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

Published: 13-10-2022
Last updated: 30-01-2025

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

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
Vedea Healthware BV

Erich Salomonstraat 480
Amsterdam 1087JA
NL
Scientific
Vedea Healthware BV

Erich Salomonstraat 480
Amsterdam 1087JA
NL

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