Citation: Lawrenson JG, Hull CC, Downie LE.The effect of blue-light blocking spectacle lenses on visual performance, macular health and the sleep-wake cycle: a systematic review of the literature. Ophthalmic Physiol Opt. 2017 Nov;37(6):644-654. doi: 10.1111/opo.12406. Review.

The effect of blue-light blocking spectacle lenses on visual performance, macular health and the sleep-wake cycle: a systematic review of the literature

John G Lawrenson[1]*, Christopher C Hull[1] and Laura E Downie[2]

1. *Centre for Applied Vision Research, Division of Optometry and Visual Science, City University of London, UK.*
2. *Department of Optometry and Vision Sciences, The University of Melbourne, Parkville, Victoria Australia.*

*Corresponding author: j.g.lawrenson@city.ac.uk

Disclosure

The authors report no proprietary interest in any of the materials mentioned in this article. The lead reviewer (JL) has given lectures on this topic at conferences for which travel and accommodation has been paid by the organisers. The other two authors (CH, LD) declare that they have no known conflicts of interest related to the review topic.

ABSTRACT

Purpose: Blue-blocking (BB) spectacle lenses, which attenuate short-wavelength light, are being marketed to alleviate eyestrain and discomfort when using digital devices, improve sleep quality and potentially confer protection from retinal phototoxicity. The aim of this review was to investigate the relative benefits and potential harms of these lenses.

***Methods*:** We included randomised controlled trials (RCTs), recruiting adults from the general population, which investigated the effect of BB spectacle lenses on visual performance, symptoms of eyestrain or eye fatigue, changes to macular integrity and subjective sleep quality. We searched MEDLINE, EMBASE, the Cochrane Library and clinical trial registers, until 30 April 2017. Risk of bias was assessed using the Cochrane tool.

***Results*:** Three studies (with 136 participants) met our inclusion criteria; these had limitations in study design and/or implementation. One study compared the effect of BB lenses with clear lenses on contrast sensitivity (CS) and colour vision (CV) using a pseudo-RCT crossover design; there was no observed difference between lens types (log CS; Mean Difference (MD)=-0.01 [-0.03, 0.01], CV total error score on 100-hue; MD=1.30 [-7.84, 10.44]). Another study measured critical fusion frequency (CFF), as a proxy for eye fatigue, on wearers of low and high BB lenses, pre- and post- a 2-hour computer task. There was no observed difference between low BB and standard lens groups, but there was a less negative change in CFF between the high and low BB groups (MD=1.81 [0.57, 3.05]). Both studies compared eyestrain symptoms with Likert scales. There was no evidence of inter-group differences for either low BB (MD=0.00 [-0.22, 0.22]) or high BB lenses (MD=-0.05 [-0.31, 0.21]), nor evidence of a difference in the proportion of participants showing an improvement in symptoms of eyestrain or eye fatigue. One study reported a small improvement in sleep quality in people with self-reported insomnia after wearing high compared to low-BB lenses (MD=0.80 [0.17, 1.43]) using a 10-point Likert scale. A study involving normal participants found no observed difference in sleep quality. We found no studies investigating effects on macular structure or function.

***Conclusions*:** We find a lack of high quality evidence to support using BB spectacle lenses for the general population to improve visual performance or sleep quality, alleviate eye fatigue or conserve macular health.

Keywords: Spectacles, blue light blocking, visual performance, macular changes, sleep-wake cycle, systematic review

Running head: Blue-light blocking spectacle lenses

INTRODUCTION

Rationale

Studies, in animal models[1, 2] and cell culture,[3, 4] have shown that wavelengths in the blue portion of the electromagnetic spectrum (400-500nm) can induce phototoxic retinal damage. Historically, two mechanisms of photochemical damage have been recognised and eponymously named as 'Noell damage' and 'Ham damage' after the original investigators.[1, 5] Noell, or Class I, damage was first observed following prolonged exposure of albino rats to fluorescent light (490-580nm). Cellular disruption occurred initially in photoreceptors, followed by the retinal pigment epithelium (RPE). By contrast, Ham[5] (Class II damage) described disruption that occurred after shorter, high intensity light exposures (between 10s and 2h duration). Shorter wavelengths were associated with more intense cellular damage, initially at the level of the RPE, with a peak of the action spectrum occurring at around 440nm in the phakic eye. International standards have been developed based on these empirical studies[6], which define exposure limits, below which adverse effects are unlikely to occur. However, driven by requirements for brighter and lower energy lighting, the last 10 years has seen significant changes in light sources for both commercial and domestic applications, with an increased use of compact fluorescent lamps (CFL) and high intensity light-emitting diodes (LEDs). Moreover, white-light LEDs (the most common type of LED) have become ubiquitous in backlit displays in smartphones and tablet computers. Although the light emitted by these LEDs appears white, their emission spectra show peak emissions at wavelengths corresponding to the peak of the blue light hazard function. It has been shown that exposure of cultured RPE cells to light equivalent to that emitted from mobile display devices causes increased free radical production and reduced cell viability.[7] This has raised concerns that the cumulative exposure to blue light from such sources may induce retinal toxicity and potentially increase the risk of age-related macular degeneration.[8]

The rationale for the introduction of blue-blocking ophthalmic lenses was to mitigate the risk of retinal toxicity by blocking, or attenuating, short wavelength visible light, usually in the range 400nm to 500nm. These ophthalmic devices, which include spectacle lenses, contact lenses and intra-ocular lenses (IOLs), contain or are coated with dyes that selectively absorb blue and violet light. The choice between a conventional ultraviolet (UV) light blocking IOL and a blue-blocking IOL following cataract surgery has generated significant debate in the literature in terms of achieving a balance between photoreception and photoprotection.[9-12] Possible disadvantages of blocking short-wavelength visible light transmission include disturbances of colour perception, decreased scotopic sensitivity (leading to poorer performance in dim lighting conditions) and disruption of the timing of the circadian system.[13] Intrinsically photosensitive retinal ganglion cells, which provide photic input to the central circadian clock in the suprachiasmatic nucleus, express melanopsin and have an absorption peak at approximately 480nm in the blue part of the spectrum.[14]

Compared to their intra-ocular counterpart, blue-blocking spectacle lenses have received relatively little scientific attention. Standard spectacle lenses generally offer protection against UV (up to wavelengths of 380nm) and the adding of a yellow chromophore can also reduce or eliminate blue

light transmission. Alternatively, anti-reflection interference coatings can be applied to both the anterior and posterior lens surfaces, to selectively attenuate parts of the blue-violet light spectrum (415 to 455 nm); this range of wavelengths includes a significant proportion of the blue light hazard function[15], while the lens remains transparent to other wavelengths of visible light. In addition to their putative benefit for retinal protection, blue-blocking spectacle lenses have also been claimed to improve sleep quality following the use of electronic devices at night,[16] and reduce eye fatigue and symptoms of eye strain during intensive computer tasks.[17]

A systematic review of the best available research evidence is essential to assess the appropriateness of marketing blue-blocking spectacle lenses at the general spectacle wearing population. This evaluation will consider both the relative benefits and potential harms of these lenses.

