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Blue-light filtering spectacle lenses for visual performance, sleep, and macular health in adults (Protocol)

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[Intervention Protocol]

Blue-light filtering spectacle lenses for visual performance, sleep, and macular health in adults

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ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

To assess whether blue-light filtering spectacle lenses impart effects on visual function, provide protection to the macula, or both. We will also examine potential effects on the sleep-wake cycle.

BACKGROUND

Description of the condition

The ubiquitous use of technology and increasing exposure to modern lighting sources that emit relatively higher amounts of blue light than traditional light sources (e.g. light emitting diodes (LEDs) and compact fluorescent lamps (CFLs) (O'Hagan 2016)), both in working and domestic environments, has raised questions concerning the potential adverse effects of excessive exposure to short-wavelength visible light. In terms of digital devices, use of LED-backlit liquid crystal displays (LCDs) has been associated with both symptoms of visual fatigue and changes to visual function, as quantified by a relative reduction in critical fusion frequency (CFF), being the frequency at which an intermittent (flickering) light stimulus appears to be in a complete steady stage to a human observer (Isono 2013). In modern times, the range of eye and vision-related symptoms associated with prolonged computer, tablet, and e-reader use has been collectively defined as a multifactorial condition known as "Computer Vision Syndrome" (CVS) (American Optometric Association 1995; American Optometry Association 2018; Sheppard 2018).

Asthenopic symptoms, such as sore eyes, eye fatigue, headaches, blurred vision, and dry eye, have been reported to affect up to 90% of computer users (Rosenfield 2011). However, given the multifactorial nature of CVS, and that other ocular conditions (e.g. binocular vision disorders, uncorrected refractive error or presbyopia, and tear film dysfunction) can elicit similar symptomatology, the relative contribution of blue light to CVS is difficult to ascertain. Despite the absence of a clear link between blue light and CVS, a range of claims have been made in relation to the potential adverse effects of blue-light emission from digital devices. This potential

association forms the rationale for a variety of commercially-available interventions that reduce blue-light transmission to the eye (e.g. spectacle lenses, downloadable software applications, filter attachments to digital device screens, and changing internal settings on electronic devices, such as 'night mode' settings).

With respect to potential effects on sleep, the increasing use of digital devices that emit relatively higher levels of short-wavelength visible light than traditional incandescent light sources (e.g. LED-backlit computer displays) has also raised concerns about the effect(s) of blue light (particularly evening exposure) on sleep. Such effects on human chronobiology are considered to depend upon the timing, duration, intensity, and spectral composition of the light exposure (Czeisler 2013). Some epidemiological evidence supports an association between evening use of electronic devices and adverse sleep quality, altered circadian timing and reduced daytime alertness (Chang 2015; Gamble 2014). However, experimental investigation has also failed to demonstrate an association between short-duration (one hour or less) screen use immediately prior to bedtime and altered sleep onset (Heath 2014). Some evidence suggests disruptions to biological cycles and circadian rhythm can potentially have adverse effects on a diverse range of health parameters (Hatori 2017), including associations between abnormal sleeping patterns and serious conditions such as sleep disorders (Flo 2013), metabolic dysfunction (Karlsson 2001), and cancer (Kolstad 2008). Understanding the role of blue-light filters in reducing such outcomes thus has significant public health implications.

In terms of potential effects on macular health, the maintenance of macular integrity is essential to normal visual function. In 2010, it was estimated that 2.1 million people worldwide were blind, and 6.0 million people were visually impaired, as a consequence of macular disease (Jonas 2014). A leading cause of macular disease and adult vision impairment is age-related macular degeneration (AMD) (Coleman 2008; Congdon 2004; Pascolini 2012), a slowly progressive retinal degenerative condition that increases in prevalence with age (Owen 2003; Wong 2014). About one-third of individuals aged 80 years will show some clinical signs of AMD (Klein 1992), with approximately 6% having late-stage AMD by this age, and 20% at age 90 (Rudnicka 2012). Risk factors for AMD include genetic factors (Klein 2005; Warwick 2017; Yang 2006), and tobacco smoking (Downie 2014; Thornton 2005). It is currently unclear how other factors, including short-wavelength light exposure, might contribute to the development of AMD, progression of AMD, or both (Beatty 1999). Given there is currently no means for preventing AMD onset, nor a cure for the disease, there is significant interest in novel methods for preserving macular integrity through life.

