

## **A randomized clustered clinical trial to assess the efficacy of vision screening in children aged 3-6 years.**

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**Purpose:** To conduct a randomized clustered clinical trial to assess the efficacy of vision screening to detect vision problems in children aged 3-6 years.

**Study Design:** 24 kindergarten classrooms (mean = 30.1 children per classroom) were randomly assigned to “Early” vs. “Late” screening. The primary measure was the *number of children wearing glasses* in Early classrooms (i.e. after intervention) versus in Late classrooms (i.e. before intervention). The secondary measure was the presence of vision problems, such as amblyopia, amblyopia risk factors (e.g. strabismus), and clinically significant refractive errors, as determined by gold standard eye examinations, against which the screening results were tested.

**Methods:** Five screening tools were used: Cambridge Crowded Acuity Cards, Preschool Randot Stereoacuity test, Plusoptix and Spot autorefractors, and the Pediatric Vision Scanner, a new device that assesses binocular fixation. Children in Early classrooms were screened at the beginning of the year. Those failing any one of the screening tools were given a gold standard eye examination and fitted with glasses if needed. Children in the Late group were screened near the end of the year. Glasses counts were compared between classrooms in Early versus Late screening groups. To test the accuracy of the screening tools, all remaining children (i.e. Early group children who passed screening and all Late group children) received gold standard eye examinations. The study protocol was approved by SickKids and McMaster REB and followed the tenets of the Declaration of Helsinki.

**Results:** The odds of children wearing glasses at the end of the year in Early classrooms was 9.29 (95% CI: 3.7-31.16) times those in the Late group. Comparison of the screening results to the gold standard eye examinations (n= 712) showed that sensitivity was 84% (95% CI: 78-89, based on bootstrapping) and specificity was 48% (95% CI: 44-53). For children in senior kindergarten (mean age = 68.2 months), sensitivity was 91% (95% CI: 81-96) and specificity was 58% (95% CI: 51-65); for children in junior kindergarten (mean age = 55.6 months), sensitivity was 80% (95% CI: 72-87) and specificity was 42% (95% CI: 37-48). Overall, the screening protocol detected 180 children with vision problems (80.2% of amblyopia and risk factors; 90.1% of refractive errors).

**Conclusions:** Vision screening was more effective than “care as usual” in identifying children in need of glasses; it also detected most cases of amblyopia and amblyopia risk factors.