

**Randomized Controlled Multicenter Clinical Trial
of Multi-Periscopic Prism Glasses for Homonymous Hemianopia**

NCT04827147

Assent form for one of the study sites
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Protocol Title: Randomized Controlled Multicenter Clinical Trial of Multi-Periscopic Prism Glasses for Homonymous Hemianopia

Principal/Overall Investigator: Dr. Eli Peli

Site Principal Investigator: Dr. Nicole Ross

Description of Subject Population: Individuals with homonymous hemianopia

We are researchers from NECO Center for Eye Care, Commonwealth. We would like to learn more about the best way to help children who have a condition called hemianopia. Children who have this condition do not have any vision on one side (for example, no vision on the left side of the left eye and no vision on the left side of the right eye). This means that when they look straight ahead they cannot see anything on one side and might bump into things when walking around. Prism glasses might help people with hemianopia to see things on the side where they do not have any vision.

We are asking you and other children with hemianopia to take part in a research study. The results of the study will tell us if prism glasses will help children who have hemianopia.

If you agree to join this study, you will have to come here to see one of the researchers doing this study about four times over three months. At the first visit you will be asked to do some vision tests, like in the eye doctor's office, and we will fit you with some spectacle frames. We will take a photo of your eyes to help us figure out whether the frame will fit you well with the prisms. We will only take a photo of your eyes and not your face. If we think the glasses may help you, we will order two types of prism glasses for you to try. If we think the glasses won't help you, you won't be in the study, but your eye doctor might be able to fit you with other glasses to help.

If we order prism glasses for you, we will ask you to come back to try the glasses once they are ready. We will show you how to use the first pair of prism glasses. We will then ask you to take the first pair of glasses home and wear them as much as possible while walking around. We will contact you (or your mom or dad) by telephone one week after taking home the glasses to find out how you are getting on with the glasses. After about four weeks, we will ask you to come back so we can show you how to use the second pair of prism glasses. We will then ask you to take the second pair of glasses home and wear them as much as possible while walking around. After about four weeks we will ask you to come back for a final visit.

When you come here for a study visit, you will be asked to do some vision tests, like in the eye doctor's office, without and with the prism glasses. You will also be asked to do some video games without and with prism glasses while standing in front of a large television screen. The videos will make it seem like you are walking in a shopping mall. We will ask you to press a button whenever you see a person that you may bump into.

You might get tired during a visit. Please let us know if you feel tired. We will take breaks, as many as you need. You might feel a bit strange when you first wear the prism glasses. We will give you time to get used to them and will explain to you how to use them. If the prism glasses are too confusing or make you feel uncomfortable, you



Mass General Brigham

Research Assent Form

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Subject Identification

can take them off and wear your regular glasses instead (if you have glasses). We will ask you some questions about how you feel in the glasses. You do not have to answer any of the questions we ask if you do not want to or if they make you feel uncomfortable.

After you have tried each pair of prism glasses, you might be asked to keep one pair of prism glasses for longer. If you keep one pair for longer, a researcher will phone you after 6 months and again after 12 months to ask you some questions about how you are getting on with the prism glasses.

We do not know whether the prism glasses will help you to see things in areas where you do not have any vision, although we hope they will be helpful.

There are other ways to help your hemianopia if you don't want to be in this study. Other types of prism glasses or training can be used to help people with hemianopia.

The information collected about you during this study will be kept safely locked up, and nobody will know who you are except the people doing the research. If we write an article about what we learn from the study, we will not use your name.

Before you decide to take part in this study, we will answer any questions you have. You can also talk to your mom or dad, or your doctor. You do not have to be in this study, it is okay to say no. If you decide to be in this study, you can change your mind and stop being part of it at any time.

You will be given a copy of this form to keep for yourself.

If you decide to be in the study, please sign your name below.

Subject's Signature

Date

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