Description of the intervention

Sunlight comprises of electromagnetic radiation ranging from ultraviolet (UV) to infrared (IR). UV radiation encompasses wavelengths from approximately 200 nanometres (nm) to 400 nm (Youssef 2011). The visible light spectrum falls approximately between 400 nm to 760 nm, with 'short-wavelength' visible (blue) light ranging from 400 nm to 500 nm (Mainster 2005).

Blue-light filtering, also termed "blue-blocking", spectacle lenses are ophthalmic lenses (generally prescribed in prescription glasses) that are designed to selectively attenuate the transmission of UV radiation and short-wavelength visible light (Leung 2013; Mainster 2006). This is in contrast to standard spectacle lenses, which do not filter blue light and provide varying degrees of inherent UV protection depending on the lens material used (e.g. an uncoated polycarbonate material will inherently provide relatively greater UV attenuation than an uncoated CR-39 material lens).

Blue-light filtering spectacle lenses often contain a chromophore that reduces or eliminates the amount of blue-light that reaches the eye. Another approach involves coating the posterior and anterior lens surfaces with an anti-reflection interference coating that selectively decreases transmission of a portion of the blue-light spectrum; the target range of wavelengths is typically 415 nm to 455 nm, corresponding to the region of the spectrum considered to impart the highest risk of ocular damage (Boulton 2001).

A range of blue-light filtering spectacle lenses are currently commercially available; examples include blueEast (Bonastar), Blue control (Hoya), Crizal prevencia (Essilor), Dura vision/blue protect (Zeiss), Eyezen (Essilor), Gunnar (GUNNAR Optics), Kodak Total Blue (Signet Armolite Inc), and StressFree (Swisscoat).

How the intervention might work

By reducing the intraocular transmission of short-wavelength visible light, blue-light filtering spectacle lenses are hypothesised to potentially impart a range of benefits, including improving visual performance with digital device use, providing retinal protection from light-induced damage, and minimising sleep and circadian rhythm disruption associated with evening use of blue-light emitting devices.

Despite the existence of studies that have investigated the application of blue-light filtering spectacle lenses for reducing the signs or symptoms of CVS, or both (Leung 2013; Lin 2017), the specific mechanism(s) underlying how these devices might impart such benefit(s) are not known. The rationale for claims that blue light-light filtering lenses attenuate CVS is based upon the premise that modern digital devices (that emit relatively higher amounts of blue light than traditional lighting sources) are frequently being used for several hours per day and many device users experience ocular discomfort. Given that there is a correlation between discomfort glare sensitivity and brightness sensitivity with blue LEDs (Kimura-Minoda 2011), a potential mechanism may involve a reduction in discomfort glare from a LED-backlit display; however, there is no direct evidence to support this hypothesis.

With respect to the potential for intraocular light transmission to pose an ocular hazard, retinal exposure to certain wavelengths of

radiation is fortunately limited by the physiological absorbance characteristics of the anterior eye. Ultraviolet wavelengths below 300 nm are absorbed by the cornea (Boettner 1962), and wavelengths between 300 nm and 400 nm are predominantly attenuated by the crystalline lens (Boettner 1962; Norren 1974). With age, the crystalline lens becomes relatively less transparent and more yellow in colour, resulting in a reduction in the degree of retinal transmission of short-wavelength visible light (400 nm to 500 nm), effectively acting as a natural blue-light filter (van Norren 2007). The change in lenticular absorbance of blue light occurs exponentially (Weale 1988), such that by 50 years of age, only 20% of short-wavelength visible light reaches the retina (Dillon 2004). In this respect, it is unclear how blue-light filtering spectacle lenses might provide any benefit(s) in adults with a physiologically-yellowed lens due to age.

A population that theoretically may be relatively advantaged by blue-light filtering spectacle lenses are individuals who have undergone cataract surgery, with implantation of an intraocular lens (IOL) that enables relatively more blue-light transmittance than the aged crystalline lens (i.e. an UV-only filtering IOL) (Dillon 2004). There is experimental evidence from animal studies (Ham 1982; Noell 1966), and cell culture experiments (Sparrow 2004), that demonstrates short-wavelength visible light exposure can induce retinal phototoxicity. The mechanism involves retinal photochemical damage (Youssef 2011), as a result of reactive oxygen species (ROS) generation, which induces protein oxidation and lipid peroxidation (Boulton 2001). Whilst the retina has several mechanisms of defence to mitigate ROS-dependent damage, these processes become less efficient with age (Margrain 2004), thus potentially rendering the ageing retina more vulnerable to phototoxicity. As a result of their relatively high oxygen requirements, the retinal pigment epithelium (RPE) and photoreceptors are considered most susceptible to blue light-induced photochemical damage (Ham 1978; Ham 1984). This experimental evidence provides the basis for a hypothesis that blue light may also induce retinal damage in humans and contribute to macular changes in AMD. In this respect, spectacle lenses that attenuate retinal blue-light exposure have been proposed to potentially be valuable for providing macular protection, and reducing the risk of AMD development progression (Beatty 1999; Bernstein 2010); a similar rationale applies to the implantation of blue-light filtering IOLs, following cataract surgery, however evidence for such a benefit is currently lacking (Downie 2018).

The potential effects of blue light exposure on sleep quality and circadian rhythm are also of relevance (Mainster 2006). The circadian clock is regulated by the suprachiasmatic nucleus in the hypothalamus, which controls melatonin secretion from the pineal gland (Goel 2013). Daytime blue-light exposure can promote subjective alertness by inhibiting the secretion of melatonin (Viola 2008). It follows that evening light exposure, particularly to short-wavelength light (between 465 nm and 495 nm), may disrupt the physiological circadian clock through a similar mechanism (Khalsa 2003; McIntyre 1989; Rahman 2014; Zeitzer 2000). This effect has received particular attention owing to the extensive use of digital devices in the evening, close to bedtime, and the potential impacts of this exposure on disrupting sleep quantity and quality (Chinoy 2018). Based upon this rationale, it has been proposed that limiting intraocular exposure to blue light in the evening, through measures such as blue-light filtering spectacle filters and using 'night mode' settings on devices, may be of value for mitigating these potentially negative effects on sleep.

Why it is important to do this review

There remains significant debate surrounding whether blue-light filtering spectacle lenses have merit in ophthalmic practice (Downie 2017). Although it is currently unknown how frequently these lenses are being prescribed (in preference to standard spectacles lenses), a range of marketing claims exist surrounding their potential benefits. In particular, it has been proposed that blue-light filtering spectacles may alleviate eye strain associated with digital device use (Ide 2015; Lin 2017), improve sleep quality (Ayaki 2016), and protect the retina, specifically the macula, from phototoxicity (Blue Light Exposed 2015; Symes 2012). However, in 2015, the UK Advertising Standards Authority (ASA) found that an advertisement by an optical retailer promoting the use of blue-light filtering spectacle lenses to "filter out harmful blue light" represented misleading advertising "in the absence of adequate substantiation" linking blue-light exposure to retinal damage in clinical populations (McCormick 2016; UK Advertising Standards Authority 2015).

There is currently a relative paucity of clinical evidence to support many claims surrounding the deleterious effects of blue-light exposure. Although ocular discomfort symptoms have been long-associated with computer and video display terminal use (Smith 1981; Ustinaviciene 2006), the relative contribution of blue light per se (rather than other potential causative factors, such binocular vision anomalies, postural factors and/or tear film dysfunction) remains unclear.

