Evaluation of the effectiveness of the Super Enhanced Single Vision Lens 01 (SESL01) in reducing symptoms of Computer Vision Syndrome (CVS): a study protocol for a double-blind, two-arm parallel randomized controlled trial

Authors
Rupal Lovell-Patel[1], Aderonke Ajiboye[2], Andrea Manfrin[2]
[1]School of Medicine, Faculty of Clinical and Biomedical Sciences, University of Central Lancashire, Preston, UK
[2]Faculty of Clinical and Biomedical Sciences, University of Central Lancashire, Preston, UK

Corresponding author:
Name: Aderonke Ajiboye
Address: Faculty of Clinical and Biomedical Sciences, University of Central Lancashire, Preston
Email: AAjiboye@uclan.ac.uk

Authors' ORCID Number
Rupal Lovell-Patel: 0000-0002-1549-6913
Andrea Manfrin: 0000-0003-3457-9981
Aderonke Ajiboye: 0000-0001-5989-9522

Abstract

Background: The increased use of digital devices has implications for health and, particularly, the eyes, due to Computer Vision Syndrome (CVS). Millions of individuals of all ages are at risk of CVS, and its prevalence ranges from 25% to 93%. This trial will evaluate the effectiveness of the Super Enhanced Single Vision Lens 01 (SESL01) versus standard single vision lens in reducing symptoms of CVS assessed by the Computer Vision Syndrome Questionnaire (CVS-Q®) scores.

Method: A double-blind, two-arm parallel randomized controlled trial will be conducted at the University of Central Lancashire, Preston (UK), recruiting students and staff with CVS-Q score ≥6. A 1:1 randomization and a sample size of 300 participants will be sufficient to detect a 2-point difference in the CVS-Q score between the intervention and control groups with an alpha of 5%, two-sided, allowing for a dropout of 10%. The control group will use standard single vision lenses, and the intervention group SESL01. The primary outcome to week 14 will be the difference in the CVS-Q score between SESL01 and standard single vision lenses. Secondary outcomes include the percentage of participants with CVS-Q score <6 (no symptoms) and CVS-Q score ≥6 (symptoms) in the SESL01 and the standard single vision group at weeks 6, 10 and 14; the percentage of participants in each group with a total CVS-Q score <6, 6-12, 13-19, and ≥20 at weeks 6, 10 and 14. The primary analysis will be the intention to treat.

Discussion: Findings may inform decisions about adopting the SESL01 lenses to reduce CVS.

Trial registration: clinicaltrial.gov identifier: NCT05545878. Registered: Sept. 19, 2022

Keywords : Computer vision syndrome, Digital devices, Lenses

1. Background

What is the problem to be addressed?

In the last two decades, people have dramatically changed the way in which they acquire information(1,2) . During that time, engagement with digital devices in developed countries has increased significantly, particularly in the field of mobile media(3). The increased use of digital devices has implications for health, eyes, and vision. A European study found that by the age of 3, 68% of children regularly use a computer and 54% undertake online activities (4). In 2016, it was estimated that UK adults typically spend almost 5 hours a day using digital media, with a similar pattern developing in the USA(5). The use of digital devices has caused Computer Vision Syndrome (CVS), also called Digital Eye Strain (DES) or Visual Fatigue (VF), which has been well described in the literature for over 20 years (6–9).

What is Computer Vision Syndrome?

The American Optometric Association defines Computer Vision Syndrome (CVS) as a group of eye and vision-related problems resulting from prolonged exposure to digital devices/computers (10). CVS has been linked to using a variety of digital devices (9)such as computer/laptop screens, tablets and smartphones, which has been steadily growing (10). The most common symptoms are eye strain, tired eyes, irritation, burning sensation, redness, blurred vision, and double vision (8,11). Therefore, a person using digital devices and complaining about one or more of those symptoms might be suffering from CVS. Furthermore, CVS could cause non-ocular symptoms such as headaches and pain in the shoulders, neck, and/or back. Blehm et al.(8) identified four CVS categories. The first is asthenopia: eye strain, tired eyes, sore. The second is ocular and related to eye surface: dry eyes, watery eyes, irritated eyes, and contact lens problems. The third is the visual category: blurred vision and slowness of focus. The fourth category is extraocular and is represented by neck, shoulder, and back pain.

CVS symptoms result in poorer visual performance, and even though they are transient, they occur frequently and cause considerable discomfort for sufferers. CVS lowers productivity (increased errors and more frequent breaks) and impinges on job satisfaction and quality of life (12). Millions of individuals of all ages are at risk of CVS, and according to different studies, the prevalence of CVS ranges from 25% to 93%, depending on the cohort of the studied population, definition and methodology employed to measure CVS (6). These results indicate that a large proportion of the population may need treatment for CVS.

