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

NCT04827147

Consent 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 Investigator: Eli Peli

Site Principal Investigator: Nicole Ross

Description of Subject Population: Individuals with homonymous hemianopia

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Some of the people who are eligible to take part in this study may not be able to give consent because they are less than 18 years of age (a minor). Instead, we will ask their parent(s) to give permission for them to take part in the study and will ask them to agree (give their assent) to take part. Throughout the consent form, "you" always refers to the person who takes part in the study.

If you turn 18 years of age while you are taking part in this study, we will ask you to sign a new consent form at that time.

Key Information

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. Your decision won't change the medical care you get within NECO Center for Eye Care, Commonwealth & Roslindale, NECO Center for Eye Care at Perkins School for the Blind or NECO Center for Eyecare at Carroll Center for the Blind now or in the future.

The following key information is to help you decide whether or not to take part in this research study. We have included more details about the research in the Detailed Information section that follows the key information.

Why is this research study being done?

In this research study we want to learn more about prism glasses for people with hemianopia (the loss of one half of the field of vision on the same side in both eyes). We will compare a new design of high power prism glasses (called multi-periscopic prisms or MPP glasses) to commercially-available permanent Fresnel peripheral prism glasses (FPP glasses).

How long will you take part in this research study?

The study comprises a short-term wear phase followed by an optional extended wear phase.

Short-term wear phase

- If you join this research study, it will take you about **3 months** to complete the short-term wear phase.

Extended wear phase

- If you want to try one of the devices for a longer period of time, and it is clinically appropriate, you may be invited to continue in the extended wear part of the study. This will be an additional 12 months, making your total study time 15 months.

What will happen if you take part in this research study?

If you decide to join this research study, the following things will happen:

- We will fit you with each pair of prism glasses and train you to use them
- We will ask you to wear each pair of prism glasses when walking for about 4 weeks
- We will take some measurements of your vision without and with the prism glasses
- We will ask you to watch some videos of pedestrians walking in a virtual shopping mall and measure your responses to the pedestrians without and with the prism glasses
- We will ask you to complete some questionnaires about your vision and the prism glasses

Why might you choose to take part in this study?

We cannot promise any benefits to you from taking part in this research study. However, possible benefits may include improved ability to detect objects on the side of your visual field loss when wearing the prisms, which may help you to avoid bumping into objects or pedestrians when walking. Others with visual field loss may benefit in the future from what we learn in this study.

Why might you choose NOT to take part in this study?

Taking part in this research study has some risks and requirements that you should consider carefully.

Possible discomforts

1. Potential fatigue since study visits may last about 1 to 2 hours (though you will take breaks).
2. Minor chance of experiencing some discomfort when watching the motion videos.
3. You might feel a bit strange when you first wear the prism glasses. There may be a period of adjustment to wearing the prism glasses that is similar to getting adjusted to progressive/multifocal or bifocal lenses for the first time.

A detailed description of side effects, risks, and possible discomforts can be found later in this consent form in the section called "What are the risks and possible discomforts from being in this research study?"

Additional things to consider

1. A time commitment of about 1 to 2 hours per visit for typically 4 visits
2. Travel to NECO Center for Eye Care, located at 930 Commonwealth Avenue in Boston

What other treatments or procedures are available for your condition?

Other treatments for hemianopia include: alternative prism designs, visual scanning training, and vision restoration therapy.

If you have questions or concerns about this research study, whom can you call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Nicole Ross, OD, MSc, FAAO Telephone No: 617-869-4317 Email: rossn@neco.edu

Jem Martin, OD Telephone No: 617-587-5577 Email: martinj@neco.edu

Dr. Eliezer Peli, OD is the person in charge of this research study.
You can call him at 617-912-2597 [Monday to Friday 9.00 am – 5:00pm].

If you have questions about the scheduling of appointments or study visits:
Call Cecilia Idman-Rait at 617-519-1591. Clinical Research Project Coordinator

If you want to speak with someone **not** directly involved in this research study, please contact the Mass General Brigham IRB. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

Detailed Information

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov,* as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Why is this research study being done?

Hemianopia (homonymous hemianopia) is the loss of half of the visual field on the same side in both eyes. It can result from brain injury, stroke, or tumor. Individuals with hemianopia often have difficulty seeing objects on the side of the field loss and may bump into obstacles when walking. We are doing this research to evaluate a new design of high power prism glasses to determine how much they help people with hemianopia to see objects on the side of their field loss.