In terms of potential effects on sleep, a recent systematic review and meta-analysis (which allowed the inclusion of randomised controlled trials (RCTs), cohort, and cross-sectional studies) reported a significant association between portable screen-based media device (e.g. cell phone and table devices) access or use, in the sleep environment, and reduced sleep outcomes (including inadequate quantity, poor quality and excessive daytime sleepiness) in children (Carter 2016). However, as acknowledged by the authors of the review, the certainty of the evidence (assessed using the GRADE approach) was judged as low due to a necessary reliance on non-randomised studies (Carter 2016). Thus there is the potential for the true effect to be substantially different from the reported effect estimate.

Concerning the potential effect(s) of blue-light filtering spectacles in imparting macular protection, 10 out of the 12 major popula-

tion-based studies that sought to determine whether there was a relationship between light exposure and AMD did not report a positive association (Mainster 2006). Similarly, it is unclear whether age-related cataract surgery, in which removal of the aged crystalline lens (which acts as a physiological blue filter) and its replacement with a non-blue light filtering IOL, is a risk factor for AMD development, AMD progression, or both. Although some studies have reported a positive association (Klein 1998; Liu 1989), others have found an absence of relationship with respect to the risk of developing late-stage AMD in individuals with earlier stages of the condition (Baatz 2008; Chew 2009). Notably, observational studies have important methodological limitations, including the potential influences of bias and confounding, which limit the interpretation of these findings.

Given the relative attenuation of short-wavelength visible light with a blue-light filter, any potentially undesirable effects on visual function, in particular alterations to colour discrimination, also need to be considered. In the context of blue-light filtering IOLs, a recent systematic review by Downie 2018 concluded that, due to a paucity of studies, it is currently unclear whether these devices affect colour vision relative to non-blue light filtering IOLs. The status of the evidence relating to blue-light filtering spectacle lenses also requires clarification.

Consequently, current limitations in the scientific literature emphasise an urgent need to clarify whether blue-light filtering spectacles affect eye strain associated with digital device use, visual performance, sleep, and macular health (Lawrenson 2017). A rigorous systematic review, considering the best-available RCT evidence, is essential to objectively evaluate the relative appropriateness of prescribing blue-light filtering ophthalmic lenses for these purposes. The relative benefits and potential harms of these devices also need to be considered. This knowledge has the capacity to inform clinical practice guidelines relating to the prescription of blue-light filtering spectacle lenses, and thus is of strong relevance to clinicians, patients, researchers, and the broader ophthalmic community. We expect that this systematic review may also identify important areas for future research in the field, to fill any evidence gaps.

OBJECTIVES

To assess whether blue-light filtering spectacle lenses impart effects on visual function, provide protection to the macula, or both. We will also examine potential effects on the sleep-wake cycle.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs).

Types of participants

Participants in the RCTs will be adults (i.e. at least 18 years of age).

Types of interventions

We will include RCTs that compared blue-light filtering spectacle lenses with non-blue-light filtering spectacle lenses. We will exclude studies that investigated blue-light filtering spectacle lenses in combination with any other intervention, unless the same intervention was also used in the comparator group.

Types of outcome measures

Primary outcomes

The primary outcomes, measured at one month of follow-up (with an acceptable follow-up range of between two weeks and three months), will be:

- Change in visual fatigue or discomfort, measured using a questionnaire or visual analogue scale;
- Change in CFF, measured in Hertz (Hz).

Secondary outcomes

We will consider the following secondary outcomes:

- change in best-corrected visual acuity (BCVA), with or without (disability) glare, measured in logMAR;
- change in contrast sensitivity, measured in log contrast sensitivity, with and without (disability) glare;
- change in discomfort glare, measured using a questionnaire (e.g. de Boer scale) or objectively (e.g. electromyogram);
- proportion of eyes, or individuals (as determined by the unit of analysis), with a finding of a pathological structural change at the macula, detected by clinical observation, optical coherence tomography (OCT) or retinal fundus photography;
- change in colour discrimination, considered as the standard mean difference for panel tests (e.g. Farnsworth D15 and 100-hue) or the number of errors on plate tests (e.g. Ishihara), measured under photopic, mesopic, or scotopic conditions;
- daytime alertness, considered as the proportion of participants who had reduced daytime alertness, measured using a subjective scale;
- change in serum melatonin levels, measured in pg/mL;
- sleep quality, measured using questionnaires or rating scales;
- overall patient satisfaction with their visual performance, measured using questionnaires or rating scales.

