Assessment of slow vision

No registrations found.

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

Summary

ID

NL-OMON21874

Source
NTR

Brief title
TBA

Health condition

Cerebral visual impairment (CVI).
Other visual impairments.

Sponsors and support

Primary sponsor: Koninklijke Visio. Radboudumc; Donders Institute.
Source(s) of monetary or material Support: Katholieke Stichting voor Blinden en Slechtzienden (KSBS)

Intervention

Outcome measures

Primary outcome

Reaction time to stimulus in the speed acuity test

Secondary outcome

Diagnostic feasibility of the speed acuity test

Study description

Background summary

At present, the definition of visual impairment is primarily based on distant visual acuity and visual field size. There are no nationally or internationally accepted tests to measure reaction time in acuity testing. Nevertheless, many children and adults, both normally sighted as visually impaired, complain about problems in coping with various daily activities due to slow vision.
The main goal of this project is to develop and validate a practical method to quantify "slow vision"; the time the brain needs to process visual information. We have therefore developed a new tool, the speed acuity test, to measure “perception time” during the assessment of visual acuity in healthy normally sighted children (Barsingerhorn et al., 2018). The current study will continue with the validation of this test in children with visual impairments.

Study objective

The speed acuity test can detect slow vision and thereby aid in the diagnosis of visual impairments.

Study design

Data collection: 9 months. Data analysis: 3 months

Intervention

Participation in speed acuity test: participants have to press a button when a visual stimulus is presented on a computer screen.

Contacts

Public
Donders institute for brain and cognition, Radboudumc, Nijmegen
Nouk Tanke

024-3668579
Scientific
Donders institute for brain and cognition, Radboudumc, Nijmegen
Nouk Tanke

024-3668579

Eligibility criteria

Inclusion criteria

Children aged 4 to 17 years, diagnosed with cerebral visual impairments (CVI) or other visual impairments, visiting Koninklijke Visio for regular rehabilitation, treatment, diagnosis or checkups.

Exclusion criteria

Retinal pathology leading to a central scotoma, or diagnosis of additional mental impairments.
Severe mental retardation and/or motor problems leading to problems to understand or execute the test used in the study.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2020
Enrollment:	50
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
The handling of personal data complies with the Dutch Personal Data Protection Act. Data of all the tests are stored in separate folders on data servers of our research group with automatically generated back-ups. The additional parameters and outcome parameters of the test and the location of the raw data will be stored within the validated data management system Castor EDC. It is necessary to be able to trace data back to an individual subject, therefore a subject identification code is used to link the data to the subject. The key to the code is safeguarded by the investigator and being stored at another location than the data. Data are handled confidentially by the principal investigator. After the end of the study all essential documents pertaining to the conduct of the study, including screening forms, patient files, originals of test result reports, correspondence, records of informed consent etc., will be archived by the investigator for a period of 15 years in accordance with the standard operating procedure of the Radboudumc.
Anonymized data will be published in a scientific journal.

Ethics review

Positive opinion

Date:	22-06-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47506
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8723
CCMO	NL48708.091.14
OMON	NL-OMON47506

Study results

Summary results

Barsingerhorn, A.D., Boonstra, F.N. & Goossens, J. (2018a). Development of symbol discrimination speed in children with normal vision. Invest Ophthalmol Vis Sci, 59(10), 3973-3983.