Protocol Title: Randomized Clinical Trial of Streaming Dichoptic Movies versus Patching for Treatment of Amblyopia in Children Aged 3 to 7 Years

Date: January 31, 2019

clincaltrials.gov identifier: NCT03825107

Financial support: National Institutes of Health Grant EY022313 (Birch, PI)

Principal Investigator: Eileen E Birch, PhD
Senior Research Scientist
Pediatric Vision Laboratory
Retina Foundation of the Southwest
9600 North Central Expressway, Suite 200
Dallas, TX 75231
phone: (214) 363-3911
email: ebirch@retinafoundation.org

Single site study conducted at: Retina Foundation of the Southwest
9600 North Central Expressway, Suite 200
Dallas, TX 75231

Sample Size and Statistical Plan

The primary outcome is change in amblyopic eye BCVA at the 2-week visit. The analysis will be conducted with a modified intent-to-treat approach, limited to participants who completed the 2-week visit within the pre-specified analysis window (± 3 days after the baseline/randomization visit) and no imputation for missing data. A t-test will be used to compare the visual acuity change in the two treatment groups.

Based on our recent prospective study of contrast re-balanced dichoptic movies as a treatment for amblyopia,[4,5] we anticipate a 0.15±0.10 logMAR (7.5 letters) improvement in visual acuity at the 2-week primary outcome visit for children assigned to the dichoptic movie arm. For children assigned to the patching group, we anticipate a 0.07±0.10 logMAR (3.5 letters) improvement at 2 weeks based on results from our prior study of patching versus a contrast-rebalanced dichoptic game as a treatment for amblyopia.[2] With these expected means, a sample size of 28 per group (56 total) will provide 85% power to declare that the two groups have significantly different means, using a two-sided p-value of less than 0.05. We will enroll and randomize 62 children (31 per group) to account for potential 10% loss to follow-up.

As a secondary analysis of BCVA at the 2-week primary outcome visit, one sample t-tests will be conducted to determine whether amblyopic eye BCVA improvement at the 2-week visit is significant in each group. In addition, confidence intervals (95%) will be calculated to determine whether there are significant improvements in stereoacuity, depth of suppression, or extent of suppression at the 2-week primary outcome for each group. Exploratory analyses will be conducted to determine whether any improvement in BCVA at the 2-week visit is associated with the child's baseline visual acuity, baseline stereoacuity, or their response to conventional treatment with glasses and patching prior to enrollment.