# Manifest vs. Online Refraction Evaluation, clinical validation of online refraction

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The aim of this study is to validate a recently created online refraction method by comparing the outcomes of the online refraction method with the \*golden standard\* manifest refraction.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vision disorders
Study type	Observational non invasive

## **Summary**

### ID

NL-OMON47922

**Source** ToetsingOnline

Brief title The MORE study

### Condition

• Vision disorders

**Synonym** ametropia, refractive error

**Research involving** Human

### **Sponsors and support**

**Primary sponsor:** Universitair Medisch Centrum Utrecht **Source(s) of monetary or material Support:** easee

### Intervention

Keyword: manifest refraction, online refraction

### **Outcome measures**

#### **Primary outcome**

- Refractive outcomes

Values of the sphere, cylinder and axis components, obtained by the following

tests: 1: automatic, 2: manifest and 3: online (Easee). These are converted

into vectors by Fourier analysis.

#### Secondary outcome

- Visual acuity (converted into LogMAR values for statistical analysis)
- Gender (men/women)
- Telemetry (duration of the test in minutes)
- Age (in years)
- Degree of ametropia (in diopters)

## **Study description**

#### **Background summary**

Uncorrected refractive errors cause significant economic implications in both high and low income countries in terms of the loss of potential productivity (Williams et al. (2015)). The prevalence of uncorrected refractive errors is, despite of the available clinical services, still huge; visual impairment is in 42 percent of the cases the result of an uncorrected refractive error worldwide (Williams et al. (2015)). Even in high income countries, this issue remains prevalent. Therefore, the access to the available clinical services has to be simplified. The development of an online refraction method will make a refraction more accessible for patients and can be cost-saving. Clinicians can easily take an online method to places where it\*s needed for example in low income countries. There are several methods to measure a refractive error. The \*golden standard\* to prescribe spectacles is a manifest refraction (Thibos, Hong, Bradley & Applegate (2004)). This method has been described by F.C. Donders in 1864 and is performed with trial lenses and a visual acuity chart to measure the refraction error (Donders (1864)). Automated refraction, another refraction method, is mainly used as a starting point for a manifest refraction and is based on retinoscopy. (Nissman et al., (2004)).

At the moment, several online refraction methods are available. However, these methods are not scientifically validated, unavailable in other countries besides the United States of America (USA) or are not designed for customers. One of these online refraction methods is Opternative (Opternative (2017)). Opternative is currently used in the USA and is still developing (Opternative (2017)). It\*s a self-directed online refraction method by using a computer-based response to presented stimuli with the use of a smartphone and a computer. Another method is EyeNetra (EyeNetra (2017) & Ohlendorf, Leube & Wahl (2016)). The use of this method is limited due to the need of special equipment such as a portable autorefractor, an autolensometer and a phoropter. Therefore, EyeNetra is mainly designed for optometrists and ophthalmologists. The same applies to SVOne; this method uses a Hartmann-Shack wavefront aberrometer which you can attach to a smartphone (Ohlendorf, Leube & Wahl (2016)). Another online refraction method has not been released yet (6over6, (2017)).

There are also online visual acuity tests to measure the visual acuity only. The mobile devices to test the visual acuity are PeekVision, 6over6, Opternative, Eyenetra and DigiSight (Ludwig et al., (2016)).

At this day, digitalization is already affecting our way of living. Technology can be used to design products to easily determine if someone has a refractive error. This can, in the future, solve a big part of the problem of uncorrected refractive errors and the leading cause of blindness worldwide. The aim of this study is to validate a recently created online refraction method by comparing the outcomes of the online refraction method with the \*golden standard\* manifest refraction.

#### **Study objective**

The aim of this study is to validate a recently created online refraction method by comparing the outcomes of the online refraction method with the \*golden standard\* manifest refraction.

#### Study design

Part one and part two: prospective comparative monocenter study

#### Study burden and risks

not applicable

## Contacts

#### Public

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

Age Adults (18-64 years) Elderly (65 years and older)

#### **Inclusion criteria**

Age: 18-40 years Master the Dutch language Capable to perform the tests adequately.

### **Exclusion criteria**

No informed consent Diabetes High hypermetropia/myopia Mental incompetence

## Study design

## Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Treatment	

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	28-12-2017
Enrollment:	150
Туре:	Actual

## **Ethics review**

Approved WMO Date:	17-10-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	10-07-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

## **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** NL61478.041.17