CVS affects all age groups, including older age groups (aged 65+), in which the use of technology is also rapidly growing (13). However, the most affected population are younger users, who are more likely to simultaneously use two or more digital devices. For example, recent US data indicates that while adults aged 60 years and over prefer using laptops and desktops, younger adults are more likely to use smartphones too (5). Since they use digital devices for work and social purposes (e.g., social media), they often multitask and switch between different devices.

The COVID-19 pandemic introduced homeworking and remote learning and further increased exposure to digital screens. Moreover, lockdowns increased unhealthy digital recreational activities, with people turning to television and social media for entertainment (14).

Management of Computer Vision Syndrome

CVS management includes correction of refractive error and/or presbyopia (long-sightedness caused by loss of elasticity of the lens of the eye, occurring typically in middle and old age; managed by prescribing a 'near add'), dry eye management, regular screen breaks, and eye exercises for vergence and accommodative problems (such as a lag in changing the focus from near to far distance) (6,15). In a recent systematic review, which included 45 randomized controlled trials (RCT), the authors did not find high-certainty evidence supporting the use of any of the therapies analyzed(16). Some studies (6) have explored the role of blue light-filtering spectacle lenses with mixed results, indicating that blue light filters may not alleviate symptoms of CVS. Given the high prevalence of CVS and near-universal use of digital devices, it is essential that eye care practitioners can provide advice and management options that are evidence-based.

2. Aim

To evaluate the effectiveness and safety of the Super Enhanced Single Vision Lens 01 (SESL01) in reducing symptoms of Computer Vision Syndrome.

Key research questions

The key research questions of this study are:

Is the SESL01 lens effective in

I. Reducing the symptoms of the CVS compared with standard single vision lenses, assessed by the Computer Vision Syndrome Questionnaire (CVS-Q®) scores?

II. Improving near visual performance when using digital devices, compared with standard single vision lenses, assessed by clinical measurement of accommodative facility using the standard ± 2.00 dioptre spherical lens flippers, measured as cycles per minute.

3. Trial Design

It is a double-blind two-arm parallel randomized control trial that aims to evaluate the effectiveness and safety of SESL01 in CVS management. The study will mimic the routine optometric practice, except that patients will be randomly allocated to the intervention or control groups. The patient's follow-up period is 14-week from the baseline.

4. Methods

Study setting

The study will be conducted at the University of Central Lancashire on the Preston campus in the UK.

Participants eligibility criteria

Inclusion criteria:

I. Able to give informed consent

II. 21-45 years of age

III. Adults diagnosed with CSV-Q score ≥6

IV. Participants WITH AND WITHOUT refractive error are acceptable BUT none should have previously worn a "near add" correction (e.g., no previous bifocal/varifocal/enhanced single vision lens [ESL] wear)

V. Range of refractive errors should be no more than +4.00 to -6.00 dioptric spherical power (DS) and +2.00 dioptric cylindrical power (DC)

VI. Must use digital devices for work and/or leisure for at least 1 hour per day (this includes smartphones, tablets, and laptops but EXCLUDES PC-only users)

VII. Participants MUST have visual symptoms associated with digital device use, e.g., one or more of the following symptoms:

   a. Tired eyes
   b. Eye strain
   c. Blurred vision
   d. Frontal headaches
   e. Difficulties in keeping clear vision when changing focus from near to distance
   f. Difficulties in keeping clear vision when changing focus from one device to another

Exclusion Criteria:

I. Lack of capacity to give informed consent.

II. Amblyopia

III. Pregnancy

IV. Diagnosed dry eye disease

V. If a participant develops dry eye symptoms or is diagnosed at follow-up appointments, treatment will be started and assessed in two weeks.

VI. On anti-depressants (or other medication that can affect accommodation, such as reduced focusing power)

VII. Any diagnosed ocular pathology (such as glaucoma, corneal dystrophies, lid disorders, and retinal pathologies)

VIII. Change in ±0.75DS/DC in the spectacle prescription (17,18).

Intervention

Participants in the intervention group will wear the newly designed SESL01 lens. The SESL01 is an Enhanced Single Vision Lens design. Enhanced Single Vision Lenses (ESL) have a small amount of positive power towards the bottom of the lens, as this is the area that is in line with the eye when looking downwards for near tasks. The small amount of positive power is expected to reduce the effort by the eyes to maintain a clear, in-focus image when looking at tasks at near.

Participants in the control group will be corrected with standard single vision lenses with an anti-reflection coating. The SESL01 and the single vision lenses will have the same anti-reflection coating so there is no difference in the appearance of the lenses.

