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Proactive management to understand contact lens wearers success

Submission date	Recruitment status	[_] Prospectively registered
10/12/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/01/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/07/2021	Eye Diseases	

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?
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Contact information

Type(s)
Public

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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 ≥14 and/or comfortable wearing time ≤ 9hrs; 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 ≥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?
Basic results	version v0.1		20/07/2021	No	No
HRA research summary			28/06/2023	No	No