Evaluating the myopia progression control efficacy of defocus incorporated multiple segments (DIMS) lenses and Apollo progressive addition spectacle lenses (PALs) in 6- to 12-year-old children: study protocol for a prospective, multicenter, randomized controlled trial

Yan Li
Peking University People's Hospital
Yafei Fu
Peking University People's Hospital
Kai Wang
Peking University People's Hospital
Zhiming Liu
Peking University People's Hospital
Xiaoqing Shi
Peking University People's Hospital
Mingwei Zhao (dr_zhaomw_pkupk@163.com)
Peking University People's Hospital

Study protocol

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Abstract

Background: Myopia is increasing in prevalence and is currently recognized as a significant public health issue worldwide, particularly in China. Once myopia develops, appropriate clinical interventions need to be prescribed to slow its progression. Currently, solid evidence indicates that myopic defocus (MD) retards eye growth and myopia progression. However, no clinical trial has compared the outcomes of different MD spectacle lenses in the same observational group, especially in mainland China. The aim of the present study is to compare the myopia control efficiency of two different MD spectacle lenses, i.e., defocus incorporated multiple segments (DIMS) and Apollo progressive addition spectacle lenses (PALs).

Methods: The trial is a 3-year, prospective, randomized, multicenter clinical trial of school children with DIMS and PALs. A total of 600 Chinese primary school children aged 6-12 years will be recruited, and each group is intended to include 300 subjects. The inclusion criteria are myopia between −1.00 and −5.00 D and astigmatism ≤1.50 D. The primary outcomes are cycloplegic spherical equivalent refraction (SER), measured at 6-month intervals, and the changes between groups compared over the study period. The secondary outcomes are axial length, compliance and questionnaires related to wearing experiences. The exploratory outcomes include ocular biometric measures, peripheral refraction, binocular vision, and accommodation.

Discussion: The present study is the first randomized controlled trial of DIMS and PALs treatment for primary school children with myopia in China. The results will indicate whether and how much of different MD mechanisms approach retards myopia progression and axial elongation. In addition, the comparison will provide information on the clinical effectiveness and safety of DIMS and APLs, including wearing experiences, visual functions, etc.

Trial registration: Chinese Clinical Trial Registry (ChiCTR) Identifier: ChiCTR1900025645. Date of registration: 3 September 2019. http://www.chictr.org.cn/showproj.aspx?proj=42927

Background

Myopia (also called nearsightedness) affects 50% of the world population by 2050 [1–3]. With the growing prevalence of myopia in young generations, this “epidemic” disease is currently recognized as a public health issue, particularly in China [4]. The annual incidence of myopia onset is constantly growing between 7 and 15 years, and by the age of 18 years, ~80% of the urban-based Han population in mainland China is myopic, regardless of geographic locality. Control of myopia progression and prevention of myopia complications that result in irreversible visual loss, such as myopia maculopathy, retinal detachment, glaucoma, and cataracts [5], will require collaborative efforts worldwide.

Several clinical interventions are currently used for myopia control, including spectacle lenses, contact lenses, and pharmacological treatment, etc [6]. Regardless of the treatment strategy, slowing the progression of myopia after onset is the most important therapeutic goal [1, 4]. It has been reported that single-vision (SV) spectacle lenses designed to alter peripheral defocus achieve less than a 14% reduction in myopia progression. Bifocal-vision (BV) and progressive addition spectacles lenses (PALs) have variable clinical significance treatment effects, which are between 6% and 50% in different study [7, 8]. Orthokeratology has proven to be effective in slowing myopia progression and axial length elongation by between 30% and 55% [7]. Additionally, 0.01% atropine showed an effect on refractive error retardation (approximately 45%) and no apparent effect of axial length compared to historical control groups [7, 8].

Once a myopic child has been identified, an appropriate management should be subscribed in conjunction with the patient and parents/guardians based on several aspects such as age onset, baseline refractive status, visual environment, treatment strategy risks-benefits, compliance, and annual cost taken into account [7, 8]. Among all the treatment options, spectacle lenses intervention is simple to use and is the least invasive method in contrast to contact lenses and pharmacological treatments for children and their parents, especially for younger children under 8 years old [7]. Considering numerous patient-specific factors related to myopia development and progression, optimum prescription needs to be verified according to associated risk factors [4, 7].

Currently, there are multiple solid evidence that myopic defocus (MD) retards eye growth and myopia progression, whereas hyperopic defocus (HD) promotes eye growth in animal and human studies compared to SV spectacle lenses [9–12]. In clinical practice, there are two major spectacle lenses designed with the idea of MD: defocus incorporated multiple segments (DIMS) and Apollo progressive addition spectacle lenses (PALs) [10, 13, 14]. Although both are recommended that manipulate optical defocus across the visual field have been suggested to result in greater myopia control, to date, several issues still under exploring, including (1) systematic investigation comparing the efficacy of myopia control effects associated with add powers in the a same observational multicenter

clinical trial; (2) the efficacy in children between 6- to 12-year-old primary school students in mainland China, who are especially prone to progressive myopia; (3) quality of vision, particularly with higher added powers.

Methods/design

Aim of the study

The current prospective, multicenter randomized controlled trial study evaluated the myopia progression control efficacy of two clinical broadly used MD designed spectacle lenses, DIMS lenses and PALs, in 6- to 12-year-old myopia children of primary school. The primary aim is to compare changes in spherical equivalent refraction (SER) and axial length (AL) at baseline and every 6 months over 3 years. Other changes are also compared over the study period, including risk factors, ocular health, uncorrected relative peripheral refraction, binocular vision function (principally vergence), accommodation (particularly lag and amplitude) assessment, sub-foveal choroidal thickness, visual environment, wearing experiences, etc [15].

Study settings

Five trial sites are involved, including Peking University People's Hospital, Peking University International Hospital, Kunming City Maternal and Child Health Hospital, Beijing Haidian Maternal and Child Health Hospital, and ChuiYang Liu Hospital affiliated with Tsinghua University. Each of the hospitals is large centers with ophthalmology clinics and optometrists, and data will be collected at each site.

Study design and recruitment

This is a 3-year, prospective, randomized, multicenter clinical trial. Recruitment began on 15 October 2019 and is scheduled to end on 30 October 2020. A total of 600 primary school children (aged 6–12 years) were recruited, and each of the participants will be followed up for 3 years. Randomization was performed with a random number table, and each group (DIMS, PALs) contained 300 subjects. The final distance prescription was determined by the unblinded investigator using cycloplegic subjective refraction measured by the blinded investigator. The lenses were replaced with an updated prescription when the change in SER was more than 0.50 D.

Potential participants (and parents/guardians) will be identified through referrals by ophthalmologists and optometrists. Potential participants will contact a study team member and will be provided with an informed consent and all the information is confidential. Interested participants will be invited for an eligibility and baseline assessments by the study staffs.

Myopia defocus spectacle lenses systems and spectacle prescription

DISM: the DIMS lens is a custom-made plastic spectacle lens. It comprises a central optical zone (9 mm in diameter) for correcting distance refractive errors and an annular multiple focal zone with multiple segments (33 mm in diameter) having a relative positive power (+3.50 D). The diameter of each segment is 1.03 mm [10].

Apollo spectacle: the Apollo spectacle comprises an asymmetric defocusing design with a 3 MD zone, including a +2.50 D full positive power superior zone, an 80% full MD power nasal zone, and a 60% full MD power temporal zone.

Both of the spectacle lenses are designed simultaneously provide clear vision for the wearer at viewing distances and introduce MD for peripheral retina, which is that MD proved a plane in front of the retina, which would be received as blur images on the retina [5]. All of the children will be instructed to wear lenses all the time throughout the whole study.