If a participant in either group withdraws from the study, any data collected prior to withdrawal will be included in the analysis related to specific visits.

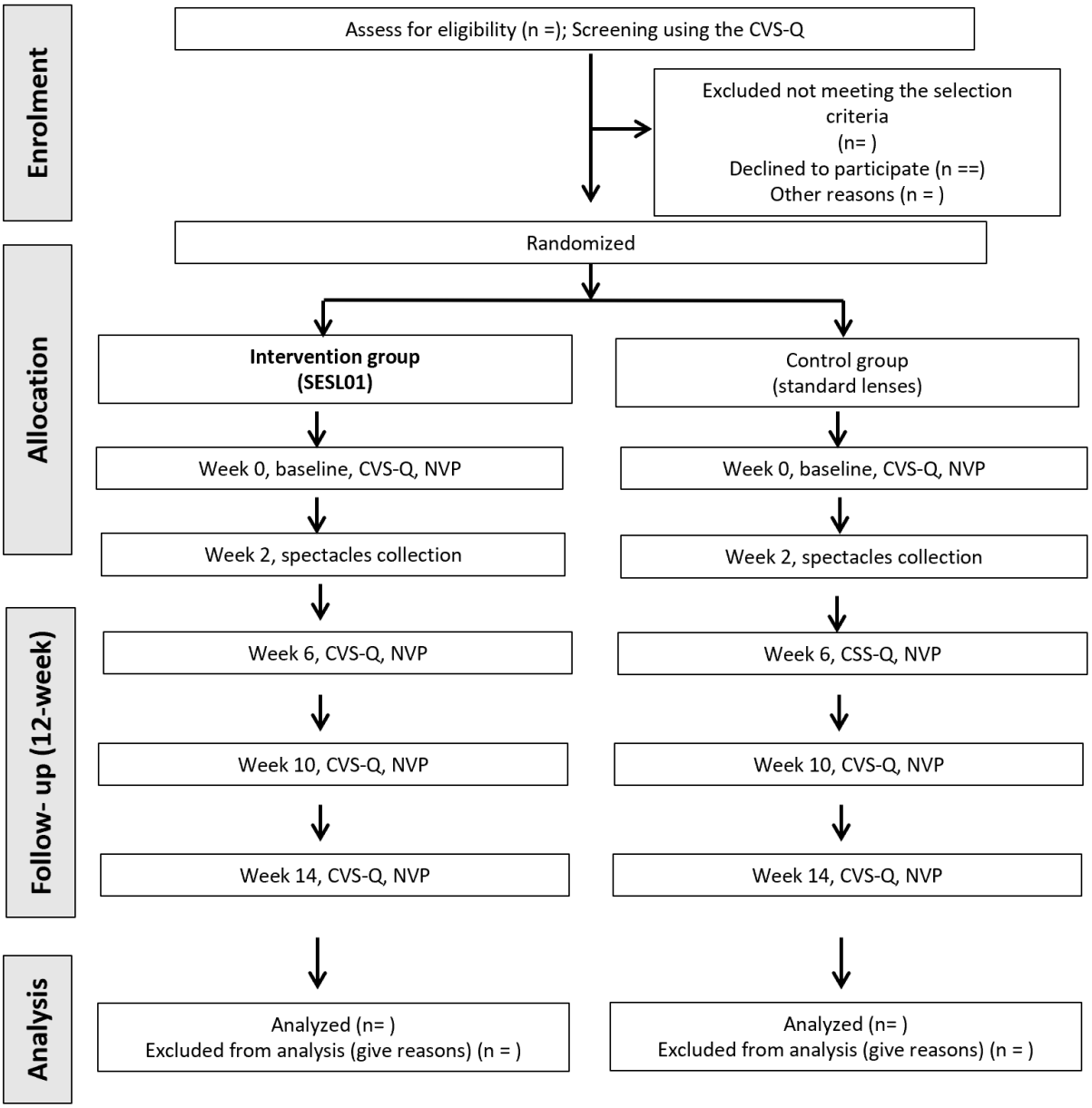
Both participant groups will have a choice of spectacle frames (within a set price range of up to £70) to select for their new spectacle correction. At the end of the study, all spectacles will be returned to the research team so that they can be reglazed with standard single vision lenses with an anti-reflection coating, and they will be returned to participants. The purpose of reglazing is to ensure that the intervention lens (SESL01) is not in the public domain ahead of its official release.

