



New virtual reality-based treatment for amblyopia in children 8 to 12 years of age

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.

Why are we doing this study?

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. If you decide to take part, you and your child will be part of a research study that will provide answers about how to best treat amblyopia.

What is involved in the study if I agree to have my child take part?

A computer program will decide if your 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.

If your child is eligible for this study, your child will have their vision tested in their glasses and answer questions (about their eyes and how they feel). Your child will have follow-up vision testing and answer similar questions 9 weeks and 18 weeks after the first visit. If your 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. Your child would then have two more follow up visits at 27 weeks and 36 weeks. As the parent or legally authorized representative, you will also answer questions about your child's eyes. You will be expected to bring your child to all study visits and to try your best to have your child use the prescribed treatment. You will record the amount of time your 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, you will be provided a \$100 Amazon electronic gift card for completing each exam, up to \$500.

For more information, please contact:

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What is amblyopia?

Amblyopia is sometimes called “lazy eye.” It is the term used when the vision in one of the eyes is reduced. The eye is not being used properly because the brain is favoring the other eye.

How common is amblyopia?

Amblyopia is one of the most common causes of decreased vision in children. It affects about 2 or 3 out of every 100 children.

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.

How is amblyopia usually treated?

Treatment of amblyopia usually starts with glasses. After treatment with glasses alone, if the vision is still reduced, doctors often try other treatments like having the child wear a patch over the “good” eye.

Why are we doing this study?

The purpose of this study is to find out if watching shows using the Luminopia headset or playing games using the Vivid Vision headset improves amblyopic eye vision better than wearing glasses alone. Both headsets present images differently to each eye to try to restore the balance between the two eyes.

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

The study is being conducted by the Pediatric Eye Disease Investigator Group (PEDIG). Your child’s eye doctor is a member of this group. 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.

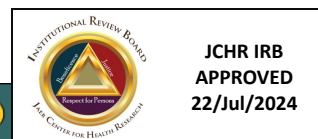
What are the study procedures?

If you decide to have your child take part in the study, a computer program will be used to decide whether your child will start the study wearing glasses alone, watching shows using the Luminopia virtual reality headset (1 hour a day, 6 days a week), or playing games using the Vivid Vision virtual reality headset (25 minutes per day, 6 days per week). This is like flipping a coin to decide which approach will be followed.

If your child is eligible for this study, your child will have their vision tested in their glasses and answer questions (about their eyes and how they feel). Your child will have follow-up vision testing and answer similar questions 9 weeks and 18 weeks after the first visit. If your child starts the study with glasses alone, they will have the opportunity to try the Luminopia or Vivid Vision headset for 18 weeks if they still have amblyopia. Your child would then have two more follow up visits at 27 weeks and 36 weeks. If you provide your mobile number, you will receive a text message before each visit to remind you of your appointment.

What will be my responsibilities if I agree to have my child take part in the study?

If you agree to have your child be a part of the study, you will be expected to bring your child to all follow-up visits and to try your best to have your child use the treatment that is prescribed. You will record the amount of time your child uses the treatment each day on a calendar. You will also answer questions about your child’s eyes. A study like this takes a lot of effort from everyone involved. You and your child will be a very important part of the research team, and like its other members, you will have a commitment to the study.





What costs will be my responsibility?

The study will pay for visits that are done just for the research study. You and your insurance company will not be responsible for the cost of visits done just for the research study. The study will not pay for usual care visits that would occur even if your child is not in the study. The cost of usual care visits will be your or your insurance company's responsibility like it would be normally. The study will provide the Luminopia or Vivid Vision headset and any new glasses needed during the study to you at no cost. The headsets will need to be returned to your study doctor when the study ends.

To cover travel and other visit-related expenses, you will be paid \$100 for completing each follow-up exam, up to \$500.

Why should I volunteer to have my child take part in the study?

You and your child will be part of a research study that will provide answers about how to best treat amblyopia. Although the results may not be of direct benefit to your child, they are expected to benefit other children with amblyopia.

What do I need to do to have my child take part in the study?

To find out if your child is eligible to be in the study, please contact a PEDIG eye doctor. You will be asked to sign a form giving your consent. This form will provide you with more details about the study.

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Amblyopia Treatment Study

A Randomized Trial of Virtual Reality Video Treatment for Amblyopia in Children 8 to 12 Years of Age

Information for Parents



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