The final distance prescription of spectacles is determined on cycloplegic subjective refraction performed by the masked optometrist. The spectacle lenses will be replaced and upgraded if the SER is changed by 0.5D or more is either eye compared with wearing spectacle refraction.

Eligibility criteria

The following eligibility criteria exist for this trial are modified from Interventions Myopia Institute (IMI) an related studies [6, 10, 15]:

- Mainland Chinese, the Han nationality.
- Age at enrollment: 6–12 years old.
- Cycloplegic SER: −1.00 to −4.00 D. SER is calculated as the sphere plus 0.5 x the cylinder in D. (Recommended dosage for cycloplegic refraction is 2 drops of 1% tropicamide given 5 minutes separately. Cycloplegic refraction outcome measures should be performed 30–45 minutes after the first drop of tropicamide is instilled, which ensure the maximal cycloplegic effect.)
- Astigmatism: 1.50 D or less.
- Anisometropia: 1.50 D or less.
- Difference between right and left pupil sizes: 2 mm or less.
- Monocular best corrected visual acuity (BCVA): 20/20 (0.0 LogMAR) or better (LogMAR chart).
- Willingness to wear spectacle lenses regularly.
- Acceptance of random group allocation and the masked study design.

The exclusion criteria are as follows:

- Strabismus: checked by cover test at far and near distances.
- Any ocular and systemic diseases, including abnormalities, might affect visual functions or refractive development.
- Previous experience of myopia control, including orthokeratology, PALs, bifocal lenses, pharmaceutical treatment (e.g., atropine), etc.

Study outcomes

In the present study, primary, secondary and expletory outcomes were evaluated during the follow-up according to schedule (Table 1). The primary outcome is the recognized indicator, which is changes in cycloplegic SER.

Several innate and environmental factors are useful in understanding the control of myopia progression [6, 8, 15], including age and refractive error of onset, family history (e.g., parental myopic status), AL with cycloplegia (mm, measured with noncontact interferometry), visual and environment habits (e.g., near work time, outdoor time, spectacle ware time, brightness of light exposure, etc.), binocular vision (e.g., accommodative lag, elevated accommodative convergence to accommodation [AC/A] ratios, etc.), peripheral refraction, pupil size, treatment compliance, etc. Thus, we evaluated these factors as secondary and exploratory outcome measure items in the present study, as shown in Tables 1, 2, 3, and 4.

Follow-up timeline: outcome measures will be assessed at 1 month, 3 months, 6 months, and every 6 months until 3 years after randomization. Myopia progression over 3 years will be determined by the difference between SER at the last follow-up and the baseline visits.

Sample size calculation

This is a prospective observational study, and there is no previous reports to refer to. In designing the clinical trial, all of the experts in this study reviewed published articles, and found the sample size per group variables from ~70 to 333 children during 2 to 3 years follow-up [15].

Besides, we also use statistical formulas for calculation, and the parameters used include a significance level of 0.05, 95% confidence interval (CI), 90% power and 1:1 allocation. Base on the clinical experiences and published data, the trial is powered to detect a noninferiority margin (Δ) of 10%. A 20% increase was added for loss to 3 years follow-up.

Based on the expert consensus of article review and statistical calculation, a sample of 300 eligible children will be required in each arm of the trial. We do not plan any stratified subgroup.

Randomization and masking

In the present study, all of the participants' randomization was masked to investigators until the group assignments were revealed. After the participants' enrollment eligibility was confirmed, an unblinded investigator allocated all of the children between the DIMS Group and the PALs Group using a random number table. During the clinical trials, all of the investigators performing the enrollment and all of the examiners were blinded to the purpose of the study to minimize the potential for bias.

Data management and data analyses

All staff in this clinical trial should undergo standard training, including measurement of BCVA, refraction, AL, binocular vision, corneal curvature, peripheral refraction, questionnaire inquiry, and instruction on data recording.