Table 1 Schedule of enrolment, intervention, and assessments

	Study period					
	Enrolment Screening	**Allocation Baseline**	**Spectacle collection**	**Post-allocation**		**Closeout**
Timepoint (weeks)	**-W0**	**W0**	**W2**	**W6**	**W10**	**W14**
Enrolment						
Eligibility screen for patients	x					
Informed consent for patients		x				
Randomization for patients		x				
Spectacles collection			x			
Intervention Group will use the Super Enhanced Single Vision Lens L01 (SESL01)			x	x	x	x
Control Group will use the standard single vision lenses			x	x	x	x
Assessments						
Computer Vision Syndrome Questionnaire (CVS-Q)	x	x		x	x	x
LogMAR Vision and Visual Acuity (using a computerized chart: 6/6 minimum monocular distance VA and N6 monocular)		x		x	x	x
Non-cycloplegic refractive error assessment (anisometropia of ≤1.50DS in any one meridian, +4.00 to 6.00DS and +2.00DC)		x				
Cover test (D&N)		x				
Ocular Motility		x				
Pupil size (D&N)		x				
Fixation Disparity (D&N)		x				
Monocular and binocular amplitude of accommodation		x		x	x	x
Near point of convergence		x		x	x	x
Slit lamp Assessment (including measuring of tear break-up time, less than 11sec is an exclusion criteria)		x				
Indirect assessment of the fundus (Volk)		x				
Optical Coherence Tomography imaging		x				
Intra-Ocular Pressure measurements for those aged 40yrs and over		x				
Visual Fields		x				
Wilkins Rate of Reading		x		x	x	x
Accommodative Facility in cycles per minute (with spherical lens flippers and Zeiss own brand app)		x		x	x	x
Thomson Clinical Eye Tracking (with blink rate)		x		x	x	x

Near Visual Performance (NVP) includes all the assessments (variables) listed after the CVS-Q

Figure 1 CONSORT Flow Diagram



CVS-Q: Computer Vision Syndrome Questionnaire; NVP: Near Visual Performance

5. Criteria for discontinuing or modifying allocated interventions

i. Participant withdraws consent
ii. The trial is discontinued
iii. Participant requires hospitalization or out-patient ocular surgical treatment

The reasons for discontinuation will be documented. Participants will be invited to participate in an outcome-related assessment to determine the effectiveness of the intervention. Participants will be asked to return the spectacles provided for the study.

6. Strategies for monitoring and improving protocol adherence

There are some measures that clinicians could adopt to improve participant adherence to the research protocol, such as telephone calls, text reminders, and social support to educate patients on using their spectacles. In addition, clinicians will have to create a welcoming, non-judgmental, and accepting environment; educate participants about their role as research participants; establish a routine while maintaining flexibility; provide incentives for participation, such as Amazon vouchers, parking spaces.

7. Research instrument

The CVS will be assessed using the CVS Questionnaire (CVS-Q) developed by Seguí et al.' (19) The CVS-Q has questions on 16 ocular and visual-related symptoms which will be presented to the patients. These symptoms are burning, itching, feeling of a foreign body in the eye, tearing, excessive blinking, eye redness, eye pain, heavy eyelids, dryness, blurred vision, double vision, difficulty in focusing on near objects, increased sensitivity to light, colored halos around objects, feeling that sight is worsening and headache. The frequency of these symptoms is defined based on how often they occur: sometimes or occasionally, once per week, always or often if they occur two to three times per week or every day(7). The intensity of the symptoms is scored as never=0, mild to moderate=1 and severe=2. To measure the frequency of the symptoms, patients will be asked to choose the following options for each of them: never=0, sometimes or occasionally=1, always or often=2.

The following formula will be used to calculate the total score

$$\text{Score} \sum_{i=1}^{16} (\text{frequency of symptom})_i \times (\text{intensity of symptom})_i$$

Seguí et al. (19) suggested that a good balance between sensitivity and specificity is represented by a cut-off value of 6 for the total CVS-Q score. Therefore, patients with a CVS-Q total score ≥6 are suffering from CVS and will be included in the study. In the absence of a universal consensus on CVS severity grading, Alhasan et al. (14) adopted the following criteria: participants with a total score of 6-12 were deemed to have mild CVS, those with a score of 13-19 moderate, and those with a score ≥20 were considered to have severe CVS.

8. Outcomes

Primary outcome

- It is the difference in the means (medians) of the CVS-Q score on SESL01 vs standard single vision lenses to week 14.

Secondary outcomes

- The improvement of the near visual performance when using digital devices using SESL01 compared with standard single vision lenses, assessed using the clinical measurement of the accommodative facility in cycles per minute using spherical lens flippers at weeks 6, 10 and 14, as well as optometric tests such as near LogMAR visual acuity, the amplitude of accommodation, the near point of convergence and rate of reading.
- The percentage of participants with a CVS-Q score <6 (no symptoms) and CVS-Q score ≥6 (symptoms) in the SESL01 and standard single vision group at weeks 6, 10 and 14.
- The percentage of participants in each group with a total CVS-Q score <6, 6-12, 13-19, and ≥20 at weeks 6, 10 and 14. In addition to the performance of the lens in terms of reducing CVS and improving near vision function, the study will consider the safety of the lens before it can be prescribed safely to the wider population.

9. Sample size

Seguí-Crespo et al.(20) and Alhasan et al. (14) suggested that the CVS-Q score is not normally distributed. Alghamdi and Alrasheed (21) and Sanchez Brau et al. (22) summarized their findings using means and a wide range of standard. Therefore, in our study, it was decided to conduct the power calculation using a standard deviation of 3.5, which is within the 1.8-6 range. We also assumed a normal distribution in the arms with expected means of 8 in the control and 6 in experimental groups. We then estimated the power for different sample sizes by simulation, truncating the values generated to select those of at least 6. The result was that a sample size of 150 per group would give us the power of 80% to detect the clinically important difference of 2, with a type 1 error (alpha) of 5%, two-sided, allowing for a dropout of 10%. Therefore, with a 1:1 allocation and sample size of 300 patients (150 in the intervention group [IG] and 150 in the control group [CG]), we expect there to be sufficient power to detect this effect size.

10. Recruitment

Recruitment will be focused mainly on students and staff within the University of Central Lancashire.

Student recruitment: Announcements on the virtual learning platform (the Blackboard) will be used along with posters around the campus with the details of the study. Project invites can be sent out via Social Media accounts and student email addresses. The university has a large portion of mature students, so recruiting patients within the required age range will be possible.

Staff recruitment: Emails, announcements on internal comms, social media accounts, work

email addresses, and posters will be used to encourage colleagues to participate.

Recruitment will start as soon as University ethics and NHS REC approval have been granted and the sponsor has opened the study site.

The recruitment strategy will increase potential participants' awareness of the health problem being studied, its potential impact on their health, and engagement in the learning and training of healthcare professionals.

Clinician-patient ratio

For eye tests and clinical measurements, the ratio of participants to clinicians is 150:1, but each interaction/data collection appointment will be on a 1:1 basis.

For spectacle frame selection and measurements, the ratio is 300:1; however, each interaction will be on a 1:1 basis.

11. Randomization, sequence generation, allocation, and blinding

Randomization

An academic from UCLan, who is an expert in the use of statistics, will oversee the randomization process. The total number of patients (n=300; IG=150, CG=150) will be randomized with a 1:1 ratio using permutated block randomization. The groups will have equal sizes and will tend to be uniformly distributed by key outcome-related characteristics (23). The randomization scheme will not be disclosed by the statistician unless deemed necessary for safety reasons.

Unit of randomization and intervention

The patient is the unit of randomization and intervention.

Block size

Blocked randomization will provide a balance between study arms, reducing the opportunity for bias and confounding (23).

Sequence generation

The sequence generation will be conducted using randomization with block permutation without stratification.

The block permutation, randomization and sequence generation will be performed using PASS (Power Analysis and Sample Size Software) 2021, (NCSS, LLC. Kaysville, Utah, USA, ncss.com/software/pass).

Allocation concealment

The procedure adopted in this study for assuring allocation concealment will be the use of sequentially numbered, opaque and sealed envelopes (SNOSE).

Blinding

In our study, the clinicians (opticians) performing assessment and follow-up and the patients receiving and wearing the spectacles will be blinded to the treatment.

12. Data collection

Clinicians will collect data at baseline and 4-week intervals using paper questionnaires

and records. The amount of time spent on each device will be noted at each visit.

13. Data management

Data will be managed following the procedure used in a previous study(20). Input data will be saved and stored on a password-protected system. Only individuals authorized by the CI will be allowed to access the data. Paper data will be kept in a locked cabinet by the research team. Patients' informed consent will be kept by the clinicians in a locked cabinet.

14. Statistical methods

The primary analysis will be the intention-to-treat (ITT), including all randomized participants in the group where they were randomly assigned, regardless of their adherence to the protocol or their withdrawal.

Missing data will be assessed and treated using multiple imputations, assuming that data will be missing at random (MAR). A sensitivity analysis will be performed to assess whether the findings are robust to different assumptions regarding missingness.

To check for normality, each variable will be analyzed using the Kolmogorov-Smirnov and Shapiro-Wilk tests.

