection of data concerning compliance would be of value in evaluating results from studies conducted over time. It would also be of value to monitor the level of home or school assistance over time. Some of the included RCTs did report this. There is also a need for studies to be conducted in adult populations alone since identification of RD and measures used for outcome testing may differ between children and adults.

A key quality issue with many of the included studies was the placebo control. Placebo controls need to be carefully constructed to ensure blinding remains throughout the study.

There is also a need for studies evaluating behavioural and socio-economic outcomes, such as effects of poor reading performance on academic success and confidence. Where possible outcome measures should be objective rather than subjective to limit bias in the results.

A subgroup of subjects with reading disability may benefit from the use of individually prescribed coloured filters. The identification of this population would be useful for practitioners involved in learning difficulties and vision assessment.

Research, which investigates the relationship between improvements in reading levels and long-term outcomes, would be valuable.

5. CONCLUSIONS

Due to the poor quality, and limited number of included studies identified in this review there was no convincing evidence to suggest that coloured filters can successfully improve reading ability in subjects with reading disability or dyslexia when compared to placebo, or other types of control. The studies included and discussed in this review reported both significant improvement and complete lack of improvement of reading, which was not clarified by the combining of data in a meta-analysis. The available evidence on which this conclusion is based was limited in the number and quality of the studies.

A clear sustained benefit to the use of coloured filters would be necessary before a decision on funding could be made.

6. APPENDICES

Appendix 1 ARIF search protocol (version October 2007)

In the first instance the focus of ARIF's response to requests is to identify systematic reviews of research. The following will generally be searched, with the addition of any specialist sources as appropriate to the request.

1. Cochrane Library
- Cochrane Reviews
- Database of Abstracts of Reviews of Effects (DARE)
- Cochrane Central Register of Controlled Trials (CENTRAL)
- Health Technology Assessment (HTA) database

2. ARIF Database
An in-house database of reviews compiled by scanning current journals and appropriate WWW sites. Many reviews produced by the organisations listed below are included.

3. NHS CRD
- DARE
- Health Technology Assessment Database
- Completed and ongoing CRD reviews

4. Health Technology Assessments
- NICE guidance (all programmes)
- West Midlands Health Technology Assessment Collaboration
- Evidence Based Commissioning Collaboration (Trent R & D Support Unit). Links to Trent Purchasing Consortia reports and Wessex DEC reports (both no longer published)
- SBU – Swedish Council on Technology Assessment in Health Care
- NHS Coordinating Centre for Health Technology Assessments
- Canadian Agency for Drugs and Technologies in Health
- New Zealand Health Technology Assessment
- Agency for Healthcare Research and Quality (AHRQ)
- Alberta Heritage Foundation
- McGill Medicine Technology Assessment Unit of MUHC (McGill University Health Centre)
- Monash reports – Centre for Clinical Effectiveness, Monash University
- US Department of Veterans Affairs
- NHS QIS (Quality Improvement Scotland)
- SIGN (Scottish Intercollegiate Guidelines Network)

5. Clinical Evidence

6. Bandolier

7. National Horizon Scanning Centre

8. TRIP Database

9. Bibliographic Databases
- Medline – systematic reviews
- Embase – systematic reviews
- Other specialist databases

10. Contacts
- Cochrane Collaboration (via Cochrane Library)
- Regional experts, especially Pharmacy Prescribing Unit, Keele University (& MTRAC) and West Midlands Drug Information Service for any enquiry involving drug products.

Appendix 2 Search strategies

a. Clinical effectiveness searches

Database: Cochrane Library (Wiley) 2007 Issue 3
Search strategy

1 (irlen* or colored or coloured or tint*) next (lens* or filter* or glass* or spectacle* or overlay*)
2 dyslexia
3 reading
4 MeSH descriptor Dyslexia explode all trees
5 MeSH descriptor Autistic Disorder explode all trees
6 autism
7 autistic
8 learning next (disorder* or disabilit*)
9 MeSH descriptor Learning Disorders explode all trees
10 scotopic next sensitiv*
11 sss
12 irlen*
13 visual* near percept*
14 (#2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13)
15 (#1 AND #14)

Database: Ovid MEDLINE(R) 1950 to September Week 2 2007
Search Strategy:

1 irlen$.mp.
2 scotopic sensitivity.mp.
3 sss.mp.
4 exp Dyslexia/ or dyslexia.mp.
5 autism.mp. or exp Autistic Disorder/
6 learning disorder$.mp. or exp Learning Disorders/
7 learning disabilit$.tw.
8 exp Reading/ or read$.mp.
9 (visual$ adj2 percept$).mp.
10 visual stress.tw.
11 or/1-10
12 ((irlen$ or colo?r$ or tint$) adj (lens$ or overlay$ or glass$ or spectacle$ or filter$)).mp.
13 precision tint$.tw.
14 or/12-13
15 11 and 14
16 (systematic adj review$).tw.
17 (data adj synthesis).tw.
18 (published adj studies).ab.
19 (data adj extraction).ab.
20 meta-analysis/
21 meta-analysis.ti.