Data from the two groups will be presented as the mean ± SD. Data from a random eye will be used for data analysis according to a random table considering high correlation between two eyes of the same participant. Baseline group data will be analyzed by unpaired t-tests. Repeated measures ANOVAs were used to compare the changes from the baseline over time and between the two study groups. Bonferroni corrections were used to take account of *post hoc* comparisons. Correlation between changes will be calculated using Pearson's correlation coefficient. Data will be monitored by data monitoring committee and performed quarterly.

Ethical approval and conduct

The ethical approval has been proven in Peking University People's Hospital, all the amendments will be re-submit to the ethics committee. Patient recruitment has not yet started.

Discussion

The necessity of the current study

The average age of myopia onset is 8 years of age in the United States and Singapore, while it is approximately 6 to 7 years old in Asians [4, 16, 17]. At the myopia onset age before 8, there are not many alternative treatments, and making the spectacle lenses propitiate potential choice for parents and children [7, 8, 15]. Although the prominent theory of myopia control (SER progression and AL elongation) hypothesizes that peripheral MD slows progression [9, 18, 19], evidence on the efficacy in children under the same inclusion criterial comparing various optical designs is lacking. Additionally, evidence has shown that the myopia control effects of plus defocus are weaker and less consistent in human myopia clinical trials with spectacle [13, 14, 20, 21].

Additionally, the MD spectacle lenses need to be regularly adjusted, which is due to frame downward slippage, to ensure that the child is looking through the near addition as much as possible in nearsighted, while looking through the center when viewing at distant. When looking through the addition lenses, the children wil undergo special visual experience, which is not fully understood.

Thus, the current study aim to (1) systematic investigate the myopia control effect of different MD spectacle lenses in 600 early onset myopia children between 6- to 12-year-old; (2) detailed comparison of various indicators, including primary, secondary, and expletory factors, in a 3 year long-term study; (3) to minimize bias, multi-center and multi-area research group is adapted in the present study. The results will broaden our understanding of whether and how much of different MD designed approach retards myopia progression.

Rationale for the study design

Myopia is a progression eye disease and is reported to remain stable approximately 16 years [4]. Because myopia control interventions will be applied for multiple years through the time myopia is progression, it is important that clinical trials evaluated efficacy over a long period to ensure continued efficacy beyond any initial treatment effect [15]. Several clinical trials showed evidence of diminishing efficacy beyond the first year, with no continuous myopia progression control effect after 1-year treatment during the following 2 subsequent years [6, 15]. This phenomenon could lead to incorrect decisions in clinical consensus. Thus, as recommended by the international myopia institution (IMI), 3 years is chosen as the follow-up length of the present clinical trial assessing the efficacy of the treatment efficacy between different MD spectacle lenses [15, 20].

Although SV spectacles are recommended for the control group, we did not choose the SV lenses in the present study. Instead, we included a large number of subjects (n = 300 in each group) to directly compare the myopia control effect in the 6–12-year age group. The reasons behind not choosing SV spectacles are as follows: (1) single-vision spectacles have been proven to have little or no effect on myopia progression control; (2) patients and their guardians rarely agree to accept SV lenses; and (3) SV spectacles are not recommended as a first-line treatment strategy based on the consensus of the Chinese Journal of Optometry Ophthalmology and Visual Science. Considering the risk-benefit assessment for the patients in the long-term clinical trial study, we tested only the spectacle lenses that had already been found effective in myopia control.

The principle of outcome selection

Visual function has many aspects, so it is recommended to be included in clinical trial when performing myopia control evaluation [15]. The most common primary outcome measure in the myopia control study is refractive error, which is directly related to the tested treatment efficacy. To ensure the consistency of measurement results in each research center as much as possible, we specified a standard method of cycloplegia (refer to method section).

