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Myopia Control Efficacy of Modified Defocus Incorporated Multiple Segments Spectacle Lenses on Fast Progressing Myopes: Study Protocol of a Randomized Controlled Trial (Phase 1)

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Purpose

A modified Defocus Incorporated Multiple Segments (DIMS) spectacle lens (D2) is developed and clinically tested to evaluate changes in myopia progression and axial length (AL), compared with different spectacle lenses, in children with early-onset and fast progressing myopia.

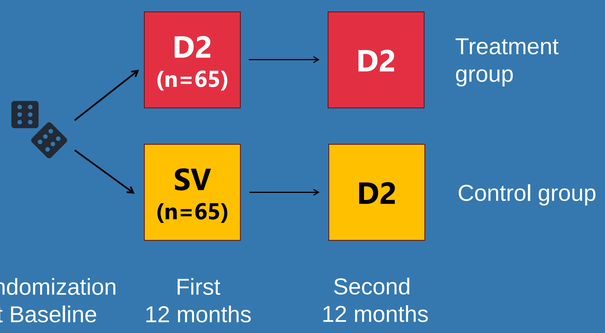
We describe a protocol of a randomized controlled trial (RCT), detailing the study design and planned analyses.

Methods

Study design

Phase 1

The study is a parallel group, placebo-controlled, double-masked, randomized trial in the first 12 months and a follow-up period in the next 12 months. The control group will start wearing D2 spectacle lenses after the 12-month timepoint.



Phase 2

An auxiliary group will be established to compare the performance of D2 with the currently available DIMS.

ClinicalTrials.gov identifier: NCT05888792

Inclusion criteria

- Hong Kong Chinese children aged 4-12 years old
- Myopia: ≤ -0.75D in both eyes

- **Fast progressing myopes:**
  - Myopia progression: ≥ 0.50D/year in 1 eye or both eyes, OR
  - Axial elongation: ≥ 0.27mm/year in 1 eye or both eyes
- **Early-onset myopes:**
  - 4- to 5-year-olds: myopia ≤ -0.75D in both eyes[1]
  - 6-year-olds: myopia ≤ -1.25D in at least 1 eye, with the other eye ≤ -0.75D[1]

- Best corrected visual acuity matches age norms
- Anisometropia ≤ 1.50D
- Astigmatism ≤ 2.00D
- No ocular and systemic disease
- No prior history of myopia control

Interventions

D2 is an experimental lens with modified myopic defocus power and area ratio between the defocus zone and distance correction zone compared to the currently available DIMS lens.

Sample size

Changes of spherical equivalent refraction (SER) between the baseline (BL) and the 12-month timepoints will be analyzed.
A power analysis was performed based on reference data from a similar trial [2]:
- Alpha level = 0.025, 2-tailed
- Effect size = 0.66
- Power = 90%
- N = 65 per arm (including 10 % dropout)

Outcome measures

The primary outcome is the change in cycloplegic SER from BL over a 12-month RCT period. Other outcomes and their collected timepoints are listed below.

TIMEPOINT	BL	1M	6M	12M	13M	18M	24M
ENROLMENT							
Informed consent & assent Allocation	√						
INTERVENTIONS							
Single-vision spectacle lenses		√	√	√			
D2 spectacle lenses		√	√	√	√*	√	√
ASSESSMENTS							
Main Outcomes: *Cycloplegic objective SER* *AL*	√		√	√		√	√
Other outcomes:							
Visual acuities *Choroidal thickness*	√	√	√	√	√*	√	√
Accommodative function *Pupil size* *Peripheral refraction*	√		√	√		√	√
Treatment compliance *Adverse events*		√	√	√	√*	√	√

Table 1. SPIRIT Schedule of enrolment, interventions, and assessments.
Abbreviation: BL, baseline; SER, spherical equivalent refraction; AL, axial length.
*Applicable to subjects who crossover from the control group to the treatment group.

Conclusions

This study will provide evidence on the efficacy of a modified DIMS design in controlling myopia in children with early-onset and fast progressing myopia, thereby supporting evidence-based approaches in myopia management.

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References

1. Chen Y, et al. PLoS One. 2016;11(12):e0167642.
2. Lam CSY, et al. Br J of Ophthalmol. 2020;104(3):363-8.

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