22 comment.pt.
23 letter.pt.
24 editorial.pt.
25 animal/
26 human/
27 25 not (25 and 26)
28 15 not (22 or 23 or 24 or 27)
29 or/16-21
30 28 and 29

Database: Ovid MEDLINE(R) 1950 to September Week 2 2007
Search Strategy:

1 irlen$.mp.
2 scotopic sensitivity.mp.
3 sss.mp. (1416)
4 exp Dyslexia/ or dyslexia.mp.
5 autism.mp. or exp Autistic Disorder/
6 learning disorder$.mp. or exp Learning Disorders/
7 learning disabilit$.tw.
8 exp Reading/ or read$.mp.
9 (visual$ adj2 percept$).mp.
10 visual stress.tw.
11 or/1-10
12 ((irlen$ or colo?r$ or tint$) adj (lens$ or overlay$ or glass$ or spectacle$ or filter$)).mp.
13 precision tint$.tw.
14 or/12-13
15 11 and 14
16 randomized controlled trial.pt.
17 controlled clinical trial.pt.
18 randomized controlled trials.sh.
19 random allocation.sh.
20 double blind method.sh.
21 single-blind method.sh.
22 or/16-21
23 (animals not human).sh.
24 22 not 23
25 clinical trial.pt.
26 exp clinical trials/
27 (clin$ adj25 trial$).ti,ab.
28 ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).ti,ab.
29 placebos.sh.
30 placebo$.ti,ab.
31 random$.ti,ab.
32 research design.sh.
33 or/25-32
34 33 not 23
35 34 not 24
36 comparative study.sh.

37 exp evaluation studies/
38 follow up studies.sh.
39 prospective studies.sh.
40 (control$ or prospectiv$ or volunteer$).ti,ab.
41 or/36-40
42 41 not 23
43 42 not (24 or 35)
44 24 or 35 or 43
45 case.mp. or Case-Control Studies/
46 exp Cohort Studies/ or cohort.mp.
47 or/45-46
48 44 or 47
49 15 and 48

Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations September 25, 2007

1 ((irlen$ or colo?r$ or tint$) adj (lens$ or overlay$ or glass$ or spectacle$ or filter$)).mp.
2 precision tint$.tw.
3 irlen$.mp.
4 scotopic sensitivity.mp.
5 sss.mp.
6 dyslexia.mp.
7 read$.mp.
8 autism.mp.
9 autistic.mp.
10 (learning adj (disorder$ or disabilit$)).mp.
11 (visual$ adj2 percept$).mp.
12 visual stress.tw.
13 or/3-12
14 or/1-2
15 14 and 13

Database: EMBASE (Ovid) 1980 to 2007 Week 38
Search Strategy:

1 irlen.mp. or exp irlen syndrome/
2 scotopic sensitivity.mp.
3 sss.mp.
4 dyslexia.mp. or exp DYSLEXIA/
5 exp AUTISM/ or autism.mp.
6 read$.mp. or exp Reading/
7 (learning adj (disorder$ or disabilit$)).mp.
8 learning disorder.mp. or Learning Disorder/
9 (visual$ adj2 percept$).mp.
10 visual stress.tw.
11 or/1-10
12 ((irlen$ or colo?r$ or tint$) adj (lens$ or overlay$ or glass$ or spectacle$ or filter$)).mp.

13 precision tint$.tw.
14 or/12-13
15 11 and 14
16 "meta-analysis"/
17 metaanalys$.ti,ab.
18 meta-analys$.ti,ab.
19 meta analys$.ti,ab.
20 cochrane.ti,ab,de.
21 (review$ or overview$).ti,ab.
22 (synthes$ adj3 (literature$ or research$ or study or studies or data)).mp.
23 pooled analy$.ti,ab.
24 (systematic$ adj2 review$).ti,ab.
25 or/16-24
26 15 and 25

Database: EMBASE (Ovid) 1980 to 2007 Week 38
Search Strategy:

1 irlen.mp. or exp irlen syndrome/
2 scotopic sensitivity.mp.
3 sss.mp.
4 dyslexia.mp. or exp DYSLEXIA/
5 exp AUTISM/ or autism.mp.
6 read$.mp. or exp Reading/
7 (learning adj (disorder$ or disabilit$)).mp.
8 learning disorder.mp. or Learning Disorder/
9 (visual$ adj2 percept$).mp.
10 visual stress.tw.
11 or/1-10
12 ((irlen$ or colo?r$ or tint$) adj (lens$ or overlay$ or glass$ or spectacle$ or filter$)).mp.
13 precision tint$.tw.
14 or/12-13
15 11 and 14
16 randomized controlled trial/
17 exp clinical trial/
18 exp controlled study/
19 double blind procedure/
20 randomization/
21 placebo/
22 single blind procedure/
23 (control$ adj (trial$ or stud$ or evaluation$ or experiment$)).mp.
24 ((singl$ or doubl$ or trebl$ or tripl$) adj5 (blind$ or mask$)).mp.
25 (placebo$ or matched communities or matched schools or matched populations).mp.
26 (comparison group$ or control group$).mp.
27 (clinical trial$ or random$).mp.
28 (quasiexperimental or quasi experimental or pseudo experimental).mp.
29 matched pairs.mp.
30 or/16-29

31 15 and 30

Database: CINAHL - Cumulative Index to Nursing & Allied Health Literature 1982 to September 2007
Search Strategy:

1 dyslexia.mp. or exp DYSLEXIA/
2 read$.mp.
3 scotopic sensitivity.tw.
4 (irlen adj2 syndrome).mp.
5 autism.mp. or exp Autistic Disorder/
6 (learning adj (disorder$ or disabilit$)).mp.
7 or/1-6
8 ((irlen or colo?r$ or tint$) adj (lens$ or overlay$ or glass$ or spectacle$ or filter$)).mp.
9 7 and 8

Database: PsycINFO (Ovid) 1967 to September Week 4 2007
Search Strategy:

1 irlen$.mp.
2 scotopic sensitivity.mp.
3 sss.mp.
4 dyslexia.mp. or exp Dyslexia/
5 autism.mp. or exp Autism/
6 learning disorder$.mp. or exp Learning Disorders/
7 learning disabilit$.tw.
8 exp Reading/ or read$.mp.
9 (visual$ adj2 percept$).mp.
10 visual stress.tw.
11 or/1-10
12 ((irlen$ or colo?r$ or tint$) adj (lens$ or overlay$ or glass$ or spectacle$ or filter$)).mp.
13 precision tint$.tw.
14 or/12-13
15 11 and 14

Database: PsycINFO (Ovid) 1967 to September Week 4 2007
Search Strategy:

1 irlen$.mp.
2 scotopic sensitivity.mp.
3 1 or 2

Database: Science Citation Index 1900 – 2007 (Web of Science) searched September 2007

Search terms:

(irlen* or tinted or colored or coloured)
AND
(lens* or glass* or spectacle* or overlay* or filter*)
AND
(reading or dyslex* or autis* or learning)

b. Additional searches for long-term outcomes

Database: Ovid MEDLINE(R) 1950 to December week 1 2007
Search Strategy:

1 reading ability.mp.
2 educational attainment.mp.
3 reading age.mp.
4 literacy.mp.
5 exp Follow-Up Studies/ or follow-up.mp.
6 long-term.mp.
7 outcome$.mp.
8 or/5-7
9 meta-analysis.mp. or exp Meta-Analysis/
10 systematic review$.mp.
11 trial$.mp.
12 exp Cohort Studies/ or cohort.mp.
13 or/9-12
14 or/1-4
15 8 and 13 and 14

Database: PsycINFO (Ovid) 1967 to December Week 1 2007
Search Strategy:

1 reading skill$.mp. or exp Reading Skills/
2 reading ability.mp. or exp Reading Ability/
3 reading age.mp.
4 literacy.mp. or exp LITERACY/
5 or/1-4
6 exp Followup Studies/ or follow-up.mp.
7 long-term.mp.
8 outcome$.mp.
9 or/6-8
10 meta-analysis.mp. or exp Meta Analysis/
11 systematic review$.mp.
12 trial$.mp.
13 exp COHORT ANALYSIS/ or cohort.mp.
14 or/10-13
15 5 and 9 and 14

Database: ERIC (CSA) 1967 – 12 December 2007
Search strategy:

((reading skills) or (reading age) or (reading ability) or
literacy) and ((follow-up) or (long-term) or outcome*) and (meta or
systematic review* or trial* or cohort)

c. Cost effectiveness searches

Database: Ovid MEDLINE(R) 1950 to September Week 3 2007
Search Strategy:

