



Preparation of the **Early Glasses Study**: a randomized, controlled trial investigating the effect of early glasses for high refractive error on the development of amblyopia

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Summary

Photorefraction of young children is currently practiced nation-wide in Flanders, Belgium, at age 1. Children with high refractive error are referred to an ophthalmologist – there are few orthoptists - and most are prescribed glasses and rarely patched. Wearing of glasses has increased from 4.7% to 6.4% in four-year-olds in Flanders between 2012 and 2017 but it is unknown how many cases of amblyopia have been prevented from developing by the prescription of early glasses. In a randomized controlled trial (RCT), we will establish whether early glasses for high refractive error at age 1 reduces the development of amblyopia between age 1 and 4. As a secondary outcome, early literacy will be compared in groups with high refractive error with and without glasses.

Purpose

The Early Glasses Studies is a randomized controlled preventative interventional trial, where children with high refractive errors > AAPOS 2003 criteria (the AAPOS 2012 criteria are too restrictive) at age 1 will receive either intervention (early spectacles and orthoptic exams) or regular orthoptic exams only.

Main outcome measure:

- The prevalence of amblyopia among children with high refractive error with glasses and without glasses (stratified by severity / visual acuity (VA)) at age 4

Secondary outcome measures:

- The prevalence of amblyopia at age 1
- The type and severity of refractive errors at age 1
- Electronically measured compliance with early spectacles wearing
- The effect of early glasses on early literacy skills
- The relation between refractive error at age 1 - and it's increase or decrease - and VA at age 4



Methods

Five study orthoptists will perform retinoscopy in cycloplegia at age 1, randomization of children surpassing the AAPOS 2003 criteria and follow-up examination until age 4.

To obtain a random sample of all children in the Dutch population, recruitment is done with the help of Children's Healthcare Centers (CHCs). 97% of all Dutch children age 1 visit the CHC, so an almost random sample of the population is eligible.

Retinoscopy in cycloplegia is performed at age 1 (12-18 months) by a study orthoptist in all children.

Children with refraction > AAPOS 2003 criteria, approximately 8%, are randomized into 2 groups:

- Intervention group receives glasses at the age of 1 and is examined 1-3 times per year by the study orthoptist
- Control group does not receive glasses, but is examined 1-3 times a year by the study orthoptist

At age 4, it is examined whether more children have developed amblyopia in the control group compared to the intervention group. Differences in pre-reading skills, measured with the Test of Preschool Early Literacy (TOPEL), are also examined between the control group and the intervention group at age 4.

In children with refraction <AAPOS 2003 criteria (approximately 92%), VA is measured at the CHC at 45 months.

Before analysing the efficacy of the study intervention, a marginal test is performed, using logistic regression on the 4% children with high refractive error at age 1 who do not receive glasses and the 92% children without high refractive error at age 1, in order to investigate whether refractive error surpassing AAPOS 2003 at age 1 is a strong enough predictor to justify treating all children with high refractive error with glasses.

Results

In preparation of the RCT, CHCs, research-orthoptists and facilities for the examination of children were recruited. Youth Healthcare Physicians (YHPs) were contacted in most healthcare regions in the Netherlands, to engage clusters of CHCs in child-rich neighborhoods. Research-orthoptists were found via orthoptic professional societies, meetings and announcements. Locations for examination of the children were found among institutions for visually impaired, CHCs and hospitals.

Five preventive healthcare organizations will participate with clusters of CHCs:

1. Utrecht Neighborhood Leidsche Rijn & Vleuten/De Meern
2. Harderwijk, Ermelo, Putten
3. Eindhoven-North
4. Limburg-North
5. Tiel, Geldermalsen, Culemborg



Study locations were ensured in two institutions for visually impaired, one in a CHC and one in a hospital.

Conclusion

Sufficient CHCs, YHPs & nurses and research-orthoptists have committed themselves to this RCT in order to investigate whether early glasses for high refractive error at age 1 reduces the development of amblyopia at age 4 and if the extra costs made by the purchase of early glasses and the measurement of refractive error at age 1 could be justified.