Objectives

The primary aim of this systematic review is to evaluate the effectiveness of blue-blocking spectacle lenses for improving visual performance and reducing visual fatigue. Our secondary aims are to assess whether these lenses are effective in maintaining macular health and to determine any positive or negative effects on the sleep-wake cycle. The review will attempt to find scientific evidence to answer the following questions:

1. Compared to standard (non blue-blocking) spectacle lenses, do blue-blocking lenses enhance visual performance?
2. Compared to standard spectacle lenses, do blue-blocking lenses improve visual comfort and/or reduce symptoms of visual fatigue?
3. What is the evidence that blue-blocking spectacle lenses provide protection to the macular and preserve macular function?
4. What is the evidence that blue-blocking spectacle lenses disrupt circadian entrainment and affect alertness and/or sleep quality?

METHODS

The protocol for this review was prospectively published on PROSPERO (2017:CRD42017064117) Available from http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42017064117),

Search strategy

We conducted searches using the following bibliographic databases: Ovid MEDLINE, Ovid EMBASE, PubMed and the Cochrane Library for relevant articles published before May 2017. We did not use any date or language restrictions for the bibliographic searches. An example search strategy for one of the databases (Ovid MEDLINE) is included in Supplementary File 1. We also scanned the reference list of included studies and contacted experts in the field to ask if they were aware of additional published or ongoing trials investigating blue-blocking lenses. We searched the PROSPERO database for relevant systematic reviews and searched clinical trials registries (Clinical trials.gov and the ISRCTN registry) for recently completed or ongoing trials.

Inclusion and exclusion criteria

We included randomised controlled trials (RCTs) and pseudo-randomised controlled trials, which recruited adults, aged 18 years and above, from the general population and compared blue-blocking

spectacle lenses to standard spectacles lenses, or any other comparator, where it was possible to isolate the effect of the blue-blocking lens for any of our primary or secondary outcomes. We defined blue-blocking lenses as those that block or attenuate short wavelength optical radiation between 400nm and 500nm. The review team decided post-hoc that this should include comparisons between high and low blue-blocking lenses.

The following outcomes were considered:

Primary outcomes:

- Any measure of visual performance (e.g., logMAR visual acuity, contrast sensitivity, critical fusion frequency (CFF), colour discrimination under photopic or mesopic conditions, scotopic sensitivity, dark adaptation, stray light and glare sensitivity) conducted during the follow up period of the trial.
- Any measure of visual fatigue or discomfort (e.g., using questionnaires or visual analogue scales) conducted during the follow-up period of the trial.

Secondary outcomes:

- Proportion of eyes with a structural change in the macula using clinical observation, fundus photography or optical coherence tomography (OCT) between six and 24 months following the start of the intervention. This could include development of early AMD, progression of AMD or progression to late stage AMD, as defined by the trial investigators.
- Objective or subjective assessment of alertness and/or sleepiness.
- Effect on average macular pigment optical density (MPOD), measured as the proportion of eyes that had a significant increase in MPOD at six months.
- Overall participant satisfaction with blue-blocking lenses (e.g,. using questionnaires or rating scales).

Adverse effects:

- Any ocular and systemic adverse effects associated with the intervention, as reported by the study authors.

For the evaluation of visual performance and effect of the intervention on alertness and/or sleep quality, we included any measure conducted during the follow-up period of the trial. To assess the effects of blue-blocking spectacle lenses on macular health or function, studies had to be at least six months duration.

Data extraction and analysis

Following removal of duplicates, two reviewers (JL and CH) independently screened the titles and abstracts identified from the bibliographic searches and resolved any discrepancies by discussion and consensus. We obtained full-text copies of potentially eligible studies and these were assessed by both reviewers to decide whether they met the inclusion criteria. Reasons for exclusion were documented at this stage. We used a data extraction form that was developed and piloted for the purpose of this review. We collected data on: study design, details of participants, details of intervention, methodology, quantitative data on outcomes and funding sources. Data extraction was

conducted independently by two reviewers (JL and CH) and any discrepancies resolved by discussion. The extracted numerical data was entered into Revman 5[18] meta-analytical software by one reviewer (JL) and this was checked by a second reviewer (CH).

Two review authors (JL and CH) independently assessed the risk of bias in included studies using the Cochrane Risk of Bias tool as detailed in Chapter 8 of the Cochrane Handbook.[19] We evaluated risk of bias using the following bias 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).

Any differences of opinion in risk of bias assessments were resolved by discussion.

Our measure of treatment effect was the risk ratio (RR) for dichotomous outcomes and the mean difference (MD) for continuous outcomes, with 95% confidence intervals [CIs].

By definition, the intervention was applied to the person and therefore the unit of analysis was the same as the unit of randomisation. However, where data was presented from both eyes, we analysed the data from the right eye only to avoid a unit of analysis error. Insufficient studies were available to conduct the planned meta-analysis. However a descriptive summary of the results of the included studies has been provided. Publication bias could not be assessed, as there were an insufficient number of studies to conduct this analysis.

We assessed the certainty of the evidence using the Grades of Recommendation, Assessment and Evaluation (GRADE) Working Group approach,[20] using customised software (GRADEpro GDT). One reviewer (JL) conducted the initial assessment and this was checked by the other reviewers (CH and LD). We considered risk of bias, inconsistency, indirectness, imprecision, and publication bias when judging the certainty of the evidence.

RESULTS

Results of the searches

The electronic searches yielded 118 references (see Figure 1 for the PRISMA flow diagram). After 19 duplicates were removed, we screened the remaining 99 references and obtained the full-text reports of 15 references for further assessment. Twelve of these[17, 21-31] were eliminated (see Table of Excluded Studies in Supplementary File 2 and three RCTs that met the *a priori* criteria for inclusion were included in the final analysis (see Characteristics of Included Studies in Supplementary File 3. We did not identify any ongoing studies from our searches of the clinical trials registries.

