

What is amblyopia ("lazy eye") and how is it treated?

Amblyopia is one of the most common causes of decreased vision in children. It affects about 2 or 3 out of every 100 children. The eye is not being used properly because the brain is favoring the other eye. Treatment usually includes glasses or wearing a patch over the "good" eye.

What causes amblyopia?

Amblyopia may be caused by any condition that affects normal visual development. This can be due to an imbalance in the positioning of the eyes (strabismus), which can be either a turning in (esotropia) or out (exotropia) of the eyes. In many cases it is caused by a difference in the amount of farsightedness and/or astigmatism between the two eyes.

Why is this study being done?

This study is designed to find out if watching shows wearing the Luminopia headset (1 hour per day 6 days per week) or playing games using the Vivid Vision headset (25 minutes per day, 6 days per week) improves vision better than glasses alone. Those who volunteer to participate will be part of a research study designed to provide answers about how to best treat amblyopia.

What is the Pediatric Eye Disease Investigator Group (PEDIG)?

The study is being conducted by the Pediatric Eye Disease Investigator Group (PEDIG). The study will include about 252 children at pediatric eye centers across North America.

The Jaeb Center for Health Research is the coordinating center (data center) which is organizing the study. The National Eye Institute is providing the funding for the study.

What is involved in the study for children who participate?

is in association with the Pediatric Eye Disease Investigator Group

(PEDIG) and sponsored by the National Eye Institute.

If eligible for this study, the child will have their vision tested in their glasses and answer some initial questions.

A computer program will decide whether the child will start the study wearing glasses alone, watching shows using the Luminopia headset, or playing games using the Vivid Vision headset. This is like flipping a coin to decide which approach will be followed.

The child will have follow-up vision testing and answer similar questions 9 weeks and 18 weeks after the first visit. If the child starts the study with glasses alone, they will have a chance to try one of the headsets for 18 weeks if they still have amblyopia. The child would then have two more follow up visits at 27 weeks and 36 weeks. The parent or legally authorized representative will also answer questions about their child's eyes.

What are the parents' responsibilities related to the study?

Parents are expected to bring their child to all study visits and to try their best to have the child use the prescribed treatment. Parents will record the amount of time the child uses the treatment each day on a calendar.

The study will provide the headsets. The headsets will need to be returned to your study doctor when the study ends. If new glasses are needed during the study, they will be provided at no cost. To cover travel and other visit-related expenses, parents will be provided a \$100 Amazon electronic gift card for completing each exam, up to \$500.



Please feel free to contact us for more information and to inquire about eligibility to participate in the study.

UND PEDIG Group

Dr. Biberdorf, OD, principal investigator 701-777-6843 | UND.eyeclinictrials@UND.edu