Long-term effects of the crowding training and transfer to untrained tasks

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• Determine to which extent near visual acuity and crowding improvements are retained at 6 and 12 months after training • Determine transfer of training effects to untrained tasks, in this case reading and fine motor performance.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Eye disorders congenital
Study type	Interventional

Summary

ID

NL-OMON42964

Source
ToetsingOnline

Brief title
Long-term effects crowding training

Condition

- Eye disorders congenital
- Congenital eye disorders (excl glaucoma)

Synonym
low vision

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Geld van Ministerie van VWS aan de Programmaraad Visueel.

Intervention

Keyword: Children, Consolidation, Near visual acuity, Visual training

Outcome measures

Primary outcome

The main study parameter is visual acuity. We measure uncrowded and crowded visual acuities by the conventional manner and by using a computerized test (which is in line with recently developed guidelines for improved vision screening: [1]). Crowding intensity can be calculated by subtracting the uncrowded acuity (logMAR) from the crowded acuity (logMAR).

Secondary outcome

Secondary study parameters are fine motor skills (measured with the Beery VMI) and reading skills (measured with the Radner or DMT).

Study description

Background summary

The crowding training is an evidence-based intervention for 4-8 year old children with a visual impairment who suffer from crowding and/or have a poorer near visual acuity than distance visual acuity. The training reduces crowding and improves near visual acuity: children show an average visual acuity improvement of 1.7 lines on the crowded chart and an improvement of 1.3 lines on the uncrowded chart. In addition, we found shorter visual search times after training. It is unclear to which extent training effects are retained after training.

The project has two goals: 1) to detemine how much of the training effects are retained after 6 and 12 months, and 2) to determine whether the training improves reading and/or fine motor skills. We expect that the results of this project will be in line with earlier studies and expect that 80-90% of the treatment effects will be retained after 6 to 12 months. We also expect that children will be able to read smaller font sizes after training.

Study objective

• Determine to which extent near visual acuity and crowding improvements are retained at 6 and 12 months after training
• Determine transfer of training effects to untrained tasks, in this case reading and fine motor performance.

Study design

Non-randomized pretest-posttest design.

Intervention

The *crowding training* is an evidence-based intervention that has been implemented at Bartiméus and Royal Dutch Visio (also see project number 2010/037). The *crowding training* is a behavioural treatment in which children are instructed to draw a line across near-threshold, closely spaced, inversed Es in a booklet. By training with Es that at presented in a crowded setting, selective visual attention, eye-hand coordination and visual acuity are trained. The training will be given during 6 weeks, with 2 training sessions per week (12 × 0.5h training sessions in total).

Study burden and risks

The burden on parents and children will be minimized by training the children at school and collecting the pre- and posttest data directly before and after training at school. The post-tests at 6 and 12 months will be conducted at the research institute with the same standardized tests that are used for the pre-test and first post-test. Pre- and post-tests can be collected within 30-40 minutes. Training sessions will occur at school. Benefits for the participants are that they can use an evidence-based training to improve near visual acuity and reduce crowding. Near visual acuity is an important outcome measure, especially in subjects with a visual impairment because they are more dependent on this function than individuals with normal vision. There are no risks associated with this child-friendly validated behavioural treatment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Age 4-8 years;
- Visual acuity >=20/400 and <=20/40;
- Normal birth weight;
- Birth at term;
- No perinatal complications;
- Normal development;
- No motor or mental impairments

Exclusion criteria

- motor or mental impairment
- visual acuity < 20/400 or >20/40
- the presence of a developmental disorder

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-04-2017
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	09-01-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 25290
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL59403.091.16

Register	ID
OMON	NL-OMON25290