1 irlen$.mp.
2 scotopic sensitivity.mp.
3 sss.mp.
4 exp Dyslexia/ or dyslexia.mp.
5 autism.mp. or exp Autistic Disorder/
6 learning disorder$.mp. or exp Learning Disorders/
7 learning disabilit$.tw.
8 exp Reading/ or read$.mp.
9 (visual$ adj2 percept$).mp.
10 visual stress.tw.
11 or/1-10
12 ((irlen$ or colo?r$ or tint$) adj (lens$ or overlay$ or glass$ or spectacle$ or filter$)).mp.
13 precision tint$.tw.
14 or/12-13
15 11 and 14
16 economics/
17 exp "costs and cost analysis"/
18 cost of illness/
19 exp health care costs/
20 economic value of life/
21 exp economics medical/
22 exp economics hospital/
23 economics pharmaceutical/
24 exp "fees and charges"/
25 (econom$ or cost or costs or costly or costing or price or pricing or pharmacoeconomic$).tw.
26 (expenditure$ not energy).tw.
27 (value adj1 money).tw.
28 budget$.tw.
29 or/16-28
30 15 and 29
31 14 and 29
32 1 and 29
33 30 or 31 or 32

Database: EMBASE (Ovid) 1980 to 2007 Week 38
Search Strategy:

1 irlen.mp.
2 ((colo?r$ or tint$ or irlen$) adj (lens$ or glass$ or overlay$ or spectacle$ or filter$)).mp.
3 precision tint$.tw.
4 or/1-3
5 dyslexia.mp. or exp DYSLEXIA/
6 read$.mp.
7 scotopic sensitivity.mp.
8 irlen syndrome/ or irlen syndrome.mp.
9 (learning adj (disorder$ or disabilit$)).mp.
10 autism.mp.
11 autistic$.mp.
12 visual stress.tw.
13 or/5-12
14 4 and 13
15 cost benefit analysis/
16 cost effectiveness analysis/
17 cost minimization analysis/
18 cost utility analysis/
19 economic evaluation/
20 (cost or costs or costed or costly or costing).tw.
21 (economic$ or pharmacoeconomic$ or price$ or pricing).tw.
22 (technology adj assessment$).tw.
23 or/15-22
24 14 and 23
25 13 and 23
26 5 and 23
27 24 or 26

Database: CINAHL - Cumulative Index to Nursing & Allied Health Literature 1982 to September 2007
Search Strategy:

1 dyslexia.mp. or exp DYSLEXIA/
2 read$.mp.
3 scotopic sensitivity.tw.
4 (irlen adj2 syndrome).mp.
6 (learning adj (disorder$ or disabilit$)).mp.
7 visual stress.tw.
8 (visual adj2 perception$).mp.
9 or/1-8
10 ((irlen or colo?r$ or tint$) adj (lens$ or overlay$ or glass$ or spectacle$ or filter$)).mp.
11 precision tint$.tw.
12 or/10-11
13 9 and 12

Database: Cochrane Library (Wiley) 2007 Issue 3 (NHS EED)
Search strategy:

1 (irlen* or colored or coloured or tint*) next (lens* or filter* or glass* or spectacle* or overlay*)
2 dyslexia
3 reading
4 MeSH descriptor Dyslexia explode all trees
5 MeSH descriptor Autistic Disorder explode all trees
6 autism
7 autistic
8 learning next (disorder* or disabilit*)
9 MeSH descriptor Learning Disorders explode all trees
10 scotopic next sensitiv*
11 sss
12 irlen*
13 visual* near percept*
14 (#2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13)
15 (#1 AND #14)

Database: Ovid MEDLINE(R) 1950 to November Week 2 2007
Search Strategy:

1 exp Dyslexia/ or dyslexia.mp.
2 reading difficult$.mp.
3 reading problem$.mp.
4 literacy.mp. or exp Educational Status/
5 illiteracy.mp.
6 or/1-5
7 exp "costs and cost analysis"/
8 6 and 7

Database: Ovid MEDLINE(R) 1950 to November Week 2 2007
Search Strategy:

1 exp Dyslexia/ or dyslexia.mp.
2 autism.mp. or exp Autistic Disorder/
3 learning difficult$.mp.
4 or/1-3
5 economics/
6 exp "costs and cost analysis"/
7 cost of illness/
8 exp health care costs/
9 economic value of life/
10 exp economics medical/
11 exp economics hospital/
12 economics pharmaceutical/
13 exp "fees and charges"/

14 (econom$ or cost or costs or costly or costing or price or pricing or pharmacoeconomic$).tw.
15 (expenditure$ not energy).tw.
16 (value adj1 money).tw.
17 budget$.tw.
18 or/5-17
19 4 and 18

Database: ERIC (CSA) 1967 – 12 December 2007
Search strategy : TI=(reading or dyslexia or literacy) and TI=(cost* or expenditure)