Characteristics of included studies

We included three studies in this review.[32-34] Two of the studies were conducted in the USA and one in Hong Kong.

Burkhart and Phelps[32] randomised 20 adult volunteers reporting sleep difficulty to wear either amber tinted glasses (blocking wavelengths <550nm) or yellow tinted placebo glasses (blocking wavelengths <465nm) for 3h prior to sleep. The primary outcome measure was sleep quality as determined by sleep diaries, which incorporated a 10-point Likert sleep quality scale. Sleep diaries were completed for one week prior to the intervention (baseline) and for two weeks afterwards.

Leung and co-workers[33] conducted a pseudo-randomised controlled trial involving 80 computer users from two age cohorts: young adults, 18-30 years, n=40 and middle aged adults 40-55 years, n=40. Participants were randomised into one of three groups to assess the performance of two blue-blocking spectacle lenses (blue-blocking anti-reflection coating and a brown tinted lens) and a regular clear control lens, using a crossover design. The primary outcomes were contrast sensitivity, using the Mars contrast sensitivity letter chart under standard and glare conditions, and colour discrimination using the Farnsworth-Munsell 100-hue test. Following the visual assessment tests, participants wore each assigned lens for one month for a minimum of 2h per day. At the end of each wearing period, lens performance was subjectively assessed using a 13-item questionnaire. Each question was rated on a 1-5 scale (where 1=very unsatisfactory and 5=very satisfactory).

Lin and co-workers[34] recruited 36 adult subjects who were randomised to one of three groups and wore either spectacles with low or high blue-blocking lenses or non-blue blocking lenses for a 2 hour computer task using a laptop computer. At the end of the task, critical fusion frequency (CFF) was assessed and symptoms of eyestrain were evaluated using a 15-item questionnaire. The CFF is the lowest level of continuous flicker that is perceived as a steady source of light and a reduction in CFF was interpreted as a measure of eye fatigue.

Risk of bias and certainty of the evidence

We evaluated the risk of bias in the included studies using the Cochrane risk of bias tool.[19] Figures 2 and 3 present a graph and summary of the risk of bias for the included studies. Overall the studies were at an unclear or high risk of bias. We rated two studies[32, 34] as having an unclear risk of selection bias, since they did not describe the method for random sequence generation or how this was concealed. Leung and colleagues[33] allocated participants to different sequences of lens wear by date of admission and therefore the sequence was non-random and at a high risk of selection bias. Given that two of the included studies randomised small numbers of participants,[32, 34] there were baseline differences in the outcome of interest, which may have affected the results. Although attempts were made to mask outcome assessors to the intervention received, it was not possible to mask participants due to differences in appearance between the lenses being tested. We judged one study[34] to be at a high risk of selective reporting bias, due to a failure to report on 2/15 of the questions from the symptom questionnaire and no protocol or trial registration was available. Two studies[32, 33] were judged to be at an unclear risk of selective reporting since either no protocol or trial registry entry was available, or in one case the trial was retrospectively registered.[33]

We rated the certainty of evidence for each outcome using GRADE (see Table 1).

Effects of the intervention

Primary outcome measures

Two studies[33, 34] randomising 116 participants, provided data on differences in visual performance with blue-blocking lenses compared to a clear control lens. Leung et al[33] investigated the effect of blue-blocking lenses on contrast sensitivity and colour vision using a crossover design. There was no evidence of a difference in log contrast sensitivity or total error score on the FM 100-hue test between the intervention and control lenses (Table 1). Lin et al[34] measured CFF (a proxy measure of eye fatigue) before and after a 2-hour computer task. There was no observed difference between the low-blocking and no-blocking (clear) lens groups, but there was evidence of a less negative change in CFF between the high and low-blocking lens groups indicating less fatigue with computer use for the high-block group (Figure 4).

These studies also compared symptoms of eyestrain for the intervention and control lenses using Likert rating scales.[33, 34] Leung et al.[33] measured symptoms of eyestrain on a 5-point scale after one month of wearing low blue-blocking (blue-filtering anti-reflection coating), high blue-blocking (brown-tinted) or control (non blue-blocking) lenses. There was no significant difference between the intervention and control lenses for either the low blue-blocking lens (Mean difference (MD)= 0.00 [-0.22, 0.22]) or the high blue-blocking lens (MD=-0.05 [-0.31, 0.21]). Lin et al[34] compared symptoms related to eye fatigue or eye strain before and after a two hour computer task for participants wearing clear (control) lenses or low or high blue-blocking lenses using a 15-item questionnaire. Since there was no statistical difference between the low blue-blocking and clear lens groups, the study authors pooled the data for the low blue-blocking and clear lens participants and compared the symptom scores, after the task, for each question. Statistical differences between groups, for each questionnaire item, were then investigated using the Mann-Whitney U test. For the current review, we analysed the ordinal data from the 13 questionnaire items reported and calculated the proportion of subjects in each group showing a post-task symptomatic improvement for each question. The risk ratio (RR) with 95% confidence intervals was calculated for each question using Revman[18] (Table 2). A significant symptomatic improvement was found for only one question 'My eyes feel itchy' (RR 2.68 [1.32, 5.44]).

Secondary outcomes

There was no available data on the proportion of eyes with any structural change in the macula or the effect of blue-blocking spectacle lenses on average MPOD.

Two studies provided data on the subjective assessment of sleep quality. Leung et al.[33] found no evidence of a difference in sleep quality for low or high blue-blocking lenses compared to control lenses for normal participants (low blue-blocking, MD=0.04 [-0.26, 0.18]; high blue-blocking, MD=0.00 [-0.23, 0.23]). By contrast, Burkhart and Phelps[32] found a small improvement in sleep quality in participants wearing high blue-blocking lenses compared to low blue-blocking lenses in individuals experiencing sleep-onset or mid-sleep insomnia (MD=0.80 [0.17, 1.43]).

One study[33] reported on the overall performance of blue-blocking lenses. There was no evidence of a difference in performance for either low or high blue-blocking lenses compared with control lenses.

None of the included studies reported on ocular or systemic adverse effects associated with the interventions.