To minimize evaluation biases and help with data interpretation, several indicators related to changes in refractive error and myopia progression are also measured, including AL, corneal curvature, peripheral refraction, parental myopia status, environmental influences, education insensitivity, etc. In addition, the self-report questionnaire is used to evaluate compliance and wearing experiences [22].

As mentioned before, the underlying principle through which MD can slow down myopia progression is that it provides blurry images in front of the retina when objects are viewed at close range. MD may induce unexpected effects on vision, including aspects such as contrast sensitivity, stereopsis, accommodation, and convergence. Therefore, in addition to regular examination items, all of the aforementioned items are measured in the current study.

MD has been proven to reduce myopia progression and axial elongation and induce great interest in preventive treatment for myopia with few adverse effects in early childhood. The purpose of this study was to investigate the myopia control effects of the two types of MD designed spectacle lenses for 3 years of follow-up in 6- to 12-year-old schoolchildren. The findings from the present study are proposed as a resource to inform future clinical practices.

Trial status

The ethical approval has been proven in Peking University People's Hospital (protocol version number: 2019PHA049–001, V1.0; date: 2019–9–9). Participant recruitment has not yet begun as of this submission. The clinical trial is intended to recruit participant from 15 October 2019, and the approximate date when recruitment will be completed is 30 March 2020.

List Of Abbreviations

DIMS: defocus incorporated multiple segments; PLAs: Apollo progressive addition spectacle lenses; MD: myopic defocus; SER: spherical equivalent refraction; ChiCTR: Chinese Clinical Trial Registry; SV: single-vision; HD: myopic defocus; AL: axial length; IMI: Interventions Myopia Institute; BCVA: best corrected visual acuity; AC/A: accommodative convergence to accommodation; CI: confidence interval.

Declarations

The authors declare that have no competing interests.

Ethics approval and consent to participate

The ethical approval has been proven in Peking University People's Hospital. Informed consent will be obtained from all participants prior to their inclusion in the study. Patient recruitment has not yet started.

The study has not gained ethical approval at both central and local levels. Central ethical approval has been confirmed from Peking University People's Hospital (approval no. 2019PHA049–001) and we will not begin recruiting at other centers in the trial until local

ethical approval has been obtained.

Consent for publication

Not applicable.

Availability of data and materials

Not applicable. Data sharing is not applicable to this article because no datasets were generated or analyzed during the current study. After the clinical trial is finished, the original data will be uploaded to the ResMan Primitive Data Sharing Platform (IPD Sharing Platform) of the China Clinical Trials Registry at http://wwww.medresman.org:22280/login.aspx.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

YL and MWZ initiated the study design. FYF, ZML, and XQS prepare the consent form. YL, KW and MWZ drafted and finalized the study protocol. All authors reviewed the study protocol and approved the final manuscript.

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Tables

Table 1. Schedule of assessments and examination items

Procedures/Measurements		Enrollment (-2 to 0 week)	Baseline	1 week (±1 day)	1 month (±3 days)	3 months (±7 days)	6 months (±14 days)	12 months (±21 days)	18 months (±28 days)	24 months (±35 days)	30 months (±42 days)	36 months (±60 days)
Consent form signed			×									
Basic information	Demography	×										
	History	×	×	×	×	×	×	×	×	×	×	×
Refraction	Noncycloplegic autorefraction	×	×				×	×	×	×	×	×
	Subjective refraction	×	×				×	×	×	×	×	×
	Cycloplegic subjective refraction*		×				×	×	×	×	×	×
	Cycloplegic autorefraction*		×				×	×	×	×	×	×
	Peripheral refraction*		×				×	×	×	×	×	×
Visual acuity	Habitual spectacle VA	×	×				×	×	×	×	×	×
	Best corrected VA (BCVA)	×	×				×	×	×	×	×	×
Ocular alignment	Cover test (distance, near)	×										
	Phoria (distance, near)		×				×	×	×	×	×	×
Accommodation	Lag		×				×	×	×	×	×	×
	Amplitude		×				×	×	×	×	×	×
Eye examinations	Slit-lamp exam, external ocular health check	×	×				×	×	×	×	×	×
	IOP measurement	×	×				×	×	×	×	×	×
	Pupil size		×				×	×	×	×	×	×
	Keratometry		×				×	×	×	×	×	×
	Contrast sensitivity											
	Stereopsis		×				×	×	×	×	×	×
	Axial length (mm)* (IOL Master [Zeiss, Oberkochen, Germany], measure between 9:00-11:00 AM)		×				×	×	×	×	×	×
	Choroidal thickness measurement		×				×	×	×	×	×	×
	Fundus exam*		×				×	×	×	×	×	×
Questionnaire	Visual habits		×									×
	Spectacle lens performance		×									×