The follow-up period for secondary outcomes will be measured at one month (with an acceptable range of two weeks to three months), with the exception of the 'proportion of eyes, or individuals, with a finding of a pathological structural change at the macula', which will be measured at 12 months (with an acceptable range of six to 24 months).

Adverse effects

We will tabulate any ocular or systemic adverse effects, as reported in the included trials.

Search methods for identification of studies

Electronic searches

The Cochrane Eyes and Vision Information Specialist will search the following electronic databases. There will be no language or publication year restrictions.

- Cochrane Central Register of Controlled Trials (CENTRAL) (which contains the Cochrane Eyes and Vision Trials Register) in the Cochrane Library (latest issue) (Appendix 1);
- MEDLINE Ovid (1946 to present) (Appendix 2);
- Embase Ovid (1980 to present) (Appendix 3);
- LILACS (1982 to present) (Appendix 4);
- ISRCTN registry (www.isrctn.com/editAdvancedSearch) (Appendix 5);
- US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (www.clinicaltrials.gov) (Appendix 6);
- World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) (www.who.int/ictrp) (Appendix 7).

Searching other resources

We will undertake additional searching, using the bibliographies of included RCTs, to identify any other potentially relevant studies.

Data collection and analysis

Selection of studies

We will adopt a two-stage process to identify relevant trials.
First, two review authors will independently evaluate the title and abstract results from the search strategies, to identify studies potentially suitable for inclusion. We will obtain full-text articles of records that at least one review author judges as relevant, or possibly relevant. Two review authors will independently assess every full-text article and assess its suitability for inclusion in the review, according to the Criteria for considering studies for this review.
We will resolve any disagreements in classification by discussion and consensus between the two review authors; if required, we will consult a third review author for a final judgement with respect to eligibility.
For records where more information is considered necessary to determine eligibility, we will contact the trial authors by email to request this information. If we do not receive a response within four weeks, we will use the information provided within the full-text article to assess eligibility. We will provide details relating to the reason for excluding studies that progress to the full-text review stage, in a 'Characteristics of excluded studies' table.

Data extraction and management

Two review authors will independently extract key study data (detailed in Appendix 8) using Covidence (Covidence). In brief, relevant information to capture will include details of the study design, country, setting, participant characteristics, number of participants, outcomes, results, and any other relevant information (e.g. funding sources, declarations of interest). Wherever possible, we will extract quantitative data for pre-specified outcomes. The two review authors will resolve any discrepancies in data extraction by discussion to reach consensus; if necessary, they will consult a third review author who will adjudicate. After reaching consensus in Covidence, one review author will export the collated data into Cochrane's Review Manager 5 (RevMan 5) software (Review Manager 2014). A second review author will independently verify the data.

Assessment of risk of bias in included studies

Two review authors will independently assess the risk of bias in each of the included trials using the guidelines in Chapter 8 of the *Cochrane Handbook for Systematic Review of Interventions* (Higgins 2017). We will evaluate risk of bias in the following domains:

- selection bias (random sequence generation and allocation concealment);
- performance bias (masking of participants and personnel);
- detection bias (masking of outcome assessment);
- attrition bias (incomplete outcome data);
- reporting bias (selective reporting of outcomes);
- other bias (funding source, other conflicts of interest).

Two review authors will judge the risk of each bias in each of the included studies as: (i) low risk, (ii) unclear risk (due to either lack of information or uncertainty over the potential for bias) or (iii) high risk. We will resolve any disagreements in risk of bias assessment by consensus.

