

# The direct effect of short-term monochromatic light exposure on choroidal thickness in humans.

Published: 05-04-2023

Last updated: 07-04-2024

The primary objective of this study is to obtain insight in how the light spectra may regulate eye growth and control emmetropization by studying the choroidal thickness in human eyes after exposure to monochromatic light conditions. Based on...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Vision disorders
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON53328

### Source

ToetsingOnline

### Brief title

M-Light

### Condition

- Vision disorders

### Synonym

Myopia; Near-sightedness

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Choroid, Monochromatic, Myopia, OCT

## Outcome measures

### Primary outcome

The primary outcome is change in choroidal thickness during monochromatic light exposure.

### Secondary outcome

Secondary outcomes are change in choroidal thickness between different light conditions (different wavelengths) and change in axial length before and after light conditions.

## Study description

### Background summary

The prevalence of myopia is rising rapidly throughout the world, with 10% of the world population expected to be highly myopic (<-6 diopters) by 2050. Individuals with high myopia have a 1 in 3 chance to develop visual impairment by age 75 years. Therefore, myopia will become a vast social (economic) burden in the future. Animal research has shown that monochromatic light slows myopization and could hypothetically be used as a preventive therapy.

### Study objective

The primary objective of this study is to obtain insight in how the light spectra may regulate eye growth and control emmetropization by studying the choroidal thickness in human eyes after exposure to monochromatic light conditions. Based on previous literature and earlier experiments we conducted in zebra fish, we expect red (633 nm) and blue (423 nm or 463 nm) light to cause transient choroidal thickening.

### Study design

After signing written consent and filling-out a questionnaire, participants are placed in a dark room (<10 lux) for 10 minutes. Afterwards, the room is

monochromatically lit for 30 minutes. We conduct ocular measurements at the start, during, and at the end of the light exposure (5-minute interval). We repeat this a total of 5 times with different colors.

## **Intervention**

Participants are placed in a dark room (<10 lux) for 10 minutes, after which they are exposed to monochromatic (single wavelength) light for 30 minutes. We repeat this process several times for different wavelengths, each time preceded by 10 minutes of darkness.

We use commercially available LEDs, verified by handheld photospectrometer to emit light of similar irradiance.

## **Study burden and risks**

We expect the burden of participation to be negligible. There are no invasive or harmful measurements (ocular measurements are non-contact and use no radiation). During the experiment, there may be a very small discomfort from being placed in a monochromatically lit room. No lasting side-effects are expected or previously mentioned in the literature. The experiment is conducted in one site visit. The questionnaire contains no burdensome questions.

## **Contacts**

### **Public**

Erasmus MC, Universitair Medisch Centrum Rotterdam

Doctor Molewaterplein 40  
Rotterdam 3015 GD  
NL

### **Scientific**

Erasmus MC, Universitair Medisch Centrum Rotterdam

Doctor Molewaterplein 40  
Rotterdam 3015 GD  
NL

## **Trial sites**

## Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

### Inclusion criteria

Age between 18 to 35 years old.

No caffeine or alcohol consumption 10 hours prior to the start of the experiment.

### Exclusion criteria

Ocular pathology or systemic pathology with ocular manifestations.

Factors known to alter the circadian rhythm or sleep.

Pregnancy, breast feeding.

Smoking.

Previous myopia control treatments.

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

### Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 03-04-2023

Enrollment: 30

Type: Anticipated

## Ethics review

Approved WMO

Date: 05-04-2023

Application type: First submission

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

#### Register

CCMO

#### ID

NL83619.078.23