# Implementation of Compliance Improvement for Amblyopia Prevention.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON24124

**Source**
Nationaal Trial Register

**Brief title**
ICI-AP.

**Health condition**

Amblyopia

### Sponsors and support

**Source(s) of monetary or material Support:** Zon-Mw (The Netherlands Organization for Heath Research and Development)

### Intervention

### Outcome measures

#### Primary outcome

Whether the orthoptists work 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

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

# Study description

### Background summary

For one year children are referred as usual from Child Health Care centres (CHC) via the general practitioner to hospitals located in low-SES neighbourhoods to ophthalmologist or orthoptist. Those children get occlusion therapy by the orthoptist as usual. Orthoptic findings and patient flows will be registered, and compliance with occlusion therapy in 3-6 years old children, who are newly diagnosed with amblyopia, will be monitored. A training course on detection and prevention of non-compliance will be developed and given to the orthoptists at the end of year one. In the second year, the implementation phase will follow, where orthoptists will carry out the changings in the primary process i.e. (1) use the information programme, (2) check in the CHC-referrals, (3) pay attention to good communication towards parents, (4) take more measures of information hand outs for foreign parents with low-SES, with support from compliance-predictable software. Primary outcome is whether the orthoptists work effectual, based on measurements at the start of the study, before and after the course, and at the end of the second year.
Secondary, the electronic occlusion measurements for compliance, the fraction realized CHC-referrals and the overall acuity improvement will be determined.

### Study objective

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

### Intervention

At end of year one orthoptist 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 child’s perspective.

# Contacts

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# Eligibility criteria

## Inclusion criteria

1. All newly diagnosed children with an inter-ocular difference in visual acuity of >2 logMAR, strabismus and/or an anisometropia or a deprivation (e.g. cataract);
2. Age: 3 – 6 years;
3. Both genders;
4. Children living in an area with low-SES in the four big cities of the Netherlands.

## 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, decreased visual acuity caused by brain damage or trauma.

# Study design

## Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Masking: | Open (masking not used) |
| Control: | Placebo |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-05-2006 |
| Enrollment: | 300 |
| Type: | Anticipated |

# Ethics review

Positive opinion

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|---|---|
| Date: | 09-06-2006 |
| Application type: | First submission |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL652 |
| NTR-old | NTR713 |
| Other | : N/A |
| ISRCTN | ISRCTN22835481 |

# Study results

**Summary results**
N/A