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[Intervention Review]

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

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ABSTRACT

Background

'Blue-light filtering', or 'blue-light blocking', spectacle lenses filter ultraviolet radiation and varying portions of short-wavelength visible light from reaching the eye. Various blue-light filtering lenses are commercially available. Some claims exist that they can improve visual performance with digital device use, provide retinal protection, and promote sleep quality. We investigated clinical trial evidence for these suggested effects, and considered any potential adverse effects.

Objectives

To assess the effects of blue-light filtering lenses compared with non-blue-light filtering lenses, for improving visual performance, providing macular protection, and improving sleep quality in adults.

Search methods

We searched the Cochrane Central Register of Controlled Trials (CENTRAL; containing the Cochrane Eyes and Vision Trials Register; 2022, Issue 3); Ovid MEDLINE; Ovid Embase; LILACS; the ISRCTN registry; ClinicalTrials.gov and WHO ICTRP, with no date or language restrictions. We last searched the electronic databases on 22 March 2022.

Selection criteria

We included randomised controlled trials (RCTs), involving adult participants, where blue-light filtering spectacle lenses were compared with non-blue-light filtering spectacle lenses.

Data collection and analysis

Primary outcomes were the change in visual fatigue score and critical flicker-fusion frequency (CFF), as continuous outcomes, between baseline and one month of follow-up. Secondary outcomes included best-corrected visual acuity (BCVA), contrast sensitivity, discomfort glare, proportion of eyes with a pathological macular finding, colour discrimination, proportion of participants with reduced daytime alertness, serum melatonin levels, subjective sleep quality, and patient satisfaction with their visual performance. We evaluated findings related to ocular and systemic adverse effects.

We followed standard Cochrane methods for data extraction and assessed risk of bias using the Cochrane Risk of Bias 1 (RoB 1) tool. We used GRADE to assess the certainty of the evidence for each outcome.

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Main results

We included 17 RCTs, with sample sizes ranging from five to 156 participants, and intervention follow-up periods from less than one day to five weeks. About half of included trials used a parallel-arm design; the rest adopted a cross-over design. A variety of participant characteristics was represented across the studies, ranging from healthy adults to individuals with mental health and sleep disorders.

None of the studies had a low risk of bias in all seven Cochrane RoB 1 domains. We judged 65% of studies to have a high risk of bias due to outcome assessors not being masked (detection bias) and 59% to be at high risk of bias of performance bias as participants and personnel were not masked. Thirty-five per cent of studies were pre-registered on a trial registry. We did not perform meta-analyses for any of the outcome measures, due to lack of available quantitative data, heterogenous study populations, and differences in intervention follow-up periods.

There may be no difference in subjective visual fatigue scores with blue-light filtering lenses compared to non-blue-light filtering lenses, at less than one week of follow-up (low-certainty evidence). One RCT reported no difference between intervention arms (mean difference (MD) 9.76 units (indicating worse symptoms), 95% confidence interval (CI) -33.95 to 53.47; 120 participants). Further, two studies (46 participants, combined) that measured visual fatigue scores reported no significant difference between intervention arms.

There may be little to no difference in CFF with blue-light filtering lenses compared to non-blue-light filtering lenses, measured at less than one day of follow-up (low-certainty evidence). One study reported no significant difference between intervention arms (MD - 1.13 Hz lower (indicating poorer performance), 95% CI - 3.00 to 0.74; 120 participants). Another study reported a less negative change in CFF (indicating less visual fatigue) with high- compared to low-blue-light filtering and no blue-light filtering lenses.

Compared to non-blue-light filtering lenses, there is probably little or no effect with blue-light filtering lenses on visual performance (BCVA) (MD 0.00 logMAR units, 95% CI -0.02 to 0.02; 1 study, 156 participants; moderate-certainty evidence), and unknown effects on daytime alertness (2 RCTs, 42 participants; very low-certainty evidence); uncertainty in these effects was due to lack of available data and the small number of studies reporting these outcomes. We do not know if blue-light filtering spectacle lenses are equivalent or superior to non-blue-light filtering spectacle lenses with respect to sleep quality (very low-certainty evidence). Inconsistent findings were evident across six RCTs (148 participants); three studies reported a significant improvement in sleep scores with blue-light filtering lenses compared to non-blue-light filtering lenses, and the other three studies reported no significant difference between intervention arms. We noted differences in the populations across studies and a lack of quantitative data.

Device-related adverse effects were not consistently reported (9 RCTs, 333 participants; low-certainty evidence). Nine studies reported on adverse events related to study interventions; three studies described the occurrence of such events. Reported adverse events related to blue-light filtering lenses were infrequent, but included increased depressive symptoms, headache, discomfort wearing the glasses, and lower mood. Adverse events associated with non-blue-light filtering lenses were occasional hyperthymia, and discomfort wearing the spectacles.

We were unable to determine whether blue-light filtering lenses affect contrast sensitivity, colour discrimination, discomfort glare, macular health, serum melatonin levels or overall patient visual satisfaction, compared to non-blue-light filtering lenses, as none of the studies evaluated these outcomes.

Authors' conclusions

This systematic review found that blue-light filtering spectacle lenses may not attenuate symptoms of eye strain with computer use, over a short-term follow-up period, compared to non-blue-light filtering lenses. Further, this review found no clinically meaningful difference in changes to CFF with blue-light filtering lenses compared to non-blue-light filtering lenses. Based on the current best available evidence, there is probably little or no effect of blue-light filtering lenses on BCVA compared with non-blue-light filtering lenses. Potential effects on sleep quality were also indeterminate, with included trials reporting mixed outcomes among heterogeneous study populations. There was no evidence from RCT publications relating to the outcomes of contrast sensitivity, colour discrimination, discomfort glare, macular health, serum melatonin levels, or overall patient visual satisfaction. Future high-quality randomised trials are required to define more clearly the effects of blue-light filtering lenses on visual performance, macular health and sleep, in adult populations.

PLAIN LANGUAGE SUMMARY

Blue-light filtering spectacle lenses for visual performance, macular (back part of the eye) protection, and improving sleep quality

What is the aim of this review?

This Cochrane Review aimed to investigate the possible benefits and safety of blue-light filtering spectacle lenses, also known as blue-light blocking spectacle lenses, on visual performance, macular protection, and sleep quality. Cochrane Review authors collected and analysed all relevant studies to summarise the best available research evidence.

Key message

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Blue-light filtering lenses may not reduce short-term eyestrain associated with computer work, compared to non-blue-light filtering lenses. Potential harmful effects were temporary and generally mild, and mostly thought to be related to the glasses more generally rather than specifically the lenses themselves.

There is a need for future research to provide evidence for the effects of blue-light filtering lenses on multiple aspects of visual performance and sleep, including vision level (best corrected visual acuity), ability to detect differences in shading and patterns (contrast sensitivity), colour discrimination, reducing glare due to bright light (discomfort glare), the health of the retina at the back of the eye (macular health), sleep measures (including blood melatonin levels and sleep quality), and patient satisfaction.

What was studied in the review?

The primary measures were the change in perceived and quantifiable assessments of eye strain, measured after at least one month of using the lenses. The other assessments considered a range of clinical measures and side effects.

What are the main results of the review?

We included 17 studies that recruited 619 people and took place in six countries. This review showed the following.

(i) There may be no short-term advantages with using blue-light filtering lenses to reduce visual fatigue with computer use, compared to non-blue-light filtering lenses.

(ii) There is limited information about the potential effect(s) of blue-light filtering lenses on visual acuity and the effects on sleep-related measures are unclear. The existing evidence regarding these measures is inconclusive.

(iii) None of the included studies investigated contrast sensitivity, colour discrimination, discomfort glare, macular health, serum melatonin levels or overall patient visual satisfaction; no conclusions could be drawn in relation to these measures.

(iv) There is some evidence that harmful effects that may be related to using blue-light filtering lenses include headache (1 study, 8%), increased depressive symptoms (1 study, 17%), lowered mood (1 study, 5%), and discomfort wearing the glasses (2 studies (combined), 22%), although similar adverse effects were also reported with non-blue-light filtering lenses and there were not enough data to accurately measure or determine possible harmful effects with certainty.

How up-to-date is this review?

The Cochrane Review authors searched for studies that had been published up to 22 March 2022.

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SUMMARY OF FINDINGS

Summary of findings 1. Summary of findings 1: blue-light filtering lenses compared to non-blue-light filtering lenses

Blue-light filtering lenses compared with non-blue-light filtering lenses

Patient or population: adults

Setting: any setting

Intervention: blue-light filtering lenses

Comparison: non-blue-light filtering lenses

Outcome	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	Number of participants (Number of studies)	Certainty of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Risk with non-blue light-filtering lenses	Risk with blue-light filtering lenses				
Visual fatigue score, measured using a Likert scale or VAS, with follow-up ranging from < 1 to 5 days (higher values indicate a poorer outcome)	The mean change in visual fatigue score in the non-blue-light filtering lens group was on average 86.92 units higher (55.42 higher to 118.4 higher).	The mean change in visual fatigue score in the blue-light filtering lens group was on average 96.68 units higher (65.07 higher to 128.3 higher) (Singh 2021).	9.76 units higher (33.95 lower to 53.47 higher)	120 (1 RCT)	⊕⊕⊖⊖[a] Low	Quantitative data reported for this outcome derive from Singh 2021 (120 participants). Symptom scores were reported only as P values or in a non-numeric form in 1 study (Lin 2017), and another study presented data as the average daily change over a 5-day period, rather than as the change from baseline or endpoint data value (Dabrowiecki 2020). 2 trials reported no significant difference between intervention arms (Dabrowiecki 2020; Lin 2017).
CFF, measured in Hz, with a follow-up of 2 hours (lower values indicate a poorer outcome)	The mean change in CFF in the non-blue-light filtering lens group was on average 0.12 Hz lower (1.47 lower to 1.24 higher) (Singh 2021).	The mean change in CFF in the blue-light filtering lens group was on average 1.25 Hz lower (2.60 lower to 0.09 higher) (Singh 2021).	1.13 Hz lower (3.00 lower to 0.74 higher)	120 (1 RCT)	⊕⊕⊖⊖[b] Low	Quantitative data reported for this outcome derive from Singh 2021 (120 participants). CFF data were reported only as P values or in a non-numeric form

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						in one study (Lin 2017). Lin 2017 reported a significantly less negative change in CFF (i.e. less visual fatigue) with high blue-light filtering lenses compared to low blue-light filtering and non-blue-light filtering lenses.
BCVA, measured in log units, with follow-up of less than 1 day (higher values indicate a poorer outcome)	The mean BCVA in the non-blue-light filtering lens group was on average 0.049 units.	The mean BCVA in the blue-light filtering lens group was on average 0.051 units.	0.00 log units (0.02 lower to 0.02 higher)	156 (1 RCT)	⊕⊕⊕⊖[c] Moderate	Quantitative data reported for this outcome derive from Hammond 2015.
Proportion of eyes or individuals that developed macular structural changes	-			-	-	No relevant data were available for this outcome.
Colour discrimination, measured using the FM-100 hue test	-			-	-	No relevant data were available for this outcome.
Subjective sleep scores, measured using a VAS or Likert scale, with follow-up ranging from 4 days to 5 weeks (higher values indicate a poorer outcome)	6 studies reported subjective sleep scores (Burkhart 2009; Esaki 2017; Esaki 2020; Janku 2020; Knufinke 2019; Shechter 2018). Of these, 3 studies reported a significant improvement in sleep scores with blue-light filtering lenses compared to non-blue-light filtering lenses (Burkhart 2009; Knufinke 2019; Shechter 2018); however, the magnitude of the difference between intervention arms could not be calculated, due to a lack of complete data reporting. The other 3 studies reported no significant difference in subjective sleep scores between intervention arms (Esaki 2017; Esaki 2020; Janku 2020). For these 3 studies, the difference between intervention arms ranged from 19.90 units higher (indicating poor sleep) (1.86 lower to 41.66 higher, 20 participants) to 0.03 units higher (2.53 lower to 2.59 higher, 27 participants).			148 (6 RCTs)	⊕⊖⊖⊖[d] Very low	Subjective sleep scores were reported only as P values or in a non-numeric form in 1 study (Burkhart 2009). Data were presented as the average daily change, rather than the change from baseline or endpoint data in 1 study (Shechter 2018).
Proportion of participants with adverse events with a probable causal linked with the study intervention	4 studies reported adverse events, consisting of increased depressive symptoms, headache, lower mood, and pain or discomfort from wearing the spectacles across the study intervention arms. In the control arms, reported adverse events were hyperthermia and discomfort from wearing the spectacles.			333 (9 RCTs)	⊕⊕⊖⊖[e] Low	There were no adverse events reported across both intervention and control groups in 5 studies (Burkhart 2009; Janku 2020; Perez Algorta 2018; Shechter 2018; Singh 2021).

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			1 study reported adverse events in only the active intervention (blue-light filtering lens) group (n = 3/13 participants) (Henriksen 2016). 1 study reported an identical number of adverse events across both the active intervention and control arms (n = 4/10 versus n = 4/10) (Esaki 2017). 2 studies reported more adverse events in the control arm than with the active intervention (n = 0/19 versus n = 2/16, and n = 4/44 versus n = 7/44 participants) (Danilenko 2019; Esaki 2020).

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

BCVA: best-corrected visual acuity; CI: confidence interval; MD: mean difference; CFF: critical flicker-fusion frequency; Hz: hertz; VAS: visual analogue scale; FM: Farnsworth Munsell.; RCT: randomised controlled trial.

GRADE Working Group grades of evidence.

High quality: further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: we are very uncertain about the estimate.

[a]Downgraded two levels for risk of bias and imprecision, because outcome assessors were not masked in one study (Dabrowiecki 2020), one study did not mask participants and study personnel (Lin 2017), and one study had wide confidence intervals (Singh 2021).

[b]Downgraded one level each for risk of bias and inconsistency, because one study did not mask participants and study personnel (Lin 2017), and one study showed no intergroup differences (Singh 2021) while the other reported a positive effect with the blue-light filtering intervention (Lin 2017).

[c]Downgraded one level for risk of bias, because data derived from one study, in which the outcome assessor was not masked (Hammond 2015).

[d]Downgraded three levels for risk of bias, imprecision and inconsistency. In four studies, participants or study personnel, or both, were not masked (Burkhart 2009; Janku 2020; Knufinke 2019; Shechter 2018), and in three studies outcome assessors were not masked (Burkhart 2009; Knufinke 2019; Shechter 2018). Two studies were at high risk of other bias due to significant baseline imbalance (Burkhart 2009; Esaki 2017). Further, the included studies had small sample sizes and reported variable findings.

[e]Downgraded two levels for risk of bias and inconsistency. In four studies, participants and study personnel were not masked (Burkhart 2009; Janku 2020; Perez Algorta 2018; Shechter 2018), and in four studies outcome assessors were not masked (Burkhart 2009; Henriksen 2016; Perez Algorta 2018; Shechter 2018). Two studies were at high risk of other bias due to significant baseline imbalance (Burkhart 2009; Esaki 2017). Further, the reported adverse events were observed to vary across the studies.

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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 (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 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), 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, 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) (Singh 2019).

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 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; Singh 2019). 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 is currently commercially available; examples include blueEast (Bonastar), Blue control (Hoya), Crizal prevencia (Essilor), Dura vision/blue protect (Zeiss), 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

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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; Singh 2021), the specific mechanism(s) underlying how these devices might impart such benefit(s) are not known. The rationale for claims that blue-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 (Sheppard 2018). 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; 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 is people 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. a UV-only filtering IOL) (Dillon 2004). There is experimental evidence from animal studies (Ham 1982; Noell 1966), and cell culture experiments (Sparrow 2004), which demonstrates that 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 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 and/or 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).

Blue light also has potential effects on sleep quality and circadian rhythm (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 that reduce blue light emissions, may be of value for mitigating these potentially negative effects on sleep. Similar rationale has been proposed for the use of these interventions in promoting sleep in people with major depression and bipolar disorders (Esaki 2017; Henriksen 2020).

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). These lenses are frequently prescribed (sometimes in preference to standard spectacles lenses) in eye care practice (Singh 2019), and 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 poorer 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

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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 population-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 between cataract surgery and AMD (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.

A recent systematic review investigating the potential benefits and adverse events of different interventions for treating CVS concluded that blue-light filtering spectacles are ineffective in reducing visual fatigue associated with computer use, compared to non-blue-light filtering spectacles, based on findings reported from three RCTs (Singh 2022). There is a need to clarify whether blue-light filtering spectacles affect other parameters, such as 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 the effects of blue-light filtering lenses compared with non-blue-light filtering lenses, for improving visual performance, providing macular protection, and improving sleep quality in adults.

METHODS

Criteria for considering studies for this review

Types of studies

We only included randomised controlled trials (RCTs).

Types of participants

We included trials in which participants were adults (i.e. at least 18 years of age).

Types of interventions

We included RCTs that compared blue-light filtering spectacle lenses with non-blue-light filtering spectacle lenses. We excluded 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 prespecified primary outcomes, measured at one-month of follow-up, were:

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

CFF is defined as the frequency at which a flickering light stimulus appears to be continuous to a human observer (Iwasaki 1991). It is regarded as an indicator of arousal levels (Davranche 2005), and is also often used as an outcome measure to quantify visual fatigue in studies investigating interventions for CVS (Lin 2017; Morita 2018; Nagaki 2002; Okamoto 2018; Ozawa 2015; Singh 2021; Stringham 2017; Yamashita 2019; Zhang 2004). Acknowledging that there remains some debate about the validity of CFF as a measure of visual fatigue (Yan 2022), in the absence of a gold-standard measure for quantifying visual fatigue, we selected CFF as a co-primary outcome measure, in addition to symptoms, for this review.

For both of these outcomes, the acceptable follow-up range was defined as between two weeks and three months.

Secondary outcomes

We considered 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;

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- 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 secondary outcomes were measured at one month (with an acceptable range of two weeks to three months), except for the 'proportion of eyes, or individuals, with a finding of a pathological structural change at the macula', which was measured at 12 months (with an acceptable range of six to 24 months).

Adverse effects

We extracted data relating to both ocular and systematic adverse events from the included studies.

Search methods for identification of studies

Electronic searches

The Cochrane Eyes and Vision Information Specialist searched the following databases for randomised controlled trials and controlled clinical trials. There were no restrictions to language or year of publication. The date of the search was 22 March 2022.

- Cochrane Central Register of Controlled Trials (CENTRAL) (which contains the Cochrane Eyes and Vision Trials Register) in the Cochrane Library (searched 22 March 2022) (Appendix 1).
- MEDLINE Ovid (1946 to 22 March 2022) (Appendix 2).
- Embase Ovid (1980 to 22 March 2022) (Appendix 3).
- LILACS (1982 to 22 March 2022) (Appendix 4).
- ISRCTN registry (www.isrctn.com/editAdvancedSearch; searched 22 March 2022) (Appendix 5).
- US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (www.clinicaltrials.gov; searched 22 March 2022) (Appendix 6).
- World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) (www.who.int/ictrp; searched 22 March 2022) (Appendix 7).

Searching other resources

We searched the bibliographies of included RCTs to identify any other potentially relevant studies.

Data collection and analysis

Selection of studies

We adopted a two-stage process to identify relevant RCTs.

First, two review authors (two of LED, SS, and PM) independently evaluated the title and abstract results from the search strategies, to identify studies potentially suitable for inclusion. We then obtained full-text articles of records that at least one review author judged as relevant, or possibly relevant. Two review authors (two of LED, SS, and PM) then independently assessed each full-text article and assessed its suitability for inclusion, according to the Criteria for considering studies for this review.

Any disagreements in classification were resolved by discussion and consensus between the two review authors; if required, we consulted a third review author for a final judgement with respect to eligibility.

For records where more information was considered necessary to determine eligibility, we contacted the trial authors by email to request this information. If we did not receive a response within four weeks, we used the information provided within the full-text article to assess eligibility. We provided details relating to the reason for excluding studies that progress to the full-text review stage, in the Characteristics of excluded studies table.

Data extraction and management

Two review authors (two of LED, SS, AL, EM, PM, JL, and CH) independently extracted key study data (detailed in Appendix 8) using Covidence. The relevant information captured included 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 extracted quantitative data for our prespecified outcomes.

The two review authors resolved any discrepancies in data extraction by discussion to reach consensus; if necessary, they consulted a third review author. After reaching consensus in Covidence, one review author (SS) exported the collated data into Cochrane's Review Manager Web (RevMan Web) software (RevMan Web 2022), and a second review author independently verified the data.

Assessment of risk of bias in included studies

Two review authors (two of LED, SS, AL, EM, PM, JL, and CH) independently assessed the risk of bias in each of the included RCTs using the guidelines in Chapter 8 of the *Cochrane Handbook for Systematic Review of Interventions* (Higgins 2017). Risk of bias was evaluated 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)

We performed risk of bias assessments for cross-over studies in a similar way to parallel-arm design studies. Carry-over and/or washout-period effects generally relevant to cross-over study designs were considered unlikely to occur in studies relevant to this review, as any potential benefits or harms derived from the optical intervention would likely only occur during the acute phase of exposure, with minimal longevity to any such potential effect(s) upon cessation.

Two review authors (two of LED, SS, AL, EM, PM, JL, and CH) judged 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 resolved any disagreements in risk of bias assessment by consensus.

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Measures of treatment effect

We undertook 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 extracted information on the change from baseline of the outcome measures for the intervention and comparator groups at the specified follow-up period(s). We extracted data as means and standard deviations (SDs) of the changes. Where measures of change were not reported, we extracted the mean and SD values of the outcome for the intervention and comparator groups at the specified follow-up period(s).

We expressed treatment effects as the mean difference (MD), with 95% confidence intervals (CIs), between the intervention and comparator groups. For studies that had more than one intervention or control group, we had planned to combined data from the relevant study groups, as appropriate. However, there were no instances where this was required.

For dichotomous outcomes, we had planned to extract the proportion of participants who experienced the outcome of interest in the intervention and comparator groups and to present these data as risk ratios (RRs) with 95% CIs. However, no combinable data were available for these outcomes.

Unit of analysis issues

The unit of analysis was the study participant.

When a study reported data on more than one eye per participant, we had planned to follow the guidelines for clustering or paired-eye designs as described in Chapter 16 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). When only one eye per person was included in the trial, we had planned to document how the eye was selected (if specified in the study report). If individual participants were randomly allocated to the intervention, but data from both eyes were included and reported, we had proposed to analyse this as clustered data, with an adjustment for within-person correlation.

However, as no quantitative analyses were feasible, these factors were not relevant to the current narrative synthesis. Further, cross-over studies were treated similar to parallel-arm design studies; no unit of analysis issues were identified.

Dealing with missing data

For all reporting, we used the information available in the full-text publications.

We had planned to use imputed data if the trial authors reported these data, and had derived the data using a robust method. We had not planned to directly impute data ourselves. However, no imputed data were described in the included studies.

Assessment of heterogeneity

If meta-analyses had been performed, we had planned to assess heterogeneity using the recommendations outlined in Chapter 9 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2017). However, this step was not required because quantitative data syntheses were not feasible.

Assessment of reporting biases

For each eligible study, we assessed selective outcome reporting as part of the risk of bias assessment.

We had intended to assess for potential publication bias using a funnel plot, if there were 10 or more studies to include in a meta-analysis, by interpreting any asymmetries in the funnel plot in association with the trial characteristics, and by considering factors such as sample size. However, as we were unable to perform any meta-analyses due to lack of combinable data, we could not assess for potential publication bias.

Data synthesis

We had intended to perform meta-analyses for the primary and secondary outcomes, and to use a fixed-effect model if there were fewer than three trials or a random-effects model if there were three or more trials with relevant data. We had planned to assess for inconsistency in the trial findings (e.g. effects in different directions, or I^2 statistic > 60%, or a Chi^2 test P value < 0.10). If we did not consider the pooled result to provide an appropriate summary of the findings, we had planned to describe the pattern of individual trial results. Further, if statistical heterogeneity was noted but all the effect estimates were in a consistent direction such that a pooled estimate would seem to provide an appropriate summary of the individual RCT results, we had planned to pool these data in a meta-analysis.

However, we did not perform meta-analyses in this review as the study populations, outcome measures, frequency and time of spectacle wear, and intervention follow-up periods varied substantially across the included studies. It was our view that pooled estimates would not be meaningful. Hence, we have provided descriptive summaries of individual trial findings for each outcome measure.

Subgroup analysis and investigation of heterogeneity

In our protocol, we had specified that if sufficient quantitative data were available, we would perform subgroup analyses to consider 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). However, as meta-analyses were not performed, we also could not undertake any subgroup analyses.

Sensitivity analysis

We had planned to perform a sensitivity analysis on 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 (participants and personnel, or outcome assessors), (ii) were unpublished, and (iii) were funded by industry. However, there was an insufficient number of studies to perform this analysis.

Summary of findings and assessment of the certainty of the evidence

We created a summary of findings table summarising the results of the analyses, using the approach described in Chapter 11 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Schünemann 2017).

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We adopted the GRADE Working Group approach to grade the certainty of evidence (GRADEpro GDT).

Outcomes, measured between the intervention and control groups, included:

- change in subjective 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 continuous outcomes, we extracted information on the change from baseline to one month of follow-up (with an acceptable range of two weeks to three months). For dichotomous outcomes, we extracted the proportion of participants in the intervention and comparator groups who experienced the outcome of interest at the follow-up period(s) reported by the trial authors.

RESULTS

Description of studies

Results of the search

The electronic database searches performed on 22 March 2022 identified a total of 259 records (Figure 1). The Cochrane Information Specialist removed 74 duplicate records, and two review authors independently screened titles/abstracts of a total of 185 records. Of these, 60 records were judged to be relevant, or potentially relevant, and proceeded to the full-text review stage.