Primary outcome

The primary outcome measure is the difference in the means (medians) of the CVS-Q score on SESL01 vs standard single vision lenses, which will be assessed at week 14 using an unpaired analysis (t-test or Mann-Whitney U test according to the distribution of the variables). The analysis will be performed without adjustments; then, it will be adjusted using the baseline CVS-Q scores, age, sex and ethnicity (as suggested by the Department of Health and Social Care) and the CVS-Q at 6 and 10 weeks using generalized estimating equations (GEE), which is a semiparametric technique useful for repeated measures that work for dichotomous and continuous data, as in our case. Time spent on each device will be recorded at each visit.

Secondary outcomes

The secondary outcome measure is the improvement of the near visual performance when using digital devices using SESL01 compared with standard single vision lenses, which will be assessed using the clinical measurement of the accommodative facility in cycles per minute using spherical lens flippers (±2.00DS) at weeks 6, 10 and 14, as well as optometric tests such as near LogMAR visual acuity, the amplitude of accommodation, the near point of convergence and rate of reading. As these will be continuous variables, the difference between the groups will be assessed at 14 weeks using the unpaired t-test or Mann-Whitney U test according to the distribution of the variables.

Secondary analysis: The secondary analyses will be performed by looking at:

- The percentage of participants with a CVS-Q score <6 (no symptoms) and CVS-Q score ≥6 (symptoms) in the SESL01 and standard single vision groups at weeks 6, 10 and 14. The results will be presented using descriptive statistics, and the differences at 14 weeks will be assessed using Pearson's Chi-square test or Fisher's exact test and odds ratio (OR).
- The percentage of participants in each group with a total CVS-Q score <6, 6-12, 13-19, and ≥20 at weeks 6, 10 and 14. The results will be presented using descriptive statistics at each time point, and the differences will be assessed at 14 weeks using the Mann-Whitney U test.

A P-value of ≤0.05 will be considered statistically significant and presented with a 95% confidence interval where appropriate. The statistical analysis will be performed using SPSS (IBM Corp. Released 2021. IBM SPSS Statistics for Windows, Version 28.0. Armonk, NY: IBM Corp).

15. Data monitoring

This trial was designed to minimize the risk, as demonstrated in a previous trial (20). Therefore, no formal committee has been organized, and no interim analysis of the impact of the intervention has been planned. This is a monocentric study conducted at the UCLan campus in Preston.

16. Risk and safety issues, harm and process for dealing with a case of spectacle non-tolerance are described in Appendix 1

Auditing

No audit has been planned at this time.

17. Regulatory approvals

Ethics approval was obtained from the Northwest-Greater Manchester South Research Ethics Committee (August 22nd, 2022), and from the UCLan University REC (Ref: HEALTH 0360, Sept. 1st, 2022). Notice of no objection was obtained from the Medicines and Healthcare products Regulatory Agency (MHRA).

18. Protocol amendments

We are not expecting to make any changes to the eligibility criteria, outcomes, and analyses during our study. Any amendments made to the protocol will be submitted to the MHRA and/or REC as appropriate.

19. Discussion

The use of digital devices was growing steadily even before their rapid uptake due to the COVID-19 pandemic, increasing the prevalence of CVS. CVS is caused by people spending more time on their digital devices and because people have multiple devices and use them simultaneously.

Previous research has indicated that CVS symptoms can be due to accommodative issues as the prolonged and sustained use of multiple devices within the range of 25cm (wearable devices) to 65cm (average screen distance) can cause accommodative fatigue and cause the change in focusing power to slow. Accommodative facility measurement can show whether focusing is slowing down or not.

This study is evaluating a new spectacle lens design which could reduce CVS symptoms in this population. It will investigate whether the lens affects the accommodation facility, which is an essential factor in changing focus between screens that are at different distances. If positive, the results of this study could inform policy and practice. Furthermore, the possibility of using lenses that could reduce CVS will be welcomed by many people using digital devices for work and leisure.

20. Conclusion

The project results could provide useful information regarding the adoption of SESL01 lenses to reduce the symptoms of CVS.

21. Consent, invitation, and confidentiality

Consent will be obtained according to the International Standards Organization (ISO) 14155 – Clinical investigation of medical devices for human subjects — Good clinical practice guidelines. The Chief Investigator (CI) or another qualified member of the study team will decide whether a potential participant is suitable for screening and/or enrolment into the study. The potential participant will then be given the patient information leaflet and consent form and will have a discussion with a study team member.

The potential participant will then be given time to consider taking part and discuss the study with others such as friends and family. Once the potential participant is satisfied that they have been fully informed, and they have decided that they wish to enter the study, they will be asked to sign a consent form.

The study team member who performs the informed consent discussion will sign the consent form. The consent will be confirmed by the personally dated signature of the participant.