Measures of treatment effect

We will undertake the data analyses according to the approach described in Chapter 9 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2017).

For continuous outcomes, we will extract information on the change, from baseline, in means (and standard deviations (SDs) of changes) of the outcome measures for the intervention and comparator groups at the specified follow-up period(s). Where measures of change are not reported, we will extract the mean and SD values of the outcome for the intervention and comparator groups at the specified follow-up period(s). We will express treatment effects as the mean difference (MD), with 95% confidence intervals (CIs), between the intervention and comparator groups.

For the dichotomous outcome (i.e. proportion of participants who had reduced daytime alertness), we will compare data between the intervention and comparator groups and will present it as risk ratios (RRs) with 95% CIs.

Unit of analysis issues

For the purpose of this review, the unit of analysis will be the study participant.

Given the nature of spectacles, trials are predicted to randomise individuals (rather than eyes) to the intervention and comparator. Although paired-eye studies are unlikely, we will include these if identified.

It is possible that for some outcomes (e.g. BCVA, contrast sensitivity) data may be collected from both eyes. Where the study collected data on more than one eye per participant, we will follow guidelines for clustering or paired-eye design described in Chapter 16 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). If only one eye per person is included in the trial, there will not be a unit of analysis issue, and we will document how the eye was selected (if specified in the study report). If individual participants are randomly allocated to the intervention but data from both eyes are included and reported, we will analyse this as 'clustered data' (i.e. with an adjustment for within-person correlation); if necessary, we may contact the trial investigators for more information to perform this analysis. For the outcome measure relating to pathological structural change at the macula, we will report either the proportion of eyes (for paired-eye studies) or the proportion of participants with structural changes in one or both eyes (for trials randomising individuals).

Dealing with missing data

For studies that have missing outcome data (e.g. omitted standard deviations or standard errors), we will attempt to contact the trial authors via email for the necessary information. If we do not receive a response within four weeks, or if the trial authors are unable to provide this information, we will use the information available in the full-text publication.

If feasible, we will undertake an intention-to-treat (ITT) analysis. We will use imputed data if the trial authors provide it using a robust method; however we will not directly impute data ourselves. If ITT data are not provided in the included trials, we will undertake an available case analysis, which assumes that data are missing at random. We will assess if this assumption is reasonable by collecting data on the number of participants excluded or lost to follow-up, and the reasons for loss to follow-up by treatment group, from each included study (as reported).

Assessment of heterogeneity

We will assess trials for heterogeneity using the recommendations outlined in Chapter 9 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2017). We will examine clinical and methodological heterogeneity between trials by considering differences in RCT design, participant characteristics at baseline (e.g. age, gender, eligibility criteria, etc.), and the risk of bias. Statistical heterogeneity between studies will be quantified using the I^2 statistic (Higgins 2003). We will interpret an I^2 statistic of 60% or more to be at risk of moderate heterogeneity (Ng 2014). In identifying and measuring heterogeneity, we will consider the magnitude and direction of effects of individual trials, and the strength of evidence for heterogeneity (using a P value < 0.10, from the Chi^2 test as an indicator of significant heterogeneity).

Assessment of reporting biases

We will examine the risk of reporting bias (due to selective reporting of outcomes) by comparing the outcomes defined in the trial protocol (where available) or clinical trial registry, with those in the full-text publication(s).

If there are 10 or more studies to include in a meta-analysis, we will assess for any potential publication bias using a funnel plot. We will interpret any asymmetries in the funnel plot in association with the trial characteristics, in consideration of factors such as sample size.

Data synthesis

We will perform meta-analyses for the primary and secondary outcomes, if appropriate. If fewer than three trials are included in the meta-analysis, we will use a fixed-effect model; otherwise we will use a random-effects model.