Dr. Peli, the Principal Investigator on this study, is an inventor of technology that is used in this study. The hospital owns this technology and therefore Dr. Peli and the hospital may benefit financially if this study shows that the technology is valuable. The hospital's conflict of interest policies are handled by the hospital's owner, Mass General Brigham. In accordance with these policies, Mass General Brigham has determined that the interests create no significant risk to the welfare of participants in this study or to the integrity of the research. If you want more information about this, please contact the Mass General Brigham Office for Interactions with Industry at 857-282-2024.

Who will take part in this research?

We are asking you to take part in this research study because you have hemianopia (the loss of half of the visual field on the same side in both eyes). In total, about 65 people with hemianopia will take part in this research study. About 10 people will take part at NECO Center for Eye Care, Commonwealth.

The National Eye Institute of the National Institutes of Health is paying for this research study to be done.

What will happen in this research study?

If you choose to take part in this study, we will ask you to sign this consent form before we do any study procedures.

The study comprises a short-term wear phase during which you will try two types of prism glasses followed by an optional extended wear phase during which you will use only one of the devices (if the researchers decide that it is clinically appropriate, and you want to continue to use the device for a longer period of time).

The short-term wear part of the study involves about 4 study visits to NECO Center for Eye Care, Commonwealth.

- over about 3 months. Each visit will last about 1 to 2 hours. **It is very important that you attend all of the study visits as scheduled.** During the short-term wear, you will be asked to use each pair of prism glasses at home for about 4 weeks.

The extended wear part of the study lasts for an additional 12 months. We will contact you twice during that time to administer a telephone questionnaire. You will not have to make any study visits to NECO Center for Eye Care, Commonwealth.

- during the extended wear phase (unless you are having difficulties with the prism glasses).

Description of prism glasses

In this study, we will compare a new design of high power prism glasses (called multi-periscopic prisms or MPP glasses) to commercially-available, permanent Fresnel peripheral prism glasses (FPP glasses). Both types of prism glasses contain small prisms mounted on one spectacle lens, above and below the central area of the lens, leaving a clear central view. The prisms shift images from the side of the field loss into portions of the wearer's remaining, seeing, field of vision. For the study, the prisms will be mounted in basic eyewear (lenses and frames).

Short-term wear of each type of prism glasses

In the first part of the study, we will ask you to use each type of prism glasses at home for about 4 weeks. The order in which you receive the prism glasses will be randomized. This means that about half of the participants will use the MPP glasses first and the FPP glasses second while the other half will use the FPP glasses first and the MPP glasses second.

You will first be asked to visit NECO Center for Eye Care, Commonwealth for a screening visit. If the research team determines that you qualify for the study, we will ask you to come back for about three more visits. We expect that the time between visits will be about 4 weeks, and each visit will last about 1 to 2 hours. **It is possible that the duration between visits may be longer**

than anticipated due to delays in processing and shipping glasses or scheduling visits. We will contact you to confirm appointments.

Visit 1 - Screening Visit:
At the screening visit, we may do some or all of the following:

- Ask questions about your eye and general medical history
- Test your vision on an eye chart
- Measure your field of vision
- Check for glasses prescription, if needed
- Check your binocular vision (coordination between the two eyes) using standard clinical tests
- Check the health of your eyes using standard clinical tests (we will not dilate your pupils)
- Pen-and-paper tests for hemi-spatial neglect
- A test to evaluate memory and thinking
- Measurements for prism glasses (similar to measurements taken when fitting regular spectacles; additionally, we will take a photo of your eyes while wearing the frame for the prism glasses. The photo will only show your eyes and the frame. It will not contain any other identifying information).
- **Pedestrian collision detection task:** in addition, we might ask you to practice the pedestrian collision detection task without the prism glasses. (You will stand in front of a large television screen and watch videos of pedestrians in a virtual shopping mall. We will ask you to imagine that you are walking and move a lever when you see a pedestrian that might collide with you.

If the research team determines that you qualify for the study, prism glasses will be ordered for you and you will be asked to come back for three more visits (Visits 2, 3 and 4).

