

# European Paediatric and Amblyopia Treatment study for Children (EuPATCH): the role of feedback on adherence to amblyopia treatment

<b>Submission date</b> 31/07/2013	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/08/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 11/06/2020	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Amblyopia (also called lazy eye) is the most common disease affecting vision in childhood. Currently 30% of children treated for amblyopia do not reach normal vision after a year or more of treatment. Poor adherence to patching (wearing an eye patch) and glasses wearing has been identified as a potential contributing factor for this problem. Electronic monitors have been used in various studies. However, at present none of these studies have provided feedback to parents about the results of the measurements. In other diseases feedback about compliance to treatment has been shown to be of benefit. For example, it has been shown that feedback to parents and patients about the frequency of use of steroid inhalers can significantly increase adherence to the daily use of inhaled steroids in children with asthma. The aim of this study will be to investigate whether giving feedback to families about the amount of spectacle and patch wear can improve adherence and in turn the outcome of amblyopia therapy.

### Who can participate?

Amblyopic children aged between 2 and 8 years.

### What does the study involve?

Children will be randomly allocated to one of two groups: the feedback group and the control group. Both groups will be asked to wear their glasses full time and to patch (10 hours/day, 6 days/week) during a 12-week period. Patients will be examined every 3 weeks. Patients within the feedback group will be given feedback from information provided by the monitors.

### What are the possible benefits and risks of participating?

There may be no direct benefit to the patient; however, we anticipate that patients in the study will have shorter waiting times and will be seen more often than the comparative NHS treatment, leading to the possible total treatment time being reduced. The study is likely to have only minimal risk with possible occurrence of side effects similar to the usual clinical treatment, including increase of squint, double vision or reduced vision in the better eye (which is almost always reversible).

Where is the study run from?  
University of Leicester (UK).

When is the study starting and how long is it expected to run for?  
The study is expected to start in September 2013 and run for about 2 years; recruitment will be during the first 1.5 years of the study.

Who is funding the study?  
National Eye Research Centre (NERC), UK

Who is the main contact?  
Professor Irene Gottlob  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
Version 1

## Study information

**Scientific Title**

The effect of feedback to adherence to glasses and patch wear in amblyopia treatment: a randomised clinical trial

**Acronym**

EuPATCH

**Study objectives**

The adherence to amblyopia treatment in children receiving feedback about the level of adherence to patching after 720 hours of prescribed patching over 12 weeks will be significantly higher than those who do not receive feedback.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

NRES Committee East Midlands - Derby, 15/08/2013, ref: 13/EM/0285

**Study design**

Unmasked randomised controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**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**

Amblyopia

**Interventions**

There will be two treatment arms:

A. Feedback Group: A period of 12 weeks of full-time glasses wearing and patching (10 hrs/day, 6 days/week) followed by feedback on hours of glasses and patch wear at each examination (n=51).

B. Control Group: A period of 12 weeks of full-time glasses wearing and patching (10 hrs/day, 6 days/week) without feedback on hours of glasses and patch wear at each examination (n=51).

The total time the patients will be in the trial is 12 weeks.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Adherence is determined as the the number of hours patched patching over 12 weeks.

**Secondary outcome measures**

1. Number of hours of glasses wear over the 12 week period.
2. Visual outcome using the formula described by Stewart et al. (% deficit corrected) over the 12 week period

**Overall study start date**

15/08/2013

**Completion date**

31/12/2018

**Eligibility****Key inclusion criteria**

1. Children (age range is between 2-8 years inclusive) with monocular amblyopia (difference of  $\geq 0.3$  logMAR visual acuity between eyes) due to anisometropia ( $\geq 1.5D$  in at least one eye or 1D difference between the two eyes), strabismus or both
2. Previous patching  $\leq 18$  months

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

2 Years

**Upper age limit**

8 Years

**Sex**

Both

**Target number of participants**

102

**Key exclusion criteria**

Children with other ophthalmic or neurological diseases, bilateral amblyopia or premature children.

**Date of first enrolment**

01/10/2013

**Date of final enrolment**

31/12/2017

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**University of Leicester**

Leicester

United Kingdom

LE2 7LX

## **Sponsor information**

**Organisation**

University of Leicester (UK)

**Sponsor details**

College of Medicine

Biological Sciences and Psychology

Level 4, MSB

Leicester

England

United Kingdom

LE1 7RH

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**Sponsor type**

University/education

**ROR**

<https://ror.org/04h699437>

## **Funder(s)**

**Funder type**

Charity

**Funder Name**

National Eye Research Centre (NERC) (UK)

**Alternative Name(s)**

National Eye Research Centre, SightResearchUK, SRUK, NERC

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

Planned publication in a high-impact peer reviewed journal.

**Intention to publish date**

01/12/2020

**Individual participant data (IPD) sharing plan**

The data sharing plans for the current study are unknown and will be made available at a later date.

**IPD sharing plan summary**

Data sharing statement to be made available at a later date

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No