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# Early presbyopia population characterisation

**Submission date**
17/07/2025

**Recruitment status**
Recruiting

**Registration date**
29/07/2025

**Overall study status**
Ongoing

**Last Edited**
29/07/2025

**Condition category**
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

**Plain English summary of protocol**

Background and study aims
The onset of presbyopia is a continuous physiological phenomenon. Typically, the timing of the initial correction of presbyopia, whether with contact lenses or spectacles, is when patients report near vision-associated symptoms. This study aims to characterise the early presbyopic population with a view to identify factors likely to contribute to the difficulty in transferring from single vision to multifocal vision correction and to differentiate between asymptomatic adaptors during the period preceding the use of a multifocal correction.

Who can participate?
Early presbyopes aged between 40 to 50 years old with single vision correction or no vision correction.

What does the study involve?
The study involves attending one study visit and completing a set of remote questionnaires in 10 days following the study visit.

What are the possible benefits and risks?
The study results will contribute to additional information on early presbyopia.

No risks given at registration

Where is the study running from?
Ocular Technology Group - International (OTG-i) (UK)

When is the study starting and how long is it expected to run for?
March 2025 to September 2025

Who is funding the study?
CooperVision International Limited (UK)

Who is the main contact?
Deborah Moore, dmoore@otg.co.uk

## Contact information

**Type(s)**
Scientific, Principal Investigator

**Contact name**
Dr Michel Guillon

**Contact details**
66 Buckingham Gate
London
United Kingdom
SW1E 6AU
+44 (0)2072224224
MGuillon@otg.co.uk

**Type(s)**
Public

**Contact name**
Miss Deborah Moore

**Contact details**
66 Buckingham Gate
London
United Kingdom
SW1E 6AU
+44 (0)2072224224
dmoore@otg.co.uk

# Additional identifiers

**EudraCT/CTIS number**
Nil known

**IRAS number**
354245

**ClinicalTrials.gov number**
Nil known

**Secondary identifying numbers**
CV24-52

# Study information

**Scientific Title**
Early presbyopia program phase 1 population characterisation

**Study objectives**

The study will be an observational study to increase knowledge on early presbyopia, therefore, no specific hypothesis will be tested, however, the study results will make it possible to develop specific hypotheses to be tested to improve the management of early presbyopia.

## Ethics approval required
Ethics approval required

## Ethics approval(s)
Approved 30/05/2025, London-Brent Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)2071048128, 207 104 8117, 2071048131; brent.rec@hra.nhs.uk), ref: 25/PR/0578

## Study design
Single-visit in-clinic prospective observational study

## Primary study design
Observational

## Secondary study design
Case series

## Study setting(s)
Other

## Study type(s)
Other

## Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

## Health condition(s) or problem(s) studied
Early presbyopia

## Interventions
The study will be a single-visit, in-clinic, prospective observational study followed by three remote time-controlled questionnaires implemented on three different days within the following 10-day period.

The participants will attend the clinic wearing their habitual visual correction and will bring their electronic devices (e.g. laptops, tablets, electronic books, smartphones) to quantify their near environment needs. The potential participants will be screened and enrolled on the study. Once enrolled, the participant will complete a set of questionnaires, and then the investigator will carry out a set of non-invasive clinical measurements. At the end of the visit, a remote electronic controlled questionnaire will be set up.
The participants will complete three remote electronic questionnaires each on three different days within the following 10-day period.

## Intervention Type
Other

### Primary outcome measure
1. Optical and visual characteristics of the early presbyopic population measured using time-controlled visual acuity at two points during the study visit
2. Identify differentiating factors between symptomatic and asymptomatic early presbyopes measured using subjective questionnaires during the study visit and remotely after the study visit

### Secondary outcome measures
There are no secondary outcome measures

### Overall study start date
05/03/2025

### Completion date
30/09/2025

## Eligibility

### Key inclusion criteria
The entry criteria will be:
1. Age 40 to 50 years
2. Vision correction:
2.1. Distance Vision Correction only
2.1.1. Single vision distance spectacles
2.1.2. Single vision distance contact lenses
2.1.3. No vision correction
3. Spectacle refraction:
3.1. Distance: Sphere: -6.00D to + 3.00D
3.2. Astigmatism: 0.00D to -2.50
4. Best corrected distance visual acuity of at least 20/25 in each eye

### Participant type(s)
Healthy volunteer

### Age group
Adult

### Lower age limit
40 Years

### Upper age limit
50 Years

### Sex
Both

### Target number of participants
up to 100

### Key exclusion criteria
1. Acute and subacute inflammation or infection of the anterior chamber of the eye
2. Any eye disease, injury or abnormality that affects the cornea, conjunctiva or eyelids that would contraindicate contact lens wear
3. Corneal hypoesthesia (reduced corneal sensitivity), if not aphakic
4. Severe insufficiency of lacrimal secretion (dry eyes)
5. Any systemic disease that may affect the eye or may be exaggerated by wearing contact lenses (e.g. acne and eczema)
6. Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
7. Any active corneal infection (bacterial, fungal, protozoal or viral)
8. Newly prescribed (within the past 30 days) use of some systemic medications (such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, stimulants, anti-depressants, anti-psychotics, oral contraceptives) or new prescription eyedrops which is not rewetting/lubricating eyedrops for which contact lens wear could be contraindicated as determined by the investigator
9. Monocular participants (only one eye with functional vision) or participants fit with only one contact lens
10. Subjects with slit lamp findings greater than grade 1 (e.g. edema, infiltrates, corneal neovascularization, corneal staining, tarsal abnormalities, conjunctival, anterior segment inflammation) as recorded during the clinical visit, any previous history or signs of a contact lens related corneal inflammatory event (past corneal ulcers), or any other ocular abnormality that may contraindicate contact lens wear at the enrolment visit
11. History of corneal refractive surgery
12. Enrolment of the family members of the investigator, family members of the investigator's staff, or individuals living in the households of these individuals.

### Date of first enrolment
05/06/2025

### Date of final enrolment
30/09/2025

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
### Ocular Technology Group International
66 Buckingham Gate
London
United Kingdom
SW1E 6AU

# Sponsor information

**Organisation**
CooperVision International Limited

**Sponsor details**
Delta Park, Concorde Way, Segensworth North
Fareham
England
United Kingdom
PO15 5RL
+44 (0)19252516682
PLazon@coopervision.com

**Sponsor type**
Industry

**Website**
https://coopervision.com

# Funder(s)

**Funder type**
Industry

**Funder Name**
CooperVision

# Results and Publications

**Publication and dissemination plan**
There are no plans at this stage for publication or dissemination.

**Intention to publish date**
30/09/2026

**Individual participant data (IPD) sharing plan**
The data-sharing plans for the current study are unknown and will be made available at a later date

**IPD sharing plan summary**
Data sharing statement to be made available at a later date