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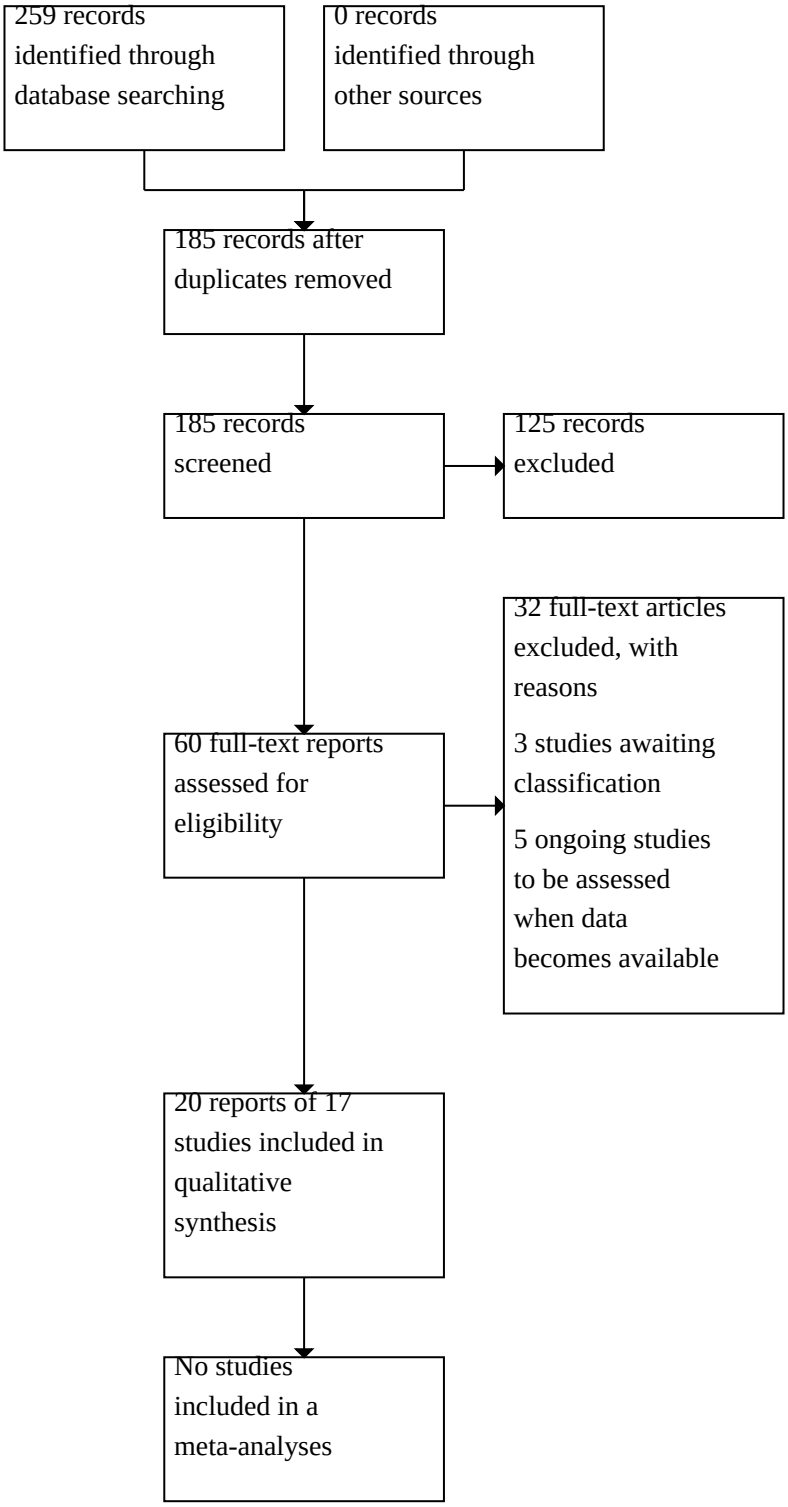
Figure 1. Study flow diagram



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Two review authors independently screened the full-text articles. We included 20 reports of 17 studies and excluded 32 studies (see Characteristics of excluded studies). Three trials were published as conference abstracts, and we could not identify full-text publications. Hence, these three conference abstracts are awaiting classification (Smolders 2016; Wolffsohn 2007; Youngstrom 2014) (see Characteristics of studies awaiting classification). We classified five listings in clinical trial registries as 'potentially relevant' ongoing studies (see Characteristics of ongoing studies); two of these trials were marked as not yet recruiting (NCT04904328; NCT05206747), one study was marked as active but not recruiting (NCT03114072), one trial was marked as recruiting (NCT04578249), and one study was marked as having completed study participant recruitment but had not published their study results (ChiCTR1800020191).

Included studies

We included 17 unique trials that had published full texts. Table 1 presents the key characteristics of these studies, including their designs, participant population(s), comparator(s), recruited sample size, and intervention duration. Further study-specific details are provided in the Characteristics of included studies table.

Types of studies

The 17 trials were published between 2009 and 2021. Of these, nine had a parallel-arm trial design (Burkhart 2009; Danilenko 2019; Esaki 2017; Esaki 2020; Henriksen 2016; Henriksen 2020; Janku 2020; Lin 2017; Singh 2021), and the remaining eight trials were cross-over studies.

The unit of randomisation was the participant in all studies, and the unit of analysis was also the participant in most studies (Alzahrani 2021; Alzahrani 2020; Bigalke 2021; Burkhart 2009; Dabrowiecki 2020; Danilenko 2019; Esaki 2017; Esaki 2020; Henriksen 2016; Henriksen 2020; Janku 2020; Knufinke 2019; Lin 2017; Perez Algorta 2018; Shechter 2018; Singh 2021). In one study, the unit of analysis was a randomly selected eye (Hammond 2015).

Types of participants

In total the 17 included studies recruited 619 participants, with individual sample sizes ranging from five to 156 participants. The intervention duration ranged from less than one day to five weeks, but was not reported in three studies (Alzahrani 2021; Alzahrani 2020; Hammond 2015).

The studies were conducted across six countries: five in the USA (Bigalke 2021; Burkhart 2009; Hammond 2015; Lin 2017; Shechter 2018), two in Norway (Henriksen 2016; Henriksen 2020), two in Japan (Esaki 2017; Esaki 2020), one in the UK (Perez Algorta 2018), one in Australia (Singh 2021), and one in the Czech Republic (Janku 2020). Five studies did not report the country in which the trial was conducted (Alzahrani 2021; Alzahrani 2020; Dabrowiecki 2020; Danilenko 2019; Knufinke 2019).

The participant inclusion criteria varied across the included studies, as follows.

- Healthy volunteers with uncorrected vision or contact lens–corrected vision of 20/30 or better with both eyes (Lin 2017)
- Symptomatic computer users (Singh 2021)
- Participants with no history of ocular disease or abnormal vision (Alzahrani 2020)
- Recreational athletes (Knufinke 2019)
- Radiology residents (Dabrowiecki 2020)
- Participants with bilateral pseudophakia and ≥3 months post-implantation with clear IOLs (Hammond 2015)
- Undergraduate students with sleep complaints/disorders (Perez Algorta 2018)
- Participants with chronic insomnia symptoms (Shechter 2018)
- Participants with sleep difficulty (sleep onset insomnia, mid-sleep insomnia, and terminal insomnia) (Burkhart 2009)
- Participants with bipolar disorder diagnosis (Esaki 2020; Henriksen 2016; Henriksen 2020)
- Participants with an insomnia diagnosis (Janku 2020)
- Participants with major depressive disorder with sleep onset insomnia (Esaki 2017)
- Participants with major depressive disorder or persistent depressive disorder (dysthymia) (Danilenko 2019)
- Healthy participants with no information relating to the inclusion criteria (Alzahrani 2021; Bigalke 2021)

Types of interventions

All trials compared blue-light filtering spectacle lenses with non-blue-light filtering spectacle lenses.

Table 1 provides details of the type of blue-light filtering spectacle lenses used in the included trials. Although most studies investigated and compared one type of blue-light filtering spectacle lens with a non-blue-light filtering spectacle lens, two studies compared different brands of blue-light filtering spectacle lenses with non-blue-light filtering lenses (Alzahrani 2021; Alzahrani 2020), and one study compared blue-light filtering spectacle lenses that attenuated a relatively high or low percentage of blue light, with non-blue-light filtering spectacle lenses (Lin 2017).

Outcomes

Most of the studies included in this review reported the outcome(s) at a shorter follow-up period of two weeks or less. The time point of interest defined in our protocol involved outcomes measured at one month of follow-up, with an acceptable follow-up range of between two weeks and three months (Downie 2019b). The exception to this was the measure of the proportion of eyes, or individuals, with a finding of a pathological structural change at the macula, measured at 12 months (with an acceptable follow-up range of six to 24 months).

To ensure maximum representation of the available evidence, we have descriptively reported the outcomes from studies with reported follow-up times that are different to those defined a priori in our protocol.

Primary outcomes - visual fatigue

Three trials reported change in subjective visual fatigue or discomfort scores (Dabrowiecki 2020; Lin 2017; Singh 2021). One study measured this outcome using a visual analogue scale (Singh 2021), and the other two studies used Likert scales (Dabrowiecki 2020; Lin 2017). One trial reported change from baseline data (Singh 2021), one trial presented change from baseline scores and reported data in the form of figures (Lin 2017), and one study

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reported average daily change in visual fatigue scores over a five-day period, compared to change from baseline or endpoint outcomes (Dabrowiecki 2020).

Two studies reported CFF data (Lin 2017; Singh 2021), with one study reporting change from baseline (Singh 2021), and the other study presenting data in the form of figures without reporting quantitative data (Lin 2017).

Secondary outcomes

Best-corrected visual acuity

One cross-over trial measured logMAR visual acuity (Hammond 2015). The unit of analysis in this study was a randomly selected eye (right or left). BCVA was quantified by having participants wear each of the study lenses in a randomised order.

Daytime alertness

Although none of the included studies explicitly reported the proportion of participants who had reduced daytime alertness, two trials quantified parameters relevant to this outcome (Janku 2020; Knufinke 2019). One trial measured daytime alertness using the Hyperarousal Scale (HAS), with scores ranging from 0 to 73, and reported change from baseline (Janku 2020). Another trial measured morning and evening alertness using the Karolinska Sleepiness Scale (KSS), with scores ranging from 0 to 9, and reported the daily average change in outcome, rather than change from baseline or endpoint data (Knufinke 2019).

Sleep quality

Six trials assessed outcomes related to subjective sleep quality (Burkhart 2009; Esaki 2017; Esaki 2020; Janku 2020; Knufinke 2019; Shechter 2018). Of these, four trials used Likert scales (Burkhart 2009; Janku 2020; Knufinke 2019; Shechter 2018), and two trials used a visual analogue scale (Esaki 2017; Esaki 2020). One study did not provide quantitative data (Burkhart 2009), three trials reported change from baseline data (Esaki 2017; Esaki 2020; Janku 2020), and two studies reported the daily average change in the outcome rather than the change from baseline or endpoint data (Knufinke 2019; Shechter 2018).

Other outcomes

None of the included trials assessed the following outcomes:

- 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;
- change in serum melatonin levels, measured in pg/mL;
- overall patient satisfaction with their visual performance, measured using questionnaires or rating scales.

Adverse events

Among the 17 included trials, nine assessed adverse events (Danilenko 2019; Burkhart 2009; Esaki 2017; Esaki 2020; Henriksen 2016; Janku 2020; Perez Algorta 2018; Shechter 2018; Singh 2021). Together, these studies included 333 participants. Of these, four studies (n = 130) reported an adverse event (Danilenko 2019; Esaki 2017; Esaki 2020; Henriksen 2016); details relating to these adverse events are summarised in Table 2.

Excluded studies

Following the full-text screening stage, we excluded 32 studies. The primary reason(s) for excluding each study is provided in the Characteristics of excluded studies table.

The most common reasons for excluding studies were due to the study having an ineligible design (non-RCT) (Al-Azawi 2019; Cozza 2020; Ide 2015; Ishizawa 2021; Kaido 2016; Leung 2017; Luria 1972; Monteiro 2017; NCT04076410; Otsuka 2020; Phelps 2016; Rosenfield 2020; Sasseville 2006; Shirahama 2018; Smotek 2019; Teran 2020), not investigating blue-light filtering spectacle lenses (Bennett 2009; Danilenko 2016; Figueiro 2011; Figueiro 2013; Figueiro 2020; NCT02982239; NCT03831919; NL9458; Redondo 2020; Sasseville 2006; Wood 2013), the comparator not being a non-blue-light filtering lens (NCT04463498; NCT04804501; RBR-3snw7t, NCT05177055), or the spectacle lenses not being similar across the intervention and comparator groups (NCT04827446).

Five trials were listed as 'ongoing'; study details are provided in the Characteristics of ongoing studies table.

Risk of bias in included studies

Figure 2 and Figure 3 summarise the risk of bias assessments for the included studies. Details related to risk of bias judgements for individual studies are summarised in the Characteristics of included studies table.

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Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study

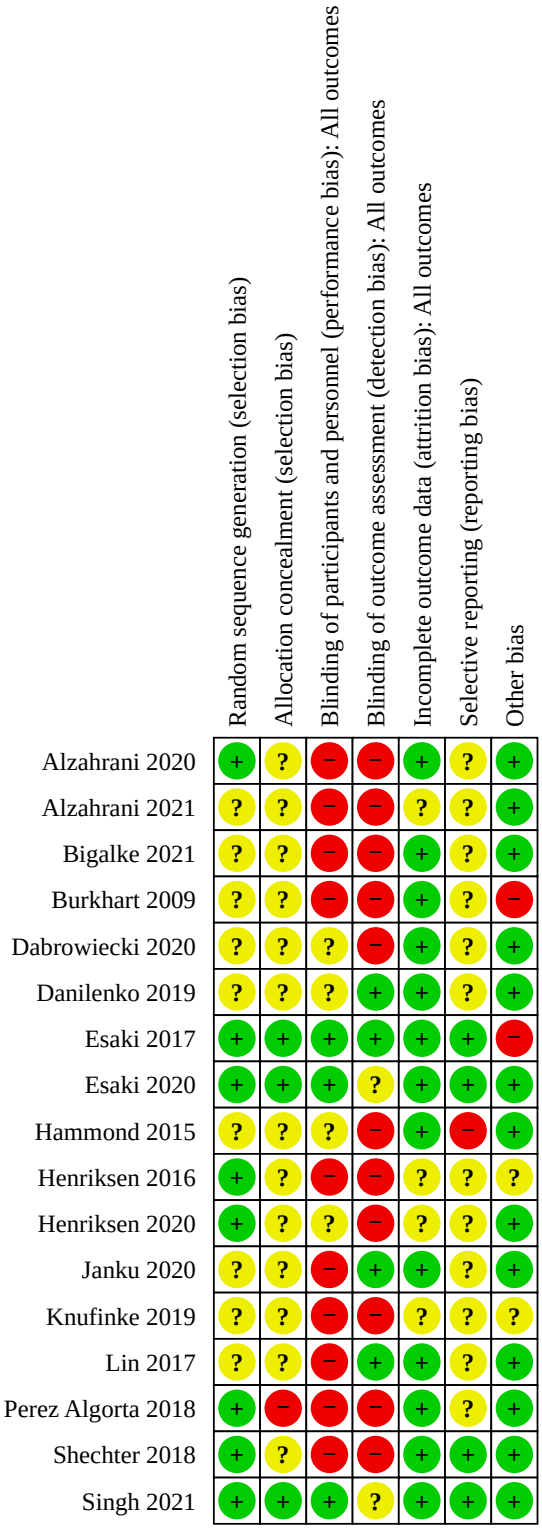

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Figure 2. (Continued)

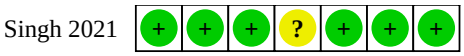
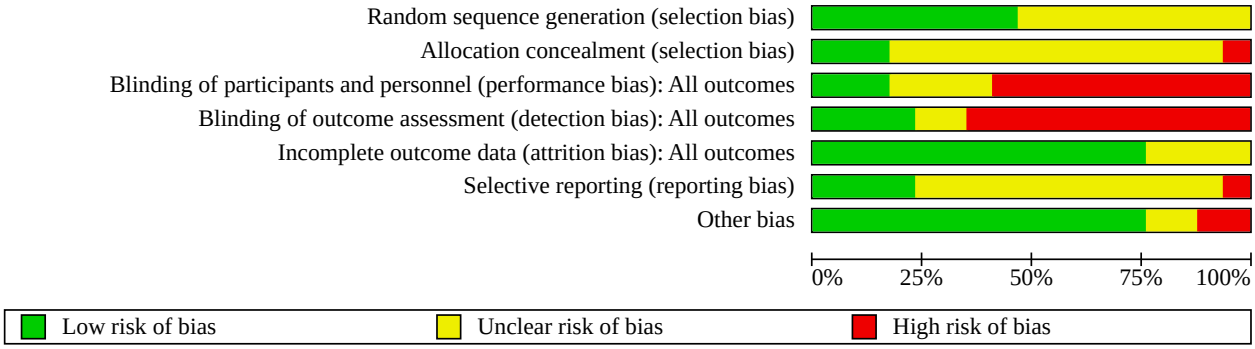


Figure 3. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies



Of the 17 included trials, none were judged to have a low risk of bias across all seven domains. We judged three studies to have low risks of bias in six out of seven domains (Esaki 2017; Esaki 2020; Singh 2021).

Across all eligible trials, the most well-reported domain was incomplete outcome data (attrition bias), with 76% of included trials considered to have low risk of bias in this methodological criterion. We judged more than half of the studies to have a high risk of performance bias and detection bias, due to the studies not masking participants, personnel, or outcome assessors, or at least one of these parties.

Allocation

Sequence generation

Eight trials (40%) reported how the randomisation sequence was generated, and we judged these to have a low risk of bias in this domain. Six trials used computer software (Alzahrani 2020; Esaki 2017; Esaki 2020; Perez Algorta 2018; Shechter 2018; Singh 2021), and two trials from the same research group used a manual drawing method (Henriksen 2016; Henriksen 2020). Nine trials were described as 'randomised' but did not report how the random sequence was generated; we judged these trials to have an unclear risk of bias for this domain (Alzahrani 2021; Bigalke 2021; Burkhart 2009; Dabrowiecki 2020; Danilenko 2019; Hammond 2015; Janku 2020; Knufinke 2019; Lin 2017). None of the trials had a high risk of bias for this domain.

Allocation concealment

We judged three trials (18%) to have a low risk of bias for allocation concealment. One study used computer-generated files that concealed the allocation (Singh 2021), one study used sealed envelopes (Esaki 2017), and in another study allocation was performed by personnel not otherwise involved in the study (Esaki 2020).

Thirteen trials (76%) did not report the method of allocation concealment, and we judged these to have an unclear risk of bias in this domain (Alzahrani 2021; Alzahrani 2020; Bigalke 2021; Burkhart 2009; Dabrowiecki 2020; Danilenko 2019; Hammond 2015; Henriksen 2016; Henriksen 2020; Janku 2020; Knufinke 2019; Lin 2017; Shechter 2018). We considered one study to have a high risk of bias as the principal investigator delivered the study intervention and no information was provided about allocation concealment (Perez Algorta 2018).

Blinding

For performance bias, three studies clearly specified the masking of study participants and study personnel, and we judged these to have a low risk of bias (Esaki 2017; Esaki 2020; Singh 2021). Four trials only masked study participants, and no information was provided about possible masking of the study personnel involved with delivering the intervention. Hence, we judged the potential risk of performance bias for these studies to be unclear (Dabrowiecki 2020; Danilenko 2019; Hammond 2015; Henriksen 2020). Nine trials did not report whether participants and study personnel were masked (Alzahrani 2021; Alzahrani 2020; Bigalke 2021; Burkhart 2009; Janku 2020; Knufinke 2019; Lin 2017; Perez Algorta 2018; Shechter 2018), and in one study participants were masked, but the study personnel involved with delivering the study intervention were not masked (Henriksen 2016). We judged these 10 trials to have a high risk of performance bias.

For masking of outcome assessors (detection bias), we judged four trials to have a low risk of bias (Danilenko 2019; Esaki 2017; Janku 2020; Lin 2017). One trial was described as 'double-blind', but did not provide details with regard to how this was achieved (Esaki 2020). One trial reported how the masking of outcome assessors was achieved, but on analysing the outcome assessors' guessing of participant assignment to the study groups, this level of masking was reported to be unsuccessful (Singh 2021). We considered both of these studies to have an unclear risk of detection bias. Eleven trials had a high risk of bias for this domain, due to the studies providing no information relating to the masking of outcome

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assessors (Alzahrani 2021; Alzahrani 2020; Bigalke 2021; Burkhart 2009; Dabrowiecki 2020; Hammond 2015; Henriksen 2020; Knufinke 2019; Perez Algorta 2018; Shechter 2018), or the study explicitly reporting that the outcome assessor was not masked (Henriksen 2016).

Incomplete outcome data

Thirteen trials (76%) had a low risk of attrition bias (Alzahrani 2020; Bigalke 2021; Burkhart 2009; Dabrowiecki 2020; Danilenko 2019; Esaki 2017; Esaki 2020; Hammond 2015; Janku 2020; Lin 2017; Perez Algorta 2018; Shechter 2018; Singh 2021), either because there were no losses to follow-up, or missing data were less than 20% and there was equal follow-up between the study arms with no obvious reasons for the loss of follow-up to be linked to the outcome. We judged the risk of attrition bias to be unclear in four studies, as the follow-up was not clearly stated (Alzahrani 2021; Knufinke 2019), or the trials had missing data of more than 20% with equal follow-up across the study arms (Henriksen 2016; Henriksen 2020). Two studies specifically reported undertaking intention-to treat analyses (Esaki 2020; Henriksen 2016). We did not judge any of the trials to have a high risk of attrition bias.

Selective reporting

Eleven trials (65%) did not report information about registration in a clinical trial registry, and lack of this information led to a judgement of an unclear risk of reporting bias (Alzahrani 2021; Alzahrani 2020; Bigalke 2021; Burkhart 2009; Dabrowiecki 2020; Danilenko 2019; Henriksen 2016; Janku 2020; Knufinke 2019; Lin 2017; Perez Algorta 2018). We considered one other study to have an unclear risk of bias, as the study commenced recruitment in February 2012 but only registered the study protocol in March 2013 (Henriksen 2020). We judged four trials to have a low risk of reporting bias as they reported all the prespecified study protocol outcomes in the final published paper (Esaki 2017; Esaki 2020; Shechter 2018; Singh 2021). We judged one trial to be at high risk of reporting bias, as a "glare disability threshold" outcome was reported in the final published paper but not mentioned in the prior registered study protocol (Hammond 2015).

Other potential sources of bias

No other potential sources of bias were identified in 13 trials (Alzahrani 2021; Alzahrani 2020; Bigalke 2021; Dabrowiecki 2020; Danilenko 2019; Esaki 2020; Hammond 2015; Henriksen 2020; Janku 2020; Lin 2017; Perez Algorta 2018; Shechter 2018; Singh 2021). Two trials had an unclear risk of 'other' sources of bias (Henriksen 2016; Knufinke 2019). Henriksen 2016 stopped early due to growing public awareness on blue-light filtering lenses. In Knufinke 2019, the effects of allowing only a one-day washout period for one of the study intervention groups (light-emitting goggles) was unclear, resulting in lack of complete information to judge this domain. We considered two trials to be at high risk of 'other' potential sources of bias due to reported significant baseline differences between the participant groups that might have impacted the overall study findings (Burkhart 2009; Esaki 2017).

Effects of interventions

See: **Summary of findings 1** Summary of findings 1: blue-light filtering lenses compared to non-blue-light filtering lenses

See: Summary of findings 1 for the main comparison of blue-light filtering lenses compared to non-blue-light filtering lenses for prespecified outcomes.

Primary outcome: change in visual fatigue or discomfort scores

Three trials reported data relating to visual fatigue or discomfort scores, with follow-up periods ranging from less than one day (Lin 2017; Singh 2021) to five days (Dabrowiecki 2020). These three trials included both parallel-arm (Lin 2017; Singh 2021) and cross-over designs (Dabrowiecki 2020). Two trials reported change form baseline data (Lin 2017; Singh 2021), and one study reported the average daily change in visual fatigue scores over the quantified five-day period (Dabrowiecki 2020). Measurement tools included both Likert scales (Dabrowiecki 2020; Lin 2017) and a visual analogue scale (Singh 2021). The participant eligibility criteria differed between the studies, involving the recruitment of healthy volunteers (Lin 2017), symptomatic computer users (Singh 2021), and radiology residents (Dabrowiecki 2020). The unit of analysis was per participant for all three trials.

We did not conduct a meta-analysis as only one study reported quantitative data that could be used to calculate the effect size of interest (Singh 2021). Singh 2021 reported no significant difference for the change in subjective visual fatigue scores among symptomatic computer users, measured as the change pre- and post-computer task (two hours) with blue-light filtering lenses compared to non-blue-light filtering lenses (mean difference (MD) 9.76 units, 95% confidence interval (CI) -33.95 to 53.47 units; P = 0.66; 120 participants). One trial that included 36 participants reported no significant difference between intervention arms for the change in visual fatigue score, but did not provide quantitative data (Lin 2017). The third trial included 10 participants and reported no change for the average daily change in visual fatigue score with blue-light filtering lenses compared to non-blue-light filtering lenses (Dabrowiecki 2020).

We used the GRADE approach to judge the certainty of the body of evidence for this outcome and downgraded the certainty by two levels to low, as in two studies participant/personnel or outcome assessors were not masked, and one study had wide confidence intervals (Singh 2021).

Primary outcome: change in CFF

Two trials reported data related to the change in CFF, with a follow-up of less than one day (Lin 2017; Singh 2021). Both trials used a parallel-arm design. One trial recruited healthy participants (Lin 2017) and the other recruited symptomatic computer users (Singh 2021). The unit of analysis was per participant for both trials. Singh 2021 reported no change in CFF with blue-light filtering lenses compared to non-blue-light filtering lenses (MD -1.13 Hz, 95% CI, -3.00 to 0.74 Hz; P = 0.24). Lin 2017, involving 36 participants, described a significant difference between 'high' blue-light filtering lenses compared to both 'low' blue-light filtering (P = 0.008) and non-blue-light filtering lenses (P = 0.027). However, this trial did not report quantitative data (Lin 2017).

We judged the certainty of evidence as low for this outcome, downgrading by one level each for inconsistency of results (as one study reported no significant intergroup differences and one study reported a positive effect with 'high' block blue-light filtering

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lenses), and risk of bias (as one study was at high risk of bias in the domain relating to masking of study participant and personnel).

Secondary outcome: change in BCVA

One cross-over trial reported findings relevant to the measure of BCVA, measured in logMAR units without glare conditions (Hammond 2015). This trial included 156 bilateral pseudophakic participants, and the unit of analysis was a single eye. The follow-up period of this study was unclear. The trial reported no difference in logMAR BCVA between blue-light filtering lenses and non-blue-light filtering lenses (MD 0.00, 95% CI -0.02 to 0.02 log units; P = 0.86). These results should be interpreted with caution as the study did not report the total number of participants included/excluded for this outcome measure; we made the assumption that all recruited participants completed the study.

We judged the certainty of evidence for this outcome as moderate using GRADE, and downgraded by one level for risk of bias as the study outcome assessor was not masked in the study that assessed this outcome.

Secondary outcome: change in contrast sensitivity

None of the 17 included trials provided data related to contrast sensitivity.

