TITLE: Evaluation of the effectiveness of the Super Enhanced Single Vision Lens L01 (SESL01) in reducing symptoms of Computer Vision Syndrome (CVS): a double-blind two-arm parallel randomised controlled trial

ACRONYM: SESL01-Trial

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Trial registration TBC

Study design Double-blind two-arm parallel randomised controlled trial

Funding and support Carl Zeiss Vision International GmbH c/o; Carl Zeiss Vision UK Ltd

Project CODE

Contents

KEY STUDY CONTACTS

Chief Investigator	Andrea Manfrin
Principal investigator	Rupal Lovell-Patel (RLovell-Patel@uclan.ac.uk)
Sponsor	Zeiss Vision Care, UK
Funder(s)	Zeiss Vision Care, UK
Key Protocol contributors	Rupal Lovell-Patel, Izabella Penier, Miland Joshi, Andrea Manfrin

Study summary

Study title	Evaluation of the effectiveness of the Super Enhanced Single Vision Lens L01 (SESL01) in reducing symptoms of the Computer Vision Syndrome (CVS): a double-blind two-arm parallel randomised controlled trial
Internal ref.no. (or short title)	SESL01-Trial
Study design	A double-blind two-arm parallel randomised controlled trial
Study participants	Patients
Planned size of Sample	300 patients
Planned study Period	June-September
Research Questions/Aim(s)	**Research questions**: Is the Super Enhanced Single Vision Lens 01 (SESL01) effective in I. Reducing symptoms of the Computer Vision Syndrome (CVS), compared with standard single vision lenses, assessed by the Computer Vision Syndrome Questionnaire (CVS-Q®) scores? II. Improving the 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. **Aim**: To evaluate the effectiveness and safety of the SESL01 in reducing symptoms of the Computer Vision Syndrome.

FUNDING AND SUPPORT IN KIND

FUNDER(S)	Carl Zeiss Vision International GmbH c/o Carl Zeiss Vision UK Ltd

ROLE OF STUDY SPONSOR AND FUNDER

The sponsor, Carl Zeiss Vision International GmbH c/o Carl Zeiss Vision UK Ltd, takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project

Study coordination

Rupal Lovel-Patel, the Principal investigator (PI), will be responsible for the research site under the Chief investigator's supervision.

LAY SUMMARY

The increased use of digital devices such as computers, smartphones, tablets, and laptops has transformed how people learn and work and has increased the use of screens. This has created visual challenges for some users, such as maintaining a clear vision for a long period even when looking at different devices. Consequently, digital device users can experience eye problems such as blurred vision, eye strain, headaches, and dry eyes. Such problems are more common in people aged 21-45, and it seems that the COVID-19 pandemic has worsened them. Studies suggest that using specially designed spectacle lenses could reduce these problems. Therefore, we aim to study whether specially designed spectacle lenses are more effective than standard ones in minimising these problems. The study will be conducted at the University of Central Lancashire at the Preston campus (UK). We will recruit 300 patients divided into two equal groups. Patients in group A will receive spectacles with special lenses while group B will receive spectacles with standard lenses. These two groups of patients will be assessed three times, at 4-week intervals, and the final analysis will be performed at 14 weeks. The reduction of the eye problems will be assessed using a validated questionnaire which will produce a score that will be compared between the two groups at the end of the study. The study will start in June and end in September.

The study's potential benefits are twofold:

1) Patients using the new lenses will hopefully see a reduction in eye problems
2) Opticians will provide be able to provide better patient care.

Carl Zeiss Vision International GmbH c/o (Carl Zeiss Vision UK Ltd) has funded the study. In addition to free eye examinations and spectacles, participants will receive £60 Amazon vouchers at the end of the study as compensation for their time and costs incurred to participate in the study. All participants will need to return the spectacles supplied as part of this study so that they can be reglazed with standard lenses. All participants will be able to use their Zeiss spectacles with standard lenses after the study is complete.

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

Background

What is the problem to be addressed?