*with cycloplegia

Table 2. Wearing experience questionnaire - 1

Activities		Content		
Parental Myopia		0 person	1 person	2 persons
Clarity	Short distance	Good	Fair	Poor
	Intermediate vision distance	Good	Fair	Poor
	Long distance	Good	Fair	Poor
Time wear spectacles (hr/day)	Weekdays (Monday to Friday)			
	Weekends (Saturday to Sunday)			
Time spend at work	Near work (hr)			
	Middle-distance work (hr)			
Time spent on activities	Outdoor			
	Indoor			
Sleeping time				

Modified from: Defocus Incorporated Multiple Segments (DIMS) spectacle lenses slow myopia progression: a 2-year randomised clinical trial (doi: 10.1136/bjophthalmol-2018-313739.)

Table 3. Wearing experience questionnaire - 2

		Poorest	□	Acceptable	□	Fair	□	□	Good	□	Excellent
1	Vision at a distance (clarity)	1	2	3	4	5	6	7	8	9	10
2	Vision stability at a distance	1	2	3	4	5	6	7	8	9	10
3	Clarity of vision for intermediate distances (e.g., computer, watching TV)	1	2	3	4	5	6	7	8	9	10
4	Clarity of vision for near tasks (e.g., reading, using smartphone)	1	2	3	4	5	6	7	8	9	10
5	Vision stability at close range	1	2	3	4	5	6	7	8	9	10
6	Vision stability at a distance	1	2	3	4	5	6	7	8	9	10
7	Vision comfort	1	2	3	4	5	6	7	8	9	10
8	Vision outdoors	1	2	3	4	5	6	7	8	9	10
9	Ease of lens adaption	1	2	3	4	5	6	7	8	9	10
10	Overall performance	1	2	3	4	5	6	7	8	9	10

Modified from: Defocus Incorporated Multiple Segments (DIMS) spectacle lenses slow myopia progression: a 2-year randomised clinical trial (doi: 10.1136/bjophthalmol-2018-313739.)

Table 4. Wearing experience questionnaire - 3

Do you have the following symptoms when you wear the spectacles?

		Never	□	Seldom	□	Sometimes	□	□	Often	□	Always
1	Blurred vision at a long distance	1	2	3	4	5	6	7	8	9	10
2	Blurred vision at an intermediate distance (e.g., computer)	1	2	3	4	5	6	7	8	9	10
3	Blurred vision at a short distance (e.g., reading, smartphone)	1	2	3	4	5	6	7	8	9	10
4	Ghosting image	1	2	3	4	5	6	7	8	9	10
5	Unstable vision at a distance	1	2	3	4	5	6	7	8	9	10
6	Unstable vision at close range	1	2	3	4	5	6	7	8	9	10
7	Difficulty or slowness in refocusing your eye from one distance to other	1	2	3	4	5	6	7	8	9	10
8	Eyestrain	1	2	3	4	5	6	7	8	9	10
9	Double vision	1	2	3	4	5	6	7	8	9	10
10	Dizziness	1	2	3	4	5	6	7	8	9	10
11	Headache	1	2	3	4	5	6	7	8	9	10

Modified from: Defocus Incorporated Multiple Segments (DIMS) spectacle lenses slow myopia progression: a 2-year randomised clinical trial

(doi: 10.1136/bjophthalmol-2018-313739.)

