# Validation and development of new dichoptic VR-gaming method to treat childhood amblyopia; Vedea Amblyopia Therapy (VAT)

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The VAT project is set out to prove that this approach is superior and that the Quality of Life of children with amblyopia might be significantly improved in comparison to occlusion therapy.

**Ethical review** Approved WMO **Status** Completed

**Health condition type** Eye disorders NEC **Study type** Interventional

## **Summary**

#### ID

NL-OMON51760

**Source** 

ToetsingOnline

**Brief title** 

VR & Amblyopia

#### **Condition**

• Eye disorders NEC

#### Synonym

amblyopia

#### Research involving

Human

## **Sponsors and support**

Primary sponsor: Vedea Healthware BV

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Source(s) of monetary or material Support: Stichting Life Sciences Health - TKI

#### Intervention

**Keyword:** Amblyopia, dichoptic training, Patching, VR-gaming

#### **Outcome measures**

#### **Primary outcome**

Visual acuity as measured in logmar lines

#### **Secondary outcome**

Compliance

# **Study description**

#### **Background summary**

3 to 5% of children in the Western world have amblyopia, popularly referred to as "lazy eye".

Amblyopia is the most common cause of unilateral visual impairment in children and young adults and results from impaired visual development in the first years of life.

Amblyopia is primarily a neurological defect: the part of the brain that processes visual

signals is insufficiently stimulated by an incomplete development of the relevant neural

network between the (lazy) eye and the brain. People with amblyopia therefore have

difficulty with the perception of depth and forming 3D models of the world around them.

The current treatment is occlusion: masking the good eye for a number of hours per day,

often over a period of a few years. There are a number of drawbacks to this treatment.

The moment an eyepatch is applied the child becomes instantly visually impaired. This

reduces the child's quality of life. Faithfully maintaining the therapy is therefore not easy

and this can be seen in the adherence data (<50%).

Based on an increased understanding of the cortical processes underlying

amblyopia, new treatment approaches have been studied. These new approaches are based on simultaneous binocular visual stimulation and aim to improve visual acuity in the amblyopic eye, but also to promote binocularity. Efforts are being made to make these treatments appealing to children. The Vedea Amblyopia Treatment (VAT) combines mobile VR technology with an extensive gaming library. By playing adapted games and exercises, the "lazy eye" is activated. Studies show that this treatment is faster and more effective than occlusion. The Vedea solution aims to shorten the total treatment process while reducing daily therapy from hours per day to 30 minutes.

#### Study objective

The VAT project is set out to prove that this approach is superior and that the Quality of Life of children with amblyopia might be significantly improved in comparison to occlusion therapy.

#### Study design

Randomised, partial cross-over, comparative design

#### Intervention

Use of the VAT for 16 straight weeks for 30 minutes of play per day

#### Study burden and risks

The American Academy of Ophthalmology has currently no evidence that too much screen time has permanent negative consequences for eye health and the development of the developing visual system. There is one study specifically aimed at researching the risk of VR in young children that concludes that no such (substantial) risks are present during, straight after and one week after playing two 30-minute sets of very high-risk gameplay.

## **Contacts**

#### **Public**

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## **Trial sites**

#### **Listed location countries**

**Netherlands** 

# **Eligibility criteria**

#### Age

Children (2-11 years)

#### Inclusion criteria

informed consent aged between 4 and 10 years old wearing full corrected refraction for >=14 weeks diagnosed with an unilateral anisometric, strabismic and/or deprivation amblyopia currently under treatment or starting treatment for unilateral amblyopia access to an Android device equal to or higher than a Samsung Galaxy S8

#### **Exclusion criteria**

current treatment with atropine penalisation documented history of severe negative side effects that occur with exposure to VR usage (eg. seizures or epileptic spasms) photosensitivity no developmental delay coexisting ocular pathology or systemic diseases

# Study design

## **Design**

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking: Open (masking not used)

Control: Active

Primary purpose: Treatment

#### Recruitment

NL

Recruitment status: Completed Start date (anticipated): 22-02-2023

Enrollment: 74

Type: Actual

### Medical products/devices used

Generic name: Vedea Amblyopia Treatment (VAT)

Registration: No

## **Ethics review**

Approved WMO

Date: 13-10-2022

Application type: First submission

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam

(Rotterdam)

Approved WMO

Date: 19-01-2024
Application type: Amendment

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 NL79107.000.22