Secondary outcome: change in discomfort glare

None of the 17 included trials provided data related to discomfort glare.

Secondary outcome: proportion of eyes, or individuals, with a finding of pathological structural change at the macula

None of the 17 included trials reported on macular structural changes.

Secondary outcome: change in colour discrimination

None of the 17 included trials provided data related to colour discrimination.

Secondary outcome: daytime alertness, considered as the proportion of participants who had reduced daytime alertness

None of the included trials described the proportion of participants who had reduced daytime alertness. However, two studies measured alertness using Likert scale-based questionnaires (Janku 2020; Knufinke 2019); one used a cross-over design (Knufinke 2019) and the other used a parallel-group design (Janku 2020).

Janku 2020, involving 27 people diagnosed with insomnia, measured the change in daytime alertness using the Hyperarousal Scale (HAS), with scores ranging between 0 and 73 (scores above 40 indicate increased arousal levels). This trial reported no difference in HAS scores between participants using blue-light filtering and non-blue-light filtering lenses over five weeks (MD 1.24 units 95% CI -4.93 to 7.41 units; P = 0.69).

The cross-over trial by Knufinke 2019 involved 15 recreational athletes and reported endpoint data for morning and evening alertness, measured using the Karolinska Sleepiness Scale (KSS), with scores ranging from 0 to 9 (higher scores indicating higher sleepiness). This trial reported no significant difference in the average daily change for both morning and evening alertness scores, measured between blue-light filtering and non-blue-light filtering lenses. However, this trial did not report change from baseline or endpoint outcome data.

We judged the GRADE certainty of evidence as very low and downgraded by three levels for risk of bias and imprecision, as in one study the participants and personnel were not masked, and in another study the study participants, personnel, and outcome assessor(s) were not masked. Both studies had small sample sizes.

Secondary outcome: change in serum melatonin levels

None of the 17 included trials provided information related to serum melatonin levels.

Secondary outcome: sleep quality

Six trials reported findings related to subjective sleep quality (Burkhart 2009; Esaki 2017; Esaki 2020; Janku 2020; Knufinke 2019; Shechter 2018). Together, these studies involved 148 participants with heterogeneous characteristics, and measured subjective sleep quality using a visual analogue scale or Likert scale-based questionnaire. The recruited study populations included recreational athletes (Knufinke 2019), participants with sleep difficulty (Burkhart 2009), participants with chronic insomnia symptoms (Shechter 2018), participants with a bipolar disorder diagnosis (Esaki 2020), participants with an insomnia diagnosis (Janku 2020), and participants with major depressive disorder and sleep onset insomnia (Esaki 2017). Trial follow-up periods ranged from one week (Shechter 2018) to five weeks (Janku 2020).

Three studies provided quantitative data related to sleep quality (Esaki 2017; Esaki 2020; Janku 2020). We did not perform a meta-analysis as the study population and follow-up periods varied between these studies. The key outcomes of the studies that reported subjective sleep quality are as follows.

- Esaki 2017, involving 20 participants with major depressive disorder and sleep onset insomnia, reported no significant difference for the change in subjective sleep quality measured using a visual analogue scale (0 = good sleep to 100 = poor sleep) at two weeks of follow-up, with blue-light filtering lenses compared to non-blue-light filtering lenses (MD 19.90 units, 95% CI -1.86 to 41.66 units; P = 0.07).
- Esaki 2020, involving 43 participants with bipolar disorder, measured the change in subjective sleep quality using a visual analogue scale (0 = good sleep to 100 = poor sleep), at two weeks of follow-up, and reported no significant difference between blue-light filtering lenses and non-blue-light filtering lenses (MD 8.90 units, 95% CI -6.13 to 23.93 units; P = 0.25).
- Janku 2020, involving 27 participants with insomnia, measured the change in subjective sleep quality after six weeks of follow-up, using the Pittsburgh Sleep Quality Index (PSQI). The PSQI ranges from 0 to 21, and a score of six was defined as the cut-off for significant insomnia symptoms. The study reported no significant difference between blue-light filtering lenses compared to non-blue-light filtering lenses (MD 0.03 units, 95% CI -2.53 to 2.59 units; P = 0.98).
- Burkhart 2009, involving 20 participants with sleep difficulty, measured the change in subjective sleep quality using a Likert scale (0 = very poor sleep and 10 = good sleep) and reported a significant improvement in sleep quality with blue-light filtering lenses compared to non-blue-light filtering lenses. This study

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presented the results in a figure and did not report the numeric data in the main text of the publication.

- Knufinke 2019, involving 15 participants who were "recreational athletes", reported an improvement in the daily average change in subjective sleep scores measured over nine days with blue-light filtering lenses compared to non-blue-light filtering lenses. This study did not report either the change from baseline or endpoint outcome data.
- Shechter 2018, involving 15 participants with chronic insomnia symptoms, measured the daily average change in subjective sleep scores over one week, and reported an improvement in subjective sleep with blue-light filtering lenses compared to non-blue-light filtering lenses. This study did not report change from baseline or endpoint data.

We judged the GRADE certainty of evidence as very low for this outcome and downgraded by three levels for risk of bias, as in four studies participants and study personnel were not masked, and in three studies outcome assessors were not masked. Two studies had other risks of bias due to significant baseline imbalances between participant groups. Further, the included studies had small sample sizes and reported variable findings.

Secondary outcome: overall patient satisfaction with their visual performance

None of the included trials provided information related to patient satisfaction with their visual performance.

Adverse outcomes

Table 2 summarises adverse events as reported in the included studies. Five of the nine studies that assessed adverse events did not report any such events (Burkhart 2009; Janku 2020; Perez Algorta 2018; Shechter 2018; Singh 2021). The reported adverse events in the other included studies were as follows.

- Henriksen 2016 (n = 32) reported increased depressive symptoms (n = 2) and headache (n = 1) in participants assigned to the blue-light filtering lens group. However, the authors did not explicitly state the proportion of adverse events in the non-blue-light filtering lens group.
- Esaki 2017 (n = 20) reported pain or discomfort from wearing the spectacles across both the blue-light filtering (n = 4) and non-blue-light filtering (n = 4) lens groups. However, the authors mentioned that the provided spectacles were of a single size, and concluded that the discomfort reported could be due to the spectacle frames, rather than the type of lenses, indicating the adverse events may not have been related to the study intervention itself.
- Danilenko 2019 (n = 35) reported no adverse events in the blue-light filtering lens group and that two participants in the non-blue-light filtering group were occasionally hyperthymic.
- Esaki 2020 (n = 43) reported discomfort from wearing the glasses (n = 2), pain from the face contacting part of the glasses (n = 1), and lowered mood (n = 1) in the blue-light filtering lens group. In the control group, participants reported discomfort from wearing the glasses (n = 3) and pain from the face contacting part of the glasses (n = 4).

We judged the GRADE certainty of evidence for this outcome as low. It was downgraded by one level each for risk of bias and inconsistency, as in four studies participants, study personnel and outcome assessors were not masked, and two studies had an 'other' risk of bias due to baseline imbalance. Further, we noted variability in the reported adverse events across the studies.

DISCUSSION

Blue-light filtering spectacle lenses have been widely advertised by some members of the optical industry, with claims that they can reduce visual fatigue from digital device use, protect the macula, and improve sleep quality. The mechanism(s) by which these lenses might impart at least some of these effects remains unclear. Despite this, the prescribing rate of blue-light filtering lenses among eye care practitioners has increased over the last decade (Singh 2019). The primary objective of this systematic review was to assess the effects of blue-light filtering spectacle lenses on eye strain, visual performance, macular health and sleep quality, in adult populations.

Summary of main results

This review identified 17 eligible RCTs in which blue-light filtering lenses were compared with non-blue-light filtering lenses. Individual study sample sizes ranged from five to 156 participants, with follow-up periods ranging from less than one day to five weeks. The studies were conducted in six countries, and included diverse study populations, ranging from healthy adults through to those with significant health conditions (e.g. bipolar disorder, insomnia). Overall, there was no high-certainty evidence for any of the prespecified outcome measures (see Summary of findings 1 for details). For risk of bias assessment, none of the included studies were judged to have 'low' risk of bias across all seven assessment domains. The two domains judged to have the lowest overall risk of bias across the included trials were 'incomplete outcome data' (attrition bias) and 'other potential sources of bias'.

We did not perform meta-analyses for any of the outcome measures due to a lack of available quantitative data in the study reports, heterogenous study populations, and the relatively short follow-up period in most studies (i.e. less than two weeks) compared to the follow-up period of interest defined in our protocol (being one month, with an acceptable range of between two weeks and three months). This highlights a research gap with respect to studies evaluating the longer-term effects of blue-light filtering spectacles, and led to the presentation of only descriptive syntheses in the present review.

Information relating to the efficacy outcome measures were available for: change in visual fatigue scores (three trials), change in CFF (two trials), change in BCVA (one trial), proportion of participants with reduced daytime alertness (two trials), and change in subjective sleep quality (six trials).

For the primary outcome measures, all three trials that investigated subjective visual fatigue reported no significant difference in symptoms with blue-light filtering lenses compared to non-blue-light filtering lenses (Dabrowiecki 2020; Lin 2017; Singh 2021). Of the two trials that investigated CFF, one double-masked RCT involving 120 participants with computer vision syndrome, reported no significant difference between blue- and non-blue-light filtering spectacle interventions (Singh 2021). Another study did not provide quantitative data but reported a difference between intervention arms, favouring a 'high' blue-light filtering spectacle lens type (Lin 2017). However, this study received industry funding,

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did not register the clinical trial, and did not mask outcome assessors (Lin 2017).

For the secondary outcome measures, the trial that assessed BCVA reported no significant difference between intervention arms (Hammond 2015). The two trials that evaluated daytime alertness using subjective symptom scores reported no significant difference between blue-light filtering and non-blue-light filtering lenses (Janku 2020; Knufinke 2019). For the subjective sleep outcome, different findings were reported across the studies, which likely relates to the highly divergent participant populations in the six trials. Three trials that provided quantitative data reported no significant difference in subjective sleep quality with blue-light filtering lenses compared to non-blue-light filtering lenses (Esaki 2017; Esaki 2020; Janku 2020). One trial with a small sample size (n = 20) that did not provide quantitative data reported an improvement in subjective sleep quality with blue-light filtering lenses compared to non-blue-light filtering lenses (Burkhart 2009). This trial had important baseline differences between the participant groups that might have had affected the reported results (Burkhart 2009). Two trials that did not mask participants, personnel or outcome assessors reported an average daily improvement in subjective sleep quality with blue-light filtering lenses compared to non-blue-light filtering lenses (Knufinke 2019; Shechter 2018).

For the safety outcomes, nine studies reported outcomes for adverse events. Of these, participants in four studies experienced adverse events (Danilenko 2019; Esaki 2017; Esaki 2020; Henriksen 2016), with three describing events that were considered related to the study intervention (Danilenko 2019; Esaki 2020; Henriksen 2016). Such events were generally mild, and mainly related to discomfort from wearing the spectacles. We did not perform meta-analyses as one study had a different participant population (Danilenko 2019), and another study did not report the proportion of adverse events in the non-blue-light filtering lens group (Henriksen 2016).

We did not identify any RCTs evaluating affects of blue-light filtering spectacle lenses on contrast sensitivity, discomfort glare, colour discrimination, macular health, or serum melatonin levels. In addition, none of the included studies evaluated overall patient satisfaction with their visual performance.

Overall completeness and applicability of evidence

The majority (94%) of the 17 included RCTs were published after 2010, indicating a growing interest in the area of blue-light filtering spectacle lenses over the last decade. The inclusion of a diverse group of participants across the included studies (refer to table of Included studies) limited our ability to perform meta-analyses, as did the lack of reported quantitative data in the study reports.

A notable finding was that 65% of included trials had a follow-up period of less than two weeks. As such, the longer-term potential benefits and adverse effects of blue-light filtering lenses on the prespecified outcomes investigated in this review are not known. On assessing the age group of the participant population across the included trials, 47% of the included trials investigated populations over 40 years of age. However, 88% of these studies specifically targeted populations with mania, depression and insomnia symptoms, with the intent of investigating the utility of blue-light filtering spectacle lenses for specific purposes (e.g. improving sleep quality). Hence, there was limited information relating to the effects of blue-light filtering lenses in healthy older adults. Based on the limited availability of data, it is unclear if there might be a difference in the measured outcomes among individuals less than 40 years old versus those over 40 years of age. This consideration is relevant, given that there is a natural reduction in blue light transmission within the eye associated with yellowing of the human crystalline lens; such effects may alter the relative efficacy of a blue-light filtering spectacle lenses as a function of participant age.

The three studies that evaluated subjective visual fatigue reported no significant difference between blue-light filtering lenses compared to non-blue-light filtering lenses (Dabrowiecki 2020; Lin 2017; Singh 2021). However, we judged only one trial to have robust methodology based on the risk of bias assessments, as defined by prospective clinical trial registration, allocation concealment, double-masking, and the development of an a priori data analysis plan before performing the formal data analyses (Singh 2021). Further, only the Singh 2021 trial recruited symptomatic computer users, who are the primary population that blue-light filtering lenses are marketed to. The other two trials enrolled computer users without specifying whether they were necessarily symptomatic of eye strain (Lin 2017), and radiology residents (Dabrowiecki 2020). Overall, the relatively consistent findings reported across the three trials that evaluated this outcome suggest blue-light filtering lenses may not reduce symptoms of visual fatigue with computer use compared to non-blue-light filtering lenses.

The two trials that evaluated CFF reported opposite findings (Lin 2017; Singh 2021). The industry-sponsored trial by Lin 2017 reported a significant benefit with a 'high' blue-light filtering lens product compared to both 'low' blue-light filtering and non-blue-light filtering lenses. However, the double-masked RCT by Singh 2021 reported no significant difference between blue-light filtering and non-blue-light filtering lenses for this outcome. Visually inspecting the plots in the trial report of Lin 2017, which did not provide numeric quantitative data, suggests an approximate change of 2 Hz with the 'high' blue-light filtering lenses; although described as "statistically significant", the clinical significance of this small change remains unclear. Two recent studies that evaluated the association between CFF and visual fatigue, determined via a symptom questionnaire, reported no association between these outcome measures (Anderson 2022; Yan 2022). These findings suggest that using CFF as a surrogate objective marker of visual fatigue symptoms, as has been adopted in previous studies, may not be appropriate.

Regarding the six studies that investigated subjective sleep quality, aside from one study that recruited recreational athletes (Knufinke 2019), none included healthy individuals, and instead focused on evaluating whether blue-light filtering lenses might have benefit in individuals with significant health disorders, including insomnia, manic depression and bipolar disorder. This finding was unexpected given that computer users are a key consumer population targeted by the optical industry with claims that blue-light filtering lenses can benefit sleep cycles. The overall body of evidence relating to the potential role of blue-light filtering lenses for promoting subjective sleep quality is inconclusive, given the high degree of variability reported across the included studies.

Although the link between blue-light exposure and age-related macular degeneration in humans remains unclear, there have been

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claims by certain members of the optical industry and mainstream media that blue light can cause retinal phototoxicity, and that blue-light filtering lenses offer protection against such damage (Singh 2019). None of the 17 studies included in this review evaluated the role of blue-light filtering lenses for protecting the macula. As such, we were unable to identify any RCT evidence to support the application of blue-light filtering lenses, in preference to non-blue-light filtering lenses, for providing macular protection. Such studies have a range of practical challenges with their execution, including the need to evaluate large groups of individuals over protracted periods of time in order to detect potential intergroup differences in the outcome of interest. Nevertheless, it is important that consumers and practitioners are aware of the lack of current clinical studies evaluating whether blue-light filtering lenses have any utility in this potential application.

Despite the establishment of the International Medical Device Regulators Forum (IMDRF) in 2011, adverse events were not consistently assessed or reported in the included trials. Three of the nine studies that assessed adverse events reported side effects that were deemed to be associated with the study intervention (Danilenko 2019; Esaki 2020; Henriksen 2016). All the adverse events were relatively mild, with studies reporting increased depressive symptoms, headache, and discomfort from wearing the glasses. Similar symptoms of discomfort from wearing glasses were reported, along with occasional hyperthymia, in participants assigned to non-blue-light filtering lenses. It should be noted that these three studies involved participants with bipolar or depressive disorders. The rate of adverse events with blue-light filtering lenses compared to non-blue-light filtering in healthy individuals thus remains uncertain. As this is the population that typically presents for routine eye care and is prescribed these lenses, there is a need to ensure that future trials fully report adverse events, in order to obtain a more comprehensive (and generalisable) understanding of any potential side effects.

Another important consideration with interpreting the presented findings is that the included studies used a wide range of blue-light filtering spectacle lens products that filter blue light by different amounts (see Table 1 for details). Given a lack of suitable available data, subgroup analyses could not be performed to assess whether there was any difference between blue-light filtering lenses that attenuate different amounts of blue light for the prespecified study outcome measures. This is another relevant question that might be addressed with the availability of data from future studies.

Overall, as only one study evaluated the potential change in BCVA with the use of blue-light filtering lenses compared to non-blue-light filtering lenses, current evidence for effect(s) on this outcome suggests little or no effect. There is also currently no RCT evidence to draw conclusions on whether blue-light filtering lenses modify aspects of visual performance (i.e. discomfort glare, contrast sensitivity and colour discrimination), serum melatonin levels, or their potential effect(s) on patient visual satisfaction, compared with non-blue-light filtering lenses.

Quality of the evidence

Overall, we graded the certainty of the body of evidence for all prespecified outcomes as moderate, low or very low, using the GRADE approach (see Summary of findings 1 for details).

We judged the certainty of the evidence for both the primary outcomes (subjective visual fatigue score and CFF) to be low. For subjective symptom scores, we downgraded the evidence due to a high risk of bias detected across domains relating to performance bias and detection bias, and due to imprecision (wide confidence intervals). For the CFF outcome, we downgraded evidence certainty due to a high risk of performance bias and due to inconsistent findings between studies (with one study reporting positive effects with blue-light filtering lenses and another study reporting no significant difference between the study groups).

For BCVA, we downgraded the certainty of evidence to moderate due to a high risk of detection bias. We downgraded the certainty of evidence for the subjective sleep score outcome to very low, due to studies having small sample sizes and reporting variable findings, and high risks detected across the domains of performance bias, detection bias, and other bias (studies reporting significant baseline imbalance).

We downgraded the certainty of evidence for adverse events to low, due to inconsistency in the reported study findings and our evaluation of high risks of bias for selection bias, performance bias, detection bias, and other risk of bias (studies reporting significant baseline imbalance between the participant groups).

Potential biases in the review process

We followed the standard methodological procedures recommended by Cochrane to minimise any potential bias in the conduct of this systematic review. Two of the review authors (SS and LED) were first- (SS) and senior-authors (LED), respectively, on one of the studies included in this review (Singh 2021). For this study, two independent review authors (JL and CH) performed the risk of bias assessment and consensus. Overall, we consider this process to have mitigated this potential bias.

Agreements and disagreements with other studies or reviews

A previous systematic review investigated the potential benefits and harms of blue-light filtering lenses on visual performance, macular health and the sleep-wake cycle (Lawrenson 2017). The review included both randomised and pseudo-randomised controlled trials, and three studies met the authors' eligibility criteria. All three studies were reported to have an unclear or high risk of selection bias. Overall, the review found a lack of high-quality evidence to support the use of blue-light blocking lenses by the general population to improve ocular health, sleep patterns or eye strain, compared to non-blue-light filtering lenses. The findings reported in the systematic review by Lawrenson 2017 broadly align with the findings in the current review.

One recently published systematic review evaluated the benefits and harms of interventions available for the treatment of computer vision syndrome (Singh 2022). This review included only RCTs and considered outcomes related to visual fatigue symptoms, CFF, quality of life, dry eye symptoms, amplitude of accommodation, near point of convergence, blink rate, overall patient satisfaction, and adverse events. This review investigated a diverse range of interventions, including a comparison between blue-light filtering versus non-blue-light filtering spectacle lenses. The review included three RCTs that had evaluated visual fatigue symptoms, and two studies that had quantified CFF; these studies mirror those

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included in the current review. Singh 2022 reported there may be no overall effect on visual fatigue, and little to no effect on CFF, with blue-light filtering lenses compared to non-blue-light filtering lenses. These findings are similar to the appraisal of the evidence in the current review.

Another recent systematic review investigated the effect of blue-light filtering lenses (both spectacles and IOLs) on the progression of age-related macular degeneration, visual fatigue symptoms, and sleep quality (Vagge 2021). The review reported individual study findings to be inconsistent in relation to the potential application of blue-light blocking devices for protecting macular health, reducing visual fatigue, or promoting sleep quality. Although these findings are broadly consistent with the current review, it should be noted that this review by Vagge 2021 was not prospectively registered on a public systematic review registry, did not perform risk of bias assessments on the included studies, and did not evaluate the overall evidence certainty using an approach such as GRADE.

Two other systematic reviews have evaluated the effects of blue-light filtering spectacle lenses on sleep-related outcomes (Hester 2021; Shechter 2020). Shechter 2020 included 12 studies with study populations comprising both healthy individuals and people with pathological conditions (i.e. medical, psychiatric, sleep, or circadian rhythms disorders). Shechter 2020 concluded there to be some evidence that the use of blue-light filtering lenses can improve sleep in people with certain pathological conditions. The other systematic review included 29 studies with heterogeneous study designs (Hester 2021). This review focused on clinical populations with sleep and mood disorders, and concluded that blue-light filtering lenses could improve sleep in people reporting insomnia or a delayed sleep phase. However, the review by Hester 2021 was not prospectively registered and risk of bias assessments were not undertaken. The findings reported in the systematic reviews by Hester 2021 and somewhat contrast with those reported in the current review. A likely reason is that the current review included only RCTs, whereas Shechter 2020 included RCTs, single-arm trials and pre-/post-intervention designs, and Hester 2021 included RCTs, uncontrolled trials, a case series and a case study. The inclusion of study designs with the potential for more bias reduces the certainty of the conclusions in these earlier reviews, and thus their findings should be interpreted with caution.

A prior Cochrane Review and meta-analysis by Downie 2018 examined the potential benefits and adverse effects of blue-light blocking IOLs, compared to non-blue-light blocking IOLs, for protecting macular health, and modulating visual function (i.e. BCVA, colour discrimination and contrast sensitivity). Based on analysing data from 51 eligible RCTs, the authors concluded that there was a lack of clinical evidence to support the use of blue-light blocking IOLs for protecting macular health, or altering the risks associated with the development and progression of AMD (Downie 2019). The authors found no significant difference in short-term BCVA between blue-light blocking IOLs and non-blue-light blocking IOLs. Furthermore, there were no relevant combinable data to ascertain the potential effects of blue-light blocking IOLs on contrast sensitivity or colour discrimination. The findings related to visual function, and macular health outcomes were similar to the findings reported in the current review that investigated blue-light filtering spectacle lenses.

AUTHORS' CONCLUSIONS

Implications for practice

Based on the current best available research evidence, this systematic review finds that there may be no clinically meaningful difference in short-term (less than one day) subjective visual fatigue scores or critical fusion frequency (CFF) with the use of blue-light filtering lenses compared to non-blue-light filtering lenses.

Our ability to draw conclusions about the effect of blue-light filtering spectacle lenses on many of the prespecified secondary outcomes was limited by the available evidence, with most trials not reporting quantitative data, having shorter follow-up periods than the period of interest defined in our systematic review protocol, or heterogeneous study populations that limited our capacity for quantitative syntheses.

There may be no difference between blue-light filtering and non-blue-light filtering spectacle lenses with respect to best-corrected visual acuity (BCVA), based on one study with a follow-up period of less than one day. We are highly uncertain of whether blue-light filtering lenses affect daytime alertness relative to non-blue-light filtering lenses. The study follow-up periods for daytime alertness ranged from seven days to five weeks. For subjective sleep quality, with study follow-up periods ranging between one and five weeks, limited quantitative data were available, and individual studies investigated different study populations; the effect of blue-light filtering spectacles on this outcome thus remains very uncertain. Overall, the main reasons for downgrading the certainty of the evidence were due to risks of bias (i.e. performance bias, detection bias and other bias).

As none of the eligible trials evaluated outcomes related to contrast sensitivity, discomfort glare, colour discrimination, effects on macular health, serum melatonin levels or overall patient visual satisfaction, we are unable to comment on the potential effect(s) of blue-light filtering lenses, relative to non-blue-light filtering lenses, on these outcomes. Further, there is no clear evidence from reports of adverse events that blue-light filtering spectacle lenses are unsafe to wear.

Overall, based on relatively limited clinical trial data, these findings do not support the prescription of blue-light filtering lenses to the general population for the purpose of reducing visual fatigue or enhancing BCVA. Potential effects on sleep are indeterminate due to lack of clarity with respect to how individuals with different medical conditions might, or might not, respond differentially to the intervention.

Implications for research

Beyond the putative link between blue light and (temporary) visual fatigue from computer use, from a public health perspective a particularly concerning notion is the prospect that environmental blue-light exposure might induce permanent retinal damage, and promote the development or progression of age-related macular degeneration (AMD). This association remains controversial (Downie 2019). The current review did not identify any randomised controlled trial (RCT) evidence from which to draw conclusions regarding whether blue-light filtering spectacle lenses impart macular protection. Although environmental light sources (e.g. lights and electronic devices) might irradiate the eye for an extended period, the amount of blue light emitted from these

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sources is significantly less than the amount of blue light from natural daylight (de Gálvez 2022; O'Hagan 2016). For longer-term viewing, the International Commission on Non-ionising Radiation Protection (ICNIRP) has suggested exposure limits of greater than 100 W m^{-2} sr^{-1} can cause ocular damage; however, the amount of blue light emitted from electronic devices has been measured to be between 0.034 to 0.380 W m^{-2} sr^{-1}; at least 100-fold less than the intensity considered to have the potential to cause eye damage. Based on these data, it is unlikely that environmental sources of blue light will cause retinal damage.

While the current epidemiological evidence suggests the risk of blue-light-induced retinal damage from regular environmental exposure is low (Darzins 1997; Delcourt 2001; McCarty 2001; Taylor 1992), any measure that might prevent or reduce the risk of AMD, or slow its progression, has the potential to have broad public health benefit. Hence, there may be merit in future studies evaluating whether blue-light filtering spectacle lenses confer any degree of macular protection. Such studies are, however, practically challenging, likely requiring very large sample sizes, with clinical evaluation over years (possibly decades, depending on the study population) to ascertain any potential benefit(s).

In relation to trial follow-up periods, most studies included in this review had follow-up periods of less than four weeks. This limited period of evaluation restricted our ability to consider the potential longer-term outcomes from the use of blue-light filtering lenses. Future studies with longer follow-up periods are warranted, as appropriate to the intended research question. As discussed above, identifying macular structural change might require a follow-up period of several years, whereas studies evaluating sleep may optimally address questions relating to efficacy or safety over follow-up periods of weeks to months.

The observed inconsistency in findings related to subjective sleep outcomes likely reflects the variability in the study populations among included studies. Given the rationale that any potential effects on sleep may be population dependent, there is a need for more studies that investigate specific participant populations; this would potentially then allow for data pooling across several studies investigating the same study population, to provide more certain evidence about any effects on sleep in specific segments of the population, including healthy adults.

Sixty-five per cent of included trials were not registered on a clinical trial registry, resulting in an inability to assess the risk of reporting bias in these studies. This finding is surprising, given that prospective registration of clinical trials has gained high importance in the last two decades, with journals making registration of study protocols compulsory to submit the research for publication (De Angelis 2006). Likewise, only 47% of included trials reported a sample size calculation, indicating a lack of clarity with respect to whether these studies were appropriately powered to find a difference between the interventions. These factors should be considered in the design and reporting of future RCTs.

The variability in the methodology and outcome measures used in the eligible RCTs highlights the potential benefit of developing a core outcome set, with an agreed set of measures to be quantified and reported in future clinical trials. The adoption, and associated reporting, of core outcome measures in RCT publications will, in the longer term, contribute to enhancing capacity to pool data across multiple studies in future meta-analyses, and thus assist with more clearly determining the efficacy and safety of the intervention. We did not identify any RCTs that assessed contrast sensitivity, discomfort glare, colour discrimination, serum melatonin levels, or patient visual satisfaction with blue-light filtering spectacle lenses. Given the clinical relevance of these parameters, we suggest that future studies consider their inclusion as outcome measures, and that they also be considered for potential inclusion in a relevant core outcome set.

For risk of bias assessment, the domains most frequently judged to be at a high risk of bias among eligible trials were related to a failure to mask participants, personnel or outcome assessors, or at least one of these parties. When possible, future studies should aim for a double-masked study design. Where masking is challenging (e.g. due to familiarity of the intervention to the participants due to the difference in colouration of blue-light filtering vs non-blue-light filtering lenses), any attempts to preserve masking should be described in the body of the manuscript and if masking was not achieved this should be clearly acknowledged. An assessment of masking integrity, as was evident in one trial (Singh 2021), would also be beneficial. This information will help in making appropriate judgements for these risk of bias domains in future reviews.

Overall, the results of this review indicate that future high-quality research is required to more clearly define the potential effects of blue-light filtering lenses on visual performance, sleep and macular health, including whether efficacy and safety outcomes are distinct in different study populations.

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CHARACTERISTICS OF STUDIES

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

Alzahrani 2020

Study characteristics	
Methods	**Study design**: RCT **Study grouping**: cross-over **Exclusions after randomisation**: not reported **How missing data were handled** (e.g. available case analysis, imputation, etc.): not reported **Losses to follow-up**: not reported **Other comments** (e.g. unusual study design/issues): the study had two separate protocols, "experiment 1" and "experiment 2", where each person only participated in one protocol. Each protocol had an internal cross-over design, where each participant undertook the experiment using all of the different blue-blocking lenses and the non-blue-blocking control in a random order. **Reported power calculation?** (Yes/No): no "The present study was not designed to provide population norms that would be achievable by using a larger sample size, although this may be the focus of a future study. Importantly, the sample size has been shown to be sufficient in power for a true-positive discovery, and in addition, partial η2 values are reported, which were typically large and demonstrated that larger sample size was unnecessary to the reported effects." **Trial duration**: not reported **Unit of randomisation/unit of analysis**: unit of randomisation and unit of analysis was per participant
Participants	**Country**: not reported **Total number participants**: 12 **Setting**: not reported **Baseline characteristics** • Number of participants: 12 • Sex (number of females/number of males): not reported • Age (range): mean not reported. Not reported (18 to 39 years) **Inclusion criteria**: not reported **Exclusion criteria**: Colour deficiencies; history of ocular disease

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Alzahrani 2020 *(Continued)*

	Comparison of study groups at baseline: Not applicable (cross-over)
Interventions	**Intervention characteristics** Blue-light filtering spectacle lens • Intervention name (e.g. spectacle lens name and manufacturer): four different blue-light filtering lenses were used: (UV++Blue Control (JuzVision, Bulli, NSW, Australia), Crizal Prevencia (Essilor, Silverwater, NSW, Australia), BlueGuardian (Opticare, Sydney, NSW, Australia), and Blu-OLP (GenOp, Rosebery, NSW, Australia) lenses). • Frequency with which the intervention (spectacle lenses) were worn over the trial duration: not reported • Other comments: "The participant was allowed to adapt to wearing each goggle for 2 minutes before starting the experiment." Non-blue-light filtering spectacle lens • Intervention name (e.g. spectacle lens name and manufacturer): Clear lens (CR-39 without a blue-light filtering coating, manufacturer - not reported) • Frequency with which the intervention (spectacle lenses) were worn over the trial duration: not reported • Other comments: "The participant was allowed to adapt to wearing each goggle for 2 minutes before starting the experiment."
Outcomes	Primary and secondary outcome measures were not clearly distinguished **Specified outcome(s)**: photostress recovery times **Adverse events reported?** (Y/N): N **Measurement time points**: not reported
Identification	**Dates study conducted**: not reported **Funding sources**: "None of the authors have reported funding/support." **Declaration of interest**: "None of the authors have reported a financial conflict of interest. The authors were responsible for the preparation of this article and the decision to submit this article for publication. Each of the authors had (full/limited) access to the study data and takes full responsibility for the presentation in this article." "The authors of this study wish to thank Mr. Justin Baker (JuzVision), Mr. Tim Thurn (Essilor Australia), and Ms. Dubravka Huber (Optometry Clinic, School of Optometry and Vision Science, University of New South Wales, Sydney) for providing blue-blocking lenses used in this study. The authors also thank Dr. Kathleen Watt for her valuable discussion." **Trial registration number**: not reported **Contacting study investigators**: study authors not contacted; no additional information used for review **Authors name**: Maitreyee Roy **Institution**: School of Optometry and Vision Science, University of New South Wales **Email**: maitreyee.roy@unsw.edu.au **Address**: School of Optometry and Vision Science, University of New South Wales, Kensington, Sydney, New South Wales, Australia
Notes	
Risk of bias	

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Alzahrani 2020 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "To minimize learning effects, the order of the lenses in the testing was randomized (clear lens and four different blue-blocking lens brands) using an online tool (available at www.randomization.com)." Comment: computer-generated list, random table, other method of generating random list.
Allocation concealment (selection bias)	Unclear risk	Comment: not reported how allocation was administered.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Comment: open-label or no information on masking. We assume that in the absence of reporting, participants and personnel were not masked.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Comment: open-label or no information on masking. We assume that in the absence of reporting, participants and personnel were not masked.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: follow-up not reported, and no information on missing data was reported. However, the study was small, and appears to have been conducted in a single session for each participant, so missing data is expected to be low.
Selective reporting (reporting bias)	Unclear risk	Comment: no access to protocol or clinical trials registry entry.
Other bias	Low risk	Quote: "None of the authors have reported a financial conflict of interest." Comment: no other apparent sources of bias.

Alzahrani 2021

Study characteristics	
Methods	**Study design**: RCT **Study grouping**: cross-over **Exclusions after randomisation**: not reported **How missing data were handled** (e.g. available case analysis, imputation, etc.): not reported **Losses to follow-up**: not reported **Other comments** (e.g. unusual study design/issues): none **Reported power calculation?** (Yes/No): No **Trial duration**: not reported **Unit of randomisation/unit of analysis**: unit of randomisation and unit of analysis was per participant
Participants	**Country**: not reported **Total number of participants**: 5 **Setting**: not reported

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Alzahrani 2021 *(Continued)*

	Baseline characteristics • Number of participants: 5 • Sex (number of females/number of males): 4/1 • Age (range): not reported (23 to 39 years) **Inclusion criteria**: monocular and binocular visual acuity of 6/6 or better using a Snellen chart; normal colour perception using the Ishihara Test Book 24 Plate abridged edition. **Exclusion criteria**: colour deficiencies; a history of ocular disease **Comparison of study groups at baseline**: not applicable (cross-over)
Interventions	**Intervention characteristics** Blue-light filtering spectacle lens • Intervention name (e.g. spectacle lens name and manufacturer): Crizal Prevencia (Essilor), Blue Guardian (Opticare), and Blu-OLP (GenOp) blue-light filtering lenses • Frequency with which the intervention (spectacle lenses) were worn over the trial duration: worn for the duration of the trial (single session) • Other comments: participants were allowed to wear the lens-containing goggles for 2 minutes prior to data collection to familiarise themselves with wearing the goggles. Non-blue-light filtering spectacle lens • Intervention name (e.g. spectacle lens name and manufacturer): clear lens without blue-light filtering coating (manufacturer - not reported) • Frequency with which the intervention (spectacle lenses) were worn over the trial duration: worn for the duration of the trial (single session) • Other comments: participants were allowed to wear the lens-containing goggles for 2 minutes prior to data collection to familiarise themselves with wearing the goggles.
Outcomes	Primary and secondary outcome measures were not clearly distinguished **Specified outcome(s)**: colour contrast threshold measured under low and high contrasts **Adverse events reported?** (Y/N): N **Measurement time points**: not reported
Identification	**Dates study conducted**: not reported **Funding sources**: "The authors of this study wish to thank Mr Justin Baker (JuzVision), Mr Tim Thurn (Essilor Australia) and Ms Dubravka Huber (Optometry Clinic, School of Optometry and Vision Science, UNSW Sydney) for providing the BBLs used in this study." **Declaration of interest**: not reported **Trial registration number**: not reported **Contacting study investigators**: study authors not contacted; no additional information used for review **Authors name**: Maitreyee Roy **Institution**: The University of New South Wales **Email**: maitreyee.roy@unsw.edu.au **Address**: School of Optometry and Vision Science, The University of New South Wales, Sydney, Australia

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Alzahrani 2021 *(Continued)*

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "The test order in which the BBLs and control lens were tested was randomised for each participant." Comment: not reported how list was generated. Trial was described as “randomised” but with no further details.
Allocation concealment (selection bias)	Unclear risk	Quote: "The test order in which the BBLs and control lens were tested was randomised for each participant." Comment: not reported how allocation was administered. Trial was described as “randomised” but with no further details.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Comment: open-label or no information on masking. We assume that in the absence of reporting, participants and personnel were not masked.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Comment: open-label or no information on masking. We assume that in the absence of reporting, participants and personnel were not masked.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Comment: it was not reported whether all participants completed the study or not.
Selective reporting (reporting bias)	Unclear risk	Comment: no access to protocol or clinical trials registry entry.
Other bias	Low risk	Comment: no other apparent sources of bias.

Bigalke 2021

Study characteristics

Methods	**Study design**: RCT **Study grouping**: cross-over **Exclusions after randomisation**: not reported **How missing data were handled** (e.g. available case analysis, imputation, etc.): not reported **Losses to follow-up**: not reported **Other comments** (e.g. unusual study design/issues): none **Reported power calculation?** (Yes/No): no **Trial duration**: 2 months **Unit of randomisation/unit of analysis**: unit of randomisation was per participant and unit of analysis was not explicitly stated, but the type of outcome parameters suggests no unit of analysis issues.

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Bigalke 2021 *(Continued)*

Participants	**Country**: USA **Total number of participants**: 20 **Setting**: at home setting of individuals **Baseline characteristics** • Number of participants: 20 • Sex (number of females/number of males): 9/11 • Age (mean (SD)): 32 (12) **Inclusion criteria**: healthy adults between the ages of 18 and 65 years **Exclusion criteria**: clinical diagnosis of any sleep disorder, shift work, bipolar disorder, or current use within the past month of any psychoactive drugs, hypnotics, or analgesic medication (except occasional non-narcotic analgesics). **Comparison of study groups at baseline**: not applicable (cross-over)
Interventions	**Intervention characteristics** Blue-light filtering spectacle lens • Intervention name (e.g. spectacle lens name and manufacturer): amber tinted glasses (LowBlueLights.com, University Heights, OH, USA) • Frequency with which the intervention (spectacle lenses) were worn over the trial duration: glasses were worn each night for 1 week (i.e. 7 consecutive days) from 6 pm until the participant went to bed. • Other comments: participants wore wristwatch actigraphy for the entire week and filled out a daily sleep diary. Non-blue-light filtering spectacle lens • Intervention name (e.g. spectacle lens name and manufacturer): clear lens safety glasses (Ultra-Spec 2001 OTG, Uvex, Honeywell Safety, USA) • Frequency with which the intervention (spectacle lenses) were worn over the trial duration: glasses were worn each night for 1 week (ie, 7 consecutive days) from 6 pm until the participant went to bed. • Other comments: Participants wore wristwatch actigraphy for the entire week and filled out a daily sleep diary.
Outcomes	**Primary outcome(s)**: total sleep time (measured using actigraphy wristwatch) **Secondary outcomes (s)**: sleep efficiency, sleep onset latency, wake after sleep onset, number of awakenings, daily reported screen time, and sleep quality index. **Adverse events reported?** (Y/N): N **Measurement time points**: baseline**(**week 1) and week 2 (days 1 to 7)
Identification	**Funding sources**: none **Declaration of interest**: the authors have no conflicts of interest to declare **Dates study conducted**: early May and late June **Trial registration number**: not reported **Contacting study investigators**: study authors not contacted; no additional information used for review **Authors name**: Jason R. Carter **Institution**: Montana State University

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Bigalke 2021 *(Continued)*

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Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Utilizing a randomized, controlled, crossover design, participants were randomly assigned to either a BLB or control condition" Comment: not reported how list was generated. Trial was described as “randomised” but with no further details.
Allocation concealment (selection bias)	Unclear risk	Comment: not reported how allocation was administered. Trial was described as “randomised” but with no further details.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Comment: open-label or no information on masking. We assume that in the absence of reporting, participants and personnel were not masked.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Comment: open-label or no information on masking. We assume that in the absence of reporting, participants and personnel were not masked.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "Comparison of subjective (self-report, n = 20) and objective (actigraphy, n = 19) sleep parameters between experimental conditions." Comment: Missing data less than 20% (i.e. more than 80% follow-up); equal follow-up in both groups and no obvious reason why loss to follow-up should be related to outcome.
Selective reporting (reporting bias)	Unclear risk	Comment: no access to protocol or clinical trials registry entry.
Other bias	Low risk	Comment: no other apparent sources of bias.

Burkhart 2009

Study characteristics

Methods

Study design: RCT

Study grouping: parallel

Exclusions after randomisation: not reported

How missing data were handled (e.g. available case analysis, imputation, etc.): not reported

Losses to follow-up: not explicitly reported, but there do not appear to be any losses to follow-up based upon the degrees of freedom in the statistical analyses, for the pre- and post-intervention measures.

Other comments (e.g. unusual study design/issues): none

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Burkhart 2009 *(Continued)*

Reported power calculation? (Yes/No): no

Trial duration: not reported

Unit of randomisation/unit of analysis: unit of randomisation and unit of analysis was per participant

Participants	**Country**: USA **Total number of participants**: 20 **Setting**: not reported **Baseline characteristics** Blue-light filtering spectacle lens • Number of participants: 10 • Sex (number of females/number of males): not reported • Age (mean (SD)): 35.8 (not reported) Non-blue-light filtering spectacle lens • Number of participants: 10 • Sex (number of females/number of males): not reported • Age (mean (SD)): 33.7 (not reported) Overall • Number of participants: 20 • Sex (number of females/number of males): 11/9 • Age (mean (SD)): not reported **Inclusion criteria**: individuals who reported sleep difficulty, defined as sleep-onset insomnia (difficulty falling asleep), mid-sleep insomnia (waking up after falling asleep), and terminal insomnia (waking up too early) by subjective account; no quantitative assessment was used. **Exclusion criteria**: use of any prescribed medication, oral or inhaled nicotine, or excessive caffeine use (> 2 cups at one time or > 500 mg daily). **Comparison of study groups at baseline**: "At baseline, the experimental and control groups were equivalent on self-reported negative affect (t(18) = 1.92, P = 0.056). As shown in Figures 2 and 3, the two groups were not equivalent on self-reported baseline quality of sleep (t(18) = 15.81, P <0.001) or self-reported baseline positive affect (t(18) = 9.75, P <0.001)."
Interventions	**Intervention characteristics** Blue-light filtering spectacle lens • Intervention name (e.g. spectacle lens name and manufacturer): "Amber lenses": amber-tinted safety glasses (NoIR Polycarbonate Eyewear), which blocked wavelengths < 550 nm (blue-green or longer wavelengths being transmitted) • Frequency with which the intervention (spectacle lenses) were worn over the trial duration: 3 hours prior to sleep, for 2 weeks • Other comments: none Non-blue-light filtering spectacle lens • Intervention name (e.g. spectacle lens name and manufacturer): yellow-tinted safety glasses (NoIR Polycarbonate Eyewear), blocking only ultraviolet light, were used (blue and longer wavelengths being transmitted). • Frequency with which the intervention (spectacle lenses) were worn over the trial duration: 3 hours prior to sleep, for 2 weeks

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Burkhart 2009 *(Continued)*

	• Other comments: none
Outcomes	**Primary outcome(s)**: sleep quality measured using Likert scale and positive affect and negative affect mood scale questionnaire score. **Secondary outcomes(s)**: none **Adverse events reported?** (Y/N): Y **Measurement time points**: baseline (week 1), week 2, and week 3
Identification	**Dates study conducted**: not reported **Funding sources**: "No financial support was used to conduct this research. Amber lenses were provided by Photonic Developments LLC." **Declaration of interest**: "The authors have no conflicts of interest to report. Neither author has a financial interest in the amber lenses used herein." **Trial registration number**: not reported **Contacting study investigators**: study authors not contacted; no additional information used for review **Authors name**: James R. Phelps **Institution**: Samaritan Mental Health **Email**: jphelps@samhealth.org **Address**: Samaritan Mental Health3509 Samaritan Dr.Corvallis, OR 97330, USA
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "randomly assigned" Comment: not reported how list was generated. Trial was described as “randomised” but with no further details.
Allocation concealment (selection bias)	Unclear risk	Quote: "who were randomly assigned to either receive low-blue-light or placebo glasses," Comment: not reported how allocation was administered. Trial was described as “randomised” but with no further details.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Comment: does not specify whether participants or personnel were masked.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Comment: no information on outcome assessor masking. We assume that in the absence of reporting, outcome assessors were not masked.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: although follow-up was not explicitly reported, the statistical analyses and degrees of freedom at the study end-point suggest there was full follow-up of participants.

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Burkhart 2009 *(Continued)*

Selective reporting (reporting bias)	Unclear risk	Comment: no access to protocol or clinical trials registry.
Other bias	High risk	Quote: "At baseline, the experimental and control groups were equivalent on self-reported negative affect (t(18) = 1.92, P = 0.056). As shown in Figures 2 and 3, the two groups were not equivalent on self-reported baseline quality of sleep (t(18) = 15.81, P < .001) or self-reported baseline positive affect (t(18) = 9.75, P < .001)." Comment: Important baseline imbalance that might have an effect on the results.

Dabrowiecki 2020

Study characteristics	
Methods	**Study design**: RCT **Study grouping**: cross-over **Exclusions after randomisation**: none **How missing data were handled** (e.g. available case analysis, imputation, etc.): not reported **Losses to follow-up**: not reported **Other comments** (e.g. unusual study design/issues): none **Reported power calculation?** (Yes/No): No **Trial duration**: 2 weeks **Unit of randomisation/unit of analysis**: unit of randomisation was per participant and unit of analysis was not explicitly stated, but the type of outcome parameters suggests no unit of analysis issues.
Participants	**Country**: not reported **Total number of participants**: 10 **Setting**: not reported **Baseline characteristics** • Number of participants: 10 • Sex (number of females/number of males): 6/4 • Age (mean (SD)): not reported **Inclusion criteria**: adult radiology trainees **Exclusion criteria**: not reported **Comparison of study groups at baseline**: not applicable (cross-over)
Interventions	**Intervention characteristics** Blue-light filtering spectacle lens • Intervention name (e.g. spectacle lens name and manufacturer): clear blue-light filtering lenses (Felix Gray, Inc., New York)

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Dabrowiecki 2020 *(Continued)*

- Frequency with which the intervention (spectacle lenses) were worn over the trial duration: "Participants were asked to wear their respective lens during their normal noncall diagnostic radiology workday, typically lasting from 8:00 AM to 5:00 PM from Monday through Friday."
- Other comments: participants were asked to wear contact lens if they normally wore prescription glasses during the length of this study.

Non-blue-light filtering spectacle lens

- Intervention name (e.g. spectacle lens name and manufacturer): non-blue-light filtering lenses (Felix Gray, Inc., New York)
- Frequency with which the intervention (spectacle lenses) were worn over the trial duration: "Participants were asked to wear their respective lens during their normal noncall diagnostic radiology workday, typically lasting from 8:00 AM to 5:00 PM from Monday through Friday."
- Other comments: participants were asked to wear contact lens if they normally wore prescription glasses during the length of this study.

Outcomes	Primary and secondary outcome measures were not clearly distinguished. **Specified outcome(s)**:computer vision syndrome questionnaire (CVS-Q) and the Swedish Occupational Fatigue Inventory (SOFI). **Adverse events reported?** (Y/N): N **Measurement time points**: Every day for a period of five days
Identification	**Dates study conducted**: end of October 2018 to early November 2018 **Funding sources**: not reported **Declaration of interest**: "No conflicts of interest, financial or otherwise, are declared by the authors." **Trial registration number**: not reported **Contacting study investigators**: study authors not contacted; no additional information used for review **Author's name**: Alexander Dabrowiecki **Institution**: Emory University School of Medicine **Email**: adabrow@emory.edu **Address**: Emory University School of Medicine, Department of Radiology and Imaging Sciences, Atlanta, Georgia, United States
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Inclusion criteria for the study were limited to adult radiology trainees, who were subsequently blinded and randomized to a group assigned to wear either BLFL or non-BLFL during their first week then swap for their second week." Comment: not reported how list was generated. Trial was described as “randomised” but with no further details.
Allocation concealment (selection bias)	Unclear risk	Comment: not reported how allocation was administered. Trial was described as “randomised” but with no further details.

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Dabrowiecki 2020 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Quote: "Inclusion criteria for the study were limited to adult radiology trainees, who were subsequently blinded and randomized to a group assigned to wear either BLFL or non-BLFL during their first week then swap for their second week." Comment: only participants were masked and no information relating to the person who delivered the intervention was provided.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Comment: open-label or no information on masking. We assume that in the absence of reporting, outcome assessors were not masked.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "Ten radiology residents, four males and six females with a PGY distribution of seven PGY-2, two PGY-3, and one PGY-4, volunteered and successfully completed the study. As detailed in Table 1, the questionnaire contained both SOFI and CVS-Q questions." Comment: missing data less than 20% (i.e. more than 80% follow-up); equal follow-up in both groups and no obvious reason why loss to follow-up should be related to outcome.
Selective reporting (reporting bias)	Unclear risk	Comment: no access to protocol or clinical trials registry entry.
Other bias	Low risk	Quote: "No conflicts of interest, financial or otherwise, are declared by the authors. This study was approved by our institutional review board." Comment: no other apparent sources of bias.

Danilenko 2019

Study characteristics	
Methods	**Study design**: RCT **Study grouping**: parallel **Exclusions after randomisation**: 2 participants - "Thirty-seven patients entered the study and two were later excluded due to revealed organic/somatic illnesses (N = 1) and a change of the primary diagnosis (to organic mood disorder; N = 1)." **How missing data were handled** (e.g. available case analysis, imputation, etc.): not reported **Losses to follow-up**: not explicitly mentioned, but Table 1 and Table 2 show all participants completed the study. **Other comments** (e.g. unusual study design/issues): none **Reported power calculation?** (Yes/No): no **Trial duration**: 11 months **Unit of randomisation/unit of analysis**: unit of randomisation and unit of analysis was per participant.
Participants	**Country**: not reported **Total number of participants**: 35 **Setting**: hospital

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Danilenko 2019 *(Continued)*

Baseline characteristics

Blue-light filtering spectacle lens

- Number of participants: 16
- Sex (number of females/number of males): 6/10
- Age (mean (SD)): 49.7 (12.3)

Non-blue-light filtering spectacle lens

- Number of participants: 19
- Sex (number of females/number of males): 9/10
- Age (mean (SD)): 50.9 (10.8)

Overall

- Number of participants: 35
- Sex (number of females/number of males): 15/20
- Age (mean (SD)): 50.3 (11.3)

Inclusion criteria: age ≥ 18 years; major depressive disorder (MDD), recurrent or single episode or persistent DD (dysthymia), with melancholic or atypical features (according to DSM-5 criteria; APA 2013); current depressive episode, with the 17-item Hamilton Depression Rating Scale score at least 12 (HDRS-17 interview according to Williams 1994) and Beck Depression Inventory-II score – at least 16 (BDI-II; Beck 1996); clinical predominance of depression over another psychiatric disorder, if present (e.g. personality disorder); stable dose of antidepressants (if taken) for the last 3 weeks; good general health; on stable medication(s) dosage, if suffering a chronic disease; and written informed consent to participate in the study.

Exclusion criteria: bipolar disorder; MDD with seasonal pattern, anxious distress, mixed or psychotic features; suicidal ideation; pregnancy; an acute illness; long-distance transmeridian travel during the previous week; contraindications to light therapy (retinal diseases, intake of photosensitising agents); and cataracts.

Comparison of study groups at baseline: Table 1 shows no significant difference between study arms.

Interventions

Intervention characteristics

Blue-light filtering spectacle lens

- Intervention name (e.g. spectacle lens name and manufacturer): orange glasses (Chron-optic, Québec, Canada). Reported to completely eliminate light below 540 nm.
- Frequency with which the intervention (spectacle lenses) were worn over the trial duration: worn daily for 6 consecutive days. Worn only during light therapy treatment. Light therapy duration alternated between 4 hours (on Days 3, 5, and 7 of the study), and 1 hour (on Days 4, 6, and 8 of the study).
- Other comments: light therapy began at Day 3 at 4.00am to 8.00am after waking the participant. The light therapy room was equipped with 36 Philips LED tubes (MASLED tube VLE 1200 mm 20 W/865 T8C; 6500 Kelvin). They provided "blue-enriched" light, with blue light peaking at 450 nm. The light intensity was increased hourly in the sequence of 600→1300→2200→2800 lx. On the days where light therapy was only one hour duration, the light intensity was 2800 lx.

