# Implementation of Compliance Improvement for Amblyopia Prevention

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
26/09/2006		☐ Protocol		
Registration date 26/09/2006	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
05/04/2012	Eye Diseases			

#### Plain English summary of protocol

Not provided at time of registration

## Contact information

#### Type(s)

Scientific

#### Contact name

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#### Contact details

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## Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

# Study information

#### Scientific Title

Implementation of Compliance Improvement for Amblyopia Prevention: further training course about compliance, an effective information programme and direct referral by child health care centres, primary with orthoptists in foreign and low-SES (socio-economic status) neighbourhoods

#### **Acronym**

ICI-AP

#### **Study objectives**

Orthoptists work more effectually by using an improved compliance enhanced programme and a training course on compliance.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Ethics approval received from the local medical ethics committee

#### Study design

Non-randomised, paralled armed trial

#### Primary study design

Interventional

#### Secondary study design

Non randomised controlled trial

#### Study setting(s)

Not specified

#### Study type(s)

Treatment

#### Participant information sheet

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

Amblyopia

#### **Interventions**

At end of year one the orthoptist will receive a three-days training course on compliance with amblyopia prevention. Strategies and techniques to reduce non-compliance are given during the training.

All children included in the first year are the control group: receive standard orthoptic care.

All children included in the second year is the intervention group: receive the improved educational cartoon story together with a calendar and reward stickers, and a one-page information sheet for the parents. The cartoon is designed as a picture story, without text and is designed from a childs perspective.

#### **Intervention Type**

Other

#### Phase

**Not Specified** 

#### Primary outcome measure

Whether the orthoptists work is effectual, based on measurements (i.e. questionnaires) at the start of the study, before and after the training course, and at the end of the second year.

#### Secondary outcome measures

The electronic occlusion measurements for compliance (actual occlusion time/prescribed occlusion time), the fraction realised Child Health Care centre referrals and the overall acuity improvement will be determined.

#### Overall study start date

01/05/2006

#### Completion date

01/05/2009

# **Eligibility**

#### Key inclusion criteria

- 1. All newly diagnosed children with an inter-ocular difference in visual acuity of more than two logarithm of the Minimum Angle of Resolution (logMAR), strabismus and/or an anisometropia or a deprivation (e.g. cataract)
- 2. Age: three to six years
- 3. Both genders
- 4. Children living in an area with low Socio-Economic Status (SES) in the four big cities of the Netherlands

#### Participant type(s)

Patient

#### Age group

Child

#### Lower age limit

3 Years

#### Upper age limit

6 Years

#### Sex

Both

#### Target number of participants

300

#### Key exclusion criteria

- 1. Children with equal visual acuity between the eyes (less than one logMAR line of difference in visual acuity between eyes)
- 2. Previous treatment for amblyopia, neurological disorder, medication, other eye disorder or decreased visual acuity caused by brain damage or trauma

#### Date of first enrolment

01/05/2006

#### Date of final enrolment

01/05/2009

## Locations

#### Countries of recruitment

Netherlands

# Study participating centre Erasmus Medical Center Rotterdam Rotterdam Netherlands

Netherlands 3000 CA

# Sponsor information

#### Organisation

Erasmus Medical Center (The Netherlands)

### Sponsor details

P.O. Box 2040 Rotterdam Netherlands 3000 CA

#### Sponsor type

Hospital/treatment centre

#### Website

http://www.erasmusmc.nl/content/englishindex.htm

#### ROR

https://ror.org/018906e22

# Funder(s)

#### Funder type

Research organisation

#### Funder Name

The Netherlands Organisation for Health Research and Development (Zon-MW) (The Netherlands)

# **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

### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2010		Yes	No
Results article	results	01/12/2011		Yes	No