Database: OHE HEED September 2007 Issue 3

Textwords used: irlen or dyslexia or dyslexic* or reading difficult* or reading problem* or reading ability or scotopic or sss or colour* filter* or color* filter* or overlay* or reading and vision

d. Decision analytic model searches

Database: Ovid MEDLINE(R) 1950 to September Week 3 2007
Search Strategy:

1 irlen.mp.
2 ((colo?r$ or tint$) adj (lens$ or glass$ or spectacle$ or filter$)).mp
3 precision tint$.tw.
4 or/1-3
5 exp Dyslexia/ or dyslexia.mp.
6 read$.mp.
7 scotopic sensitivity.mp.
8 irlen syndrome.mp.
9 visual stress.tw.
10 or/5-9
11 4 and 10
12 decision support techniques/
13 markov.mp.
14 exp models economic/
15 decision analysis.mp.
16 cost benefit analysis/
17 or/12-16
18 1 and 17
19 4 and 17
20 11 and 17
21 5 and 17
22 or/18-21

e. Quality of life searches

Database: Ovid MEDLINE(R) 1950 to September Week 3 2007
Search Strategy:

1 irlen.mp.
2 ((colo?r$ or tint$) adj (lens$ or glass$ or spectacle$ or filter$)).mp.
3 or/1-2
4 exp Dyslexia/ or dyslexia.mp.
5 read$.mp.
6 scotopic sensitivity.mp.
7 irlen syndrome.mp.
8 or/4-7
9 3 and 8
10 quality of life/
11 life style/
12 health status/
13 health status indicators/
14 or/10-13
15 9 and 14
16 (reading adj (difficult$ or problem$)).mp.
17 1 and 14
18 4 or 16
19 18 and 14

Database: EMBASE (Ovid) 1980 to 2007 Week 38
Search Strategy:

1 quality of life.mp. or exp "Quality of Life"/
2 life style.mp. or exp Lifestyle/
3 health status.mp. or exp Health Status/
4 or/1-3
5 (reading adj (difficult$ or problem$)).mp.
6 dyslexia.mp. or exp DYSLEXIA/
7 or/5-6
8 4 and 7

Database: CINAHL - Cumulative Index to Nursing & Allied Health Literature 1982 to September 2007
Search Strategy:

1 dyslexia.mp. or exp DYSLEXIA/
2 read$.mp.
3 scotopic sensitivity.tw.
4 (irlen adj2 syndrome).mp.
6 (learning adj (disorder$ or disabilit$)).mp.
7 visual stress.tw.
8 (visual adj2 perception$).mp.
9 or/1-8

10 ((irlen or colo?r$ or tint$) adj (lens$ or overlay$ or glass$ or spectacle$ or filter$)).mp.
11 precision tint$.tw.
12 or/10-11
13 9 and 12
14 quality of life.mp. or exp "Quality of Life"/
15 or/1-2
16 14 and 15
17 13 and 14
18 9 and 14
19 or/16-18

Appendix 3 Key excluded studies with reasons

Reference	Reason for exclusion
[92]Cotton MM, Evans KM: A review of the use of Irlen (tinted) lenses. Aust N Z J Ophthalmol 1990; 18(3):307-312.	Background only
[93]Davies M: Reading with colours ... Irlen lenses and the treatment of scotopic sensitivity syndrome. Caritas 1989; 55(71):3-4.	UNAVAILABLE
[94]Evans BJ, Joseph F: The effect of coloured filters on the rate of reading in an adult student population. Ophthalmic Physiol Opt 2002; 22(6):535-545.	No comparative intervention Randomly selected students
[88]Evans BJ, Patel R, Wilkins AJ, Lightstone A, Eperjesi F, Speedwell L, Duffy J: A review of the management of 323 consecutive patients seen in a specific learning difficulties clinic. Ophthalmic Physiol Opt 1999; 19(6):454-466.	No comparative intervention
[95]Evans BJ, Wilkins AJ, Brown J, Busby A, Wingfield A, Jeanes R, Bald J: A preliminary investigation into the aetiology of Meares-Irlen syndrome. Ophthalmic Physiol Opt 1996; 16(4):286-296.	No comparative intervention
[96]Evans BJ, Busby A, Jeanes R, Wilkins AJ: Optometric correlates of Meares-Irlen syndrome: a matched group study. Ophthalmic Physiol Opt 1995; 15(5):481-487.	No comparative intervention
[97]Evans BJ, Cook A, Richards IL, Drasdo N: Effect of pattern glare and colored overlays on a stimulated-reading task in dyslexics and normal readers. Optometry & Vision Science 1994; 71(10):619-628.	Study I- population did not have RD Study II- no included outcomes
[98]Evans BJW, Wilkins AJ: Double-masked placebo-controlled trial of the use of tinted lenses by children with reading difficulty. American Academy of Optometry 1993;84-85.	Abstract only
[99]Evans BJW, Drasdo N: Tinted Lenses and Related Therapies for Learning-Disabilities - A Review. Ophthalmic and Physiological Optics 1991; 11(3):206-217.	Background only
[100]Grisham D, Alwes W, Steve FS, Lasher D: The efficacy of using colored lenses to improve reading ease and performance. American Academy of Optometry 1990;93.	UNAVAILABLE
[101]Hollis J, Allen PM: Screening for Meares-Irlen sensitivity in adults: can assessment methods predict changes in reading speed? Ophthalmic and Physiological Optics 2006; 26(6):566-571.	Population did not have RD
[38]Irlen H, Lass MJ: Improving Reading Problems Due to Symptoms of Scotopic Sensitivity Syndrome Using Irlen Lenses and Overlays. Education 1989; 109(4):413-417.	Background only
[102]Jeanes R, Busby A, Martin J, Lewis E, Stevenson N, Pointon D, *et al*. Prolonged use of coloured overlays for classroom reading. *Br J Psychol* 1997; 88 (Pt 4):531-548.	Population did not have RD
[103]Lopez R, Yolton RL, Kohl P, Smith DL, Saxerud MH. Comparison of Irlen scotopic sensitivity syndrome test results to academic and visual performance data. *J Am Optom Assoc* 1994; 65(10):705-714.	No comparative intervention
[104]Menacker SJ, Breton ME, Breton ML, Radcliffe J, Gole GA: Tinted Lenses Did Not Improve Reading Performance in 24 Dyslexic-Children. Investigative Ophthalmology & Visual Science 1992; 33(4):718.	Abstract only Full publication included
O'Connor et al. Dyslexia and tinted lenses. Austr J of Remedial Education 1988; 20: 10-12.	UNAVAILABLE
[105]Robinson GL, McGregor NR, Roberts TK, Dunstan RH, Butt H: A biochemical analysis of people with chronic fatigue	No comparative intervention

Reference	Reason for exclusion
who have Irlen Syndrome: speculation concerning immune system dysfunction. Percept Mot Skills 2001; 93(2):486-504.	
[106]Robinson GL, Foreman PJ, Dear KB: The familial incidence of symptoms of scotopic sensitivity/Irlen syndrome: comparison of referred and mass-screened groups. Percept Mot Skills 2000; 91(3 Pt 1):707-724.	No comparative intervention
Robinson GL. The use of coloured overlays to improve visual processing: A preliminary survey. *Exceptional Child* 1987; 34(1):65-70.	No included outcomes
[107]Romanchuk KG: Scepticism about Irlen filters to treat learning disabilities. CMAJ 1995; 153(4):397.	Background only
[108]Singleton C, Trotter S: Visual stress in adults with and without dyslexia. Journal of Research in Reading 2005; 28(3):365-378.	Incorrect intervention
[109]Shute R: Treating Dyslexia with Tinted Lenses - A Review of the Evidence. Research in Education 1991;(46):39-48.	Background only
[110]Solan HAE, Solan HA: "Failure of blue-tinted lenses to change reading scores of dyslexic individuals": Response to Christenson, Griffin, and Taylor. [References]. Optometry: Journal of the American Optometric Association 2007; 73(1):Jan.	Background only
Solan HA, Ficarra A, Brannan JR, Rucker F: Eye movement efficiency in normal and reading disabled elementary school children: effects of varying luminance and wavelength. J Am Optom Assoc 1998; 69: 455-464.	No included outcomes
[111]Solan HA: An appraisal of the Irlen technique of correcting reading disorders using tinted overlays and tinted lenses. J LEARN DISABIL 1990; 23(10):621-3, 626.	Background only
[112]Solan HA, Richman J, Solan HA, Richman J: Irlen lenses: a critical appraisal.[see comment]. [Review] [26 refs]. Journal of the American Optometric Association 1990; 61(10):789-796.	Background only
[113]Solman RT, Dain SJ, Lim HS, May JG: Reading-Related Wavelength and Spatial-Frequency Effects in Visual-Spatial Location. Ophthalmic and Physiological Optics 1995; 15(2):125-132.	No included outcomes
[114]Solman RT, Cho HS, Dain SJ: Color-Mediated Grouping Effects in Good and Disabled Readers. Ophthalmic and Physiological Optics 1991; 11(4):320-327.	No included outcomes
[115]Spafford CS, Grosser GS, Donatelle JR, Squillace SR, Dana JP: Contrast sensitivity differences between proficient and disabled readers using colored lenses. J LEARN DISABIL 1995; 28(4):240-252.	Incorrect comparator
[116]Waldie M, Wilkins A. How big does a coloured overlay have to be? *Ophthalmic Physiol Opt* 2004; 24(1):57-60.	Population did not have RD
Whiting P: Improvements in reading and other skills using Irlen coloured lenses. Austr J of Remedial Education 1988; 20: 13-15.	UNAVAILABLE
[37]Wilkins A, Huang J, Cao Y: Visual stress theory and its application to reading and reading tests. Journal of Research in Reading 2004; 27(2):152-162.	Background only
[117]Wilkins A: Coloured overlays and their effects on reading speed: a review. Ophthalmic Physiol Opt 2002; 22(5):448-454.	Background only
Wilkins AJ: Coloured overlays and their benefit for reading. [References]. Journal of Research in Reading 2001; 24(1):Feb-64.	Background only

Reference	Reason for exclusion
[118]Wilkins A, Lewis E: Coloured overlays, text, and texture. Perception 1999; 28(5):641-650.	Population did not have RD
[14]Wilkins AJ, Jeanes RJ, Pumfrey PD, Laskier M: Rate of Reading Test: its reliability, and its validity in the assessment of the effects of coloured overlays. Ophthalmic Physiol Opt 1996; 16(6):491-497.	Population did not have RD
[119]Wilkins AJ, Evans BJW, Brown J, Busby A, Wingfield A, Jeanes R, Bald J: Double-blind placebo-controlled trial of precision spectral filters in children with reading difficulty. Iovs 1994; 35:ARVO.	UNAVAILABLE
Wilkins AJ: Overlays for classroom and optometric use. Ophthalmic Physiol Opt 1994;14: 97-99.	Background only
[43]Wilkins A, Neary C: Some visual, optometric and perceptual effects of coloured glasses. Ophthalmic Physiol Opt 1991; 11(2):163-171.	No included outcomes
[120]Williams GJ: The Use of Tinted Lenses and Colored Overlays for the Treatment of Dyslexia and Other Related Reading and Learning Disorders. [References]. Optometry: Journal of the American Optometric Association 2004; 75(11):Nov-722.	Background only
[121]Williams MC, Lecluyse K, Rock-Faucheux A: Effective interventions for reading disability. J Am Optom Assoc 1992; 63(6):411-417.	Incorrect intervention
Winter. Irlen lenses: An appraisal. Aust Ed Dev Psychol 1987; 4:1-5.	UNAVAILABLE

Appendix 4 Data extraction form

Patient characteristics

Patient characteristics Including colour deficiency and correction for visual anomalies	Inclusion/ exclusion criteria	Age Gender	Visual history and tests	Current symptoms/ duration Including colour deficient

Study protocol, intervention and comparator(s)

Protocol	Intervention including system (Irlen, ChromaGen, Intuitive) and format of tint	Comparator 1	Comparator 2	Comparator 3

Outcome methods

Symptoms/ method of assessment	Reading accuracy/ method of assessment	Reading speed/ method of assessment	Reading comprehension/ method of assessment	Other assessment	Duration of follow up/ time points for data collection

Outcomes

Symptoms	Reading accuracy Mean y (SD)	Reading speed Mean y (SD)	Reading comprehension Mean y (SD)	Other assessment	Duration of follow up/ time points for data collection	Summary of results

Coloured filters for reading disability

Study quality (RCTs)

Randomisation/ concealment Method of randomisation stated? Yes+1 Appropriate?Yes+1 No -1 Method of allocation concealment stated?	**Blinding/ placebo** Described as double blind? Yes+1 Appropriate? Yes+1 No-1	**Loss to follow up**	**Outcome assessment/ data presentation** Analysis by intention to treat?	**Jadad score**	**If all subjects were tested with all intervention conditions, was the order of interventions randomised?**	**Period effects test for crossover trials (ie control for effect of time?)**	**Control for effect of reading test practice?**	**Outcome assessment at baseline and end of each crossover period?**

(This table is for **information only** - enter directly into the table above)

Question		Scoring scheme	Score
1. Was the study described as randomised (this includes the use of words such as randomly, random, and randomisation)?		Yes (+1) No (0)	1
1a. The method to generate the sequence of randomisation was described and it was:	**Appropriate** (table of random numbers, computer generated, etc.)	(+1)	1
	Inappropriate (patients were allocated alternately, or according to date of birth, hospital number, etc.)	(-1)	
2. Was the study described as double blind?		Yes (+1) No (0)	1
2a. The method of double blinding was described and it was:	**Appropriate** (identical placebo, active placebo, dummy, etc.)	(+1)	1
	Inappropriate (e.g., comparison of tablet vs. injection with no double dummy)	(-1)	
3. Was there a description of withdrawals and dropouts?		Yes (+1) No (0)	1
Jadad score (0-5)			0

Guidelines for assessment

1. Randomisation: a method to generate the sequence of randomisation will be regarded as appropriate if it allowed each study participant to have the same chance of receiving each intervention and the investigators could not predict which treatment was next. Methods of allocation using date of birth, date of admission, hospital numbers, or alternation should be not regarded as appropriate.