Non-blue-light filtering spectacle lens

- Intervention name (e.g. spectacle lens name and manufacturer): clear lenses (Chron-optic, Québec, Canada)
- Frequency with which the intervention (spectacle lenses) were worn over the trial duration: worn daily for 6 consecutive days. Worn only during light therapy treatment. Light therapy duration alternated between 4 hours (on Days 3, 5, and 7 of the study), and 1 hour (on Days 4, 6, and 8 of the study).
- Other comments: light therapy began at Day 3 at 4.00am to 8.00am after waking the participant. The light therapy room was equipped with 36 Philips LED tubes (MASLED tube VLE 1200 mm 20 W/865 T8C; 6500 Kelvin). They provided "blue-enriched" light, with blue light peaking at 450 nm. The light

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Danilenko 2019 *(Continued)*

	intensity was increased hourly in the sequence of 600→1300→2200→2800 lx. On the days where light therapy was only one hour duration, the light intensity was 2800 lx.
Outcomes	**Primary outcome (s)**: change from baseline in Hamilton depression rating scale scores **Secondary outcome (s)**: change from baseline in visual analogue scales for mood and energy, and Beck Depression Inventory-II score **Adverse events reported?** (Y/N): Y **Measurement time points**: baseline, day 9
Identification	**Dates study conducted**: "The study was performed in the winter half of the year: from October 2016 to April 2017 and from December 2017 to March 2018." **Funding sources**: "The study was supported by a budgetary fund (2016) and Presidium of the Russian Academy of Sciences (Program IV.12.1, 2015–17). LED tubes for the bright light therapy room were provided by Philips Consumer Lifestyle (The Netherlands)." Declaration of interest: "No conflict of interest declared." **Trial registration number**: not reported **Contacting study investigators**: study authors not contacted; no additional information used for review **Authors name**: Konstantin V. Danilenko **Institution**: Institute of Physiology and Basic Medicine **Email**: kvdani@mail.ru **Address**: Institute of Physiology and Basic Medicine, Timakova, 4, Novosibirsk 630117, Russia
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "This was a randomized counter-balanced comparative controlled study on two groups of hospitalized patients," Comment: not reported how list was generated. Trial was described as “randomised” but with no further details.
Allocation concealment (selection bias)	Unclear risk	Quote: "The glasses were allocated to patients randomly from a batch of 2." Comment: not reported how allocation was administered. Trial was described as “randomised” but with no further details.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Quote: "The patients (up to 4 at a time) slept in the clinic, were awakened at the prescribed time to go to the light therapy room, wore neutral or orange glasses (patients of different treatment assignment could be in the light room simultaneously) and remained under supervision of the study personnel." Comment: it appears that participants were adequately masked by leading them to believe that both the blue-light blocking and the placebo glasses were different active treatments. However, it appears that study personnel were not masked.
Blinding of outcome assessment (detection bias)	Low risk	Quote: "The rater was blind to the light (white or orange) allocated to the patient."

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Danilenko 2019 *(Continued)*

All outcomes		Comment: clearly stated that the outcome assessor was masked.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "Thirty-seven patients entered the study and two were later excluded due to revealed organic/somatic illnesses (N = 1) and a change of the primary diagnosis (to organic mood disorder; N = 1)." Comment: Missing data less than 20% (i.e. more than 80% follow-up); equal follow-up in both groups and no obvious reason why loss to follow-up should be related to outcome.
Selective reporting (reporting bias)	Unclear risk	Comment: no access to protocol or clinical trials registry entry.
Other bias	Low risk	Comment: no other apparent sources of bias.

Esaki 2017

Study characteristics	
Methods	**Study design**: RCT **Study grouping**: parallel **Exclusions after randomisation**: 1 participant in the BB group discontinued the intervention after 4 days because of discomfort from wearing the glasses. In the placebo group, 1 participant discontinued the intervention after 3 days because of pain from the contacting part of the glasses, and another discontinued after 7 days because of no subjective benefit. **How missing data were handled** (e.g. available case analysis, imputation, etc.): missing data were imputed using the last observation carried forward. **Losses to follow-up**: see 'Exclusions after randomisation' section **Other comments** (e.g. unusual study design/issues): none **Reported power calculation?** (Yes/No): yes. "We substituted the power analysis from a study involving adult volunteers with sleep difficulty (Burkhart 2009). Based on sleep quality on a Likert scale used in that study, a power analysis indicated that for a probability level of 0.05 (2-tailed) and power of 0.80, 8 participants in each group would be sufficient to detect a significant difference." **Trial duration**: data were collected between 19 March 2016 and 25 July 2016. Each participant was involved in the trial for 3 weeks, with the intervention applied for 2 weeks. **Unit of randomisation/unit of analysis**: unit of randomisation and unit of analysis was per participant
Participants	**Country**: Japan **Total number of participants**: 20 **Setting**: Mental care hospital **Baseline Characteristics** Blue-light filtering spectacle lens • Number of participants: 10 • Sex (number of females/number of males): 6/4 • Age (mean (SD)): 43.4 (8.4) Non-blue-light filtering spectacle lens

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Esaki 2017 *(Continued)*

- Number of participants: 10
- Sex (number of females/number of males): 8/2
- Age (mean (SD)): 39.8 (5.8)

Overall

- Number of participants: 20
- Sex (number of females/number of males): 14/6
- Age (mean (SD)): not reported

Inclusion criteria: aged 20 to 65 years, had a diagnosis of MDD (Diagnostic and Statistical Manual of Mental Disorders, 5th edition) as assessed by a psychiatrist, a score of > 13 on the 17-item Hamilton Depression Rating Scale (HAM-D) at screening, sleep onset insomnia that had continued almost every day for more than 2 weeks, based on self-assessment, and had been on the same psychotropic medication at the same dosage for at least 2 weeks before screening.

Exclusion criteria: seasonal pattern, bipolar disorder, psychotic disorders, substance abuse or dependence within the past year, or serious suicidal risk as judged by a clinician. Participants with knowledge of BB glasses.

Comparison of study groups at baseline: "There were differences at baseline between the BB and placebo groups (including some of marginal statistical significance) in sleep quality assessed using the VAS (P = 0.015), SL (P = 0.058), and antipsychotics use (P = 0.077); other values did not significantly differ between the groups (Table 2)."

Interventions

Intervention characteristics

Blue-light filtering spectacle lens

- Intervention name (e.g. spectacle lens name and manufacturer): glasses with orange lenses (Yamamoto Kogaku, No. 360S UV Orange, Osaka, Japan) of a fit-over design. All participants wore study glasses of the same size, regardless of whether they were using regular glasses.
- Frequency with which the intervention (spectacle lenses) were worn over the trial duration: the first week was the baseline assessment period. Participants recorded a sleep diary for 1 week. For the following 2 weeks, they were randomly assigned to wearing either BB glasses or clear glasses (placebo). Participants were instructed to wear the allocated glasses from 20:00 hours until bedtime every evening.
- Other comments: usual medications and psychotherapy were maintained during the study period.

Non-blue-light filtering spectacle lens

- Intervention name (e.g. spectacle lens name and manufacturer): glasses with clear lenses of a fit-over design (manufacturer - not reported)
- Frequency with which the intervention (spectacle lenses) were worn over the trial duration: the first week was the baseline assessment period. Participants recorded a sleep diary for 1 week. For the following 2 weeks, they were randomly assigned to wearing either BB glasses or clear glasses (placebo). Participants were instructed to wear the allocated glasses from 20:00 hours until bedtime every evening.
- Other comments: Usual medications and psychotherapy were maintained during the study period.

Outcomes

Primary outcome(s): sleep quality assessed using visual analogue scale

Secondary outcome(s): Morningness–Eveningness Questionnaire (MEQ), sleep diary data (sleep onset time, wake-up time, and sleep latency), Hamilton Depression Rating Scale (HAM-D), Beck Depression Inventory (BDI), and Clinical Global Impression Severity of illness scale.

Adverse events reported? (Y/N): Y

Measurement time points: Sleep quality and MEQ were measured at after week 1 (baseline) and after 2 weeks of intervention. Sleep diary was assessed for 7 consecutive days at baseline and the last 7 days

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Esaki 2017 *(Continued)*

	of the second week of the intervention. Depressive symptoms (HAM-D), BDI, and Clinical Global Impression Severity of illness scale) were measured at baseline and at 2 weeks of intervention period.
Identification	**Dates study conducted**: March 2016 to July 2016 **Funding sources**: not reported **Declaration of interest**: "The authors report no conflicts of interest related to this research. Dr Kitajima has received speaker's honoraria from Eizai, Mitsubishi Tanabe, Otsuka, Takeda, Eli Lilly, MSD, Yoshitomi, Fukuda, Dainippon Sumitomo, and Shionogi, and has received a research grant from Eizai, MSD and Takeda. Dr. Furukawa has received speaker's honoraria from Mochida, Otsuka, Meiji, Yoshitomi, Eli Lilly, GlaxoSmithKline, Dainippon Sumitomo, and Pfizer. Dr. Moriwaki has received speaker's honoraria from Otsuka, Meiji, Eli Lilly, Dainippon Sumitomo, Shionogi, Novartis, and Janssen. Dr.Fujita has received speaker's honoraria from Dainippon Sumitomo, Eli Lilly, GlaxoSmithKline, Janssen, Yoshitomi, Otsuka, Meiji, Shionogi, Novartis, and Kracie. Dr. Iwata has received speaker's honoraria from Astellas, Dainippon Sumitomo, Eli Lilly, GlaxoSmithKline, Janssen, Yoshitomi, Otsuka, Meiji, Shionogi, Novartis, and Pfizer, and has research grants from Dainippon Sumitomo, GlaxoSmithKline, Tanabe-Mitsubishi, and Otsuka." **Trial registration number**: UMIN000021216 **Contacting study investigators**: study authors not contacted; no additional information used for review **Authors name**: Yuichi Esaki **Institution**: Fujita Health University School of Medicine **Email**: esakiz@fujita-hu.ac.jp **Address**: Department of Psychiatry, Fujita Health University School of Medicine, Toyoake, Aichi 4701192, Japan
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "1. 2.4. Computer-generated random assignments in blocks of four were used for randomization." Comment: computer-generated random assignment.
Allocation concealment (selection bias)	Low risk	Quote: "The allocated glasses were boxed and each box was numbered. Nobody knew the content of the boxes except the staff that had made the allocation." Comment: allocation was concealed from the investigators.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "Participants were masked to group assignment and received identical limited information about the purpose of the study; that is, testing the effectiveness of different types of glasses in improving sleep and mood by blocking different light wavelengths." Comment: clearly stated that participants were not aware of which treatment was received.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "in the hospital, not to research the glasses, and not to discuss their nature with medical staff (in particular, the doctor and the rating interviewer) during the study period."

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Esaki 2017 *(Continued)*

		Comment: outcome assessors were masked.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "One participant in the BB group discontinued the intervention after 4 days because of discomfort from wearing the glasses. In the placebo group, one participant discontinued the intervention after 3 days because of pain from the contacting part of the glasses, and another discontinued after 7 days because of no subjective benefit." Quote: "Data for all randomized participants were included in the analysis based on a full analysis set. Missing data were imputed using the last observation carried forward." Comment: data for all randomised participants were included, with missing data imputed.
Selective reporting (reporting bias)	Low risk	Comment: primary and secondary outcomes listed on the clinical trial registry (UMIN000021216) are reported in the manuscript.
Other bias	High risk	Quote: "There were differences at baseline between the BB and placebo groups (including some of marginal statistical significance) in sleep quality assessed using the VAS (P = 0.015), SL (P = 0.058), and antipsychotics use (P = 0.077); other values did not significantly differ between the groups (Table 2)." Comment: Significant intergroup differences at baseline that may impact upon the study findings.

Esaki 2020

Study characteristics	
Methods	**Study design**: RCT **Study grouping**: parallel **Exclusions after randomisation**: yes. 2 participants in the intervention group due to discomfort from wearing the glasses (n = 1) and patient wish to discontinue from the study (n = 1). 4 participants in the placebo group due to pain from the wearing part of the glasses (n = 2), discomfort from wearing the glasses (n = 1), and transfer to another clinic (n = 1). **How missing data were handled** (e.g. available case analysis, imputation, etc.): missing data were imputed using the last observation carried forward **Losses to follow-up**: see 'Exclusions after randomisation' section **Other comments** (e.g. unusual study design/issues): none **Reported power calculation?** (Yes/No): yes "Sample size estimates were determined using the power analysis from a study involving major depressive disorder patients with insomnia. On the basis of sleep quality evaluated by a VAS used in that study, a power analysis indicated that for a probability level of 0.05 (two-tailed) and 80% power, a total of 52 patients would be enough to detect a significant difference. However, because of the expiration of the study deadline, the final sample was 43 patients with BD." **Trial duration**: 1 year, 7 months **Unit of randomisation/unit of analysis**: unit of randomisation and unit of analysis was per participant
Participants	**Country**: Japan **Total number of participants**: 43

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Esaki 2020 *(Continued)*

Setting: mental care hospital

Baseline characteristics

Blue-light filtering spectacle lens

- Number of participants: 21
- Sex (number of females/number of males): 9/12
- Age (mean (SD)): 44.1 (11.8)

Non-blue-light filtering spectacle lens

- Number of participants: 22
- Sex (number of females/number of males): 14/8
- Age (mean (SD)): 41.1 (10.4)

Overall

- Number of participants: 43
- Sex (number of females/number of males): 23/20
- Age (mean (SD)): not reported

Inclusion criteria: aged 18 to 75 years; diagnosed with BD according to the Diagnostic and Statistical Manual of Mental Disorders (fifth edition) by an experienced psychiatrist; a score of ≥ 8 on the Insomnia Severity Index (ISI) questionnaire at the screening.

Exclusion criteria: night shift workers; people with a serious suicidal risk as judged by a clinician; acute manic, mixed, and depressive episodes (patients with only residual symptoms were enrolled in this study).

Comparison of study groups at baseline: The dosage of antidepressants was significantly higher in the blue-blocking intervention group. The MADRS (Montgomery-Asperg Depression Rating Scale) score was marginally significantly lower in the blue-blocking intervention group.

Interventions

Intervention characteristics

Blue-light filtering spectacle lens

- Intervention name (e.g. spectacle lens name and manufacturer): glasses with orange lenses (Yamamoto Kogaku, No. 360S UV Orange, Osaka, Japan).
- Frequency with which the intervention (spectacle lenses) were worn over the trial duration: the intervention was not worn for the first week as a baseline period. For the following 2 weeks, the intervention was worn from 20:00 until bedtime every evening.
- Other comments: the temple parts of the glasses used in this study utilised a size-adjustable capability to reduce discomfort from wearing the glasses.

Non-blue-light filtering spectacle lens

- Intervention name (e.g. spectacle lens name and manufacturer): glasses with clear lenses (Yamamoto Kogaku, No. 331, Osaka, Japan).
- Frequency with which the intervention (spectacle lenses) were worn over the trial duration: the intervention was not worn for the first week as a baseline period. For the following 2 weeks, the intervention was worn from 20:00 until bedtime every evening.
- Other comments: the temple parts of the glasses used in this study utilised a size-adjustable capability to reduce discomfort from wearing the glasses.

Outcomes

Primary outcome(s): sleep quality assessed using visual analogue scale

Secondary outcome(s): insomnia Severity Index questionnaire, MEQ, actigraphy data (sleep start time, sleep end time, total sleep time, sleep efficiency, wake after sleep onset, sleep onset latency, midpoint of sleep), MADRS, and the Young Mania Rating Scale (YMRS).

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Esaki 2020 *(Continued)*

Adverse events reported? (Y/N): Y

Measurement time points: sleep quality, MEQ, Insomnia Severity Index questionnaire, MADRS, and the YMRS were measured at after week 1 (baseline) and after 2 weeks of intervention. Clinical Global Impression Severity of illness scale was measured at 2 weeks of intervention period. Actigraphy data was measured for 7 consecutive days at baseline and the last 7 days of the second week of the intervention.

Identification	**Dates study conducted**: July 2017 to February 2019 **Funding sources**: not reported **Declaration of interest**: "The authors report no conflicts of interest related to this research. Dr Kitajima has received speaker's honoraria from Eisai, Mitsubishi Tanabe, Otsuka, Takeda, Eli Lilly, MSD, Yoshitomi, Fukuda, Dainippon Sumitomo, and Shionogi, and has received a research grant from Eisai, MSD and Takeda. Dr. Furukawa has received speaker's honoraria from Mochida, Otsuka, Meiji, Yoshitomi, Eli Lilly, GlaxoSmithKline, Dainippon Sumitomo, and Pfizer. Dr. Moriwaki has received speaker's honoraria from Otsuka, Meiji, Eli Lilly, Dainippon Sumitomo, Shionogi, Novartis, and Janssen. Dr.Fujita has received speaker's honoraria from Dainippon Sumitomo, Eli Lilly, GlaxoSmithKline, Janssen, Yoshitomi, Otsuka, Meiji, Shionogi, Novartis, and Kracie. Dr. Iwata has received speaker's honoraria from Astellas, Dainippon Sumitomo, Eli Lilly, GlaxoSmithKline, Janssen, Yoshitomi, Otsuka, Meiji, Shionogi, Novartis, and Pfizer, and has research grants from Dainippon Sumitomo, GlaxoSmithKline, Tanabe-Mitsubishi, and Otsuka." **Trial registration number**: UMIN000028125 **Contacting study investigators**: study authors not contacted; no additional information used for review **Authors name**: Yuichi Esaki **Institution**: Fujita Health University School of Medicine **Email**: esakiz@fujita-hu.ac.jp **Address**: Department of Psychiatry, Fujita Health University School of Medicine, Toyoake, Aichi 4701192, Japan
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Our randomization process used computer-generated random assignments in blocks of four." Comment: computer-generated list, random table, other method of generating random list.
Allocation concealment (selection bias)	Low risk	Quote: "The allocation of orange (BB) or clear glasses (placebo) was conducted by medical staff not other- wise involved in the study, and the allocated glasses were boxed." Comment: allocation performed by personnel not otherwise involved in the study, distributed in boxes.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "Any participants with knowledge of BB glasses were excluded from the study. Before and during the 3 weeks, participants were instructed in the following topics: (a) not to confirm the contents of the box while in the hospi- tal; (b) not to research their allocated glasses; and (c) not to discuss the nature of their glasses with the medical staff."

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Esaki 2020 *(Continued)*

		Quote: "The allocation of orange (BB) or clear glasses (placebo) was conducted by medical staff not otherwise involved in the study, and the allocated glasses were boxed." Comment: clearly stated that participants and personnel were not aware of which treatment was received.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: described as “double-blind”, with no information on how masking of outcome assessors was achieved.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "Of the 196 outpatients with BD who were screened, a total of 43 were randomly assigned into the two groups (BB group, 21 (48.8%), placebo group, 22 (51.1%); Figure 1). In the BB group, one participant discontinued shortly after the intervention because of discomfort from wearing the glasses, and another withdrew before the intervention because of patient wish (Figure 1). In the placebo group, a total of four participants discontinued the intervention because of pain from the contacting part of the glasses, discomfort from wearing the glasses, or transfer to another clinic (Figure 1). The number of days and the times of wearing the glasses were not significantly different between the BB and placebo groups" Comment: missing data less than 20% (i.e. more than 80% follow-up); equal follow-up in both groups and no obvious reason why loss to follow-up should be related to outcome.
Selective reporting (reporting bias)	Low risk	Quote: "The study was approved by the Ethics Committee of Okehazama Hospital and was registered at UMIN-CTR (identifier: UMIN000028125)." Comment: all outcomes in the protocol and trials registry entry were reported.
Other bias	Low risk	Comment: no other apparent sources of bias.

Hammond 2015

Study characteristics	
Methods	**Study design**: RCT **Study grouping**: cross-over **Exclusions after randomisation**: "One hundred fifty-four of 156 enrolled patients completed the study (97.5%). One patient was invalidated because they violated inclusion/exclusion criteria (implantation with a BLF IOL). Nine other patients had incomplete data sets due to physical limitations or inability to maintain alignment with the optical system." **How missing data were handled** (e.g. available case analysis, imputation, etc.): not reported **Losses to follow-up**: not reported **Other comments** (e.g. unusual study design/issues): none **Reported power calculation?** (Yes/No): yes: "Assuming a log-transformed photostress recovery time SD of 0.35, a minimum sample size of 153 patients was determined to provide 80% power to detect a 20% difference in photostress recovery time." **Trial duration**: 4 months **Unit of randomisation/unit of analysis**: 1 eye per participant was included in the study, reportedly randomly selected, but with no additional information on randomisation method. The study eye re-

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Hammond 2015 *(Continued)*

	ceived both treatments sequentially, with the order determined reportedly randomly, but with no additional information on randomisation method.
Participants	**Country**: USA **Total number of participants**: 156 **Setting**: not reported **Baseline characteristics** • Number of participants: 156 • Sex (number of females/number of males): 91/65 • Age (mean (range)): 69.8 (48-88) **Inclusion criteria**: bilaterally pseudophakic and ≥ 3 months post-implantation with clear IOLs; ≥ 21 years of age. Good ocular health (based on a clinical interview). Able to adequately participate in the psychophysical testing. **Exclusion criteria**: ocular pathology, degeneration, or media opacity that could have affected study assessments. Any conditions that could be exacerbated, triggered, or worsened by exposure to high-intensity light. **Comparison of study groups at baseline**: not applicable (cross-over)
Interventions	**Intervention characteristics** Blue-light filtering spectacle lens • Intervention name (e.g. spectacle lens name and manufacturer): "A clip-on spectacle lens with filtering characteristics matched to a commonly used BLF IOL (the AcrySof Natural IOL; Alcon Laboratories, Inc.)" Manufacturer - not reported. • Frequency with which the intervention (spectacle lenses) were worn over the trial duration: the intervention was worn for the duration of the testing period on a single day. Total time of intervention worn not reported. • Other comments: none Non-blue-light filtering spectacle lens • Intervention name (e.g. spectacle lens name and manufacturer): "Non-BLF (clear) clip-on glasses" (manufacturer - not reported). • Frequency with which the intervention (spectacle lenses) were worn over the trial duration: the intervention was worn for the duration of the testing period on a single day. Total time of intervention worn not reported. • Other comments: none
Outcomes	**Primary outcome(s)**: photostress recovery time **Secondary outcomes (s)**: glare disability threshold and corrected visual acuity **Adverse events reported?** (Y/N): N **Measurement time points**: not reported
Identification	**Dates study conducted**: "September 2014 to January 2014" reported in the paper. Presumably typographical error. **Funding sources**: "This study was funded by Alcon Research, Ltd." **Declaration of interest**: "Billy R. Hammond has received speaker fees from Alcon Research, Ltd." **Trial registration number**: NCT01938989

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Hammond 2015 *(Continued)*

Contacting study investigators: study authors not contacted; no additional information used for review

Authors name: Billy R. Hammond

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Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "This was a prospective, randomized, patient-masked crossover study" Comment: not reported how list was generated. Trial was described as “randomised” but with no further details.
Allocation concealment (selection bias)	Unclear risk	Quote: "Patients were randomized to the order of use of BLF and non-BLF (clear) clip-on glasses, which were worn over patients’ habitual correction." Comment: not reported how allocation was administered. Trial was described as “randomised” but with no further details.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Quote: "Patients were masked to the identity of the test and control clip-on glasses." Comment: As only the participants were masked of the intervention provided, we considered this 'unclear'.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Comment: No information about the outcome assessors was provided.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "One hundred fifty-four of 156 enrolled patients completed the study (97.5%). One patient was invalidated because they violated inclusion/exclusion criteria (implantation with a BLF IOL). Nine other patients had incomplete data sets due to physical limitations or inability to maintain alignment with the optical system."
Selective reporting (reporting bias)	High risk	Quote: "(This trial is registered with Clinicaltrials.gov NCT01938989)." Comment: A deviation from the a priori outcome measures. The only prespecified outcome was photostress recovery time; however, glare disability threshold was given equal emphasis in the published paper.
Other bias	Low risk	Comment: no other apparent sources of bias.

Henriksen 2016

Study characteristics

Methods

Study design: RCT

Study grouping: parallel

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Henriksen 2016 *(Continued)*

Exclusions after randomisation: intervention group: 5 participants were excluded on the first night of treatment (3 withdrew consent, 2 were unable to comply with the treatment protocol). 1 participant was excluded from analysis after the completion of the trial. Placebo group: 3 participants withdrew consent on the first night of treatment, and were excluded.

How missing data were handled (e.g. available case analysis, imputation, etc.): not reported

Losses to follow-up: in the intervention group one participant discontinued intervention after one night, due to headache. In the control group three participants discontinued the intervention, due to participant discontinuing intervention after one night (n = 1), participant demanded discharge after 5 nights (n = 1), and one participant discontinued after 6 nights.

Other comments (e.g. unusual study design/issues): none

Reported power calculation? (Yes/No): yes "Data from the literature were scarce with regard to previous trials using DT and nonexistent with regard to BB in patients with mania, making power analysis difficult. Based on the DT study (large effect sizes 0.9–1.6; Cohen's d), a power analysis indicated that, for a probability level of 0.05 (two tailed) and power set at 0.80, 21 patients in each group would be sufficient to detect a significant difference."

Trial duration: 3 years

Unit of randomisation/unit of analysis: unit of randomisation and unit of analysis was per participant

Participants	**Country**: Norway **Total number of participants**: 32 **Setting**: hospital **Baseline characteristics** Blue-light filtering spectacle lens • Number of participants: 12 • Sex (number of females/number of males): 5/7 • Age (mean (SD)): 43.0 (11.0) Non-blue-light filtering spectacle lens • Number of participants: 11 • Sex (number of females/number of males): 2/9 • Age (mean (SD)): 49.8 (13.8) Overall • Number of participants: 23 • Sex (number of females/number of males): 7/16 • Age (mean (SD)): not reported **Inclusion criteria**: patients admitted to hospital with manic symptoms and bipolar disorder according to the Diagnostic and Statistical Manual of Mental Disorders, 4th edition, Text Revision (DSM-IV-TR) criteria, and aged 18 to 70 years. **Exclusion criteria**: previous knowledge of BB glasses, not consenting to participate, daily use of beta blockers, nonsteroidal anti-inflammatory drugs (NSAIDs) or calcium antagonists, and severe eye disease or traumatic injury affecting both eyes. **Comparison of study groups at baseline**: "The pre-treatment mean YMRS score for the control group was 27.0 as compared to 23.4 in the BB group."
Interventions	**Intervention characteristics**

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Henriksen 2016 *(Continued)*

Blue-light filtering spectacle lens

- Intervention name (e.g. spectacle lens name and manufacturer): orange glasses (LowBlueLights.com, University Heights, OH,USA)
- Frequency with which the intervention (spectacle lenses) were worn over the trial duration: the glasses were worn from 6 p.m. to 8 a.m. for seven consecutive days.
- Other comments: patients were offered a choice between different models of glasses.