If we determine there to be inconsistency between trial findings (e.g. effects in different directions, or I^2 statistic more than 60%, or a Chi^2 test P value < 0.10), such that a pooled result may not provide an appropriate summary of the findings, we will describe the pattern of individual trial results. If there is statistical heterogeneity but all of the effect estimates are in a consistent direction, such that a pooled estimate would seem to provide an appropriate summary of the individual RCT results, we will pool data in a meta-analysis.

If we deem a meta-analysis to be inappropriate, we will provide a descriptive or tabulated results summary.

Subgroup analysis and investigation of heterogeneity

If a sufficient number of trials (considered two trials per subgroup or more) are available, we will perform a subgroup analysis for factors that could potentially affect outcomes. Specifically, we will assess for the potential effects of: participant age (less than 40 years versus 40 years or older), degree of blue-light attenuation imparted by the blue-light filtering lens product ('high' block versus 'low' block), and extent of digital device use (less than two hours per day versus two or more hours per day).

Sensitivity analysis

If a sufficient number of trials meet the inclusion criteria of the review, we will perform a sensitivity analysis for the primary outcome measures, to assess for the effects of excluding trials that: (i) we judged to have a high risk of bias due in the domains of allocation concealment or lack of masking (or participants and personnel, or outcome assessors), (ii) are unpublished, and (iii) were funded by industry.

Summary of findings

We will create a 'Summary of findings' table summarising the results of the analyses, provided sufficient data are available, using the approach described in Chapter 11 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Schünemann 2017). The GRADE Working Group approach will be adopted to grade the certainty of evidence. Outcomes, measured between the intervention and control groups, will include:

- change in visual fatigue or discomfort;
- change in CFF;
- change in BCVA, with or without (disability) glare;
- proportion of eyes, or individuals, with a finding of pathological structural change at the macula;
- change in colour discrimination;
- sleep quality;
- proportion of participants with adverse events with a probable causal link with the study intervention.

For all outcomes, we will measure the change from baseline at one month of follow-up (with an acceptable range of two weeks to three months), with the exception of the 'proportion of participants with adverse events with a probable causal link with the study intervention' and the 'proportion of eyes, or individuals, with a finding of a pathological structural change at the macula', which we will assess at the follow-up period(s) reported by the trial authors.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. CENTRAL search strategy

#1 MeSH descriptor: [Eyeglasses] this term only
#2 (spectacle* or eyeglasses or glasses)
#3 #1 or #2
#4 MeSH descriptor: [Filtration] this term only
#5 blue near/2 light*
#6 blue near/3 filter*
#7 blue near/3 block*
#8 violet near/3 filter*
#9 blue light near/2 (emission* or transmission*)
#10 (short next wavelength near/2 light)
#11 UV near/2 (protect* or attenuat*)
#12 (blueEast or "Blue control" or "Crizal prevencia" or "Dura vision" or Eyezen or Gunnar or "Kodak Total Blue" or StressFree)
#13 #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12
#14 #3 and #13

Appendix 2. MEDLINE Ovid search strategy

1. randomized controlled trial.pt.
2. (randomized or randomised).ab,ti.
3. placebo.ab,ti.
4. dt.fs.
5. randomly.ab,ti.
6. trial.ab,ti.
7. groups.ab,ti.
8. or/1-7
9. exp animals/
10. exp humans/
11. 9 not (9 and 10)
12. 8 not 11
13. Eyeglasses/
14. (spectacle$ or eyeglasses or glasses).tw.

15. or/13-14
16. Filtration/
17. (blue adj2 light$).tw.
18. (blue adj3 filter$).tw.
19. (blue adj3 block$).tw.
20. (violet adj3 filter$).tw.
21. (blue light adj2 (emission$ or transmission$)).tw.
22. (short adj1 wavelength adj2 light).tw.
23. (UV adj2 (protect$ or attenuat$)).tw.
24. (blueEast or “Blue control” or “Crizal prevencia” or “Dura vision” or Eyezen or Gunnar or “Kodak Total Blue” or StressFree).tw.
25. or/16-24
26. 15 and 25
27. 12 and 26

