What is amblyopia?
Amblyopia is sometimes called “lazy eye.” It is the medical term used when the vision in one of the eyes is reduced because the eye is not being used properly. The eye itself looks normal, but it is not being used normally 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. The condition affects approximately 2 or 3 out of every 100 children.

What causes amblyopia?
Amblyopia may be caused by any condition that affects the normal use of the eyes and 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 amblyopia is caused by a difference in the glasses used to correct the eyes (such as one eye having more nearsightedness, farsightedness, or astigmatism than the other eye).

How is amblyopia usually treated?
Treatment of amblyopia usually starts with optical correction (glasses). After treatment with glasses alone, if the vision is not normal, doctors often try other treatments like having the child wear a patch over the “good” eye or putting an eye drop in the good eye to blur the vision. A new treatment option for amblyopia is binocular game therapy. This treatment involves playing a special game on an iPad® while wearing red/green glasses. Some early studies have shown this new treatment may work very well in some children and adults. This study is being done to compare the new binocular game treatment with wearing glasses alone, if glasses are needed.

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 200 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 receive binocular game treatment or glasses alone (if needed), at the start of the study. This is similar to flipping a coin to decide which approach will be followed.

Half of children will receive the binocular game treatment and be given an iPad and red/green glasses at the beginning of the study. The game should be played for a total of one hour each day, 5 days a week for 8 weeks. The other half of children will wear glasses alone (if needed), for 8 weeks.

All children enrolled in the study will receive a phone call within one week of enrollment and have follow-up visits after 4 and 8 weeks. At each visit, your child’s vision and eye alignment will be checked. Children who were assigned the binocular game will end the study after the 8 week visit. Children assigned to glasses alone (if needed), for the first 8 week of the study will be offered binocular game treatment using the iPad. These children will receive a phone call one week after starting the treatment and will return for a follow-up visit 16 weeks from enrollment in to the study.

What will be my responsibilities if I agree to have my child participate 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. During the study, you must also be willing to record on a calendar the amount of time your child uses the treatment prescribed each day. You must also be willing to be contacted by phone shortly after enrollment. 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 costs of the enrollment, 4-week, 8-week and 16-week visit (if needed) will be paid for by the study. The costs of any other office visits will be your or your insurance company’s responsibility since they would be needed whether your child was in the study or not. If your child receives binocular treatment, the following will be provided by the study at no charge to you for the duration of the study: (1) an iPad with the special game, (2) a case for the iPad, and (3) red/green glasses. The iPad, case and red/green
glasses must be returned to your doctor’s office at the end of the study.

To cover travel and other visit-related expenses, you will be paid $40 for completing each follow-up exam, up to a maximum of $160 (if all 4 visits are completed).

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

You and your child will be part of a research study designed to 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?**

You will be told if your child is eligible for the study. If you want your child to be in the study, you will be asked to sign a form (Informed Consent Form) giving your consent. This form will provide you with more details about the study.

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