In the last two decades, the way people acquire information has changed dramatically [1-2]. During that time, engagement with digital devices in developed countries has increased significantly, particularly in the field of mobile media [3]. The increasing use of digital devices showed implications for health, eyes, and vision. A European study found out 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 [6-10].

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/computer devices [11]. CVS has been linked to using a variety of digital devices [10] such as computer/laptop screens, tablets, and smartphones, which has been steadily growing [11]. The most common symptoms are eye strain, tired eyes, irritation, burning sensation, redness, blurred vision, and double vision [8]. 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. [9] identified four CVS categories. The first is asthenopia: eye strain, tired eyes, sores, and dry eyes. The second is ocular and related to eye surface: watery eyes, irritated eyes, 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, the 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 [18].

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]. 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.

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?

III. 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?

Trial Design

It is a double-blind two-arm parallel randomised control trial that aims to evaluate the effectiveness 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.

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 provide informed consent
II. 21-45 years of age
III. Adults diagnosed with CVS: 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. Patients 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 keeping clear vision when changing focus from near to distance
    f. Difficulties keeping clear vision when changing focus from one device to another

Exclusion Criteria:

I. Lack of capacity to provide informed consent.
II. Amblyopia
III. Pregnancy
IV. Diagnosed dry eye disease

V. If a patient 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 [15-20].

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.

Patients in the control group will be corrected with standard single vision lenses with an anti-reflection coating.

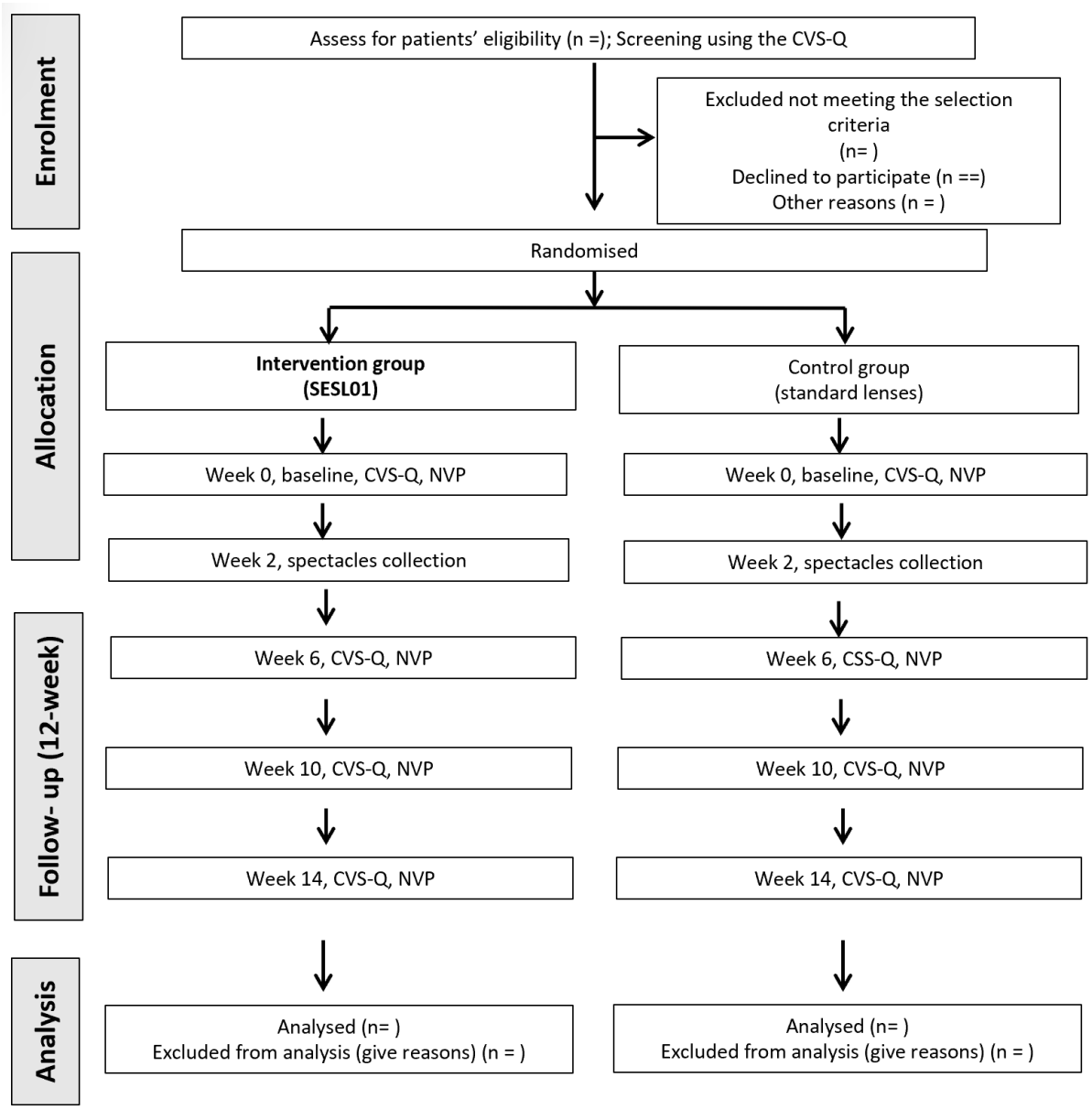
Both patient groups will have a choice of spectacle frames (within a set price range of up to £70) to select for their new spectacle correction. At the end of the study, all spectacles will be returned to the research team so that they can be reglazed with standard single vision lenses with an anti-reflection coating ensuring 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				
Randomisation 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 computerised 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