Figures

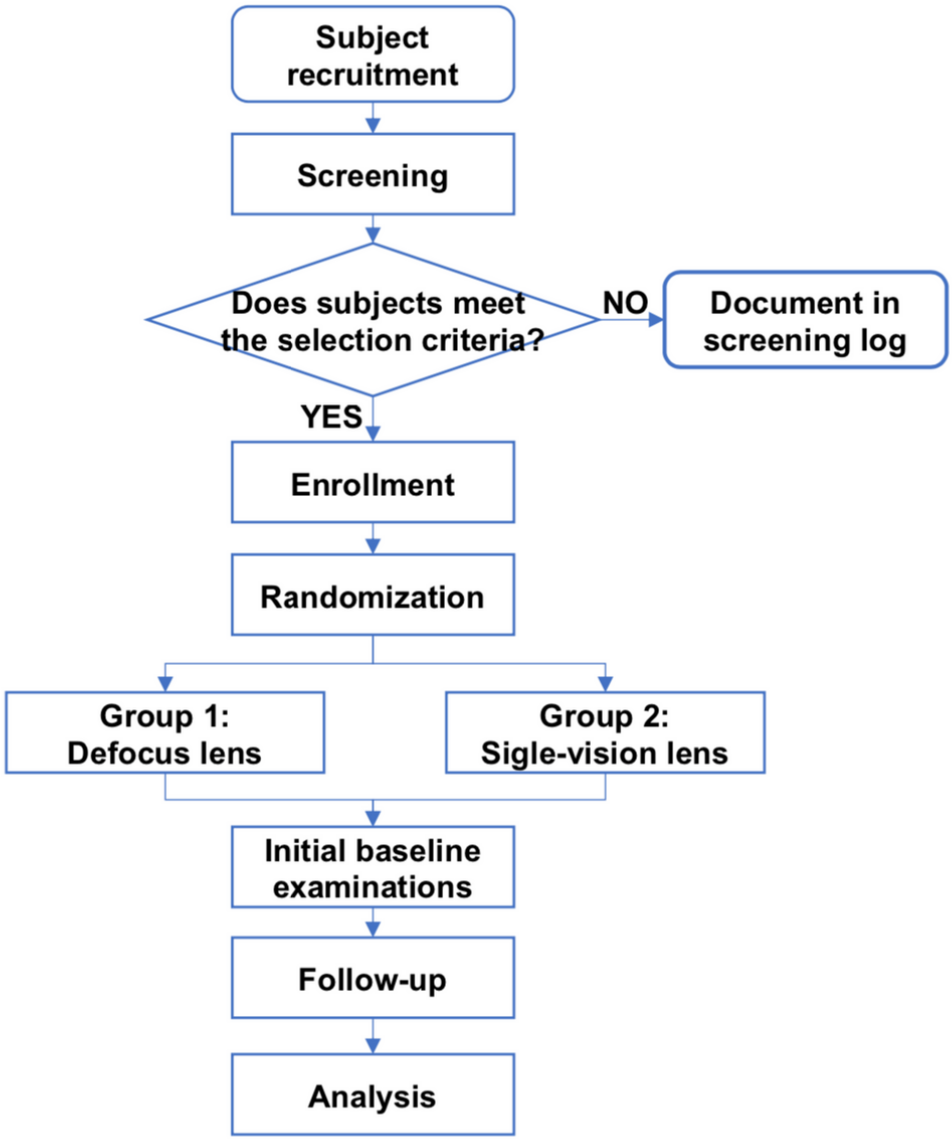

Figure 1

Schematic of the trial design.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- 4SPIRITchecklist0914.doc