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

Appendix 3. Embase Ovid search strategy

1. exp randomized controlled trial/
2. exp randomization/
3. exp double blind procedure/
4. exp single blind procedure/
5. random$.tw.
6. or/1-5
7. (animal or animal experiment).sh.
8. human.sh.
9. 7 and 8
10. 7 not 9
11. 6 not 10
12. exp clinical trial/
13. (clin$ adj3 trial$).tw.
14. ((singl$ or doubl$ or trebl$ or tripl$) adj3 (blind$ or mask$)).tw.
15. exp placebo/
16. placebo$.tw.
17. random$.tw.
18. exp experimental design/
19. exp crossover procedure/
20. exp control group/
21. exp latin square design/
22. or/12-21
23. 22 not 10
24. 23 not 11
25. exp comparative study/
26. exp evaluation/
27. exp prospective study/
28. (control$ or prospectiv$ or volunteer$).tw.
29. or/25-28
30. 29 not 10
31. 30 not (11 or 23)
32. 11 or 24 or 31
33. exp spectacles/
34. (spectacle$ or eyeglasses or glasses).tw.
35. or/33-34

36. blue light/
37. (blue adj2 light$).tw.
38. (blue adj3 filter$).tw.
39. (blue adj3 block$).tw.
40. (violet adj3 filter$).tw.
41. (blue light adj2 (emission$ or transmission$)).tw.
42. (short adj1 wavelength adj2 light).tw.
43. (UV adj2 (protect$ or attenuat$)).tw.
44. (blueEast or "Blue control" or "Crizal prevencia" or "Dura vision" or Eyezen or Gunnar or "Kodak Total Blue" or StressFree).tw.
45. or/36-44
46. 35 and 45
47. 32 and 46

Appendix 4. LILACS search strategy

(tw:(spectacles or glasses or eye glasses)) AND (tw:(blue light or blue filter or blue blocking or violet filter or UV protection))

Appendix 5. ISRCTN search strategy

(spectacles OR glasses OR eye glasses) AND (blue light OR blue filter OR blue blocking)

Appendix 6. ClinicalTrials.gov search strategy

(spectacles OR glasses OR eye glasses) AND (blue light OR blue filter OR blue blocking)

Appendix 7. WHO ICTRP search strategy

spectacles AND blue light OR glasses AND blue light OR eyeglasses AND blue light OR spectacles AND blue filter OR glasses AND blue filter OR eyeglasses AND blue filter OR spectacles AND blue blocking OR glasses AND blue blocking OR eyeglasses AND blue blocking

Appendix 8. Data on study characteristics

Primary items		Other items
Methods		
Study design	e.g. parallel group RCT, paired-eye RCT, cluster RCT, cross-over RCT, or other design	Exclusions after randomisation Losses to follow-up How missing data were handled e.g. available case analysis, imputation methods Reported power calculation (Y/N), including sample size and power Unusual study design/issues (as required)

(*Continued*)

Unit of randomisation/unit of analysis	e.g. one eye included in study, two eyes included in study, both eyes received same treatment, or two eyes included in study, eyes received different treatments	
Participants		
Country		Setting Baseline characteristics Comparison of study groups at baseline
Total number of participants		
Number (%) of men and women		
Average age and age range		
Inclusion criteria		
Exclusion criteria		
Interventions		
Intervention (n =) Comparator (n =)	Description of interventions (e.g., spectacle lens name and manufacturer) Frequency with which the intervention (spectacle lenses) were worn over the trial duration	
Outcomes		
Primary and secondary outcomes, as defined in the study report	Details of outcomes Length of follow up and intervals at which outcomes were assessed	Planned/actual length of follow-up
Notes		
Date conducted	Specify dates of recruitment of participants	Trial registration details Full study name: (if applicable) Corresponding author's name and contact details (email, mailing address) Were trial investigators contacted? (Any relevant details)
Funding sources		
Declaration of interest		

CONTRIBUTIONS OF AUTHORS

All authors contributed to the development, drafting and finalisation of this protocol.

DECLARATIONS OF INTEREST

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