Non-blue-light filtering spectacle lens

- Intervention name (e.g. spectacle lens name and manufacturer): clear-lensed glasses (Uvex, Furth, Germany and 3M, Austin,TX, USA).
- Frequency with which the intervention (spectacle lenses) were worn over the trial duration: The glasses were worn from 6 p.m. to 8 a.m. for seven consecutive days.
- Other comments: patients were offered a choice between different models of glasses.

Outcomes

Primary outcome(s): change in Young Mania Rating Scale (YMRS)

Secondary outcomes (s): change in motor activity (measured using actigraphy)

Adverse events reported? (Y/N): Y

Measurement time points: daily over a 7-day period

Identification

Dates study conducted: February 2012 to February 2015

Funding sources: "The study was supported by Fonna Local Health Authority, the Western Norway Regional Health Authority, and MoodNet, a regional research network on mood disorders, Haukeland University Hospital.The funders of the study had no role in the study design, data collection, data analysis, data interpretation, decision to publish, or writing of the report."

Declaration of interest: "The authors of this paper do not have any commercial associations that might pose a conflict of interest in connection with this manuscript."

Trial registration number: not reported

Contacting study investigators: study authors not contacted; no additional information used for review

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Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Included patients were randomly assigned to wear- ing either orange glasses (BB) or clear glasses (pla- cebo), by use of manual drawing from a fixed number of folded patches." Comment: drawing of lots method of randomisation.
Allocation concealment (selection bias)	Unclear risk	Quote: "drawing from a fixed number of folded patches. Secretaries not otherwise involved in the trial made the allocation."

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Henriksen 2016 *(Continued)*

		Quote: "Included patients were randomly assigned to wear- ing either orange glasses (BB) or clear glasses (pla- cebo), by use of manual drawing from a fixed number of folded patches." Comment: allocation patches described as "folded". There is the possibility that some of the information contained is visible, unlike if, for example, opaque envelopes were used.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Comment: participants were masked, however personnel were not masked. These same personnel (nurses) were also involved in the assessment of the outcomes.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Quote: "The persons assessing day-to-day mania symptoms and analysing the data were not blinded to group assignment." Quote: "This study was not double-blinded as the nature of the intervention (coloured glasses) made masking practically impossible. Even if raters had been blinded, it would have been difficult to blind the reporting staff, and patients in a manic state cannot be instructed to withhold information concerning treatment from the rater." Comment: outcome assessors were reported to be not masked.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Comment: missing data > 20% (i.e. follow-up < 80%) but follow-up equal in both groups.
Selective reporting (reporting bias)	Unclear risk	Comment: No access to protocol or clinical trials registry entry.
Other bias	Unclear risk	Quote: "However, after 3 years of recruitment and with a total number of 24 patients included for the intention-to-treat analysis, inclusion was ended due to the increasing risk of a selection bias because of the growing public awareness of the effects of blue light and BB glasses." Comment: trial stopped early due to perceived risk of selection bias because of growing public awareness of blue blocking glasses.

Henriksen 2020

Study characteristics	
Methods	**Study design**: RCT **Study grouping**: parallel **Exclusions after randomisation**: in the intervention group, 6 participants were excluded after randomisation: 3 participants withdrew consent after the first night of intervention, 2 participants were unable to adhere to protocol, and 1 participant was excluded from analysis. In the control group, 3 participants were excluded after randomisation due to withdrawal of consent after the first night of intervention. **How missing data were handled** (e.g. available case analysis, imputation, etc.): not reported **Losses to follow-up**: none **Other comments** (e.g. unusual study design/issues): none

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Henriksen 2020 *(Continued)*

	Reported power calculation? (Yes/No): no "The sample was small for analysing actigraphy data, making the study susceptible to type II errors." **Trial duration**: 3 years **Unit of randomisation/unit of analysis**: unit of randomisation and unit of analysis was per participant
Participants	**Country**: Norway **Total number of participants**: 32 **Setting**: hospital **Baseline characteristics** Blue-light filtering spectacle lens • Number of participants: 10 • Sex (number of females/number of males): 4/6 • Age (mean (SD)): 43.9 (11.8) Non-blue-light filtering spectacle lens • Number of participants: 10 • Sex (number of females/number of males): 2/8 • Age (mean (SD)): 48.8 (14.1) Overall • Number of participants: 20 • Sex (number of females/number of males): 6/14 • Age (mean (SD)): not reported **Inclusion criteria**: "Patients in hospital with Bipolar Disorder in a manic phase, aged 18–70 years." **Exclusion criteria**: not reported **Comparison of study groups at baseline**: "The placebo group was somewhat older (mean 48.8 years vs. 43.9 years) and had a modestly higher mean YMRS total score at the start of the intervention (26.8 vs. 23.9). The placebo group scored on average as more morning type than the BB group (MEQ: 60.4 ± 5.8 vs. 52.4 ± 14.8, respectively)."
Interventions	**Intervention characteristics** Blue-light filtering spectacle lens • Intervention name (e.g. spectacle lens name and manufacturer): blue-blocking glasses (LowBlueLights.com,University Heights, OH, USA) • Frequency with which the intervention (spectacle lenses) were worn over the trial duration: "From 18:00 to 08:00 hours for 7 days." • Other comments: participants could choose between different models of glasses according to individual comfort and preference of style. Non-blue-light filtering spectacle lens • Intervention name (e.g. spectacle lens name and manufacturer): clear-lensed glasses (Uvex, Furth, Germany, and 3M, Austin, TX, USA) • Frequency with which the intervention (spectacle lenses) were worn over the trial duration: "From 18:00 to 08:00 hours for 7 days." • Other comments: participants could choose between different models of glasses according to individual comfort and preference of style.

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Henriksen 2020 *(Continued)*

Outcomes	**Primary outcome(s)**: sleep efficiency (percentage sleep during the main rest interval) and motor activity during sleep intervals. **Secondary outcome(s)**: total sleep (hours) during the main rest interval, wake after sleep onset (minutes), number of wake episodes, sleep fragmentation index (percentage active time in sleep interval + percentage inactive bouts of 1 min duration), sleep onset, sleep offset and mid-time sleep. **Adverse events reported?** (Y/N): N **Measurement time points**: nights 1 and 5
Identification	**Dates study conducted**: February 2012 to February 2015 **Funding sources**: "The study was supported by The Western Norway Regional Health Authority, Fonna Local Health Authority, the University of Bergen and Moodnet, a regional research network on mood disorders, Haukeland University Hospital." **Declaration of interest**: "Tone E. G. Henriksen is ashareholder in Chrono Chrome AS. The disclosure does not apply to the planning and data collection for the VATMAN trial." **Trial registration number**: NTC01818622 **Contacting study investigators**: study authors not contacted; no additional information used for review **Authors name**: Tone E. G. Henriksen **Institution**: Valen Sjukehus **Email**: tgjo@helse-fonna.no **Address**: Valen Sjukehus, Sjukehusvegen 26, Valen 5451, Norway
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The included patients were randomly assigned to BB glasses or clear (placebo) glasses, by a manual draw performed by secretaries" Comment: drawing of lots method of randomisation.
Allocation concealment (selection bias)	Unclear risk	Comment: not reported how allocation was administered. Trial may be described as “randomised” but with no further details.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: described as a single-blinded trial. Participants were reported to be masked, however personnel were unmasked.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Comment: no information on masking of outcome assessors. We assume that in the absence of reporting, outcome assessors were not masked.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Quote: "Two patients were unable to adhere to the protocol and six patients withdrew consent. One patient was excluded due to withdrawal symptoms and one patient's actigraphy recording failed. In the BB group, one patient dropped out after one night and for another patient the first night recording was invalid. In the placebo group, two patients dropped out after five and six

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Henriksen 2020 *(Continued)*

		nights, respectively. This yielded 20 patients for the ANCOVA analyses, 10 patients in the BB group and 10 patients in the placebo group." Comment: follow-up not reported or missing data > 20% (i.e. follow-up < 80%) but follow-up equal in both groups.
Selective reporting (reporting bias)	Unclear risk	Quote: "The trial is registered with ClinicalTrials.gov: NTC01818622." Comment: all outcomes in the protocol and/or trials registry entry are reported. However, the trial commenced in February 2012, but it was not registered until March 2013.
Other bias	Low risk	Quote: "The study was supported by The Western Norway Regional Health Authority, Fonna Local Health Authority, the University of Bergen and Moodnet, a regional research network on mood disorders, Haukeland University Hospital. The funders had no role in the study design, data collection, data analysis, data interpretation, decision to publish or writing of the manuscript. Abstract Improvement of sleep is a central treatment goal for patients in a manic state." Comment: No other apparent sources of bias.

Janku 2020

Study characteristics	
Methods	**Study design**: RCT **Study grouping**: parallel **Exclusions after randomisation**: 5 patients did not continue after randomisation and were not used for analyses **How missing data were handled** (e.g. available case analysis, imputation, etc.): not reported **Losses to follow-up**: none **Other comments** (e.g. unusual study design/issues): none **Reported power calculation?** (Yes/No): yes: "A sample size calculation was performed before the study began using a large effect size (d = 0.90) with α = 0.05. To detect significant differences in subjective sleep parameters (SOL, SE, TST) before and after the therapy the suggested sample size was n = 6–9 in each group (Cervena 2004; Koffel 2015). For detection of differences in objective sleep parameters measured by actigraphy at least eight patients were suggested (Vallières 2003). As such, we aimed to include 30 patients in total, 15 patients in each group" **Trial duration**: not reported **Unit of randomisation/unit of analysis**: unit of randomisation and unit of analysis was per participant
Participants	**Country**: Czech Republic **Total number of participants**: 35 **Setting**: Department of Sleep Medicine of the National Institute of Mental Health **Baseline characteristics** Blue-light filtering spectacle lens • Number of participants: 15 • Sex (number of females/number of males): 6/9

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Janku 2020 *(Continued)*

- Age (mean (SD)): 42.4 (14.8)

Non-blue-light filtering spectacle lens

- Number of participants: 15
- Sex (number of females/number of males): 9/6
- Age (mean (SD)): 53.9 (15.8)

Overall

- Number of participants: 30
- Sex (number of females/number of males): 15/15
- Age (mean (SD)): 48.1 (16.1)

Inclusion criteria: minimum age of 18 years; absence of severe comorbid psychiatric, neurological or somatic dis-ease; motivation to complete CBT-I program; stable usage of medication affecting sleep.

Exclusion criteria: interrupted CBT-I program; previous experience with CBT-I; night shifts

Comparison of study groups at baseline: "The basic characteristics of the final sample can be seen in Table 1. As the age difference between groups reached the thresholdof statistical significance (t(28) = −2.052, P = .050), age was used as a confounding variable in further analyses along with gender and assigned therapist. To compare both groups at the beginning of the CBT-I program, independent-samples t-tests were carried out for all variables, including ISI, PSQI, ESS, SDS, HAS, BDI and BAI questionnaires and both subjective and objective measures of sleep parameters (SOL, TST, WASO, SE). Baseline measures in each group are presented in Table 2. The only statistically significant difference between the active and placebo group was found for sleepiness (as measured by ESS) (t = 2.437, P = .021), with higher score (indicating more sleepiness) found in the active group (8.17 ± 4.22) as compared to the placebo group (4.73 ± 3.45)."

Interventions

Intervention characteristics

Blue-light filtering spectacle lens

- Intervention name (e.g. spectacle lens name and manufacturer): blue-light blocking glasses (UVEX S1933X (US certification ANSI Z87 + and CSA Z94.3))
- Frequency with which the intervention (spectacle lenses) were worn over the trial duration: "Patients of both groups were instructed to wear the glasses 90 min prior to scheduled bedtime from week 2 till the end of the program."
- Other comments: none

Non-blue-light filtering spectacle lens

- Intervention name (e.g. spectacle lens name and manufacturer): placebo glasses (UVEX S1900 (US certification ANSI Z87 + and CSA Z94.3))
- Frequency with which the intervention (spectacle lenses) were worn over the trial duration: "Patients of both groups were instructed to wear the glasses 90 min prior to scheduled bedtime from week 2 till the end of the program."
- Other comments: none

Outcomes

Primary and secondary outcome measures were not clearly distinguished.

Specified outcome(s):**c**hange from baseline in sleep onset latency, total sleep time, wake after sleep onset, sleep effectivity, Pittsburgh Sleep Quality Index, Insomnia Severity Index, Sheehan Disability Scale (SDS), Epworth Sleepiness Scale (ESS), Beck Depression Inventory-2 (BDI-II) scale, Beck Anxiety Inventory (BAI) scale, hyperarousal scale (HAS), and actigraphy sleep data.

Adverse events reported? (Y/N): Y

Measurement time points

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Janku 2020 *(Continued)*

- Subjective sleep measures and actigraphy data (sleep onset latency, total sleep time, wake after sleep onset, sleep effectivity) – weekly measures performed at week 1 (baseline) and weeks 2 to 6.
- Pittsburgh Sleep Quality Index, Insomnia Severity Index, Sheehan Disability Scale (SDS), Epworth Sleepiness Scale (ESS), Beck Depression Inventory-2 (BDI-II) scale, Beck Anxiety Inventory (BAI) scale, hyperarousal scale (HAS) – measured at week 1 (baseline) and week 6.

Identification	**Dates study conducted**: not reported **Fundind source**: "This study is a result of the research funded by the project Nr. LO1611 with financial support from the MEYS under theNPU I program.Further supported by project "PROGRES Q35", 260388/SVV/2019 and GAUK 1064218." **Declaration of interest**: "The authors have no conflicts of interest to declare." **Trial registration number**: not reported **Contacting study investigators**: study authors not contacted; no additional information used for review **Authors name**: Michal Šmotek **Institution**: National Institute of Mental Health **Email**: michal.smotek@nudz.cz **Address**: National Institute of Mental Health, Department of Sleep Medicine, Topolová 748, Klecany 25067, Czech Republic
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "the aim of this randomized controlled trial was to for the first time assess the effect of CBT-I in combination with blue-light-blocking glasses (BB glasses)." Comment: not reported how list was generated. Trial was described as "randomised" but with no further details.
Allocation concealment (selection bias)	Unclear risk	Comment: not reported how allocation was administered. Trial was described as "randomised" but with no further details.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Comment: No information on masking. We assume that in the absence of reporting, participants and personnel were not masked.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Data were recorded continuously for six consecutive weeks before they were downloaded and analyzed by a researcher blinded to the experimental condition using MotionWare 1.4 (CamNtech)." Comment: clearly stated that outcome assessors were masked.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: Incomplete outcome dataMissing data less than 20% (i.e. more than 80% follow-up) and equal follow-up in both groups and no obvious reason why loss to follow-up should be related to outcome.
Selective reporting (reporting bias)	Unclear risk	Comment: no access to protocol or clinical trials registry entry.

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Janku 2020 *(Continued)*

Other bias	Low risk	Quote: "The authors have no conflicts of interest to declare." Quote: "This study is a result of the research funded by the project Nr. LO1611 with financial support from the MEYS under the NPU I program. Further supported by project "PROGRES Q35", 260388/SVV/2019 and GAUK 1064218." Comment: No other apparent sources of bias.

Knufinke 2019

Study characteristics	
Methods	**Study design**: RCT **Study grouping**: cross-over **Exclusions after randomisation**: not reported **How missing data were handled** (e.g. available case analysis, imputation, etc.): not reported **Losses to follow-up**: not reported **Other comments** (e.g. unusual study design/issues): none **Reported power calculation?** (Yes/No): no **Trial duration**: 1 month **Unit of randomisation/unit of analysis**: unit of randomisation and unit of analysis were per participant
Participants	**Country**: not reported **Total number of participants**: 15 **Setting**: not reported **Baseline characteristics** • Number of participants: 15 • Sex (number of females/number of males): 12/3 • Age (mean (SD)): 23.27 (3.63) **Inclusion criteria**: exercising 1 or more hours a week (endurance and/or weight training); moderate to good subjective sleep quality based on the Pittsburgh Sleep Quality Index (PSQI: all < 7; M ± SD; 3.87 ± 1.55); no severe subjective sleep complaints based on the Holland Sleep Disorder Questionnaire (HSDQ: all < 2.06; M ± SD; 1.57 ± 0.26); (4) being free of sleep medication; (5) consuming < 500 mg caffeine a day (~ 5 espressos) and < 5 standard units alcohol; (6) no current use of psychoactive medication; (7) absence of psychiatric and mood disorders; (8) no serious or unstable medical illness; (9) no diagnosed sleep disorders; (10) no time-zone crossing travel during the assessment period; (11) no pregnancy; and (12) no shift work. **Exclusion criteria**: not reported **Comparison of study groups at baseline**: not applicable (cross-over)
Interventions	**Intervention characteristics** Blue-light filtering spectacle lens

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Knufinke 2019 *(Continued)*

- Intervention name (e.g. spectacle lens name and manufacturer): amber-lens glasses (Eye shield soft red SafetyGlasses, Königswinter, Germany)
- Frequency with which the intervention (spectacle lenses) were worn over the trial duration: during the last 3 hours before bedtime and at the latest at 9.00 p.m. for 7 days.
- Other comments: none

Non-blue-light filtering spectacle lens

- Intervention name (e.g. spectacle lens name and manufacturer): transparent glasses (clear non-prescription lenses black, by Oramics)
- Frequency with which the intervention (spectacle lenses) were worn over the trial duration: during the last three hours before bedtime and at the latest at 9.00 p.m. for 7 days.
- Other comments: none

Outcomes

Primary outcome(s): sleep onset latency (measured using actigraphy)

Secondary outcome(s): wake after sleep onset, fragmentation index, total sleep time, and sleep efficiency. All outcome measured using actigraphy.

Adverse events reported? (Y/N): N

Measurement time points: Daily over a 9-night period

Identification

Dates study conducted: April 2016

Funding sources: "This research was funded by the STW Technology Foundation, The Netherlands under Grant number (STW 12865)."

Disclosure statement: "No potential conflict of interest was reported by the authors."

Trial registration number: not reported

Contacting study investigators: study authors not contacted; no additional information used for review

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Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Participants were randomly assigned to start the intervention period with either the light restriction condition (LR), or the no-light restriction condition (nLR)." Comment: not reported how list was generated. Trial was described as “randomised” but with no further details.
Allocation concealment (selection bias)	Unclear risk	Comment: not reported how allocation was administered. Trial was described as “randomised” but with no further details.

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Knufinke 2019 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "To prevent explicit outcome expectancies from influencing our findings, participants were informed that the study was designed to assess the effects of light regulation on mood and alertness." Comment: open-label or no information on masking. We assume that in the absence of reporting, participants and personnel were not masked.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Comment: open-label or no information on masking. We assume that in the absence of reporting, participants and personnel were not masked.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Comment: follow-up not reported or missing data > 20% (i.e. follow-up <80%) but follow-up equal in both groups.
Selective reporting (reporting bias)	Unclear risk	Comment: no access to protocol or clinical trials registry entry.
Other bias	Unclear risk	Quote: "To prevent any potential effect on our results – and before processing or analysing the data – we conservatively excluded night 1–3 in both conditions for all participants." Comment: a second concurrent intervention that appears to have been a light-emitting goggle to be used in the morning was aborted due to technical issues after 2 nights for both groups. The final analysis excluded nights 1 to 3. The effects of allowing only a 1-day washout period of the second concurrent intervention is unclear.

Lin 2017

Study characteristics	
Methods	**Study design**: RCT **Study grouping**: parallel **Exclusions after randomisation**: none **How missing data were handled** (e.g. available case analysis, imputation, etc.): none **Losses to follow-up**: none **Other comments** (e.g. unusual study design/issues): none **Reported power calculation? Yes/No**: Yes "We used G * Power 3. 115 to perform an a prior power calculation to determine the appropriate sample size. To detect a significant difference between the groups at the two-sided 0.05 level with an estimated effect size f of 0.8 based on a previous study and 95% power, we calculated that we needed to recruit 30 subjects. To account for up to 20% dropout, we recruited 36 subjects in total; that is,12 per group." **Trial duration**: not reported **Unit of randomisation/unit of analysis**: unit of randomisation and unit of analysis was per participant
Participants	**Country**: USA **Total number of participants**: 36 **Setting**: College of Optometry at University of Missouri–St. Louis

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Lin 2017 *(Continued)*

Baseline characteristics

Low blue-light filtering spectacle lens

- Number of participants: 12
- Sex (number of females/number of males): 7/5
- Age (mean (SD)): 24.58 (1.38)

High blue-light filtering spectacle lens

- Number of participants: 12
- Sex (number of females/number of males): 6/6
- Age (mean (SD)): 25.00 (2.73)

Non-blue-light filtering spectacle lens

- Number of participants: 12
- Sex (number of females/number of males): 3/9
- Age (mean (SD)): 23.25 (0.75)

Overall

- Number of participants: 36
- Sex (number of females/number of males): 16/20
- Age (mean (SD)): not reported

Inclusion criteria: healthy (no known significant health problems) volunteer; male or female of any ethnic group; between 21 and 39 years of age; uncorrected vision or contact lens–corrected vision of 20/30 or better with both eyesopen; not having performed VDT work for at least 1 hour before testing; and not having known visually significant ophthalmic pathology such as cataracts, macular degeneration, glaucoma, eye surgeries, or injuries based on self-reported history.

Exclusion criteria: < 21 or ≥ 40 years of age; had uncorrected vision or contact lens–corrected vision worse than 20/30 with both eyes open; self-reported a concurrent eye injury or disease; had photosensitivity, which would preclude them from comfortably performing 2 hours of VDT work; had been diagnosed with epilepsy; or had previously suffered a seizure.

Comparison of study groups at baseline: there was a statistically significant difference between the ages of the subjects randomly assigned to the no-block and low blockgroups.

Interventions

Intervention characteristics

Low blue-light filtering spectacle lens

- Intervention name (e.g. spectacle lens name and manufacturer): low blue light blocking lens (JINS CO., LTD)
- Frequency with which the intervention (spectacle lenses) were worn over the trial duration: 2 hours
- Other comments: none

High blue-light filtering spectacle lens

- Intervention name (e.g. spectacle lens name and manufacturer): high blue-light blocking lens (JINS CO., LTD)
- Frequency with which the intervention (spectacle lenses) were worn over the trial duration: 2 hours
- Other comments: none

Non-blue-light filtering spectacle lens

- Intervention name (e.g. spectacle lens name and manufacturer): clear lens (JINS CO., LTD)
- Frequency with which the intervention (spectacle lenses) were worn over the trial duration: 2 hours
- Other comments: none

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Lin 2017 *(Continued)*

Outcomes	**Primary outcome**: pre- and post-task critical fusion frequency (CFF) **Secondary outcomes**: symptoms of eyestrain using a 15-item questionnaire **Adverse events reported?** (Y/N): N **Measurement time points**: before and after 2 hours of computer task
Identification	**Dates study conducted**: not reported **Funding sources**: "JIN CO., LTD. provided the lenses used in this study, prepared the randomization schedule, and masked the investigators to the lenses used in each pair of glasses. Supported by JIN CO., LTD (CJB at UMSL) and by the UMSL Optometry Scholar Fund (BWG)." **Declaration of interest**: "The authors alone are responsible for the content and writing of this paper." **Trial registration number**: not reported **Contacting study investigators**: study authors not contacted; no additional information used for review **Authors name**: Rajendra S. Apte **Institution**: University of Missouri–St. Louis, St. Louis, Missouri, United States **Email**: apte@vision.wustl.edu **Address**: 660 South Euclid Avenue, Box 8096,St. Louis, MO 63110, USA
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Subjects were assigned randomly based on a predetermined schedule to one of the three lens groups: control lenses, low- blocking lenses, and high-blocking lenses. Since the blocking lenses can be identified potentially by their tint/color, the manufacturer packaged the eyeglasses in opaque boxes" Comment: not reported how list was generated. Trial was described as “randomised” but with no further details.
Allocation concealment (selection bias)	Unclear risk	Comment: not reported how allocation was administered. Trial was described as “randomised” but with no further details.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Comment: although study participants did not wear the eyeglasses during the CFF measurements to ensure study personnel were masked to group assignments, we cannot rule out the possibility that the participants themselves may have noticed the visual appearance of their glasses.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Comment: clearly stated that outcome assessors were masked during the measurements.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: missing data less than 20% .
Selective reporting (reporting bias)	Unclear risk	Comment: no information regarding the clinical trial registration.

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Lin 2017 *(Continued)*

Other bias	Low risk	Comment: no other apparent sources of bias.

