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Perceptual learning in enhanced amblyopia treatment

Submission date 08/10/2014	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 21/11/2014	**Overall study status** Completed	
Last Edited 09/05/2016	**Condition category** Eye Diseases	

Plain English summary of protocol

Background and study aims

Amblyopia, also known as 'lazy eye', is the most common childhood cause of visual function loss, affecting about 34% of the total population. Ambylopia is caused by problems such as an eye misalignment (squint) or difference in image quality between the two eyes (one eye focusing better than the other) leading to abnormal development of the visual areas of the brain during childhood. If untreated, amblyopia leads to permanent visual deficits and in many cases a loss or impairment of binocular vision. A common consequence of amblyopia is interocular suppression. Suppression occurs when the image from the amblyopic eye is ignored when both eyes are open, ultimately resulting in a loss or impairment of stereo (3D) vision. We have found that if we present different amounts of information to each eye then you can see both images at the same time. This discovery has been developed into an assessment technique (viewing images through dichoptic 'gaming' goggles) which measures how much difference between the eyes is required to reach a balance point where both your eyes can work together. This has been a breakthrough in amblyopia study as more research is finding binocular correlation of the eyes is vital for both amblyopia prevention and best amblyopia recovery. In a previous study we successfully demonstrated that the gaming goggles can be used to improve visual acuity and binocular correlation in amblyopic children who had no further improvement with conventional occlusion treatment. We are conducting a study of children with lazy eye who still have reduced vision quality in their lazy eye after conventional treatment is finished. The aim is to compare viewing modes for the gaming goggles treatment to determine whether the special goggles viewing mode that encourages binocular cooperation provides comparable or better treatment results than simply playing the game while looking through the lazy eye alone.

Who can participate?

We aim to recruit children aged 5 to 17 years of age – you must have a lazy eye and have finished all your hospital treatment for that. You will have been or are about to be discharged from the hospital eye service to the care of your local optometrist.

What does the study involve?

All of you will play the same video game and wear the same gaming goggles, it is how you view the game through the gaming goggles that is being compared. You will be randomly allocated to viewing the game with one eye only, with both eyes, or with both eyes with different game

elements presented to each eye to encourage binocular cooperation. You will play the video game for an hour each day, for 10 days spread over 2 weeks. If you don't experience any improvement in the quality of vision in your lazy eye or how well you can use your eyes together, you will be offered an extra 10 days of playing the video game, this time using the special viewing mode through the gaming goggles that encourages binocular cooperation.

What are the possible benefits and risks of participating?
If you enrol, you will have the possibility of experiencing an improvement in the quality of vision in your lazy eye, although this improvement does not occur in everyone who is treated. Otherwise there is no gain from participation beyond learning more about your lazy eye and helping improve lazy eye treatment in the future. This study does not use drugs, and you play the computer game for no more than an hour, with five-minute breaks offered where you need them. There is an unlikely possibility that you may develop double vision (seeing two of things) as a result of viewing through the gaming goggles – the risk of this will be minimised by monitoring your interocular suppression throughout the 10-day computer game playing period and terminating your treatment if those measurements change.

Where is the study run from?
The study will be run at Gartnavel General Hospital (lead site) and Glasgow Caledonian University Eye Clinic, with all children being recruited from Gartnavel General Hospital and offered Glasgow Caledonian University Eye Clinic as an alternate location to attend for computer game training.

When is the study starting and how long is it expected to run for?
The study started in January 2014 and is expected to last for 24 months, with the last child being recruited 9 months prior to the end of the study.

Who is funding the study?
The Chief Scientist's Office (UK).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
ETM\375

Study information

Scientific Title
Perceptual Learning in Enhanced Amblyopia Treatment: an exploratory randomised controlled trial in the treatment of amblyopia

Acronym
PLEAT

Study objectives
Perceptual learning under viewing conditions that promote binocular cooperation will result in better improvement of visual acuity and binocular function compared to viewing conditions that do not promote binocular cooperation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Glasgow Caledonian University Health and Life Sciences Research Ethics Committee, 03/11/2014
2. West of Scotland Research Ethics Committee, 26/02/2015, ref: 15/WS/0015 (Amendment 22/12/2015)

Study design
Randomised controlled trial with double-blinding

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Amblyopia

Interventions
Perceptual learning treatment administered using a computer and eMagin gaming goggles

You will be randomised to one of three treatment groups using an automated telephone service provided by the Robertson Centre of Biostatistics at the University of Glasgow. After obtaining informed consent, a telephone number is called which provides a unique participant number, which determines your treatment group.

All of you will play the same child-friendly fun video game and wear the same eMagin gaming goggles, it is how you view the game through the gaming goggles that is being compared. You

will be randomised to viewing the game with one eye only, with both eyes, or with both eyes and different game elements are presented to each eye to encourage binocular cooperation. You will play the video game for an hour each day, for 10 days spread over 2 weeks. If you don't experience any improvement in the quality of vision in your the lazy eye or how well you can use your eyes together, you will be offered an extra 10 days of playing the video game, this time using the special viewing mode through the gaming goggles that encourages binocular cooperation.

After the computer game training is completed, if you've had an improvement in vision in your lazy eye or can use your eyes together better than you could before, you will be asked to come back for a check-up of these things 3 months later, and then again another 3 months later so it will have been 6 months since you finished the computer game training. This is so we can check to see if the improvement you gained is retained over time. After this 6 month check we don't need to see you again. If you haven't had an improvement and want to do the extra 10 days of training then this is done separately from the rest of the study and we won't need to see you for any check-ups after the training is all finished.

Intervention Type
Device

Primary outcome(s)
Proportion of patients with visual acuity improvement of 0.1 log units or better in the amblyopic eye at the end of the training period

Key secondary outcome(s))
1. Sensory fusion status (assessed with Bagolini glasses)
2. Motor fusion reserves (measured using horizontal prism bar)
3. Stereoacuity (measured using Frisby and/or Preschool Randot Stereotest)
4. Interocular suppression density (measured using Sbisa bar)
5. Angle of strabismus (measured using prism cover test)
6. Severity of perceptual visual distortions (measured using a 5 minute computer game that has been extensively piloted with amblyopic and visually normal children)

These are measured at the end of training.

Completion date
05/01/2017

Eligibility

Key inclusion criteria
1. Age 5 to 17 years
2. Visual acuity of 0.2 log units or lower in worst eye and/or interocular difference of at least 0.1 log units
3. Presence of anisometropia >1.00 MSE and/or strabismus/microtropia.
4. Not receiving any active conventional amblyopia treatment
5. Participants will all have a refraction, fundus and media check within 6 months prior to enrolment and will wear their up-to-date refractive correction for testing and training. It is important to establish that full spectacle adaptation has occurred.

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 years

Upper age limit
17 years

Sex
All

Key exclusion criteria
1. Stimulus deprivation amblyopia
2. Presence of other known ophthalmic defect (bar refractive error)
3. Receiving active conventional amblyopia treatment
4. Cortical visual impairment
5. Photosensitive epilepsy
6. Physical impairment affecting ability to use mouse/keyboard
7. Previous perceptual learning treatment

Date of first enrolment
31/08/2015

Date of final enrolment
05/01/2017

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Gartnavel General Hospital
Orthoptic Department
Upper Ground Floor
Great Western Road
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Sponsor information

Organisation
NHS Greater Glasgow and Clyde (UK)

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Research organisation

Funder Name
Chief Scientist Office

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No