*Project *PLING*: development of a home-based app which uses Perceptual Learning to improve vison in children with Infantile NystaGmus*

Published: 11-12-2017
Last updated: 15-05-2024

The first goal of the PLING-project is to improve the clinical applicability of the training by developing a home-based app that can be on any Windows or Mac system. The second goal is to optimize training gain by: 1) increasing the number of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital eye disorders (excl glaucoma)
Study type	Interventional

Summary

ID

NL-OMON47749

Source
ToetsingOnline

Brief title
PLING

Condition

- Congenital eye disorders (excl glaucoma)

Synonym
infantile nystagmus syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: ZonMw;programma InZicht.

Intervention

Keyword: albinism, children, home-based training., infantile nystagmus, perceptual learning

Outcome measures

Primary outcome

Intervention study + validation study:

- Near and distance visual acuity

- Crowding intensity

Secondary outcome

Intervention study:

- Contrast sensitivity function

- Stereopsis

- Reading performance

- Eye movements (fixation stability and saccade execution)

- Compliance

- Training joy

- Vision related quality of life

Study description

Background summary

Infantile nystagmus (IN) is characterized by the presence of involuntary, oscillating eye movements with an onset in the first six months of life. The prevalence of IN is 1.4 per 1000. IN is associated with suboptimal vision and affects the quality of life. Recently we developed a computerized training which successfully improves vision in children with IN. Ten training sessions resulted in a vision improvement of ~30%, a stereopsis gain of 66% and improved

reading performance. Performance improvements were not only visible on the trained task, but were also present on non-trained tasks.

Study objective

The first goal of the PLING-project is to improve the clinical applicability of the training by developing a home-based app that can be on any Windows or Mac system. The second goal is to optimize training gain by: 1) increasing the number of training sessions, and 2) combining training conditions. The third goal is to conduct a follow up measurement 6 months after training. In addition to the development of the training app (intervention study), we will also validate a newly developed crowding app (validation study).

Study design

Intervention study: One-armed pretest-posttest design.
Validation study: Prospective cohort study.

Intervention

Intervention study: Computerized visual perceptual learning.

Study burden and risks

Intervention study: Children will visit the vision rehabilitation centre 3 times. Each measurement will take approximately 45 minutes. In addition, children have to adhere to the protocol. Children will not miss any school appointments and can use the training at home. It is very likely that children will benefit from the training, since we this approach resulted in 0.10-0.15 logMAR gains in visual acuity before (see Huurneman et al. IOVS 2016;57(10):4216-4246). There are no risks associated with the treatment. In our previous study, children indicated that they enjoyed the training (measured with a 'smiley' score).

Validation study: Because the measurements in the group of children with infantile nystagmus are already quite extensive, we have chosen to approach a new set of participants with normal vision for the validation study. Children with normal vision are seen only once at school for 30-45 minutes.

Contacts

Public
Radboud Universitair Medisch Centrum

Kapittelweg 29
Nijmegen 6525 EN
NL
Scientific
Radboud Universitair Medisch Centrum

Kapittelweg 29
Nijmegen 6525 EN
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Children with infantile nystagmus:
- Age 7-18 years
- Diagnosis albinism (with infantile nystagmus) or idiopathic infantile nystagmus
- Binocular visual acuity >=20/400 and < 20/20.
- No additional (neurological or motor) impairments
- Born at term with normal birth weight (>=3000 gr);Children with normal vision:
- Age 8-18 years (n = 30)
- Binocular visual acuity >=20/20
- Born at term (>30 weeks) with normal birth weight (>3000 gr)

Exclusion criteria

Children with infantile nystagmus:
- Received computerized visual perceptual learning before

- Neurological conditions such as cerebral visual impairment, oculomotor apraxia, hemianopia, developmental disorders.
- Visual acuity <20/400 or >= 20/20. ;Children with normal vision:
- Motor or mental impairments;
- The presence of a developmental disorder;
- Binocular visual acuity <20/20.

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):	21-02-2018
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	11-12-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	13-02-2018
Application type:	Amendment
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: 26659
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL61860.091.17
OMON	NL-OMON26659