# Smartphone use and the risk of myopia in adolescents

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Retina, choroid and vitreous haemorrhages and vascular disorders |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON46700

**Source**
ToetsingOnline

**Brief title**
myopia study

### Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

**Synonym**
myopia, nearsightedness

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam
**Source(s) of monetary or material Support:** Uitzicht en VICI

### Intervention

**Keyword:** epidemiology, myopia, nearsightedness, smartphones

## Outcome measures

### Primary outcome

The primary determinant of this study is total and continuous time per day of smartphone use. Primary outcome measures are cycloplegic refractive error provided as spherical equivalent (SE) and myopia (SE worse than -0.50) yes/no.

### Secondary outcome

Secondary determinants are reading distance, screen brightness and illuminance while using the smartphone. Secondary outcome measures are the optical components axial length, corneal curvature, corneal thickness, anterior chamber depth, and lens thickness.

# Study description

### Background summary

Myopia is a refractive error caused by elongation of the eyeball. In particular, high myopia is associated with a significant risk of severe visual impairment. Previous work from our research group showed that 1 in 3 highly myopic persons will develop severe visual impairment during his/her life. The prevalence of myopia is rising all over the world; youngsters are now more often myopic than previous generations. As the whole curve of refractive error is shifting towards myopia, the number of persons with high myopia is increasing as well, and therefore the number persons at risk of visual impairment. An established risk factor for myopia is education, and it is becoming more and more clear that increased near work and decreased outdoor exposure are important lifestyle factors. Increased use of handheld digital screens has been postulated as a causal factor, but the results of current studies based on questionnaires have been inconsistent. The most commonly used digital device among children and teenagers nowadays is the smartphone.

### Study objective

The primary objective of this study is to investigate the association between smartphone use and risk of myopia in teenagers.

### Study design

This study is designed as an observational study in secondary school children. Three schools will be invited to participate. Children in the first, second and third grade, aged 12 to 16 years will be asked to participate in the study. All participants and their parents/guardian will be informed prior to the study and should give written consent. After consent, an online questionnaire will be obtained with items related to near work activities, outdoor exposure, parental myopia and socio-economic status. The participants will then be asked to download a mobile application on their smartphones. This application will run on their mobile device for a maximum of 5 weeks, without any required actions from the participant. The mobile application records smartphone use, distance between face and screen, illuminance and screen brightness. After 5 weeks the mobile application automatically stops and transfers the obtained data to a secured server. Furthermore, outdoor exposure is measured electronically by means of a light sensor data logger on their clothing for 7 days. After 7 days, the logger will be returned to the researcher and data can be transferred from the logger via USB to a computer in the Erasmus MC. Standard eye measurements will be performed at school. First, the visual acuity will be measured to identify children that need to be referred to an ophthalmologist or optometrist. Measuring visual acuity alone is not sufficient enough to distinguish between myopia, hyperopia and astigmatism (12), therefore refractive error will be measured by means of cycloplegic autorefraction. Cycloplegic eye drops (cyclopentolate eye-drops) will be used to dilate the pupil and inhibit accommodation. After 30-40 minutes set in time for the cyclopentolate 1%, measurement of the cycloplegic refraction and ocular biometry will take place within 5 minutes. Cycloplegic refraction will be measured by means of a Retinomax and ocular biometry by means of an IOL (Intra-Ocular Lens) master.

### Study burden and risks

This study is an observational study with clinical measurements that are standard in optometric practices. Pupil dilation with cyclopentolate eye-drops are a potential burden but are obligatory to obtain accurate refractive error measurements. Side effects of these drops include temporary photophobia and reduced accommodative power for the rest of the day, which we will address by providing reading glasses.

## Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adolescents (12-15 years)
Adolescents (16-17 years)

## Inclusion criteria

Teenagers aged 12 to 16 years old.
Written informed consent from participating teenagers and their parents/guardians.

## Exclusion criteria

Younger than the age of 12 years or older than the age of 16 years.
No written informed consent from the participant or parents/guardians.

# Study design

## Design

**Study type:** Observational non invasive

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Basic science |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 06-10-2018 |
| Enrollment: | 500 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 06-03-2018 |
| 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 | ID |
|---|---|
| CCMO | NL63977.078.17 |