DISCUSSION

Blue-blocking spectacle lenses, with varying degrees of short-wavelength light attenuation (ranging from 10% to 100%), are being marketed at the general population with claims that they can alleviate eyestrain and discomfort (particularly when using computers and other digital devices), improve sleep quality and possibly confer protection from retinal phototoxicity. The current systematic review did not identify any high quality clinical trial evidence to support these claims. Rather, the included studies provided evidence, albeit of low certainty, that there was no significant difference in relation to the proportion of subjects showing an improvement in symptoms of eyestrain or eye fatigue between the intervention (blue-blocking) and control spectacle lenses. This conclusion differs from the authors of one of the included studies. Using Likert scales, Lin and colleagues compared symptoms in subjects wearing high-blocking lenses to a combined low block/no block group following a two hour computer task. They found symptomatic improvement for the high block group in 3 of the 15 questionnaire items (pain around/inside the eye , eyes were heavy and the eyes were itchy) following the computer task, compared to subjects not wearing high-blocking lenses. However, the authors did not indicate whether this analysis was pre-specified or was part of an exploratory post-hoc comparison. Furthermore, there was no suggestion that the authors had considered the risk of a type I error associated with multiple statistical comparisons.[35] For the current study we used the analysis plan that was specified prospectively in the review protocol (PROSPERO 2017:CRD42017064117). In addition, we also considered that it would be statistically more appropriate and clinically more meaningful to present the data from Lin et al[34] as a comparison of the proportion of subjects showing a post-task symptomatic improvement for each item in the questionnaire, given that we do not accept that the questionnaire responses can reasonably be considered to fall on a continuous scale.

Subjective ratings of overall lens performance were reported in one crossover trial in which 80 participants wore spectacles with low blue-blocking, high blue-blocking or control (clear) lenses for four weeks. There was no observed difference in performance ratings between lens types. A parallel group RCT reported that high blue-blocking lenses (but not low blue-blocking lenses) produced a less pronounced reduction in CFF after a two-hour computer task indicating less visual fatigue. However, the clinical significance of this finding is unclear, since CFF has been shown to decline after reading irrespective of whether the task is performed on paper or using an e-reader. This suggests that the CFF parameter may be independent of blue light exposure.[36]

In modern society, computers and other digital electronic devices are ubiquitous in both the workplace and domestic environments and given the high number of hours per day that most individuals spend viewing small text on electronic devices at short working distances, it is not surprising that up to 90% of users periodically experience asthenopic symptoms including, eyestrain, headaches, ocular discomfort, dry eye, diplopia and blurred vision.[37] However, what is now termed computer (or digital) vision syndrome is a multifactorial condition with several potential contributory causes, such as uncorrected refractive error, oculomotor disorders, tear film abnormalities and/or musculoskeletal problems.[38] Therefore, the role played by blue light in these symptoms is difficult to extricate.

Despite the putative benefits of blue light blocking lenses, concerns have been raised that these lenses could adversely affect some aspects of visual performance (e.g., contrast sensitivity or colour vision). Using standard clinical tests, Leung et al.[33] did not observe any detrimental effects on log-contrast sensitivity or total error score using the FM 100-hue colour vision test. This is consistent with a previous systematic review[39] and meta-analysis comparing blue-blocking IOLs with UV-blocking IOLs, following cataract surgery. The results showed that there was no evidence of any difference in post-operative contrast sensitivity or overall colour vision, although colour vision with blue-blocking IOLs was impaired at the blue end of the spectrum under mesopic conditions.[39]

Given the role of blue light in the timing of the circadian system we examined evidence on the influence of blue-blocking lenses on sleep quality. This outcome was reported in two studies. Leung and co-workers[33] found no observed difference in the effect of either low or high blue-blocking lenses on the subjective assessment of sleep quality in normal participants. By contrast, Burkhart and Phelps[32] recruited participants reporting sleep difficulties who wore either high or low blue-blocking lenses for three hours prior to sleep for two weeks. High blue-blocking lenses were associated with a statistically significant improvement in self-reported sleep quality, based on a 10-point Likert scale, for the high blue-blocking group compared to the low blue-blocking lens group (MD=0.80 [0.17, 1.43]: p=0.03).

No studies reporting on the effects of blue-blocking spectacle lenses on macular health were identified. With the widespread incorporation of backlit LED displays in modern digital devices, concerns have been raised regarding the long-term safety of these screens, which have emission peaks in the 460nm to 490nm spectral range. One of the suggested benefits of blue-blocking spectacle lenses is to protect the retina against these potentially damaging wavelengths. However, despite the perceived risks, the spectrally weighted irradiance from these devices does not reach international exposure limits, even for prolonged viewing. Moreover, the emissions have been shown to be lower than natural exposure from sunlight, even on a cloudy day in winter, in the United Kingdom.[40]

In summary, the findings of this systematic review indicate that there is a lack of high quality clinical evidence for a beneficial effect of blue-blocking spectacle lenses in the general population to improve visual performance or sleep quality, alleviate eye fatigue or conserve macular health. Only three studies met our inclusion criteria and these were generally poorly reported, with several limitations in study design and/or implementation. All three included studies were at risk of selection bias; differences in the appearance of the lenses meant that it was impossible to fully mask participants to the trial intervention; and we were unable to exclude the possibility of selective outcome reporting. We rated the overall certainty of the evidence using GRADE[20] as low or very low, and therefore we have little to no confidence in the effect estimates. None of the included studies reported on adverse effects associated with the use of blue-blocking lenses.

There is a need for high quality studies to address the effects of blue blocking spectacle lenses on visual performance, and the potential alleviation of symptoms of eyestrain and/or visual fatigue. There should be an agreed standard set of outcomes, known as ‘core outcome sets’ (COS) as recommended by the COMET initiative.[41] These sets could then be collected and reported to allow the results of studies to be compared and combined as appropriate. The studies investigating these outcomes should adopt a RCT design and be conducted on a general population, using blue-blocking

lenses with varying degrees of blue light attenuation. Sampling could be stratified to include participants varying in age, gender, ethnicity and occupational or domestic exposure to blue light. Outcome measures investigated in trials should include those that are important to potential blue-blocking lens users (e.g., the maintenance of macular health and function, or alleviation of digital eyestrain). Furthermore, attempts should be made to mask participants and outcome assessors to the intervention, to reduce the risk of performance bias. Finally, given the importance of blue light for scotopic sensitivity and in regulating the sleep-wake cycle, the potential harms of blue-blocking spectacle lenses should also be considered alongside the putative benefits of these devices.

