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IPS Amblyopia Treatment, phase 3: randomised controlled trial of a computer program for treating amblyopia

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Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 06/03/2015	**Condition category** Eye Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
M0003160978

Study information

Scientific Title
IPS Amblyopia Treatment, phase 3: randomised controlled trial of a computer program for treating amblyopia

Study objectives
Amblyopia has a prevalence of 1-4% and is the leading cause of monocular visual loss in the age group 20-70 years (Simons, 1996). Since AD 900 (Thabit Ibn Qurrah, 900), amblyopia has been treated by occluding the eye with better acuity. Although the lack of RCTs has been criticised (Moseley et al., 1995), this form of treatment is widely accepted clinically as long as the patient is treated within the so-called 'sensitive period' or 'critical period' of relatively high neural plasticity (Nelson, 1989).

Mallett (1983) claimed that amblyopia can be treated outside the sensitive period, in adults of up to at least 65 years. Other authors have also argued that relatively brief periods of active stimulation may be more effective than passive occlusion during everyday life (Wick et al., 1992). Mallett (1983) also claimed 'moderate success' for anisometropic amblyopes. Unfortunately, there have been no RCTs of the Mallett treatment.

Evans et al. (1999) carried out a clinical audit of Mallett's IPS treatment for amblyopia. The mean improvement was 1.5 lines of the Snellen chart and 95% of this improvement had occurred after 5 treatment sessions.

The aim of this study is to compare the Mallett IPS treatment with a placebo, using a randomised double-masked protocol.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

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
Eye Diseases: Amblyopia

Interventions
Participants will be pre-adapted to the appropriate refractive correction. Following a telephone interview, potentially suitable patients with amblyopia will be invited to attend the Institute of Optometry for an initial clinical assessment. If they meet the selection criteria then the optimal refractive correction will be determined, which will be used for all visual acuity assessments and treatments. The visual acuity will be measured by the detailed forced choice method (FCSVA) described below and orthoptic status will be determined. Participants who are currently wearing an appropriate refractive correction will be randomly allocated to one of the two treatment groups and treatment will be started.

Participants who are not currently wearing an appropriate refractive correction for their amblyopic eye will be encouraged to wear this for an adaptation period of 18 weeks. At the end of this period, their orthoptic status and FCSVA assessment will be repeated. If they still meet the entry criteria then they will be randomly allocated to one of the two treatment groups and treatment will be started.

The treatments will take place at home using either the computerised IPS or the computerised control treatment. Patients will be telephoned approximately weekly to: remind them to undertake the treatment, check progress, and to check for any adverse effects. After six treatment sessions have been completed then the participant will attend the Institute of Optometry for an appointment to check their orthoptic status and for a FCSVA assessment. Approximately two months later they will attend once more for the same tests so that the permanence of any visual improvement can be determined.

The pre-treatment visual acuity assessments will be carried out by either the Principal Investigator or by the Research Fellow). Before the first treatment, the Principal Investigator will use a random number generator to allocate participants to the experimental or control group. The patients will be instructed in the treatments by the Principal Investigator, who will also answer any enquiries about the treatments. The Research Fellow, who will be unaware of which treatment each participant has received, will carry out the post-treatment visual acuity assessments and the follow-up assessment. The double-masked code will only be broken after the follow-up assessment, when the results will be entered in a spreadsheet.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The conventional IPS treatment involved tracing on perspex slides placed over a red flashing background of various shapes and patterns, designed to stimulate different types of receptive fields in the visual system. The treatment is carried for weekly 30 minute sessions during which

the better eye is patched. Patching does not take place at other times. This treatment is very tedious for the patient and a new computerised version has been developed. Our proposed study will evaluate this new computerised version of the IPS treatment.

It has been claimed that IPS is effective because (a) it forces the person to use their amblyopic eye whilst carrying out detailed visual tasks, (b) the flashing stimulus promotes foveal fixation, and (c) the red background promotes foveal fixation. Although our previous study shows the treatment to be effective, it is unclear whether (b) and (c) are important in the treatment. It is possible that there is nothing special about IPS and the only way in which the treatment is helpful is through having the patient carry out a detailed visual task with the amblyopic eye. The aim of the proposed research is to compare the full computerised IPS treatment (with a red flashing stimulus) with a control IPS treatment that lacks a red and flashing stimulus.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/03/2005

Completion date
31/03/2008

Eligibility

Key inclusion criteria
1. No personal history of epilepsy.
2. Willing to attend the Institute of Optometry for the 1-2 pre-treatment appointments, the post treatment assessment, and the follow-up assessment
3. Access to a computer for six approximately weekly sessions for the treatment. Ideally, the treatment will take place on a home computer in a dimly lit room, to simulate the lighting in which IPS is conventionally carried out.
4. Unilateral amblyopia with visual acuity better than 6/36 but worse than 6/9 in the amblyopic eye and 6/6 or better in the non-amblyopic eye.
5. Amblyogenic factor: amblyopic eye is either strabismic or has at least 1D more hypermetropia or 2D more astigmatism than the non-amblyopic eye.
6. No ophthalmoscopically detectable anomalies of fundus or defects of the visual pathway. This will be taken to mean no clinically significant departure from a normal ophthalmoscopic appearance and 30 degree visual fields (static perimetry) within normal limits.
7. Patients must be at least 10 years old and have signed the informed consent form, or have this signed by a parent or guardian if under 16 years old.
8. No history of strabismus or other cause of reduced visual acuity (e.g., cataract) in first two years of life
9. Able and willing to meet the costs of any refractive correction). Anisometropic participants will be encouraged to wear contact lenses as this has been shown to be the best option to minimise aniseikonia (Winn et al., 1988).

The study will continue until there are 30 participants in each group.

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Personal history of epilepsy
2. Inability to attend Institute of Optometry for the 1-2 pre-treatment appointments, the post treatment assessment, and the follow-up assessment
3. No access to a computer for six approximately weekly sessions for the treatment
4. Unilateral amblyopia worse than 6/36, or better than 6/9 in the amblyopic eye or worse than 6 /6 in the non amblyopic eye.
Refractive amblyopia where the amblyopic eye has less than 1D more hypermetropia or 2D astigmatism than the non-amblyopic eye.
Any ophthalmoscopically detectable anomalies of fundus or defects of the visual pathway (30° visual fields by static perimetry outside within normal limits)
5. Patients under 10 years old
6. History of strabismus or other cause of reduced visual acuity in first 2 years of life
7. Unable or unwilling to meet costs of refractive correction

Date of first enrolment
01/03/2005

Date of final enrolment
31/03/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Optometry
London
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SE1 6DS

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

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Sponsor type
Government

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Funder(s)

Funder type
Hospital/treatment centre

Funder Name
City Eye Clinic (EYENET)

Funder Name
NHS R&D Support Funding

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration