Prevalence of amblyopia, strabismus and refractive errors amongst children of the 7th grade and influence of spectacle correction of hypermetropia on reading ability

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Main objectives: 1. to investigate the prevalence of vision abnormalities in 9- and 10 year old children; 2. to investigate the percentage of these vision abnormalities that were detected the VOV screening programme;3. to investigate whether these...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Vision disorders
Study type	Interventional

Summary

ID

NL-OMON35425

Source
ToetsingOnline

Brief title
Prevalence of visual disorders in the 7th grade

Condition

- Vision disorders

Synonym
refractive errors. Spectacle corrections

Research involving
Human

Sponsors and support

Primary sponsor: Univé verzekeringen i.s.m. Pearle Benelux
Source(s) of monetary or material Support: Univé verzekeringen ism Pearle Benelux

Intervention

Keyword: reading ability, refractive errors, retinoscopy, subjective refraction

Outcome measures

Primary outcome

1. The prevalence of visual abnormalities, in particular amblyopia, strabismus

and refractive errors.

2. The percentage of abnormalities that were adequately detected by vision

screening in the VOV protocol.

3. The outcome of treatment / management of these abnormalities

4. The effect of hyperopic spectacle correction on reading capacity.

Secondary outcome

not applicable

Study description

Background summary

In The Netherlands, eye screening of children is being performed during visits to the maternity service (consultatiebureau) and school physician (schoolarts), using the VOV protocol (Vroegtijdige Onderkenning Visuele stoornissen). This protocol aims at the detection of strabismus (squint), amblyopia (lazy eye) and refractive errors (need for spectacle correction). This screening stops before the age of 7. The rationale for this cessation of screening is that strabismus and amblyopia are usually present before the age of 7 and refractive errors do not affect the health of the eye. This point of view is disputable since vision disorders may affect intellectual development at any age during childhood. Any motivated judgement about (the need for) vision screening is hampered by the fact that the prevalence of vision disorders (before as well as beyond the age

of 7) is unknown. Moreover, it is not known whether the disorders that have been detected in the screening programme, are indeed adequately treated and managed.
As reported above, vision abnormalities may affect intellectual development. There are many reports about the association between refractive errors and reading capacity: hypermetropia (farsightedness) is associated with lesser reading capacity; myopia (nearsightedness) with higher reading capacity. However the nature of this association is not known. It is unknown whether correction of hypermetropia by means of spectacles will indeed improve reading capacity.

Study objective

Main objectives:
1. to investigate the prevalence of vision abnormalities in 9- and 10 year old children;
2. to investigate the percentage of these vision abnormalities that were detected the VOV screening programme;
3. to investigate whether these detected vision abnormalities were adequately managed / treated;
4. to investigate whether correction hypermetropic refractive errors can improve reading capacity;

Study design

The objectives (1, 2 and 3) will be investigated in a cross sectional observational study. The objective (4) will be investigated in a double blind randomized controlled interventional study (intervention: prescription of glasses).

Intervention

For the objective (4) glasses will be provided to those subjects who have relevant hyperopia, on a random basis. The effect of these glasses on the reading capacity will be investigated by repeating the reading tests after 4 months.

Study burden and risks

The risks of the study are negligible. The burden consists of one eye investigation of 8 minutes performed at the school, possibly a second investigation of 75 minutes hours (in case of suspected abnormalities) and the possibility of wearing glasses during 4 months (only in case of relevant hypermetropia, hence likely to benefit the subject).
The possible benefits consist of a thorough eye examination, revealing treatable abnormalities, correction of refractive errors (improving visual

acuity) and possibly improving reading capacity.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

age

Exclusion criteria

none

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-11-2010
Enrollment:	3000
Type:	Actual

Medical products/devices used

Generic name:	glasses
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	22-10-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL23076.029.09