

Dichoptic virtual reality training for treatment of amblyopia

Submission date 05/06/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/06/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/11/2020	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Anisometropic amblyopia occurs when there is an unequal focus between the eyes. It causes a reduction of the best corrected visual acuity (best distance vision) of the eye without an cause. This condition can lead to permanent vision loss in one eye and limit the vision with both eyes. The main treatments in amblyopia are for children and involve wearing an eye patch over one eye to strengthen the other eye. This treatment is thought to be only effective in the first years of life. A new method of treatment for amblyopia based on the use of a dichoptic (presenting independent and not coordinated stimulus to the eyes) games in a virtual reality environment could help amblyopia for those who are not children. This type of treatment is promising as is non-invasive, without risks associated and motivating for patient as it consists of a game. The aim of this study is to evaluate the effect of dichoptic visual training using a virtual reality head mounted display in a sample of anisometropic amblyopic adults and to evaluate the potential usefulness of this option of treatment.

Who can participate?

Adults aged 17 and older who have anisometropic amblyopia

What does the study involve?

Participants undergo an eye examine prior to the training. Participants receive dichoptic visual training using computer games and a wearable virtual reality system. Participants attend two training sessions a week for one month. Training sessions take 40 minutes and include two different types of games. Participants are followed up for stereopsis (the perception of depth) and visual acuity after their last training session and again three months later.

What are the possible benefits and risks of participating?

There are no notable benefits or risks with participating.

Where is the study run from?

1. Comenius University (Slovakia)
2. University of Alicante (Spain)

When is the study starting and how long is it expected to run for?

May 2016 to October 2016

Who is funding the study?

University of Alicante (Spain)

Who is the main contact?

Dr David Pablo Pinero

Contact information

Type(s)

Scientific

Contact name

Dr David Pablo Pinero

Contact details

Department of Optics

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

DVR1

Study information

Scientific Title

Amblyopia treatment of adults with Dichoptic training using the Virtual Reality oculus rift head mounted display: Preliminary results

Acronym

DVR

Study objectives

Dichoptic visual training using a virtual reality head mounted display is able to restore visual acuity and stereopsis in adults with anisometropic amblyopia.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of Jessenius Medical School Comenius University, 08/03/2016, ref: EK 1795 /2016

Study design

Prospective interventional non randomised pilot study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet'

Health condition(s) or problem(s) studied

Anisometropic amblyopia

Interventions

Participants all undergo a baseline ophthalmological examination including visual testing, manifest and cycloplegic refraction, cover test, four dot Worth test, anterior segment examination with the slit lamp, corneal topography and funduscopy.

Participants then undergo a dichoptic visual training was performed using the beta version of the computer game Diplopia Game which was run in the Oculus Rift OC DK2 virtual reality head mounted display. Two games are used, a space game in which subjects were flying spaceship through a system of rings and a breaker game which is a typical block breaker game, but played in a virtual reality 3D setting. Both games had a dichoptic setting in which the central part of the picture was different for each eye.

Each participant undergoes eight training sessions, being performed twice a week. Each session included 40 minutes of training with the two different games (20 minutes per game). This takes one month.

Stereopsis and visual acuity were tested after finishing the last session of training (one month after beginning the training) and three months after the end of training.

Intervention Type

Device

Primary outcome measure

1. Visual acuity is measured using calibrated liquid crystal display (LCD) optotype with Snellen charts (CC-X10, Topcon, Japan) at baseline, one and three months
2. Stereopsis is measured using the Stereo Randot graded circle test (Stereo Optical, IL, USA) at baseline, one and three months

Secondary outcome measures

1. Compliance is measured using the computer registration of the training sessions at one month
2. Refraction is measured using retinoscopy and subjective refraction in trial frame at baseline, one and three months

Overall study start date

10/05/2016

Completion date

10/10/2016

Eligibility**Key inclusion criteria**

1. Anisometropic amblyopia
2. Age of 17 years old or more
3. Willing to perform the visual training

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

17

Total final enrolment

17

Key exclusion criteria

1. Strabismus
2. Previous ocular surgery
3. Corneal irregularity
4. Opacification of ocular media including cataracts
5. Active ocular disease

Date of first enrolment

09/03/2016

Date of final enrolment

09/05/2016

Locations

Countries of recruitment

Slovakia

Spain

Study participating centre

Comenius University

Eye Clinic Jessenius Faculty of Medicine Martin
L. Novomeského 9
Bratislava
Slovakia
036 01

Study participating centre

University of Alicante

Department of Optics, Pharmacology and Anatomy
Ctra San Vicente del Raspeig s/n
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Alicante
Spain
03690

Sponsor information

Organisation

Comenius University

Sponsor details

Faculty of Medicine
Špitálska 24
Bratislava
Slovakia
813 72

Sponsor type

University/education

ROR

<https://ror.org/0587ef340>

Funder(s)

Funder type

University/education

Funder Name

University of Alicante

Results and Publications

Publication and dissemination plan

Planned publication of the results in BMC Ophthalmology journal.

Intention to publish date

01/09/2017

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Peter Ziak, 1ziakpeter@gmail.com or David P Piñero, david.pinyero@ua.es

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	28/06/2017	26/11/2020	Yes	No