Criteria for discontinuing or modifying allocated interventions

i. Participant withdraws consent
ii. The trial is discontinued
iii. Participant requires hospitalisation 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.

Strategies for monitoring and improving protocol adherence

There are some measures that clinicians could adopt to improve patient 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 patients about their role as research participants; establish a routine while maintaining flexibility; provide incentives for participation, such as Amazon vouchers, parking spaces, and video consultations.

Research instrument

The CVS will be assessed using the CVS Questionnaire (CVS-Q) developed by Seguí et al.' [21]. 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, coloured 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, 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

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

Seguí et al. [17] 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. [24] 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.

Outcomes

Primary outcome

The primary outcome measure is the effectiveness of the SESL01 in reducing the CVS compared with standard single vision lenses, assessed using the CVS-Q® scores at week 14.

Secondary outcome

The secondary outcome is the effectiveness of SESL01 compared with standard single vision lenses in improving the near visual performance when using digital devices assessed by clinical measurement of accommodative facility in cycles per minute using spherical lens flippers as well as optometric tests such as near LogMAR visual acuity, amplitude of accommodation, near point of convergence and rate of reading.

In addition to 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.

Sample size

Seguí-Crespo et al. [20] and Alhasan et al. [24] suggested that the CVS-Q score is not normally distributed. Alghamdi and Alrasheed [23] and Sanchez Brau et al. [25] summarised 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 an initial 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 at least 6. The result was that a sample size of 150 per group would give us a power of 80% to detect the clinically important difference of 2, even 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.

Recruitment

Recruitment will be focussed 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 test 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.

Randomisation, sequence generation, allocation, and blinding

Randomisation

An academic from UCLan, who is an expert in the use of statistics, will oversee the randomisation process. The total number of patients (n=300; IG=150, CG=150) will be randomised with a 1:1 ratio using permutated block randomisation. The groups will have equal sizes and will tend to be uniformly distributed by key-outcome-related characteristics [18].

Unit of randomisation and intervention

The patient is the unit of randomisation and intervention.

Block size

Blocked randomisation will provide a balance between study arms, reducing the opportunity for bias and confounding. The block size in this study will be two and four [19].

Sequence generation

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

The block permutation, randomisation, 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 the allocation concealment will be the use of sequentially numbered, opaque, and sealed envelopes (SNOSE).

