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Dichoptic virtual reality training for treatment of amblyopia

Submission date
05/06/2017

Recruitment status
No longer recruiting

Registration date
13/06/2017

Overall study status
Completed

Last Edited
26/11/2020

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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. Commenius 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

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Additional identifiers

Protocol serial number
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 Committe of Jessenius Medical School Commenius University, 08/03/2016, ref: EK 1795 /2016

Study design
Prospective interventional non randomised pilot study

Primary study design
Interventional

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
Commenius University
Eye Clinic Jessenius Faculty of Medicine Martin
L. Novomeského 9

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Study participating centre
University of Alicante
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Sponsor information

Organisation
Commenius University

ROR
https://ror.org/0587ef340

Funder(s)

Funder type
University/education

Funder Name
University of Alicante

Results and Publications

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