Perez Algorta 2018

Study characteristics	
Methods	**Study design**: RCT **Study grouping**: cross-over **Exclusions after randomisation**: 1 participant was unable to participate due to flooding on campus during scheduled data collection, and 1 participant was rejected for having traveled outside the UK time zone during the past 2 months. **How missing data were handled** (e.g. available case analysis, imputation, etc.): authors reported that " the level of missing data at item level was negligible". No further information was provided. **Losses to follow-up**: none reported "all participants completed the trial." **Other comments** (e.g. unusual study design/issues): study authors mentioned that they had recruited 13 participants initially. 2 exclusions were reported; however, the results included data for 12 participants, not 11. **Reported power calculation? Yes/No**: no: "given the small sample size, our analyses were not adequately powered and should be considered preliminary, pending replication in a larger, adequately powered efficacy study" **Trial duration**: 7 months **Unit of randomisation/unit of analysis**: unit of randomisation and unit of analysis was per participant
Participants	**Country**: UK **Total number of participants**: 13 **Setting**: study was conducted at Lancaster University **Baseline characteristics** • Number of participants: 12 • Sex (number of females/number of males): 8/4 • Age (mean (SD)): 18.5 (0.52) **Inclusion criteria**: "First year under-graduates students living on campus for first time with sleep complaints/disorders confirmed at screening via the Duke Structured Interview Schedule for Sleep Disorders (DSISD)" **Exclusion criteria**: "unable or unwilling to comply with protocol; reported having severe retinal or corneal damage on both eyes; reported daily use of non-steroidal anti-inflammatory drugs,beta blockers, calcium-antagonist, or central stimulants like methylphenidate or venlafaxine; reported traveling outside the UK time zone during the past 2 months; reported changes in hormonal contraceptives during the past 2 months; or had brain dysfunction as observed during the screening interview." **Comparison of study groups at baseline**: not applicable (cross-over)
Interventions	**Intervention characteristics** Blue-light filtering spectacle lens • Intervention name (e.g. spectacle lens name and manufacturer): amber glasses (active BBG; Uvex S1933X with required wave-length-blocking properties)

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Perez Algorta 2018 *(Continued)*

- Frequency with which the intervention (spectacle lenses) were worn over the trial duration: 4 days - baseline data (Days 1–3) was collected. Days 4 - 7 participants wore the glasses 3 hours prior to sleep. Days 8 - 10 was washout period. Days 11 - 14 cross-over to other intervention.
- Other comments: none

Non-blue-light filtering spectacle lens

- Intervention name (e.g. spectacle lens name and manufacturer): blue glasses (non-BBG; Uvex S1932X)
- Frequency with which the intervention (spectacle lenses) were worn over the trial duration: 4 days - baseline data (Days 1–3) was collected. Days 4 - 7 participants wore the glasses 3 hours prior to sleep. Days 8 - 10 was washout period. Days 11 - 14 cross-over to other intervention.
- Other comments: none

Outcomes	Primary and secondary outcome measures were not clearly distinguished **Specified outcome(s)**: sleep diary, actigraphy data, sleep time, pulse oximetry, 7 Up-7 Down rating scale, Positive Affect–Negative Affect Schedule (PANAS), and Morningness/eveningness Questionnaire (MEQ). **Adverse events reported?** (Y/N): Y **Measurement time points**: sleep diary and actigraphy data were measured daily for two weeks. Sleep time and pulse oximetry data were measured on days 7 and 14. 7 Up-7 Down rating scale, PANAS questionnaire, and MEQ were measured at baseline and at days 3, 7, 10, 14.
Identification	**Dates study conducted**: October 2015 to April 2016 **Funding sources**: "This work was supported by the Early Career Small Grants, Lancaster University—HRA7893." **Declaration of interest**: "Drs. GPA, AVM, SJ and FL have no conflicts of interest to disclose. EAY has consulted with Joe Startup Technologies, Janssen, Lundbeck, Otsuka, Western Psychological Services, and Pearson. BD has a licensing agreement with Lundbeck for the use of a psychosocial treatment manual for depression." **Trial registration number**: not reported **Contacting study investigators**: study authors not contacted; no additional information used for review **Authors name**: Guillermo Perez Algorta **Institution**: Spectrum Centre for Mental Health Research, Division of Health Research, Lancaster University **Email**: g.perezalgorta@lancaster.ac.uk **Address**: Spectrum Centre for Mental Health Research, Division of Health Research,Lancaster University, Furness Building C73, Lancaster LA14YT, UK
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "This study used a 2-week, balanced crossover design with computer-generated random allocation." Comment: computer generated list method of randomisation.

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Perez Algorta 2018 *(Continued)*

Allocation concealment (selection bias)	High risk	Quote: "Baseline data (days 1–3) was collected, and glasses and procedure were introduced to participants by PI." Comment: study PI delivered the intervention, and no information was provided whether the PI was masked or not. We presume that in the absence of information that the PI was not masked.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "Participants were told by PI that we were testing two pairs of glasses, each of which filtered different wave- lengths of light, to reduce the likelihood of participant expectations about the effects of the BBG versus the blue glasses)." Comment: study only mentioned reducing the expectation of the participants to the intervention. No information about masking the participants was mentioned.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Comment: no information on masking. We assume that in the absence of reporting, outcome assessors were not masked.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "We had a retention rate over the 2-week protocol of 92%; all participants completed the trial." Comment: Missing data less than 20% (i.e. more than 80% follow-up); equal follow-up in both groups and no obvious reason why loss to follow-up should be related to outcome.
Selective reporting (reporting bias)	Unclear risk	Comment: no access to protocol or clinical trials registry entry.
Other bias	Low risk	Comment: no other apparent sources of bias.

Shechter 2018

Study characteristics	
Methods	**Study design**: RCT **Study grouping**: cross-over **Exclusions after randomisation**: "One participant in the amber lenses-first condition declined to complete the second intervention phase, leaving 14 participants who completed both phases and were analyzed for primary and secondary outcomes" **How missing data were handled** (e.g. available case analysis, imputation, etc.): not reported **Losses to follow-up**: "one participant didn't complete the second intervention phase. Hence, his data was excluded from the study." **Other comments** (e.g. unusual study design/issues): none **Reported power calculation?** (Yes/No): yes: "Sample size estimates were for paired-samples, two-tailed level of significance at 0.05 and 80% power. Authors expected to be able to detect an effect size (Cohen's d) of 0.95 for significantly improved subjective sleep quality in amber vs. placebo lenses with n = 11, and to be able to detect an effect size of 0.92 for significantly decreased subjective SOL in BB vs. placebo lenses with n = 12 (Fargason 2013). Assuming a 20% drop-out rate, we aimed to recruit n = 15 to have power to detect statistically significant improvements in sleep with BB lenses". **Trial duration**: not reported

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Shechter 2018 *(Continued)*

	Unit of randomisation/unit of analysis: unit of randomisation and unit of analysis was per participant
Participants	**Country**: USA **Total number of participants**: 15 **Setting**: not reported **Baseline characteristics** • Number of participants: 14 • Sex (number of females/number of males): 8/6 • Age (mean (SD)): 46.6 (11.5) **Inclusion criteria**: chronic insomnia symptoms for > 3 months. Insomnia identification in study participants was achieved via a validated symptom questionnaire, the Insomnia Symptoms Questionnaire (ISQ) (Okun 2009). **Exclusion criteria**: Prior diagnosis of obstructive sleep apnoea (apnoea-hypopnoea index ≥15 events/h, via polysomnography,obtained from medical history in individuals who had previously undergone a diagnostic study), a score > 5 on the STOP-Bang Questionnaire (Chung 2016) which is indicative of a high risk of sleep apnoea (completed by all potential participants), or other sleep disorders such as periodic limb movement disorder, restless leg syndrome or narcolepsy (assessed via medical history); current night shift workers; and travel across time zones within 2 wk preceding study. Further exclusion criteria included current cigarette smoking, taking betablockers, diagnosis of a psychiatric disorder (based on self-report, medical history, or current use of any anti-depressive or anti-anxiety medications), child at home < 1 y old, pregnancy, breastfeeding, or excessive caffeine intake (> 400 mg/d). **Comparison of study groups at baseline**: not applicable (cross-over)
Interventions	**Intervention Characteristics** Blue-light filtering spectacle lens • Intervention name (e.g. spectacle lens name and manufacturer): amber lenses (Bandit style frames, Uvex, Honeywell Safety, Smithfield, RI, USA). The amber lenses filter out blue-wavelength light, while allowing the other visible spectrum light to pass, resulting in a blue-light absorption (BLA) of 65% and a visible light transmission (VLT) of 90%. • Frequency with which the intervention (spectacle lenses) were worn over the trial duration: 1 week - from 2 hours before bedtime (removing frames at lights-out) while they were living at home on their habitual sleep-wake schedule. • Other comments: intervention phases were separated by a 4-wk washout period, followed by cross-over to the alternate intervention phase. Non-blue-light filtering spectacle lens • Intervention name (e.g. spectacle lens name and manufacturer): clear lenses worn in wraparound frames identical to those in the BB condition (Manufacturer - not reported). The clear lenses have a VLT of 92%, while allowing for the almost complete transmission of blue-wavelength light (~90%) based on manufacturer specifications. • Frequency with which the intervention (spectacle lenses) were worn over the trial duration: 1 week - from 2 hours before bedtime (removing frames at lights-out) while they were living at home on their habitual sleep-wake schedule. • Other comments: intervention phases were separated by a 4-wk washout period, followed by cross-over to the alternate intervention phase.
Outcomes	**Primary outcome (s)**: daily average change in Pittsburgh Insomnia Rating Scale (PIRS) score over a period of 7 days **Secondary outcome (s)**: daily average change in bedtime (lights out), wake time, post-sleep questionnaire (PSQ) score, sleep onset latency, total sleep time (TST), wakefulness after sleep onset, and overall evaluation of sleep measured using a Likert scale, measured over a period of 7-days.

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Shechter 2018 *(Continued)*

	Adverse events reported? (Y/N): Y **Measurement time points**: Days 1 to 7
Identification	**Dates study conducted**: not reported **Funding Sources**: "This research was funded by a Focused-Project Award (144-FP-16;AS) from the American Sleep Medicine Foundation, a foundation of the American Academy of Sleep Medicine. This publication was also supported in part by the National Center for Advancing Translational Sciences, National Institutes of Health, through Grant NumberUL1TR001873" **Declaration of interest**: none **Trial registration number**: NCT02698800 **Contacting study investigators**: study authors not contacted; no additional information used for review **Authors name**: Ari Shechter **Institution**: Columbia University **Email**: as4874@columbia.edu **Address**: Department of Medicine, Columbia University, 622 West 168th Street, Room 9-300A, New York, NY 10032, USA
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "After enrollment, participants were randomized via simple randomization with a computer-generated random numbers generator into an intervention sequence (clear condition followed by amber condition for even numbers; amber condition followed by clear condition for odd numbers)." Comment: participants were randomised using a computer-generated list.
Allocation concealment (selection bias)	Unclear risk	Comment: not reported how allocation was administered. Trial was described as “randomised” but with no further details.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Comment: open-label or no information on masking. We assume that in the absence of reporting, participants and personnel were not masked.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Comment: open-label or no information on masking. We assume that in the absence of reporting, outcome assessors were not masked.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "by clear lenses (Fig. 1). One participant in the amber lenses-first condition declined to complete the second intervention phase, leaving 14 participants" Comment: Missing data less than 20% (i.e. more than 80% follow-up); equal follow-up in both groups and no obvious reason why loss to follow-up should be related to outcome.

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Shechter 2018 *(Continued)*

Selective reporting (reporting bias)	Low risk	Comment: all outcomes in the protocol and trials registry entry are reported.
Other bias	Low risk	Comment: no other apparent sources of bias.

Singh 2021

Study characteristics	
Methods	**Study design**: RCT **Study grouping**: parallel **Exclusions after randomisation**: none **How missing data were handled** (e.g. available case analysis, imputation, etc.): not applicable **Losses to follow-up**: none **Other comments** (e.g. unusual study design/issues): tiered randomisation to have a clinical advocacy arm as well as treatment versus control **Reported power calculation?** (Yes/No): yes **Trial duration**: not reported **Unit of randomisation/unit of analysis**: unit of randomisation and unit of analysis was per participant
Participants	**Country**: Australia **Total number of participants**: 120 **Setting**: university **Baseline characteristics** Positive advocacy + Blue-light filtering spectacle lens • Number of participants: 30 • Sex (number of females/number of males): 16/14 • Age (median (interquartile range)): 25 (22,28) Positive advocacy + Non-blue-light filtering spectacle lens • Number of participants: 30 • Sex (number of females/number of males): 20/10 • Age (median (interquartile range)): 25 (23,28) Negative advocacy + Blue-light filtering spectacle lens • Number of participants: 30 • Sex (number of females/number of males): 23/7 • Age (median (interquartile range)): 22 (21,24) Negative advocacy + Non-blue-light filtering spectacle lens • Number of participants: 30 • Sex (number of females/number of males): 21/9 • Age (median (interquartile range)): 24 (20,30)

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Singh 2021 *(Continued)*

	Overall • Number of participants: 120 • Sex (number of females/number of males): 80/40 • Age (median (interquartile range)): not reported **Inclusion criteria**: adults aged 18 to 40 years; habitual computer use without a spectacle correction; and unaided or contact lens–corrected binocular near vision of ≥ N8 print at 40 cm. **Exclusion criteria**: history of self-reported neurological disease or migraine, or nystagmus; and individuals with a professional background in eye care or spectacle lens products, or who were currently undertaking study in these fields. **Comparison of study groups at baseline**: Table 1 in the paper summarises participant demographics. Groups are well matched for age, moderately matched for gender and contact lens use. Hours and days of computer use are well matched and OSDI and CVS scores have intersecting IQR.
Interventions	**Intervention Characteristics** Positive advocacy + Blue-light filtering spectacle lens • Intervention name (e.g. spectacle lens name and manufacturer): Prevencia (Essilor, Dallas, Texas, USA) • Frequency with which the intervention (spectacle lenses) were worn over the trial duration: spectacles worn during a 2-hour computer task • Other comments: none Positive advocacy + Non-blue-light filtering spectacle lens • Intervention name (e.g. spectacle lens name and manufacturer): UV-coated lens (Crizal; Essilor) with a conventional anti-reflection coating • Frequency with which the intervention (spectacle lenses) were worn over the trial duration: spectacles worn during a 2-hour computer task • Other comments: none Negative advocacy + Blue-light filtering spectacle lens • Intervention name (e.g. spectacle lens name and manufacturer): Prevencia; Essilor, Dallas, Texas, USA • Frequency with which the intervention (spectacle lenses) were worn over the trial duration: 2 hours (worn once) • Other comments: none Negative advocacy + Non-blue-light filtering spectacle lens • Intervention name (e.g. spectacle lens name and manufacturer): UV coated lens (Crizal; Essilor) with a conventional anti-reflection coating • Frequency with which the intervention (spectacle lenses) were worn over the trial duration: 2 hours (worn once) • Other comments: none
Outcomes	**Primary outcome**: before and after total eye strain symptom score (/900) and CFF **Secondary outcomes**: before and after eye movement parameters (latency, duration, amplitude, peak velocity, and mean velocity), blink rate (blinks per minute), near point of accommodation (cm), and near point of convergence (cm) **Adverse events reported?** (Y/N): Y **Measurement time points**: before and after 2 hours of computer task
Identification	**Dates study conducted**: not reported

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Singh 2021 *(Continued)*

Sponsorship source: there is no specific funding for this study

Declaration of interest: "L.E.D. has received grants from CooperVision, Azura Ophthalmics, and Kedalion Therapeutics to conduct dry eye and contact lens research, and consulting income from Seqirus to contribute to a Dry Eye Advisory Board. These grants and consulting income are outside the submitted work. S.S. and A.J.A. have no financial disclosure to report."

Trial registration number: ACTRN12619000057189

Contacting study investigators: study authors not contacted; no additional information used for review

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Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Comment: computer-generated random sequence
Allocation concealment (selection bias)	Low risk	Comment: allocation allocation contained within MATLAB generated files.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants: Quote "Spectacles will be placed in opaque cases identified only by a number (1 through 4), with the spectacles removed only immediately prior to wearing by the participant, and replaced in the cases immediately after wearing"
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: authors comment in the discussion "Although we took measures to mask the outcome assessor to which intervention group the participants were allocated to, the outcome assessor correctly guessed the participant's spectacle type allocation 67% of the time. This percentage differed significantly from the expected 50% (P = .003), indicating that our masking efforts were insufficient for this level of sub-randomization."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: Missing data less than 20% (i.e. more than 80% follow-up); equal follow-up in both groups and no obvious reason why loss to follow-up should be related to outcome.
Selective reporting (reporting bias)	Low risk	Comment: trial was prospectively registered on the Australian and New Zealand Clinical Trials Registry (ANZCTR, ACTRN12619000057189). All prespecified primary and secondary outcomes were reported.
Other bias	Low risk	Comment: no other sources of bias.

BB: blue blocking; BD: bipolar disorder; BDI: Beck Depression Inventory; CBT-I: cognitive behavioral therapy for insomnia; CFF: critical fusion frequency; CVS: computer vision syndrome; ; DSM-5: Diagnostic and Statistical Manual of Mental Disorders, 5th edition; HAM-D: Hamilton Depression Rating Scale; IQR: interquartile range; MDD: major depressive disorder; MEQ: Morningness–Eveningness Questionnaire; OSDI: Ocular Surface Disease Index; RCT: randomised controlled trial; SL: sleep latency; VAS: visual analogue scale; VDT: visual display terminal

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

Study	Reason for exclusion
Al Azawi 2019	Ineligible study design
Bennett 2009	Ineligible intervention
Cozza 2020	Ineligible study design
Danilenko 2016	Ineligible intervention
Figueiro 2011	Ineligible intervention
Figueiro 2013	Ineligible intervention
Figueiro 2020	Ineligible intervention
Ide 2015	Ineligible study design
Ishizawa 2021	Ineligible study design
Kaido 2016	Ineligible study design
Leung 2017	Ineligible study design
Luria 1972	Ineligible study design
Monteiro 2017	Ineligible study design
NCT02982239	Ineligible intervention
NCT03831919	Ineligible intervention
NCT04076410	Ineligible study design
NCT04463498	Ineligible comparator
NCT04804501	Ineligible comparator
NCT04827446	Ineligible comparator
NCT05177055	Ineligible comparator
NL9458	Ineligible intervention
Otsuka 2020	Ineligible study design
Phelps 2016	Ineligible study design
RBR-3snw7t	Ineligible comparator
Redondo 2020	Ineligible intervention
Rosenfield 2020	Ineligible study design

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Study	Reason for exclusion
Sasseville 2006	Ineligible study design
Sasseville 2015	Ineligible intervention
Shirahama 2018	Ineligible study design
Smotek 2019	Ineligible study design
Teran 2020	Ineligible study design
Wood 2013	Ineligible intervention

Characteristics of studies awaiting classification *[ordered by study ID]*

Smolders 2016

Methods	**Study design**: RCT **Study grouping**: cross-over **Exclusions after randomisation**: not reported **How missing data were handled** (e.g. available case analysis, imputation, etc.): not reported **Losses to follow-up**: not reported **Other comments** (e.g. unusual study design/issues): none **Reported power calculation?** (Yes/No): not reported **Trial duration**: not reported **Unit of randomisation/unit of analysis**: unit of randomisation and unit of analysis was per participant
Participants	**Country**: not reported **Total number of participants**: 32 **Setting**: not reported **Baseline characteristics** • Number of participants: 32 • Sex (number of females/number of males): not reported • Age (mean (SD)): not reported **Inclusion criteria**: healthy young participants **Exclusion criteria**: not reported **Comparison of study groups at baseline**: not applicable (cross-over)
Interventions	**Intervention characteristics** Blue-light filtering spectacle lens • Intervention name (e.g. spectacle lens name and manufacturer): blue-blocking glasses (manufacturer - not reported)

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Smolders 2016 *(Continued)*

- Frequency with which the intervention (spectacle lenses) were worn over the trial duration: 4 days - from 6 pm until sleep onset.
- Other comments: none

Non-blue-light filtering spectacle lens

- Intervention name (e.g. spectacle lens name and manufacturer): transparent glasses (manufacturer - not reported)
- Frequency with which the intervention (spectacle lenses) were worn over the trial duration: 4 days - from 6 pm until sleep onset.
- Other comments: none

Outcomes	Primary and secondary outcome measures were not clearly distinguished. **Specified outcome(s)**: light exposure patterns (measured using light sensors and activity trackers) and subjective sleepiness score. **Adverse events reported?** (Y/N): N **Measurement time points**: Days 1 to 4. Sleepiness was measured from 6 pm until participants' sleep onset.
Notes	

Wolffsohn 2007

Methods	**Study design**: RCT **Study grouping**: cross-over **Exclusions after randomisation**: not reported **How missing data were handled** (e.g. available case analysis, imputation, etc.): not reported **Losses to follow-up**: not reported **Other comments** (e.g. unusual study design/issues): none **Reported power calculation?** (Yes/No): not reported **Trial duration**: not reported **Unit of randomisation/unit of analysis**: unit of randomisation was per participant. Both eyes received the same treatment. But, measurements of visual acuity (logMAR), contrast sensitivity (Pelli-Robson), colour discrimination (FM 100-Hue), short-wavelength automated perimetry (SWAP) and reading speed (MNRead) were performed on their right eye only.
Participants	**Country**: not reported **Total number of participants**: 18 **Setting**: not reported **Baseline characteristics** • Number of participants: 18 • Sex (number of females/number of males): not reported • Age (mean (SD)): 27.1 (6.7) **Inclusion criteria**: "Healthy eyes, without any color vision deficiency."

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Wolffsohn 2007 *(Continued)*

	Exclusion criteria: not reported **Comparison of study groups at baseline**: not applicable (cross-over)
Interventions	**Intervention characteristics** Blue-light filtering spectacle lens • Intervention name (e.g. spectacle lens name and manufacturer): 2 lenses were matched to the light filtering characteristics of the Alcon AcrySof® Natural blue-blocking IOL and the Bausch & Lomb SofPort® with Violet ShieldTM IOL. Brand name and manufacturer details - not reported. • Frequency with which the intervention (spectacle lenses) were worn over the trial duration: "Each spectacle lens was worn on three occasions separated by 5 to 7 days." • Other comments: none Non-blue-light filtering spectacle lens • Intervention name (e.g. spectacle lens name and manufacturer): clear lens with UV absorption (manufacturer - not reported) • Frequency with which the intervention (spectacle lenses) were worn over the trial duration: "Each spectacle lens was worn on three occasions separated by 5 to 7 days." • Other comments: The transmission profiles of the lenses are not reported. It is unclear how much blue light filtering properties there are of the intervention lenses, in particular the lens matching the light filtering characteristics of the Bausch & Lomb SofPort with Violet Shield.
Outcomes	Primary and secondary outcome measures were not clearly distinguished. **Specified outcome(s)**: visual acuity (logMAR), contrast sensitivity (Pelli-Robson), colour discrimination (FM 100-Hue), short wavelength automated perimetry (SWAP), and reading speed (MNRead) **Adverse events reported?** (Y/N): N **Measurement time points**: single session
Notes	

Youngstrom 2014

Methods	**Study design**: RCT **Study grouping**: parallel **Exclusions after randomisation**: not reported **How missing data were handled** (e.g. available case analysis, imputation, etc.): not reported **Losses to follow-up**: not reported **Other comments** (e.g. unusual study design/issues): none **Reported power calculation?** (Yes/No): No **Trial duration**: not reported **Unit of randomisation/unit of analysis**: unit of randomisation and unit of analysis was per participant
Participants	**Country**: not reported **Total number of participants**: 24

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Youngstrom 2014 *(Continued)*

	Setting: not reported **Baseline characteristics** Blue-light filtering spectacle lens • Number of participants: not reported • Sex (number of females/number of males): not reported • Age (mean (SD)): not reported Non-blue-light filtering spectacle lens • Number of participants: not reported • Sex (number of females/number of males): not reported • Age (mean (SD)): not reported Overall • Number of participants: 24 • Sex (number of females/number of males): 10/14 • Age (range): not reported (35 to 70 years) **Inclusion criteria**: not reported **Exclusion criteria**: not reported **Comparison of study groups at baseline**: not reported
Interventions	**Intervention characteristics** Blue-light filtering spectacle lens • Intervention name (e.g. spectacle lens name and manufacturer): "amber glasses" (manufacturer - not reported) • Frequency with which the intervention (spectacle lenses) were worn over the trial duration: not reported • Other comments: none Non-blue-light filtering spectacle lens • Intervention name (e.g. spectacle lens name and manufacturer): "blue glasses" (manufacturer details - not reported) • Frequency with which the intervention (spectacle lenses) were worn over the trial duration: not reported • Other comments: none
Outcomes	Primary and secondary outcome measures were not clearly distinguished. **Specified outcome(s)**: Morningness-eveningness questionnaire, positive and negative affect schedule (PANAS) mood rating scale, pittsburgh sleep quality index (PSQI), sleep quality and energy measured using a Likert scale. **Adverse events reported?** (Y/N): N **Measurement time points**: baseline, up to three times prior to travel day, and twice at the destination.
Notes	

RCT: randomised controlled trial; SD: standard deviation

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

ChiCTR1800020191

Study name	**Public title**: Evaluation of Effect of blue-light Filtering spectacles on Objective Detection and Visual Quality **Scientific title**: Evaluation of Effect of blue-light Filtering spectacles on Visual Quality in Adults
Methods	**Study design**: RCT **Study grouping**: parallel **Exclusions after randomisation**: not reported **How missing data were handled** (e.g. available case analysis, imputation, etc.): not reported **Losses to follow-up**: not reported **Other comments** (e.g. unusual study design/issues): none **Reported power calculation?** (Yes/No): No **Trial duration**: not reported **Unit of randomisation/unit of analysis**: not reported
Participants	**Country**: China **Total number of participants**: not reported **Setting**: hospital **Baseline characteristics** Blue-light filtering spectacle lens • Number of participants: not reported • Sex (number of females/number of males): not reported • Age (mean (SD)): not reported Non-blue-light filtering spectacle lens • Number of participants: not reported • Sex (number of females/number of males): not reported • Age (mean (SD)): not reported Overall • Number of participants: not reported • Sex (number of females/number of males): not reported • Age (mean (SD)): not reported **Inclusion criteria**: physically healthy; frequent users of computer, mobile phone and other digital devices; gender requirement: half male and half female; healthy eyes; visual function requires that the best corrected distal vision should be greater than 5.0 (1.0); physically and mentally healthy; willing to participate in this experiment to eliminate excessive anxiety, doubt and entanglement; can cooperate with the completion of the entire experimental process (6 months of multiple follow-up). **Exclusion criteria**: presbyopia and adjustment of aggregate dysfunction; double vision. abnormal examination of fundus, intraocular pressure, anterior chamber and lens; abnormal color perception; history of refractive surgery; pregnancy; have worn OK glasses within a month; poor compliance (not allowed to wear as directed by doctors and regular visitors); serious psychological prob-

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ChiCTR1800020191 *(Continued)*

	lems; neurotic psychological problems (anxiety, depression, etc.); other conditions considered inappropriate by the researcher for participation in this clinical study. **Comparison of study groups at baseline**: not reported
Interventions	**Intervention characteristics** Blue-light filtering spectacle lens • Intervention name (e.g. spectacle lens name and manufacturer): blue-light filtering spectacles (spectacle lens name and manufacturer details: not reported) • Frequency with which the intervention (spectacle lenses) were worn over the trial duration: not reported • Other comments: none Non-blue-light filtering spectacle lens • Intervention name (e.g. spectacle lens name and manufacturer): participants wear ordinary radiation protection lenses (spectacle lens name and manufacturer: not reported). • Frequency with which the intervention (spectacle lenses) were worn over the trial duration: not reported • Other comments: none
Outcomes	**Primary outcome(s)**: visual quality **Seondaryoutcome(s)**: not reported **Adverse events reported?** (Y/N): N **Measurement time points**: not reported
Starting date	May 2015
Contact information	Jin Wanqing 270 Xueyuan Road West, Luchen, Wenzhou, Zhejiang, China **Email**: wcyjqw@163.com
Notes	**Date of last participant enrollment**: not reported **Date clinical trial registry last updated**: December 2018 **Recruitment status**: completed **Other notes**: study commenced on May 2015 and the protocol was retrospectively registered in December 2018