Blinding

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

Data collection

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

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 authorised by the CI will be allowed to access the data. Paper data, such as clinicians' informed consent, will be kept in a locked cabinet by the research team. Patients' informed consent will be kept by the clinicians in a locked cabinet.

Statistical methods

The primary analysis will be the intention-to-treat (ITT), including all randomised 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 imputation of missing at random (MAR).

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

Primary outcome

The primary outcome measure (CVS-Q score) will be assessed at week 14 using an unpaired analysis. The analysis will be performed without adjustments; then, it will be adjusted using the baseline CVS-Q scores, age, and gender 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.

Secondary outcomes

The secondary outcome measure, the improvement of the near visual performance when using digital devices using SESL01 compared with standard single vision lenses will be assessed using the clinical measurement of accommodative facility in cycles per minute using spherical lens flippers at week 14 as well as optometric tests such as near LogMAR visual acuity, amplitude of accommodation, near point of convergence and rate of reading.

Secondary analysis

The secondary analyses will be performed looking at

- the percentage of CVS-Q score <6 (no symptoms) versus CVS-Q score ≥6 (symptoms) in each group at 14 weeks. The results will be presented using descriptive statistics at each time point, and the differences 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 week 14. The results will be presented using descriptive statistics at each time point, and the differences will be assessed using the Mann Whitney U test.

A P-value of ≤0.05 will be considered statistically significant and presented with 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).

Data monitoring

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

Risk and safety issues

During this study, there will be no risks for patients. Patients wearing the SESL01 lenses will be at no greater risk than those receiving the usual ones. Clinicians will not dispense or administer any medications based on the CSV-Q score. In addition, clinicians will not be involved in the interpretation of diagnostic tests or their results.

Covid safety protocols:

Participants will be required to wear a face covering throughout the examinations while in the eye clinic (unless they are exempt). Before the visit, participants will be asked to complete a COVID-19 Research Participant Pre-Visit Check Form, which will be used to prevent the spread of COVID-19 and to reduce the potential risk of exposure. If participants are displaying any COVID symptoms, their data collection appointment will be rescheduled by a week. If participants display any COVID-19 symptoms during, or after the visit, the PI should be informed, so that the necessary steps can be taken according to relevant government guidelines.

The clinicians in the study will be wearing personal protective equipment, and all equipment and room surfaces will be cleaned between participant visits.

Harm

We do not expect adverse events or other unintended effects. All information regarding the trial will be included in the clinicians' and patients' information sheets.

Spectacle dispensing and prescribing can cause 'non-tolerance'. Non-tolerance is when a participant is not satisfied with their spectacles, which may be due to the lack of clarity of vision or discomfort caused by the frames [20].

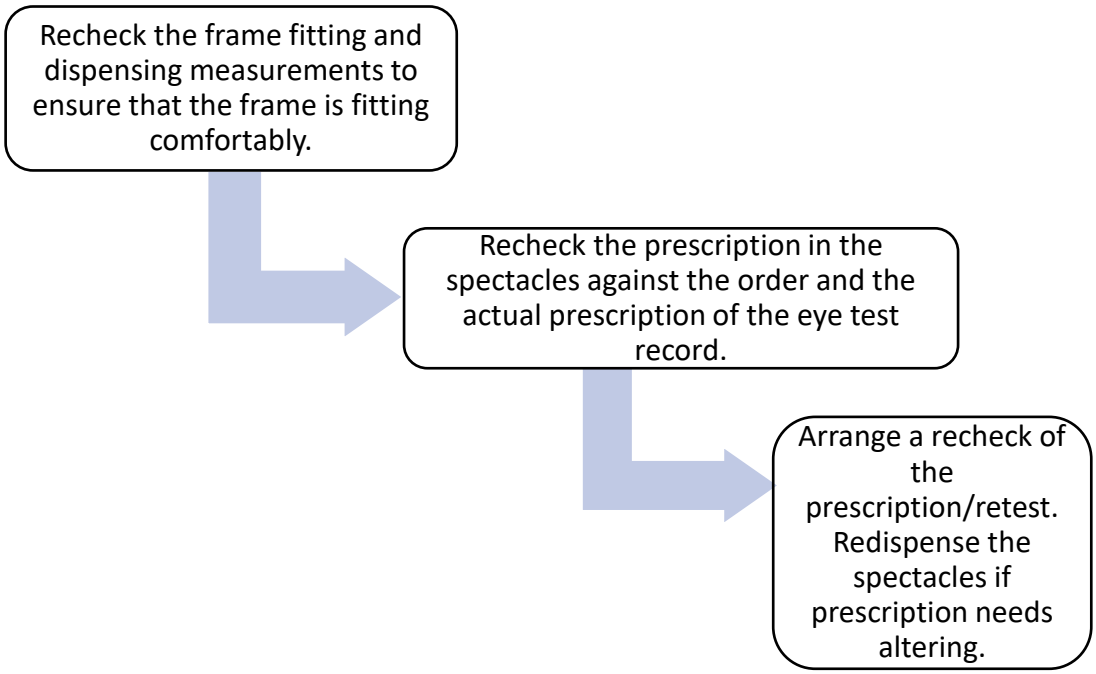
Cases of non-tolerance [15] can be split into:

I. Dispensing: This is where the fitting of the frame or the dispensing measurements were not correct for the participant.

II. Prescription: The participant is not able to adapt to the prescription or there was a data entry error, and the incorrect prescription was ordered.

Cases of non-tolerance are small; research shows that cases in general optometric practice range between 1% to 3% [16]. The implication of this data for our study is that approximately 7 participants may report dissatisfaction with their spectacles. A procedure to handle cases of non-tolerance is summarised in Figure 2.

Figure 2 Process for handling non-tolerance



Process for dealing with a case of spectacle non-tolerance.

Should symptoms of non-tolerance remain after the retest for the prescription and re-dispense, the information will be reported to Carl Zeiss Vision International GmbH c/o Carl Zeiss Vision UK Ltd as an adverse effect within 3 working days. Carl Zeiss Vision International GmbH c/o Carl Zeiss Vision UK Ltd has an adverse effect reporting template that will be filled in and sent to the relevant department within the lens manufacturer. Carl Zeiss Vision International GmbH c/o Carl Zeiss Vision UK Ltd will inform MHRA about any adverse effects.

Auditing

No audit has been planned at this time.

Research and dissemination

The study protocol and outcomes will be published in peer-review journals, conference papers and may be used in training materials for clinicians working in the optical industry.

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.

Regulatory approvals

Ethics approval will be sought from and NHS REC, and from the UCLan University REC. A notice of no objection will be sought from the MHRA.

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.

Consent, invitation, and confidentiality

Consent will be obtained according to the International Standards Organisation (ISO) 14155 – Clinical investigation of medical devices for human subjects — Good clinical practice guidelines. The Chief Investigator (CI) or other qualified member of the study team will make the decision as to whether the 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 the study team member.

The potential participant will then be given time to consider taking part and take the opportunity to discuss the study with others such as friends and family or members of their medical team, as applicable and appropriate. 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 by the study team member 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.

Declaration of interest

None

Dissemination policy

The dissemination of the study will begin immediately after the publication of the protocol. The results of this trial will be presented at national and international conferences. They will be submitted as scientific manuscripts to peer-reviewed journals. The trial results aim to inform patients, eyecare professionals and optics 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.

Ancillary post-trial care

We are not envisaging the need for the 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 the 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; the participants may be without the new spectacles and will need to wear their own spectacles for a few days.

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.

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 covering the cost of spectacle frames, lenses, and Amazon vouchers.

Acknowledgements

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In preparation of this protocol, Dr Miland Joshi acted as a critical friend for the development of the statistical analysis plan, so the research team would like to acknowledge this support.

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, Izabella Penier, Andrea Manfrin

Writing – original draft: Rupal Lovell-Patel, Andrea Manfrin

Writing – review & editing: Izabella Penier

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