A copy of the signed consent document will be given to the participant and the original signed consent will be kept by the study team. The study team will not undertake any measures specifically required for the study until valid written consent is obtained. All participants are free to withdraw from the study at any time and without giving a reason. A decision to withdraw, or a decision not to take part, will not affect the standard of care they receive from any institution subsequently.

The eye test (screening assessment) records will be stored in a locked filing cabinet in the Eye Health Clinic and would be uploaded to the UCLan Data Repository within two weeks of patients being allocated to a participant group. Anyone who is deemed unsuitable to

participate will be offered a copy of their eye test record within two weeks, and if they do not want their record, it will be shredded in line with the University's confidential shredding procedure

22. Declaration of interest

We wish to confirm that there are no known conflicts of interest associated with this publication and there has been no significant financial support for this work that could have influenced its outcome. Funding was received for this work (see 26. Funding).

23. Dissemination policy

The dissemination of the study will begin immediately after the publication of the protocol. The study outcomes will be published in peer-review journals and conference papers; they may be also used in training materials for clinicians working in the optical industry. The trial results aim to inform patients, eyecare professionals and students, who would benefit from the results. The results will be disseminated to service users and their families via media, to healthcare professionals via professional training and meetings, and to researchers via conferences and publications. Participants will be offered a copy of the final study report submitted to Carl Zeiss Vision International GmbH c/o Carl Zeiss Vision UK Ltd.

24. Ancillary post-trial care

We are not envisaging the need for provision of post-trial care. Nevertheless, all participants will be provided with an emergency contact number to reach the study investigators so that they can receive necessary support if they have any questions or problems. Spectacles provided during the study will be collected so that they can be reglazed with standard single vision lenses with anti-reflection coating, and they will be returned to participants; the participants may be without the new spectacles and will need to wear their own spectacles for a few days.

25. Patient and public involvement

The research protocol was developed during the COVID Omicron wave, December 2021 and March 2022; therefore, it was not practical to reach patients and members of the public and get their input into the protocol.

26. Funding

The research team is deeply grateful to Carl Zeiss Vision International GmbH c/o Carl Zeiss Vision UK Ltd for supporting the research project by covering the cost of spectacle frames, lenses, and Amazon vouchers for participants.

27. Acknowledgements

The research team wants to thank Dr Navneet Gupta for his support as the liaison between the research team at UCLan and Carl Zeiss Vision International GmbH c/o Carl Zeiss Vision UK Ltd.

In preparation for this protocol, Dr Miland Joshi acted as a critical friend in developing the

statistical analysis plan, so the research team would like to acknowledge this support. We thank Dr Izabella Penier for editing the manuscript.

Author contributions

Conceptualisation: Rupal Lovell-Patel and Andrea Manfrin

Data curation: Andrea Manfrin

Formal analysis: Andrea Manfrin

Funding acquisition: Rupal Lovell-Patel

Methodology: Andrea Manfrin and Rupal Lovell-Patel

Project administration: Rupal Lovell-Patel

Visualisation: Rupal Lovell-Patel, Aderonke Ajiboye, Andrea Manfrin

Writing original draft: Rupal Lovell-Patel, Aderonke Ajiboye, Andrea Manfrin

Writing review & editing: Rupal Lovell-Patel, Aderonke Ajiboye, Andrea Manfrin

References

1. Costanza M. Visual and ocular symptoms related to the use of video display terminals. J Behav Optom. 1994; 5:31–6.

2. Dain SJ, McCarthy AK, Chan-Ling T. Symptoms in VDU operators. Am J Optom Physiol Opt 1988 ;65(3):162–7. Available from: https://pubmed.ncbi.nlm.nih.gov/3364524/

3. Insider Intelligence. » eMarketer: Digital Set to Take Majority Share in UK Time Spent with Media in 2016 eMarketer Newsroom. 2015 (cited 2022 March 17) Available from: https://www.insiderintelligence.com/newsroom/index.php/emarketer-digital-set-majority-share-uk-time-spent-media-2016/

4. Palaiologou I. Children under five and digital technologies: implications for early years pedagogy. European Early Childhood Education Research Journal. 2016 Jan 2;24(1):5-24. https://doi.org/10.1080/1350293X.2014.929876

5. Insider Intelligence » Mobile Takes Majority Share of UK Time with Digital Media eMarketer Newsroom. 2016 [cited 2022 March 17]. Available from: https://www.insiderintelligence.com/newsroom/index.php/mobile-takes-majority-share-uk-time-digital-media/

6. Sheppard AL, Wolffsohn JS. Digital eye strain: prevalence, measurement and amelioration. BMJ open ophthalmology. 2018 Apr 1;3(1): e000146 https://bmjophth.bmj.com/content/3/1/e000146