NCT03114072

Study name	**Public title**: Blocking Blue Light in Pregnancy, Effects on Melatonin Profile and Sleep **Scientific title**: A Proof of Concept Clinical Investigation Designed to Evaluate the Performance of Lumishade® Lens With Frame in Alleviating the Symptoms of Photosensitive Migraine
Methods	**Study design**: RCT **Study grouping**: parallel **Exclusions after randomisation**: not reported

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NCT03114072 *(Continued)*

	How missing data were handled (e.g. available case analysis, imputation, etc.): not reported **Losses to follow-up**: not reported **Other comments** (e.g. unusual study design/issues): not reported **Reported power calculation?** (Yes/No): not reported **Trial duration**: not reported **Unit of randomisation/unit of analysis**: not reported
Participants	**Country**: not reported **Total number of participants**: 60 (estimated enrolment) **Setting**: not reported **Baseline characteristics** Blue-light filtering spectacle lens • Number of participants: not reported • Sex (number of females/number of males): not reported • Age (mean (SD)): not reported Non-blue-light filtering spectacle lens • Number of participants: not reported • Sex (number of females/number of males): not reported • Age (mean (SD)): not reported Overall • Number of participants: not reported • Sex (number of females/number of males): not reported • Age (mean (SD)): not reported **Inclusion criteria**: nulliparous women; expecting one child; being in the third trimester of a normal pregnancy; able to wear an actigraph during daytime and nighttime; able to fill out a questionnaire in Norwegian. **Exclusion criteria**: somatic or psychiatric disorders; fever and other health conditions affecting sleep; working at night during the study protocol. **Comparison of study groups at baseline**: not reported
Interventions	**Intervention characteristics** Blue-light filtering spectacle lens • Intervention name (e.g. spectacle lens name and manufacturer): "Blue-blocking glasses (orange-tinted), which remove more than 99% of the blue wavelengths (wavelengths within the visible spectrum shorter than 530 nm). Luminous transmittance: 50%." Manufacturer - not reported • Frequency with which the intervention (spectacle lenses) were worn over the trial duration: "Wear the BB-glasses from three hours before bedtime, and if needed to turn on the light, also during the night." • Other comments: none Non-blue-light filtering spectacle lens

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NCT03114072 *(Continued)*

	• Intervention name (e.g. spectacle lens name and manufacturer): "Partially blue blocking light grey glasses, blocking only about 50% of blue wavelengths (wavelengths within the visible spectra shorter than 530 nm). Luminous transmittance: 55%." Manufacturer - not reported • Frequency with which the intervention (spectacle lenses) were worn over the trial duration: "Wear the light grey glasses from three hours before bedtime, and if needed to turn on the light, also during the night." • Other comments: none
Outcomes	**Primary outcome(s)**: daily subjective estimates of sleep diary, change in motor activity (measured using actigraphy), and melatonin levels **Secondary outcomes (s)**: Bergen Insomnia Scale (BIS), Karolinska Sleepiness Scale (KSS), Pre-Sleep Arousal Scale (PSAS), Epworth Sleepiness Scale (ESS), positive and negative affect schedule (PANAS) mood rating scale, Beck Anxiety Inventory (BAI), and Beck Depression Inventory-II (BAI-II) **Adverse events reported?** (Y/N): N **Measurement time points**: all outcomes were performed during 3 weeks in the third trimester of pregnancy, except for melatonin levels which was performed during 2 weeks in the third trimester of the pregnancy.
Starting date	June 2017
Contact information	Randi Liset University of Bergen Bergen, Norway, 5232
Notes	**Date of last participant enrolment**: June 2022 (estimated study completion date) **Date clinical trial registry last updated**: September 2021 **Recruitment status**: Active, not recruiting **Other notes**: none

NCT04578249

Study name	**Public title**: Effects of Blocking Blue Light at Night Post CABG, AVR, MVR, CABG AVR, or CABG MVR **Scientific title**: Effects of Blocking Blue Light at Night on Patient Outcomes After Elective CABG, AVR, MVR, CABG AVR, or CABG MVR Surgery
Methods	**Study design**: RCT **Study grouping**: parallel **Exclusions after randomisation**: not reported **How missing data were handled** (e.g. available case analysis, imputation, etc.): not reported **Losses to follow-up**: not reported **Other comments** (e.g. unusual study design/issues): not reported **Reported power calculation?** (Yes/No): No **Trial duration**: not reported

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NCT04578249 *(Continued)*

	Unit of randomisation/unit of analysis: not reported
Participants	**Country**: not reported **Total number of participants**: 80 (estimated enrolment) **Setting**: not reported **Baseline characteristics** Blue-light filtering spectacle lens • Number of participants: not reported • Sex (number of females/number of males): not reported • Age (mean (SD)): not reported Non-blue-light filtering spectacle lens • Number of participants: not reported • Sex (number of females/number of males): not reported • Age (mean (SD)): not reported Overall • Number of participants: not reported • Sex (number of females/number of males): not reported • Age (mean (SD)): not reported **Inclusion criteria**: both men and women that are undergoing elective (non-emergency) - n-pump CABG surgery AVR, MVR, CABG AVR, or CABG MVR; and no history of diagnosed psychiatric disorders or organ failure. **Exclusion criteria**: Evidence or diagnosis of dementia or other cognitive deficit; diagnosed psychiatric disorder (including depression and anxiety); organ failure (kidney (creatine > 1.5 mg/dL), liver, etc.); chronic obstructive pulmonary disease; any immune disorder; acute infection; prior cardiac surgery; elective aneurysms; combined cardiac operations; left main stenosis greater than 70%; left ventricular ejection fraction (LVEF) lower than 0.5; any condition that increases likelihood of the need for a blood transfusion during or after the surgery; clotting disorder; and suspected less than 8th grade English reading comprehension level. **Comparison of study groups at baseline**: not reported
Interventions	**Intervention characteristics** Blue-light filtering spectacle lens • Intervention name (e.g. spectacle lens name and manufacturer): blue-light blocking goggles (Honeywell, USA) • Frequency with which the intervention (spectacle lenses) were worn over the trial duration: not reported • Other comments: none Non-blue-light filtering spectacle lens • Intervention name (e.g. spectacle lens name and manufacturer): clear goggles (Honeywell, USA) • Frequency with which the intervention (spectacle lenses) were worn over the trial duration: not reported • Other comments: none
Outcomes	**Primary outcome(s)**: serum cytokine profile, serum cardiac ischemia profile, Hamilton Depression Scale (HDS), Pittsburgh Sleep Quality Index (PSQI) survey, central executive cognitive function, Wechsler Adult Intelligence Scale-Revised (WAIS-R) questionnaire.

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NCT04578249 *(Continued)*

	Secondary outcome(s): not reported **Adverse events reported?** (Y/N): N **Measurement time points**: baseline and 5 and 30 days post cardiac surgery.
Starting date	September 2021
Contact information	James C Walton, PhD **Email**: james.walton@hsc.wvu.edu
Notes	**Date of last participant enrollment**: September 2022 (estimated study completion date) **Date clinical trial registry last updated**: November 2021 **Recruitment status**: recruiting **Other notes**: none

NCT04904328

Study name	**Public title**: A Proof of Concept Alleviating the Symptoms of Photosensitive Migraine **Scientific title**: A Proof of Concept Clinical Investigation Designed to Evaluate the Performance of Lumishade® Lens With Frame in Alleviating the Symptoms of Photosensitive Migraine
Methods	**Study design**: RCT **Study grouping**: cross-over **Exclusions after randomisation**: not reported **How missing data were handled** (e.g. available case analysis, imputation, etc.): not reported **Losses to follow-up**: not reported **Other comments** (e.g. unusual study design/issues): not reported **Reported power calculation? Yes/No**: yes. "Assuming a fairly conservative SD in the primary end-point of 8 points, a total of 56 participants would be required to have 90% power to detect a minimum clinically significant difference of 5 points in a two-sample t-test. Allowing for a 20% drop-out rate, 70 participants would need to be recruited." **Trial duration**: not reported **Unit of randomisation/unit of analysis**: not reported
Participants	**Country**: not reported **Total number of participants**: 77 (estimated enrollment) **Setting**: not reported **Baseline characteristics** • Number of participants: not reported • Sex (number of females/number of males): not reported • Age (mean (SD)): not reported

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NCT04904328 *(Continued)*

	Inclusion criteria: over 18 years old; diagnosis of migraine before the age of 50, confirmed though screening consultation with the patient; willing and able to provide written informed consent; willing to comply with study assessment schedule and patient diary entry; diagnosis of migraine, with or without aura based on the following primary headache characteristics (based on the Revised International Headache Society criteria for migraine headache - at least 5 attacks fulfilling criteria B-D,headache attacks lasting 4-72 hours (untreated or unsuccessfully treated), headache has at least two of the following characteristics: i. unilateral location ii. pulsating quality iii. moderate or severe pain intensity iv. aggravation by or causing avoidance of routine physical activity (e.g. walking or climbing stairs) d. During headache at least one of the following: i. nausea and/or vomiting ii. photophobia and phonophobia e. not attributed to another disorder); migraine associated with photophobia i.e. either photic hypersensitivity or photic allodynia or inter-ictal photophobia or migraine triggered by light according to patient or a combination of these 4 factors; No expected changes of headache preventative medications after enrolment. **Exclusion criteria**: patients with other light sensitive conditions, such as iritis or retinal disease; patients who have less than 4 headache days per month; Patients who have daily headaches; pregnant or nursing; History of cluster headache or hemiplegic migraine; evidence of seizure or major psychiatric disorder; score of 19 or higher on the BDI; active chronic pain syndrome; cardiac or hepatic disease; have taken any investigational medication within 12 weeks before randomisation, or are scheduled to receive an investigational drug; have received Botox injections for any purpose in the head or face region within 3 months of trial onset or scheduled to receive such treatment during the trial; medication overuse as per the revised ICHD-3 IHS criteria; medications that can affect light perception like ethambutol, hydroxychloroquine or amiodarone or any other according to the opinion of the investigator; patients requiring prescription/reading glasses; patients who have not responded to three or more migraine preventive drugs; patients who have a diagnosed neurological disorder that may influence the study according to the investigators. **Comparison of study groups at baseline**: not applicable (cross-over)
Interventions	**Intervention characteristics** Blue-light filtering spectacle lens • Intervention name (e.g. spectacle lens name and manufacturer): "Lumishade® Active Lens" • Frequency with which the intervention (spectacle lenses) were worn over the trial duration: not reported • Other comments: none Non-blue-light filtering spectacle lens • Intervention name (e.g. spectacle lens name and manufacturer): "Lumishade® Sham Lens" • Frequency with which the intervention (spectacle lenses) were worn over the trial duration: not reported • Other comments: none
Outcomes	**Primary outcome(s)**: Headache Impact Test 6 **Secondary outcome(s)**: assessment of headache diary to monitor the frequency of headache, identify patterns that may help determine triggers and improve treatment, track medication use and response, and maintaining long term record of the information. **Adverse events reported?** (Y/N): N **Measurement time points**: baseline and week 4
Starting date	June 2021 (estimated start date)
Contact information	Yoshito Takeuchi **Email**: Yoshito.Takeuchi@mitsuichemicals.com

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NCT04904328 *(Continued)*

Notes	**Date of last participant enrollment**: April 2022 (estimated study completion date) **Date clinical trial registry last updated**: May 2021 **Recruitment status**: not yet recruiting **Other notes**: study sponsor - Mitsui Chemicals, Inc.

NCT05206747

Study name	**Public title**: Ottawa Sunglasses at Night for Mania Study (OSAN) **Scientific title**: A Randomized Control Trial of the Effectiveness of Blue-blocking Glasses for Mania in Inpatients With Bipolar Disorder
Methods	**Study design**: RCT **Study grouping**: parallel **Exclusions after randomisation**: not reported **How missing data were handled** (e.g. available case analysis, imputation, etc.): not reported **Losses to follow-up**: not reported **Other comments** (e.g. unusual study design/issues): not reported **Reported power calculation?** (Yes/No): no **Trial duration**: not reported **Unit of randomisation/unit of analysis**: not reported
Participants	**Country**: not reported **Total number of participants**: 51 (estimated enrolment) **Setting**: not reported **Baseline characteristics** Blue-light filtering spectacle lens • Number of participants: not reported • Sex (number of females/number of males): not reported • Age (mean (SD)): not reported Non-blue-light filtering spectacle lens • Number of participants: not reported • Sex (number of females/number of males): not reported • Age (mean (SD)): not reported Overall • Number of participants: not reported • Sex (number of females/number of males): not reported • Age (mean (SD)): not reported **Inclusion criteria**: 18 to 70 years of age; have a Diagnostic and Statistical Manual of Mental Disorders (5th Edition) defined manic symptoms that persist beyond the physiological effects of a sub-

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NCT05206747 *(Continued)*

	stance; be willing to have investigators obtain information from the treatment team and electronic medical record; participants must be able to read and understand English or French, and be willing and able to provide informed consent. **Exclusion criteria**: severe eye disease or trauma; have a history of traumatic brain injury; and have sleep apnea. **Comparison of study groups at baseline**: not reported
Interventions	**Intervention characteristics** Blue-light filtering spectacle lens • Intervention name (e.g. spectacle lens name and manufacturer): blue-blocking glasses (Manufacturer - not reported) • Frequency with which the intervention (spectacle lenses) were worn over the trial duration: 2 weeks - daily, while awake from 6pm to 8am. • Other comments: blue-light filtering lenses - "transmit 45% of visible light with the following light transmission profile" Non-blue-light filtering spectacle lens • Intervention name (e.g. spectacle lens name and manufacturer): "Lightly-tinted glasses." (Manufacturer - not reported). Reported to filter ultraviolet wavelengths but not blue light. Overall transmission of visible light reported to be 91%. • Frequency with which the intervention (spectacle lenses) were worn over the trial duration: 2 weeks - daily, while awake from 6pm to 8am. • Other comments: none
Outcomes	**Primary outcome(s)**: Young Mania Rating Scale **Secondary outcome(s)**: amount of antipsychotic (and benzodiazepine used, total number of medications used, sleep efficiency (measured using actigraphy), Patient Mania Questionnaire (PMQ), Digital Self-Report Survey of Mood for Bipolar Disorder (digiBP), Altman Self-Rating Mania (ASRM) scale, Hamilton Depression Rating (HAM-D) scale, Patient Health Questionnaire (PHQ), General Anxiety Disorder (GAD) questionnaire, Morning Evening Questionnaire (MEQ), Pittsburgh Sleep Quality Index (PSQI) questionnaire, Leeds sleep evaluation questionnaire, and Pre-Sleep Arousal Scale (PSAS). **Adverse events reported?** (Y/N): N **Measurement time points**: baseline and weeks 1 and 2.
Starting date	May 2022
Contact information	Jess G Fiedorowicz, MD, PhD **Email**: jfiedorowicz@toh.ca
Notes	**Date of last participant enrolment**: May 2023 (estimated study completion date) **Date clinical trial registry last updated**: January 2022 **Recruitment status**: not yet recruiting **Other notes**: none

AVR: aortic valve replacement; CABG: coronary artery bypass graft; MVR: mitral valve replacement; RCT: randomised controlled trial; SD: standard deviation

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ADDITIONAL TABLES

Table 1. Summary of study design, participants, interventions, and follow-up periods for the included studies

Study	Study design	Recruited sample size	Participant population	Blue-light filtering lens name(s) (manufacturer)	Non-blue-light filtering lens name(s) (manufacturer)	Intervention follow-up duration
Alzahrani 2021	Randomised, cross-over, controlled trial	5	Healthy volunteers	Crizal Prevencia (Essilor), Blue Guardian (Opticare), and Blu-OLP (GenOp) lenses. Spectral transmittance data presented in figure 1 of the publication.	Not reported Spectral transmittance data presented in figure 1 of the publication.	Not reported
Alzahrani 2020	Randomised, cross-over, controlled trial	12	Individuals with no history of ocular disease or abnormal vision	UV++Blue Control (JuzVision, Bulli, NSW, Australia), Crizal Prevencia (Essilor, Silverwater, NSW, Australia), BlueGuardian (Opticare, Sydney, NSW, Australia), and Blu-OLP (GenOp, Rosebery, NSW, Australia) lenses Spectral transmittance data presented in figure 1 of the publication.	Not reported Spectral transmittance data presented in figure 1 of the publication.	Not reported
Bigalke 2021	Randomised, cross-over, controlled trial	20	Healthy volunteers	Not reported (LowBlueLights. com, University Heights, OH, USA)	Not reported (Ultra-Spec 2001 OTG, Uvex, Honeywell Safety, USA)	1 week
Burkhart 2009	Randomised, parallel-group, controlled trial	20	Sleep difficulty	Not reported (NoIR Polycarbonate Eyewear) "blocked wavelengths < 550nm (blue-green or longer wavelengths being transmitted)" Spectral transmittance data presented in figure 1 of the publication.	Not reported (NoIR Polycarbonate Eyewear) Spectral transmittance data presented in figure 1 of the publication.	2 weeks
Dabrowiecki 2020	Randomised, cross-over, controlled trial	10	Radiology residents	Not reported (Felix Gray, Inc., NewYork, New York) "The BLFL filter 50% of 380- to 500-nm blue light, nearly 90% of 400- to 440-nm blue light, and reduced glare by 99%"	Not reported (Felix Gray, Inc., NewYork, New York)	5 days
Danilenko 2019	Randomised, parallel-group,	35	Major depressive disorder or persistent depressive	Not reported (Chron-optic, Québec, Canada) "Orange glasses completely cut the wavelengths below 540 nm (Sasseville et al., 2015; Fig. 1S) and	Not reported (Chron-optic, Québec, Canada)	6 days

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Table 1. Summary of study design, participants, interventions, and follow-up periods for the included studies *(Continued)*

	controlled trial		disorder (dysthymia)	diminished the light intensity by ~70%"		
Esaki 2020	Randomised, parallel-group, controlled trial	43	Bipolar disorder	Not reported (Yamamoto Kogaku, No. 360S UV Orange, Osaka, Japan) Spectral transmittance data presented in supplementary figure 1 of the publication.	Not reported (Yamamoto Kogaku, No. 331, Osaka, Japan) Spectral transmittance data presented in supplementary figure 1 of the publication.	2 weeks
Esaki 2017	Randomised, parallel-group, controlled trial	20	Major depressive disorder with sleep onset insomnia	Not reported (Yamamoto Kogaku, No. 360S UV Orange, Osaka, Japan) Spectral transmittance data presented in figure 1 of the publication.	Not reported (Yamamoto Kogaku, No. 331, Osaka, Japan) Spectral transmittance data presented in figure 1 of the publication.	2 weeks
Hammond 2015	Randomised, cross-over, controlled trial	156	Bilateral pseudophakia	Not reported	Not reported	Not reported
Henriksen 2020	Randomised, parallel-group, controlled trial	32	Bipolar disorder	Not reported (LowBlueLights.com, University Heights, OH, USA)	Not reported (Uvex, Furth, Germany, and 3M, Austin, TX, USA)	7 days
Henriksen 2016	Randomised, parallel-group, controlled trial	32	Bipolar disorder	Not reported (LowBlueLights.com, University Heights, OH,USA) Spectral transmittance data presented in supplementary figure 1 of the publication.	Not reported (Uvex, Furth, Germany and 3M, Austin,TX, USA) Spectral transmittance data presented in supplementary figure 1 of the publication.	7 days
Janku 2020	Randomised, parallel-group, controlled trial	35	Insomnia	UVEX S1933X (not reported) "Based on the used spectrum control technology they were supposed to reduce up to 98% of the lights of blue wavelength."	UVEX S1900 (not reported) "clear glasses with no ability to filtrate blue light were used."	5 weeks

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Table 1. Summary of study design, participants, interventions, and follow-up periods for the included studies *(Continued)*

Knufinke 2019	Randomised, cross-over, controlled trial	15	Recreational athletes	Not reported (Eye shield soft red Safety Glasses, Königswinter, Germany)	Not reported (Oramics)	9 nights
Lin 2017	Randomised, parallel-group, controlled trial	36	Healthy volunteers	• High blue light blocking lenses (JINS CO., LTD) • Low blue light blocking lenses (JINS CO., LTD) Spectral transmittance data presented in figure 1 of the publication.	Not reported (JINS CO., LTD) Spectral transmittance data presented in figure 1 of the publication.	2 hours
Perez Algorta 2018	Randomised, cross-over, controlled trial	13	Sleep complaints/disorders	Uvex S1933X (not reported)	Uvex S1932X (not reported)	4 days
Shechter 2018	Randomised, cross-over, controlled trial	15	Chronic insomnia	Not reported (Bandit style frames, Uvex, Honeywell Safety, Smithfield, USA) "The amber lenses filter out blue-wavelength light, while allowing the other visible spectrum light to pass, resulting in a blue-light absorption (BLA) of 65% and a visible light transmission (VLT) of 90%"	Not reported "The clear lenses have a VLT of 92%, while allowing for the almost complete transmission of blue-wavelength light (~90%) based on manufacturer specifications"	1 week
Singh 2021	Randomised, parallel-group, controlled trial	120	Symptomatic computer users	Prevencia (Essilor, Dallas, Texas, USA) "The "active" intervention group received blue-blocking lenses (Prevencia; Essilor, Dallas, Texas, USA) that filtered blue light by front surface coating between 10% and 30% in the range of 400-500 nm. These lenses almost completely blocked transmission below 400 nm and had approximately 95% transmission between 500 and 700 nm."	Crizal UV coated lenses (Essilor)	2 hours

Abbreviations: BLFL, blue light filtering lens; nm, nanometres

Table 2. Table 2. Summary of adverse effects reported in included trials

Study ID	Number of participants and study population	Adverse event(s)

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Table 2. Table 2. Summary of adverse effects reported in included trials *(Continued)*

Burkhart 2009	20 participants with sleep difficulty	None
Danilenko 2019	35 participants with major depressive disorder or persistent depressive disorder (dysthymia)	"No eye-related adverse events were reported. All patients successfully resisted sleep during daytime, verified by actimetric data. Two patients – both from the white light group – were occasionally hyperthymic following treatment (not reaching hypomania as documented by both patient-reported questionnaire and psychiatrist)."
Esaki 2020	43 participants with bipolar disorder	Adverse events in general involved discomfort from wearing the glasses (BB group, 2; placebo group, 3) and pain from the contacting part of the glasses (BB group, 1; placebo group, 4), as well as lowered mood (BB group, 1). All participants reported that the discomfort or pain improved after removing the glasses. One participant in the BB group reported lowered mood after intervention week 1."
Esaki 2017	20 participants with major depressive disorder with sleep onset insomnia	"Adverse events involved discomfort from wearing the glasses (BB group n = 1) or pain from the contacting part of the glasses (BB group n = 3, placebo group n = 4)."
Henriksen 2016	32 participants with bipolar disorder	"With regard to side effects, two patients in the BB group reported emerging depressive symptoms on days 6 and 7, respectively." "One patient, with comorbid migraine, reported headache associated with the use of BB glasses, causing dropout on the second night of the intervention."
Janku 2020	35 participants with insomnia	None
Perez Algorta 2018	13 participants with with sleep complaints/disorders	None
Shechter 2018	15 participants with chronic insomnia symptoms	None
Singh 2021	120 symptomatic computer users	None

Abbreviations: BB, blue block.

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)

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#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/

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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)
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

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(Continued)

Total number of participants		Baseline characteristics Comparison of study groups at baseline
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		

HISTORY

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CONTRIBUTIONS OF AUTHORS

Sumeer Singh: collection of data for the review; assessment of the risk of bias in the included studies; analysis of data; assessment of the certainty in the body of evidence; interpretation of data, and writing of the review.

Peter Keller: conception of the review; design of the review; methodological advice; interpretation of data; and writing of the review.

Ljoudmila Busija: conception of the review; design of the review; methodological advice; interpretation of data; and writing of the review.

Patrick McMillan: collection of data for the review; assessment of the risk of bias in the included studies; analysis of data; and writing of the review.

Eve Makrai: collection of data for the review; assessment of the risk of bias in the included studies; analysis of data; and writing of the review.

John Lawrenson: conception of the review; design of the review; methodological advice; interpretation of data; and writing of the review.

Christopher Hull: conception of the review; design of the review; methodological advice; interpretation of data; and writing of the review.

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Laura Downie: conception of the review; design of the review; co-ordination of the review; search and selection of studies for inclusion in the review; collection of data for the review; analysis of data; assessment of the certainty in the body of evidence; interpretation of data; and writing of the review.

DECLARATIONS OF INTEREST

Laura Downie was a 2015-2017 National Health and Medical Research Council (NHMRC) Translating Research Into Practice (TRIP) Fellow and has undertaken this review as part of her fellowship project. She has previously received funding to undertake clinical trials in the field of anterior eye disease, being unrelated to this work, from Alcon Pty Ltd and Coopervision Pty Ltd. She currently practices as an optometrist in private practice (Warringal Optometrists, Victoria, Australia), providing clinical care to patients. She was also an investigator on a clinical trial of blue-light filtering lenses that is included in this systematic review (Singh 2021), but did not perform any of the risk of bias assessment or data extraction for this study.

Sumeer Singh was an investigator on a clinical trial of blue-light filtering lenses that is included in this systematic review (Singh 2021), but did not perform any of the risk of bias assessment or data extraction for this study.

Peter Keller: none known

Ljoudmila Busija: none known

Patrick McMillan: none known

Eve Makrai: none known

John Lawrenson received payment from the College of Optometrists' (UK) to co-author an article to inform practitioners about best evidence, entitled "Evidence base for the efficacy of blue blocking spectacle lenses for visual comfort and as protection against macular disease".

Christopher Hull received payment from the College of Optometrists' (UK) to co-author an article to inform practitioners about best evidence, entitled "Evidence base for the efficacy of blue blocking spectacle lenses for visual comfort and as protection against macular disease".

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- Queen's University Belfast, UK

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Due to variability in the study populations in eligible studies, a lack of studies across some outcome categories, and the fact that most of the studies had shorter follow-up periods (≤ 2 weeks) than our proposed time-point of interest for the outcome measures (one month of follow-up), several aspects of the protocol could not be performed. To maximise capture of the available evidence, we chose to provide a narrative reporting of study findings for the review outcome measures for shorter periods of participant follow-up.

We were unable to quantitatively report treatment effects due to no eligible trials being identified for several outcomes, including contrast sensitivity, colour discrimination, discomfort glare, the proportion of eyes with macular structural change, serum melatonin levels, and overall patient satisfaction with their visual performance.

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We were unable to conduct meta-analyses, or therefore to assess heterogeneity or perform subgroup analyses, for any of the prespecified outcome measures, as there was an insufficient number of studies reporting quantitative data with similar study populations to permit such analyses.

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