

# Proactive management to understand contact lens wearers success

<b>Submission date</b> 10/12/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/01/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 20/07/2021	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Contact lenses are small prescription lenses, worn in "contact" with the eye. They are designed to correct eyesight and maintain eye health.

Up to 50% of contact lens wearers report discomfort hence it is important to try to find better ways to manage their contact lenses to improve their comfort. The aim will be to test if by increasing management over routine practice results in the wearer having a greater comfort.

### Who can participate?

Soft contact lens wearers complaining of discomfort aged 18 to 40.

### What does the study involve?

The study involves 5 visits. At the first visit, the participants are screened, enrolled and fitted with the contact lenses and dispensed with their management protocol. At the other 4 visits (1, 3, 6 and 12 months), the participants are monitored to quantify any improvement from baseline. Also, the participant will complete electronic questionnaires monthly to track their progress.

### What are the possible benefits and risks of participating?

The benefits to the participant are the opportunity to try a different contact lens and or those in the test group to have increased management to solve their contact lens comfort problems than they would have in routine practice. There are no increased risks, the contact lenses and management system are all using CE marked products.

### Where is the study run from?

Ocular Technology Group - International (UK)

### When is the study starting and how long is it expected to run for?

July 2019 to May 2021

### Who is funding the study?

CooperVision Inc. (USA)

Who is the main contact?

Deborah Moore  
dmoore@otg.co.uk

## Contact information

### Type(s)

Public

### Contact name

Miss Deborah Moore

### Contact details

66 Buckingham Gate  
London  
United Kingdom  
SW1E 6AU  
+44 )0)207 2224224  
dmoore@otg.co.uk

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

266960

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

CV19-55 ID19-23, IRAS 266960

## Study information

### Scientific Title

Understanding the impact of proactive management to improve symptomatic contact lens wearers success

### Study objectives

Symptomatic contact lens wearers are refitted with a standard daily disposable contact lens, those who are proactively managed will experience lesser symptoms and longer comfortable wearing time than those who are managed by following a standard management routine.

### Ethics approval required

Old ethics approval format

## **Ethics approval(s)**

Approved 06/08/2019, Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 1048 088; nrescommittee.yorkandhumber-bradfordleeds@nhs.net), ref: 19/YH/0245

## **Study design**

Early feasibility prospective single masked open label randomized parallel-group

## **Primary study design**

Interventional

## **Study type(s)**

Other

## **Health condition(s) or problem(s) studied**

Management of soft contact lens wearing symptoms

## **Interventions**

The participants were refitted with a daily disposable contact lens, half in the control group were managed as per conventional routine practice and the other half in the test group received enhanced management. The randomisation process was a 1:1 randomisation using a computerised program.

The study involves 5 visits. At the first visit, the participants are screened, enrolled and fitted with the contact lenses and dispensed with their management protocol. At the other 4 visits (1, 3, 6 and 12 months), the participants are monitored to quantify any improvement from baseline. Also, the participant will complete electronic questionnaires monthly to track their progress.

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

1. Contact lens overall comfort measured using the CLDEQ8 questionnaire overall score at 1, 3, 6 and 12 months
2. Contact lens wearing time (hours) measured using self report at 1, 3, 6 and 12 months

## **Key secondary outcome(s)**

Contact lens comfort at different times of the day measured using 100 point Visual Analogue scale at 1, 3, 6 and 12 months

## **Completion date**

01/05/2021

# **Eligibility**

## **Key inclusion criteria**

1. Age 18 to 40 years
2. Current daily wear soft contact lens wearer who have worn contact lenses for at least six months in total
3. CLDEQ-8  $\geq 14$  and/or comfortable wearing time  $\leq 9$  hrs; with selfreported end of day dryness or

discomfort

4. Spectacle refraction:

Sphere: -6.00D to + 4.00D

Astigmatism: 0.00D to -0.75

5. Best corrected visual acuity of at least 20/30 in each eye

6. No significant ocular signs that would prohibit contact lens wear including:

6.1. Blepharitis score <3 (0 to 4-point scale)

6.2. Meibomian gland score <3 (0 to 4-point scale)

6.3. Corneal staining score <7 (0 to 10-point scale)

6.4. Conjunctival staining score <3 on (0 to 4-point scale)

6.5. TPH without contact lenses  $\geq 0.125$  mm

6.6. OSDI score without contact lenses <13

7. Have read and understood the Participant Information Sheet in English

8. Have read, signed and dated the Informed Consent

9. Have normal eyes with the exception of the need for visual correction

10. Be willing and able to adhere to the instructions set in the clinical protocol and maintain the appointment schedule

### **Participant type(s)**

Healthy volunteer

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Total final enrolment**

81

### **Key exclusion criteria**

1. Ocular anterior segment infection, inflammation, abnormality, or active disease that would contraindicate contact lens wear

2. Monocular participants (only one eye with functional vision) or participants fit with only one lens

3. Any moderate or severe ocular condition observed during the slit-lamp examination at the enrolment visit

4. History of herpetic keratitis, ocular surgery or irregular cornea

5. Known pregnancy or lactation during the study period as determined by self-report

6. Enrolment of the investigator or his/her staff, family members of the investigator, family members of the investigator's staff, or individuals living in the households of these individuals

7. Individuals who are unable to read or understand the Participant Information Sheet in English

### **Date of first enrolment**

01/08/2019

**Date of final enrolment**

23/12/2020

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Ocular Technology Group - International**

66 Buckingham Gate

London

United Kingdom

SW1E 6AU

## Sponsor information

**Organisation**

CooperVision (United States)

## Funder(s)

**Funder type**

Industry

**Funder Name**

Cooper Vision Inc. (USA)

## Results and Publications

**Individual participant data (IPD) sharing plan**

The current data sharing plans for this study are unknown and will be available at a later date.

**IPD sharing plan summary**

Data sharing statement to be made available at a later date

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Basic results</a>	version v0.1		20/07/2021	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes