

The effect of bifocals in children with Down Syndrome

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON40936

Source

ToetsingOnline

Brief title

Bifocals in Down

Condition

- Other condition
- Vision disorders

Synonym

accommodation deficit, blurred vision at near

Health condition

taakgerichtheidsproblematiek

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

Source(s) of monetary or material Support: Uitzicht: ODAS;LSBS;Novartis en Oogfonds

Intervention

Keyword: bifocals, children, Down Syndrome, Visual functions

Outcome measures

Primary outcome

- Improvement of near vision

Secondary outcome

- Improvement of visual-acuity at distance
- Improvement in accuracy of accommodation response
- Prevalence (prevention) of strabismus
- Differential effect of bifocals on task readiness

Study description

Background summary

Near vision, is reduced in 86 to 100% of the children with Down Syndrome (DS) 34,45,49. This is an additional barrier achieving their maximum potential in development.⁴⁵

DS is one of the most common genetic anomalies, occurring in about 14.6 in 10000 live births in the Netherlands in 2007. In the last two decades many research is done to find out the differences in ocular findings between children with and children without DS^{34,49}. Refraction errors, which have to be corrected with glasses, are common^{14,15,17,34,45,49} (percentages vary from 40 to 90%¹⁴) and aggravate over time. The accommodation (focussing for near) is consistent reduced in 50 to 100% of children with DS^{15,17,18,19,29,45,46,49} and does not improve with age¹⁹

In contrast to children without DS glasses for distance vision don't improve near vision.¹⁷ Children with DS see blurred at near. Some authors have suggested a relationship between this blurred retinal image and the absence of emmetropisation (decrease of refraction error)^{15,17}, others see a crucial

relationship with the defective visual development of children with DS, presenting in visual acuities that do not reach normal levels¹⁷, generally 20/40 or lower⁴⁹. Moreover the effort to accommodate may give rise to strabismus, which occurs far more often in children with DS, in 15 to 47%^{14,34,49} (versus 3 to 4% in normal population) and could be avoided or cured by wearing the right glasses. Bifocal correction is such a tailor-made treatment for the eye disorders in DS. Results shown in smaller studies on the effect of bifocals are encouraging:

- Improved visual acuity for near^{19,29,46}
- Significantly more accurate accommodation in the bifocal-treatment group^{19,29}
- Positive impact on visual functioning: Faster and improved performance on visual perceptual and some early literacy skills.^{45,46}
- Bifocals were used with good compliance^{19,29,45,46}
- Prevention of avoidable visual impairment

Study objective

To prevent avoidable visual impairment, in our controlled study, we want to contribute to the evidence of good treatment effects on visual functions (visual acuity both distances near and at distance, accuracy of accommodation), prevention of strabismus and development of task readiness using bifocal correction in children with Down Syndrome.

Study design

A multicentre randomised controlled trial (RCT), the most suitable design for effects of interventions.

Intervention

Children in the intervention group will be prescribed adjusted bifocals and the control group will be corrected in the usual way single vision glasses for distance. Follow-up 1.5 years in 5 site visits.

Study burden and risks

Patient burden will not exceed the cooperation that is needed for normal visual acuity controls and spectacle wear, except for the extra test for near vision, measurement of accommodation and assessment of task readiness. Child-friendly tests will be applied also for testing task readiness. These are like games.

Contacts

Public

Universitair Medisch Centrum Sint Radboud

Geert Grooteplein 21
Nijmegen 6525 EZ
NL

Scientific

Universitair Medisch Centrum Sint Radboud

Geert Grooteplein 21
Nijmegen 6525 EZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

1. Diagnosed with DS
2. Accommodation lag $>0.5D$ for children with DS <12 years and $>0.75D$ for children older than age 12 or
Visual acuity at near is worse than at distance and >0.1
3. Age range 2-14 years
4. Has not worn or does not wear bifocals

Exclusion criteria

- Other significant eye diseases, such as keratoconus, cataract or high myopia (>-6.00).
- Diagnoses of any neurological, sensory or behavioural disorders such as autism, microcephaly or significant hearing loss.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	15-06-2014
Enrollment:	160
Type:	Anticipated

Medical products/devices used

Generic name:	bifocals
Registration:	Yes - CE intended use

Ethics review

Approved WMO	
Date:	15-07-2014
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO	
Date:	10-07-2015
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO	
Date:	29-09-2015
Application type:	Amendment

Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO	
Date:	03-11-2015
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

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	NL48288.075.14