2. Double blinding: a study must be regarded as double blind if the word "double blind" is used. The method will be regarded as appropriate if it is stated that neither the person doing the assessments nor the study participant could identify the intervention being assessed, or if in the absence of such a statement the use of active placebos, or dummies is mentioned.

3. Withdrawals and dropouts: participants who were included in the study but did not complete the observation period or who were not included in the analysis must be described. The number **and** the reasons for withdrawal in each group must be stated. If there were no withdrawals, it should be stated in the article. If there is no statement on withdrawals, this item must be given no points.

Appendix 5 Summaries of studies examining the cost impact of illiteracy or the link between literacy, health and societal outcomes

Article	Description	Results	Notes
Studies providing information on costs associated with illiteracy			
Hurst 1981[i]	Narrative review	Passing reference to high cost of illiteracy and learning disability in summary	Validity of data underlying claims unclear
Smith 1995[ii]	Cost-of-illness study	Substantial NHS, social service and DSS costs attributable to moderate/severe learning disability in 1986 identified. Unable to identify resource use associated with mild learning disability	Thorough cost-of-illness study, but probably has not been able to identify the costs of greatest relevance.
Ziegler 1998[iii]	Editorial	Reports higher average Medicare spending per patient for those with reading difficulties	Validity of data underlying claims unclear
Greene 2000[iv]	Costing study	Estimates annual costs to businesses, colleges, and universities in Michigan to be $601 million	Covers literacy and numeracy. Costs to health care not included
Studies providing information on links between literacy and health/societal outcomes			
Reder & Wikelund 1994[v]	Pre-post evaluation	Demonstrated skill gains 1-3 years after completion of programme. Literacy gains significantly associated with reductions in future dependence on public assistance	920 clients yielded 229 participants. Analysis based on 163 of these. Health impact not specifically examined.
Maughan 1995[vi]	Narrative review	Supports view of strong link between literacy and adverse long term outcomes. Suggests effects can be ameliorated however: *"the most positive findings have consistently emerged from studies where children received support an encouragement at home, specialized attention at school, and where they themselves selected adult environments that sorted well with the balance of their personal strengths and limitations."*	Approach to identification and appraisal of literature not systematic. Some health impacts, particularly social adjustment and psychological well-being considered

Article	Description	Results	Notes
Wiggins & Wale 1996[vii]	Multivariate analysis	Some evidence that parents' writing difficulties are transmitted to their children	Evidence based on association in large cohort. Health impacts not addressed
Athanasou 2001[viii]	Multivariate analysis	Provides evidence of relationship between literacy and numeracy and educational-vocational achievement	Evidence based on association in large cohort. Health impacts not addressed
Bynner 2002[ix]	Multivariate analysis	Identifies strong links between literacy, numeracy and employability. Poor numeracy receives greater emphasis in this study than poor literacy	Evidence based on association in large cohort. Health impacts not addressed
DeWalt et al 2004[x]	Systematic review of observational studies examining association between adult literacy & health outcome	Article claims (on basis of 44 included studies): "Patients with low literacy had poorer health outcomes, including knowledge, intermediate disease markers, measures of morbidity, general health status and use of health resources. Patients with low literacy were generally 1.5 to 3 times more likely to experience a given poor outcome. The average quality of articles was fair to good. Most studies were cross-sectional in design; many failed to address adequately confounding and the use of multiple comparisons" For reasons indicated in the notes column, even this cautious statement probably overstates the strength of the relationship between literacy and health outcomes	This was a generally well conducted systematic review, although EMBASE was not searched. However, scrutiny of the table or results of the included studies (Table 4) indicates much greater variability in results than suggested in the abstract, with many included studies graded good finding "no relationship" or OR/RR values with 95% CI including 1. It should be further noted that measures of literacy are for adults and not the same as those used in the evaluations of coloured filters.

Article	Description	Results	Notes
Berkman et al 2004[xi]	Parent publication for DeWalt et al 2004. Also contains systematic review of interventional research on the effect of interventions to improve literacy	Report claims: "*Interventions to mitigate the effects of poor literacy have been studied and have shown promise for improving patient health and the receipt of health services*"	As for DeWalt 2004, this was a generally well conducted systematic review, although EMBASE was not searched. Although the findings are of considerable interest, they do not address the key issue of whether improving literacy (as opposed to designing materials which can be understood with minimal literacy) leads to improved outcomes

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