Implementation of Compliance Improvement for Amblyopia Prevention.

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24124

Bron
Nationaal Trial Register

Verkorte titel
ICI-AP.

Aandoening

Amblyopia

Ondersteuning

Overige ondersteuning: Zon-Mw (The Netherlands Organization for Heath Research and Development)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-05-2006
Aantal proefpersonen:	300
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	09-06-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL652
NTR-old	NTR713

Register	ID
Ander register	: N/A
ISRCTN	ISRCTN22835481

Resultaten

Samenvatting resultaten

N/A