Acknowledgements

Funding: JGL and CCH received funding from the College of Optometrists UK for this review

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Figure Captions

Figure 1. Study flow diagram

Figure 2. Risk of bias graph presented as a % across all included studies

Figure 3. Risk of bias for included studies

Figure 4. Comparison of change in Critical Fusion Frequency (CFF), in Hz, before and after a computer task for high and low blue-blocking lenses versus control. The high blue-blocking lens is associated with a significant change in CFF. Data from the same control group are used in both comparisons.

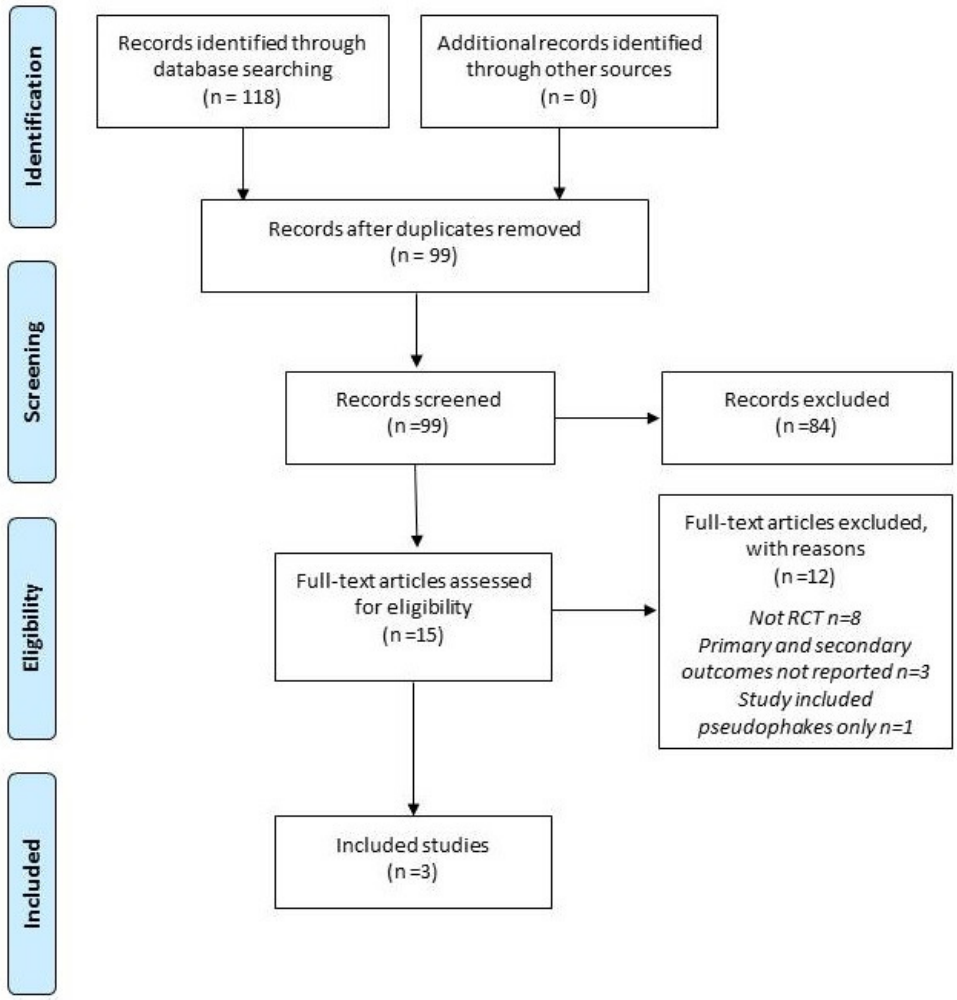
Identification
Screening
Eligibility
Included
Records identified through database searching (n = 118)
Additional records identified through other sources (n = 0)
Records after duplicates removed (n = 99)
Records screened (n =99)
Records excluded (n =84)
Full-text articles assessed for eligibility (n =15)
Full-text articles excluded, with reasons (n =12)
Not RCT n=8
Primary and secondary outcomes not reported n=3
Study included pseudophakes only n=1
Included studies (n =3)

Figure 1

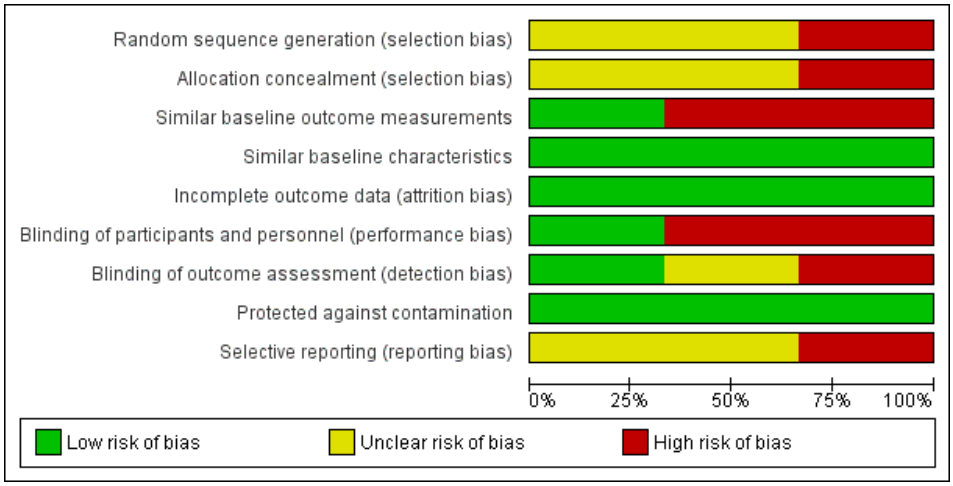
Random sequence generation (selection bias)
Allocation concealment (selection bias)
Similar baseline outcome measurements
Similar baseline characteristics
Incomplete outcome data (attrition bias)
Blinding of participants and personnel (performance bias)
Blinding of outcome assessment (detection bias)
Protected against contamination
Selective reporting (reporting bias)
0%
25%
50%
75%
100%
Low risk of bias
Unclear risk of bias
High risk of bias

Figure 2.

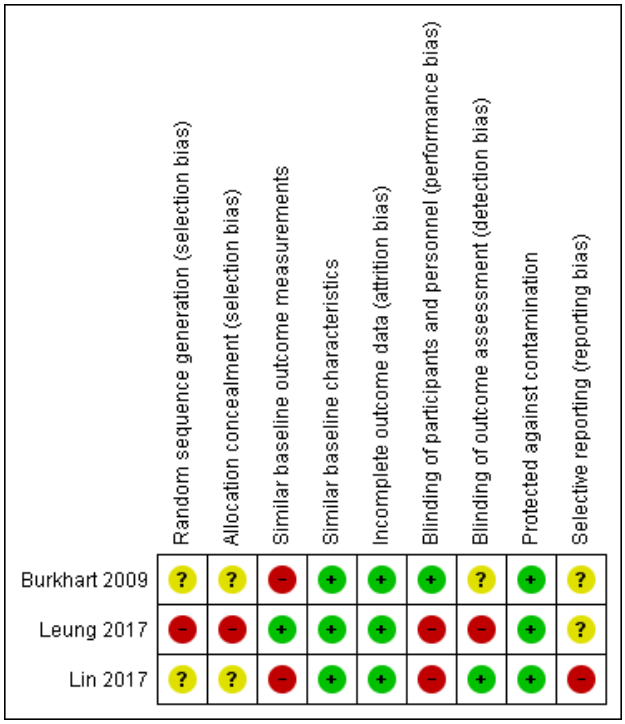
Random sequence generation (selection bias)
Allocation concealment (selection bias)
Similar baseline outcome measurements
Similar baseline characteristics
Incomplete outcome data (attrition bias)
Blinding of participants and personnel (performance bias)
Blinding of outcome assessment (detection bias)
Protected against contamination
Selective reporting (reporting bias)
Burkhart 2009
Leung 2017
Lin 2017

Figure 3.

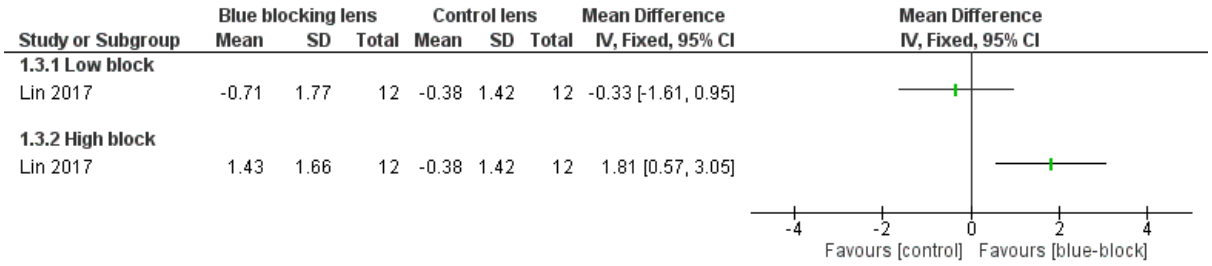
Blue blocking lens
Control lens
Mean Difference
Mean Difference
Study or Subgroup
Mean SD Total Mean SD Total
IV, Fixed, 95% CI
IV, Fixed, 95% CI
1.3.1 Low block
Lin 2017 -0.71 1.77 12 -0.38 1.42 12 -0.33 [-1.61, 0.95]
1.3.2 High block
Lin 2017 1.43 1.66 12 -0.38 1.42 12 1.81 [0.57, 3.05]
-4
-2
0
2
4
Favours [control]
Favours [blue-block]

Figure 4.

Table 1. Results table for primary and secondary outcomes

Outcome	Study	Comparison	Number of participants	Intervention effect	Certainty of Evidence (GRADE[20])
Any measure of visual performance conducted during the follow up period of the trial.	Leung 2017	Low blue-block vs clear lens	80	Log contrast sensitivity (combined young and middle aged subjects) MD=-0.01 [CI -0.03, 0.01]	LOW[1]
	Leung 2017	High blue-block vs clear lens	80	Log contrast sensitivity (combined young and middle aged subjects) MD=-0.01 [CI -0.03, 0.01]	
	Leung 2017	Low blue-block vs clear lens	80	Colour vision (TES) (combined young and middle aged subjects) MD=4.03 [CI -4.96, 13.02]	
	Leung 2017	High blue-block vs clear lens	80	Colour vision (TES) (combined young and middle aged subjects) MD=1.30 [CI -7.84, 10.44]	
	Lin 2017	Low blue-block vs clear lens	36	CFF pre- and post-task MD=-0.33 [CI-1.61, 0.95]	
	Lin 2017	High blue-block vs clear lens	36	CFF pre- and post-task MD=1.81 [CI 0.57, 3.05]	
Any measure of visual fatigue or discomfort conducted during the follow-up period of the trial.	Leung 2017	Low blue-block vs clear lens	80	Relief of eyestrain (combined young and middle aged subjects) MD=0.00 [CI -0.22, 0.22]	LOW[1]
	Leung 2017	High blue-block vs clear lens	80	Relief of eyestrain (combined young and middle aged subjects) MD=-0.05 [CI-0.31, 0.21]	
	Lin 2017	High blue-block vs not high blue-block	36	Proportion showing an improvement in symptoms of eyestrain/eye fatigue pre- and post-task. *'My eyes feel tired'*	

				RR=3.33 [0.95, 11.66]; *'I feel pain around or inside my eyes'* RR=2.60 [0.85, 7.98]; *'My eyes feel heavy'* RR=2.50 [0.95, 6.57].	
Objective or subjective assessment of alertness/ and/or sleepiness.	Leung 2017	Low blue-block vs clear lens	80	Sleep quality (combined young and middle aged subjects) MD=0.04 [CI -0.26, 0.18]	VERY LOW[1,2]
	Leung 2017	High blue-block vs clear lens	80	Sleep quality (combined young and middle aged subjects) MD=0.00 [CI-0.23, 0.23]	
	Burkhart 2009	High blue-block vs low blue-block	20	Improvement in sleep quality MD=0.80 [CI 0.08, 1.52]	
Overall participant satisfaction with blue-blocking lenses	Leung 2017	Low blue-block vs clear lens	80	Overall lens performance MD=-0.14 [CI-0.36, 0.08]	LOW[1]
	Leung 2017	High blue-block vs clear lens	80	Overall lens performance MD=0.05 [CI -0.17, 0.27]	
Proportion of eyes with a structural change in the macula following the start of the intervention.	Not reported	N/A	N/A	N/A	N/A
Effect on average macular pigment optical density (MPOD).	Not reported	N/A	N/A	N/A	N/A