7. Munshi S, Varghese A, Dhar-Munshi S. Computer vision syndrome—A common cause of unexplained visual symptoms in the modern era. International Journal of Clinical Practice. 2017 Jul;71(7): e12962.https://doi.org/10.1111/ijcp.12962

8. Blehm C, Vishnu S, Khattak A, Mitra S, Yee RW. Computer vision syndrome: a review. Survey of ophthalmology. 2005 May 1;50(3):253-62. https://doi.org/10.1016/j.survophthal.2005.02.008

9. Rosenfield M. Computer vision syndrome: A review of ocular causes and potential treatments. Ophthalmic and Physiological Optics. 2011 Sep;31(5):502–15. https://doi.org/10.1111/j.1475-1313.2011.00834.x

10. Lee P, Calugar-Pop C. Plateauing at the Peak: The State of the Smartphone. Global Mobile Consumer Survey: UK Cut. 2019 (cited 2022 March 17). Available online at: https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/technology-media-telecommunications/deloitte-uk-plateauing-at-the-peak-the-state-of-the-smartphone.pdf

11. Jaiswal S, Asper L, Long J, Lee A, Harrison K, Golebiowski B. Ocular and visual discomfort associated with smartphones, tablets and computers: what we do and do not know. 2019 ;102(5):463–77. https://doi.org/10.1111/cxo.12851

12. Daum KM, Clore KA, Simms SS, Vesely JW, Wilczek DD, Spittle BM, et al. Productivity associated with visual status of computer users. Optometry. 2004;75(1):33–47. https://doi.org/10.1016/S1529-1839(04)70009-3

13. Hayes JR, Sheedy JE, Stelmack JA, Heaney CA. Computer use, symptoms, and quality of life. Optometry and vision science. 2007 Aug 1;84(8): E738-55. https://doi.org/10.1097/opx.0b013e31812f7546

14. Alhasan AS, Aalam WA. Magnitude and Determinants of Computer Vision Syndrome Among Radiologists in Saudi Arabia: A National Survey. Acad Radiol 2022;29(9): e197–204. https://doi.org/10.1016/j.acra.2021.10.023

15. Coles-Brennan C, Sulley A, Young G. Management of digital eye strain. Clin Exp Optom 2019 Jan 1;102(1):18–29. https://doi.org/10.1111/cxo.12798

16. Singh S, McGuinness MB, Anderson AJ, Downie LE. Interventions for the Management of Computer Vision Syndrome: A Systematic Review and Meta-analysis. Ophthalmology 2022 Oct 1;129(10). https://doi.org/10.1016/j.ophtha.2022.05.009

17. Freeman CE, Evans BJW. Investigation of the causes of non-tolerance to optometric prescriptions for spectacles. Ophthalmic Physiol Opt. 2010 Jan ;30(1):1–11. https://doi.org/10.1111/j.1475-1313.2009.00682.x

18. Elliott DB, Howell-Duffy C. 'Non-tolerances' and the Science of Prescribing Spectacles. Optometry in Practice. 2015;16(4):131-44. https://www.college-optometrists.org/professional-development/college-journals/optometry-in-practice/all-oip-articles/volume-16,-issue-4/2015-11-non-tolerancesandthescienceofprescribingsp

19. Seguí MDM, Cabrero-García J, Crespo A, Verdú J, Ronda E. A reliable and valid questionnaire was developed to measure computer vision syndrome at the workplace. J Clin Epidemiol. 2015 Jun 1;68(6):662–73. https://doi.org/10.1016/j.jclinepi.2015.01.015

20. del Mar Seguí-Crespo M, Ronda-Pérez E, Yammouni R, Arroyo Sanz R, Evans BJW. Randomised controlled trial of an accommodative support lens designed for computer users. Ophthalmic and Physiological Optics. 2022 Jan 1;42(1):82–93. https://doi.org/10.1111/opo.12913

21. Alrasheed SH, Alghamdi WM. Impact of an educational intervention using the 20/20/20 rule on Computer Vision Syndrome. African Vision and Eye Health. 2020 Jan 1;79(1):1-6. https://avehjournal.org/index.php/aveh/article/view/554/1316

22. Sánchez-Brau M, Domenech-Amigot B, Brocal-Fernández F, Seguí-Crespo M. Computer vision syndrome in presbyopic digital device workers and progressive lens design. Ophthalmic Physiol Opt. 2021 Jul 1 ;41(4):922–31. https://doi.org/10.1111/opo.12832

23. Efird J. Blocked Randomization with Randomly Selected Block Sizes. Int J Environ Res Public Health. 2011;8(1):15. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3037057/