Information for optometrists

You can keep this information sheet

COSMYC+: Core Outcome Set and Study Design for clinical trials of Myopia treatments in Children and Young People

Short title: COSMYC+: Core Outcome Set for Myopia trials in Children & Young People

We would like to invite you to take part in a research study.
Before you decide to join, it is important that you understand what the study is about, why the study is being done and what it will mean if you takes part. So please read this leaflet carefully. You can also talk to your family, friends or colleagues about it if you want. If something doesn't make sense or you have more questions, you can give us a call and we can discuss the study with you. Thank you for reading this leaflet.

Our research team

Our team is led by **Dr Annegret Dahlmann-Noor,** Honorary Clinical Associate Professor at the UCL Institute of Ophthalmology and Consultant in Children's Eye Health at Moorfields Eye Hospital. **Dr Helen Baker,** Lead for Patient and Public Involvement and Engagement at the UCL Institute of Ophthalmology, supports this project with her expertise in research using focus groups and interviews. The study is also supported by **Dr Sarah Gorst,** expert at the Core Outcome Measures in Effectiveness Trials (COMET) Initiative at the University of Liverpool, and by **Prof. Nick Freemantle,** Head of the Comprehensive Clinical Trials Unit at University College London, and **Prof. Augusto Azuara-Blanco,** Clinical Professor of Ophthalmology at Queen's University Belfast, both experts in designing clinical

trials.

What is the purpose of this project?
We want to find out how researchers should design trials of new treatments for myopia (short-sightedness) in children and young people.

There are now treatments available which can slow down myopia progression: special glasses, special contact lenses, atropine eyedrops, and red light treatment.

We want to find out what children and young people, their parents/ caregivers and eye care professionals would want to know about these new treatments, so researchers can design a trial of these treatments that matters to families and professionals in the UK. We also want to find out which children/young people should be invited to take part in these research trials, for example how old they should be, and which treatments should be tested in a trial.

Why have I been chosen?
We would like to ask you to take part, because you use myopia management interventions in your practice. We will ask up to 12 optometrists and myopia researchers to take part in interviews, and up to 60 to take part in an online Delphi consensus survey.

Do I have to take part?
It is up to you to decide whether to take part or not. You can keep this information leaflet, and if you decide to take part, we will ask you to sign a consent form. **Even if you agree now, you can change your mind later.** If you change your mind after you have taken part in the study, we will keep the information you have provided until that point.

What will happen to me if I take part?
Once we have checked that you are happy to take part, and you have signed the forms, we will invite you to a semi-structured interview to talk about myopia research trials. We will talk about which outcomes you feel should be reported in clinical trials of myopia treatments. We will also discuss which children should be invited to take part in future trials, for example which age groups, and whether

children with underlying conditions should be included, which instruments should be used to measure outcomes, and which treatments should be tested.

We will record what you say as an audiorecording (no images or video), so we can transcribe and analyse what you said.

The interview may take up to 1 hour.

Around one month later, we will ask you to take part in a Delphi consensus survey on a computer or your phone, where we will show you a list of outcomes children/young people, parents/caregivers, other optometrists and researchers said are important to them, as well as which children should in the future be included as trial participants. We will ask you to indicate how important each outcome is to you. Once everybody has completed the first round of the survey, we will look at the results. We will then run another round, and show you what other participants said in the first round, and will ask you again how important each outcome is to you. Then we will look at everyone's answers again. If there are some items on which agreement could not be found, we will invite 8 stakeholders, including 1-2 optometrists/researchers to attend a meeting, and together we will agree what outcomes are most important for myopia trials with children and young people.

Then we will run a second Delphi survey with two further rounds and ask you to indicate how important each potential outcome measurement instrument is, and which myopia interventions should be tested in a future trial. This may also be followed by a final workshop.

What are the possible disadvantages and risks of taking part?
There are no disadvantages or risks.

What are the possible benefits of taking part?
Taking part will not help you, but it will help researchers design meaningful trials and might therefore help families and optometrists in the future.
To say thank you for taking part and for your time, we will give you a shopping voucher for £25 at the end of the interview and at the end of the online survey rounds and the final meeting, if you take part. We will also re-imburse any travel expenses.

What if something goes wrong?
Every care will be taken in the course of this study. However, in the unlikely event that you are injured by taking part, compensation may be available.

If you suspect that the injury is the result of the Sponsor's (University College London) or the hospital's negligence, then you may be able to claim compensation. After discussing with your clinical trial/ study doctor, please make the claim in writing to Dr Annegret Dahlmann-Noor (Anngret.dahlmann@ucl.ac.uk) who is the Chief Investigator for the study and is based at UCL. The Chief Investigator will then pass the claim to the Sponsor and on to Sponsor's Insurers.

Will my participation in this project be kept confidential?

All contact information and test data will be kept strictly confidential in a secure location. Personal data will only be accessible to research team and will not be shared with any third parties. The data from the eye tests will be stored under your initials as a pseudonym. We will store the data for 5 years, after which period we will delete them.
Please note that the trial team will keep everything confidential as far as is possible.

What will happen to the results of the research project?
We will tell families, eye care professionals and researchers about the study and what we have found. But we not mention your name; nobody will know that you and have taken part.

Local Data Protection Privacy Notice
The controller for this project will be University College London (UCL).
The UCL Data Protection Officer provides oversight of UCL activities involving the processing of personal data, and can be contacted at data-protection@ucl.ac.uk

This 'local' privacy notice sets out the information that applies to this particular study. Further information on how UCL uses participant information can be found in our 'general' privacy notice:

For participants in health and care research studies, click here

The information that is required to be provided to participants under data protection legislation (GDPR and DPA 2018) is provided across both the 'local' and 'general' privacy notices.

The lawful basis that will be used to process your personal data is: 'public task' and 'research purposes' will be the lawful basis for processing special category data.

Your personal data will be processed so long as it is required for the research project. If we are able to anonymise or pseudonymise the personal data, you provide we will undertake this and will endeavour to minimise the processing of personal data wherever possible.

If you are concerned about how your personal data is being processed, or if you would like to contact us about your rights, please contact UCL in the first instance at data-protection@ucl.ac.uk

Who is organising and funding the research?
This research is organised by University College London and funded by the National Institute for Health Research.

Who has reviewed the study?
This study has been approved by the London - Brighton & Sussex Research Ethics Committee.

Key contact for further information or general inquiries: Principal Investigator:
Dr Annegret Dahlmann-Noor
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Consultant Ophthalmologist, Moorfields Eye Hospital
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Thank you for reading this information sheet and for considering to take part in this research study.