[1]Downgraded two levels for risk of bias. [2]Downgraded one level for indirectness.
A GRADE certainty of evidence rating of "low" indicates that our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect. A GRADE certainty of "very low" indicates that we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

Legend: CFF=critical fusion frequency; MD=mean difference; RR=risk ratio; TES=total error score: N/A= not applicable

Table 2. Analysis of symptom questionnaire from Lin et al[34] comparing subjects wearing high blue blocking lenses to those wearing low blue-blocking or clear lenses . *RR=Risk Ratio.*

Question	**RR (95%CI)**
I feel pain around or inside my eyes	2.60 [0.85, 7.98]
My eyes feel heavy	2.50 [0.95, 6.57]
My eyes feel itchy	2.68 [1.32, 5.44]
My eyes feel tired	3.33 [0.95, 11.66]
I find it hard to focus my eyesight	1.75 [0.83, 3.67]
I see written or computer text as blurry	1.67 [0.54, 5.11]
My computer monitor looks too bright	1.28 [0.44, 3.67]
I feel tired when doing work	2.08 [0.74, 5.84]
My neck shoulders, back and lower back hurt	0.52 [0.13, 2.09]
My fingers hurt	0.52 [0.07, 4.17]
I feel mentally stressed	1.30 [0.54, 3.14]
The suns glare affects my eyes when outdoors	1.37 [0.55, 3.40]
I find fluorescent office lighting to be bothersome to my eyes	7.00 [0.88, 55.66]

Supplementary File 1

Ovid MEDLINE Search Strategy:

1. randomized controlled trial.pt.
2. (randomized or randomised).ab.ti
3. placebo.ab.ti
4. drug therapy.fs.
5. randomly.ab.ti
6. trial.ab. ti
7. groups.ab.ti
8. or/1-7
9. filtration.sh.
10. (blue adj2 light$ adj2 filter$).tw.
11. (blue adj3 filter$).tw.
12. or/9-12
13. eyeglasses.sh.
14. (spectacle$ or glasses).tw.
15. 13 or 14
16. 8 and 12 and 15

See the MEDLINE 2017 Database Guide for a description of search syntax and notation

http://ospguides.ovid.com/OSPguides/medline.htm

Supplementary File 2

Excluded Studies

Study	Reason for exclusion
Figueiro 2013	Conference abstract. Not RCT
Figueiro 2011	Not RCT
Hovis 1989	Not RCT
Hammond 2015	Study included pseudophakes only
Ide 2015	Not RCT
Kaido 2016	Not RCT
Lee 2002	Not RCT
Luria 1972	Not RCT
Sasseville 2006	No primary/secondary outcomes reported
Thomas 1988	Not RCT
Van Der Lely 2015	Not RCT
Wood 2013	No primary/secondary outcomes reported

Supplementary File 3

Characteristics of Included Studies

	Burkhart & Phelps 2009
Methods	**Study aim:** to evaluate the effectiveness of blue blocking spectacle lenses to improve sleep **Study design:** parallel group RCT
Participants	**Country:** USA **Total number of participants:** 20 **Percentage male:** 45% **Average age (SD):** 34yrs (8.2) **Race/Ethnicity:** not reported **Inclusion criteria:** subjects experiencing sleep difficulty by subjective account. **Exclusion criteria:** use of any prescribed medication, oral or inhaled nicotine, or excessive caffeine use (>2 cups at one time or >500 mg daily).
Intervention	**Intervention (n=10):** amber-tinted safety glasses (high blue-blocking), which blocked wavelengths <550 nm for 3h prior to bedtime **Comparator (n=10):** yellow-tinted safety glasses (low blue-blocking), which blocked wavelengths <465 nm for 3h prior to bedtime **Duration:** 3 weeks (1 week baseline assessment and 2 weeks post-intervention)
Outcomes	**Primary outcome:** sleep quality, determined by a sleep diary which included rating of sleep quality using a 10-point Likert scale (0= very poor; 10=very good) **Secondary outcomes:** Mood (positive/negative) determined by the Positive and Negative Affect Schedule (PANAS) Mood Scale
Notes	**Date conducted:** not reported **Trial registration number:** not reported **Sources of funding**: none **Declaration of interest:** authors reported no conflicts of interest

Risk of bias		
Risk of Bias Domain	**Authors' Judgement**	**Support for judgement**
Adequate sequence generation	Unclear	Not reported
Allocation concealment	Unclear	Not reported
Similar baseline outcome measurements	High	Quote: '*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).' p1607*
Similar baseline characteristics	Low	Judgement comment: participants balanced for age, time to bed and rising time. By self-report, neither group used nicotine, consumed more than 300 mg of caffeine or more than 3 oz. of alcohol/day, or used street drugs.
Incomplete outcome data addressed	Low	No missing data
Adequate blinding (participants)	Low	Quote: *'Participants were asked whether they had knowledge of glasses that were designed to improve one's sleep. All indicated they had no knowledge.'* p1606

		Quote: *'They were also instructed to refrain from researching lenses designed to improve sleep and contacting other participants to compare the effects of their glasses.'* p1606 Judgement comment: although the amber and yellow lenses could be distinguished the subjects were masked to the study hypothesis
Adequate blinding (investigators/outcome assessors)	Unclear	Not reported
Protected against contamination	Low	Judgement comment: it is unlikely that contamination occurred
Free of selective reporting	High	Judgement comment: no registered trial protocol and the results of two questions from the 15-item eyestrain symptom questionnaire
Free from other bias	Low	Judgement comment: no evidence of other source of bias

Leung, Li & Kee 2017	
Methods	**Study aim:** to evaluate the optical performance of blue-light blocking spectacle lenses and to investigate whether a reduction in blue light transmission affects visual performance and sleep quality. **Study design:** pseudo-randomised cross-over trial
Participants	**Country:** Hong Kong **Total number of participants:** 80 **Percentage male:** not reported **Average age (SD):** 35.5yrs (12.3) **Race/Ethnicity:** not reported **Inclusion criteria:** aged over 18 years with a refractive error **Exclusion criteria:** best corrected visual acuity worse than LogMAR 0 in either eye, history of ocular diseases or ocular surgery or abnormal colour vision based on the Ishihara colour vision test
Intervention	**Intervention 1 (n=80):** blue-filtering anti-reflection (AR) coated lens **Intervention 2 (n=80):** brown-tinted lens **Comparator (n=80):** regular clear anti-reflection coated lens **Duration:** 3 months (1 month using each of the three lenses)
Outcomes	**Primary outcome:** contrast sensitivity under normal and glare conditions using the Mars contrast sensitivity letter chart and colour discrimination using the Farnsworth-Munsell 100-hue test **Secondary outcomes:** subjective lens performance using a 13-item questionnaire (including overall performance and questions relating to night vision, sleep quality, colour contrast, eyestrain, vision on computers or mobile devices)
Notes	**Date conducted:** July 2014 to May 2015 **Trial registration number:** NCT02821403 (retrospectively registered) **Sources of funding**: Swiss lens laboratory Ltd **Declaration of interest:** part of the funding for the research was charged as consultancy by members of the research team

Risk of bias		
Risk of Bias Domain	**Authors' Judgement**	**Support for judgement**
Adequate sequence generation	High	Quote: *'The sequence of lens types was pseudo-randomized for each individual, i.e., participants were allocated in different sequences of lens wear by the date of admission.'* p5 Comment: non-random sequence generation
Allocation concealment	High	Judgement comment: non-random predictive sequence
Similar baseline outcome measurements	Low	Judgement comment: cross-over trial and therefore baseline outcome measurements balanced
Similar baseline characteristics	Low	Judgement comment: cross-over trial and therefore baseline characteristics balanced
Incomplete outcome data addressed	Low	Judgement comment: No missing data for any of the reported outcomes
Adequate blinding (participants)	High	Quote: *'We controlled subjective bias by allocating the lenses in a pseudo-random sequence with their identities masked, although the slight tinted appearance of the BT lens might*

		have been easier to identify.' p12 Judgement comment: participants were aware of the difference between the clear lens and brown tinted lens and possibly between the blue filtering AR coat and the clear lens for the subjective outcomes
Adequate blinding (investigators/outcome assessors)	High	Quote: *'In the second study, a single-masked pseudo-randomized controlled clinical trial was conducted to evaluate whether blue-light filtering spectacle lenses affected visual performance and sleep quality. A double-masked study as originally planned was not possible because an investigator could differentiate the three lenses due to prior experience in ophthalmic dispensing.'* p3
Protected against contamination	Low	Judgement comment: it is unlikely that contamination occurred
Free of selective reporting	Unclear	Quote: *'We registered this study retrospectively at ClinicalTrials.gov after we were reminded that our study design indeed met the WHO's definition of a clinical trial.'* p5 Judgement comment: trial retrospectively registered and not possible to assess
Free from other bias	High	Judgement comment: no attempt to control for potential carry over-effects

Lin, Gerratt, Bassi & Apte 2017	
Methods	**Study aim:** to determine whether North American subjects who wear short wavelength light-blocking glasses during a 2-hour computer task exhibit less visual fatigue and report fewer symptoms of visual discomfort than subjects wearing glasses with clear lenses. **Study design:** parallel group RCT
Participants	**Country:** USA **Total number of participants:** 36 **Percentage male:** 55.5% **Average age (SD):** 24.3yrs (1.90) **Race/Ethnicity:** Caucasian (92%), African-American (3%) Asian (4%) **Inclusion criteria:** healthy (no known significant health, problems) volunteer, being male or female of any ethnic group, between 21-39 years of age, having uncorrected vision or contact lens–corrected vision of 20/30 or better with both eyes open, 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.
Intervention	**Intervention 1 (n=12):** low blue-blocking lens (25% blue light blocking) **Intervention 2 (n=12):** High blue-blocking lens (60% blue light blocking **Comparator (n=12):** regular clear lens **Duration:** 2 hour computer task.
Outcomes	**Primary outcome:** pre- and post-task critical fusion frequency (CFF) **Secondary outcomes:** symptoms of eyestrain using a 15-item questionnaire
Notes	**Date conducted:** not reported **Trial registration number:** not reported **Sources of funding**: JIN CO LTD **Declaration of interest:** two of the authors were employed by the spectacle lens manufacturer (JIN CO LTD)

Risk of bias		
Risk of Bias Domain	**Authors' Judgement**	**Support for judgement**
Adequate sequence generation	Unclear	Not reported
Allocation concealment	Unclear	Not reported
Similar baseline outcome measurements	High	Quote: *'Although we randomly assigned subjects to each of the three lens groups, we observed a statistically significant difference in baseline CFF when comparing subjects assigned to each of the lens groups (F2,33=6.827, P<0.003): subjects in the high-block group had lower baseline CFF compared to subjects in the low-block group (P<0.002). These findings suggested that confounding variables may affect our results.'* p444

Similar baseline characteristics	Low	Quote: *'There were no differences among the three groups based on sex or race/ethnicity (Table 1). Although subjects were randomized to each lens group, post hoc testing revealed that there was a statistically significant difference between the ages of the subjects randomly assigned to the no-block and low block groups (P =0.024), but no statistically significant differences in age (P > 0.05) between any other pairs of groups (Table 1). Furthermore, there were no differences between the groups with regard to their average number of hours of sleep per night, their average weekly computer use, or whether they wore contact lenses (Table 1).*'p444-5 Judgement comment: baseline difference in age of subjects was very small
Incomplete outcome data addressed	Low	Judgement comment: No missing data for any of the reported outcomes
Adequate blinding (participants)	High	Quote: *'*We *cannot rule out the possibility that the subjects themselves may have noticed the visual appearance of their glasses. Although the control eyeglasses with the no-block lenses were constructed in a way to make them as similar as possible to the eyeglasses with low- and high-block lenses, the high-blocking lenses have a brown color, and the low-blocking lenses have a subtle blue-light reflection especially when viewed under the light, making it impossible to completely mask the subjects.*' p446-7 Quote: *'Although study subjects 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 subjects themselves may have noticed the visual appearance of their glasses.'* p446
Adequate blinding (investigators/outcome assessors)	Low	*Quote: 'Since the blocking lenses can be identified potentially by their tint/color, the manufacturer packaged the eyeglasses in opaque boxes that were marked with only a serial number to permit proper randomization.*'p443-4 Quote: *'Although study subjects 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 subjects themselves may have noticed the visual appearance of their glasses.' p446*
Protected against contamination	Low	Judgement comment: it is unlikely that contamination occurred
Free of selective reporting	Unclear	Judgement comment: trial not registered and therefore not possible to assess
Free from other bias	high	Judgement comment: two of the co-authors were employed by the company manufacturing the blue blocking lenses