Visit 2 - Prism glasses #1, fitting and training:
At Visit 2 we may do some or all of the following:

- Questionnaire about difficulties encountered when walking around
- Fit the first pair of prism glasses and train you how to use them
- Take a photo of your eyes while wearing the prism glasses. (The photo will only show your eyes and the frame)
- Walk through rooms and corridors to help you learn how to use the glasses, accompanied by a member of the research team
- Provide written instructions on how to use the glasses
- Practice pedestrian collision detection task without the prism glasses. (See Visit 1 for a description of this task)

At the end of visit 2, you will take the first pair of prism glasses home.

Home use of prism glasses #1
You will be asked to use the first pair of prism glasses as much as possible when walking around in your daily life for about 4 weeks. One week after you take the glasses home, one of our team members will phone you to check on how you are doing with the prism glasses.

Visit 3
a) Prism glasses #1 evaluation:
In the first part of Visit 3, we may do some or all of the following to evaluate the first pair of prism glasses:
- Measure your field of vision without and with the first pair of prism glasses
- Pedestrian collision detection task without and with the first pair of prism glasses (as described for Visit 2)
- Questionnaires about the first pair of prism glasses

We will then take back the first pair of prism glasses and provide you with the second pair

b) Prism glasses #2, fitting and training:
In the second part of Visit 3, we will fit the second pair of prism glasses and provide training in how to use them (see Visit 2 for list of procedures).

Home use of prism glasses #2
You will be asked to use the second pair of prism glasses as much as possible when walking around in your daily life for about 4 weeks. One week after you take the glasses home, one of our team members will phone you to check on how you are doing with the second pair of prism glasses.

Visit 4
a) Prism glasses #2 evaluation:
In the first part of Visit 4, we will evaluate the second pair of prism glasses using some or all of the procedures listed for the first part of Visit 3. In addition, we might ask you to complete a questionnaire comparing the two types of prism glasses. We will then take back the second pair of glasses.

b) Clinical decision
If you would like to continue using one of the pairs of prism glasses for a longer period of time, a member of the study team will discuss this with you. If we think that it is clinically appropriate, you will be invited to continue into the second part of the study, the extended wear phase, and you will be allowed to take the preferred pair of prism glasses home for 12 months. This will be based on your optometrist's clinical judgment, your own preference for the glasses, and your performance with the prism glasses on our tests during the study visits. If we do not think that it is clinically appropriate for you to continue to use one of the

devices, or you are not interested in participating in the extended wear phase, then your participation in the study will end and the study team will retain both pairs of prism glasses.

Extended wear

If you are invited to participate in the extended wear phase of the study, that phase will last for 12 months after Visit 4. During that time you will be asked to use the prism glasses as much as possible in your daily life. About 6 and 12 months following Visit 4, a member of the study team will contact you to conduct a short telephone questionnaire about your experiences with using the prism glasses. Normally, there will not be any study visits during the extended wear phase. (You will only be asked to visit if you are having problems with the prism glasses.) After the 12-month telephone questionnaire, you will have completed the whole study and will be permitted to keep the pair of prism glasses you used during the extended wear phase.

Study participation will be terminated, and the prism glasses will be retained by the study team if:

- It becomes apparent that you are having difficulties with the prism glasses that could endanger you or others;
- You are no longer able to participate in all the study procedures due to the onset of new physical or mental disabilities or general health problems (e.g., become unable to walk during the course of the study).
- There is a report of any risky behavior while wearing the glasses such as driving or operating heavy machinery.
- There is any event (that may or may not be a result of activities related to the study) during the time of your participation that may jeopardize your health/life based on appropriate medical judgement or an event that may require medical intervention to prevent a life threatening outcome.

A notation that you are taking part in this research study may be made in your electronic medical record. Information from the research that relates to your general medical care may be included in the record (for example, information that you have tried prism glasses). Please ask your study doctor if you have any questions about what information will be included in your electronic medical record.

How may we use and share your samples and health information for other research?

The information we collect in this study may help advance other research. If you join this study, we may remove all information that identifies you (for example, your name, medical record number, and date of birth) and use the de-identified data in other research related to visual field

loss. It won't be possible to link the information back to you. Information may be shared with investigators at our hospitals, at other academic institutions or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these uses.

Will you get the results of this research study?

You and your doctor should not expect to get information about the results of the research study or the results of your individual participation in the research study. We will study information from many people. It could take many years before anyone knows whether the results have any meaning. There is a small chance that we could find out something from the study that might be important. If this happens, we may contact you to find out if you would like to learn more. However, even if we find something important to your health, we cannot guarantee that you will be contacted.

What are the risks and possible discomforts from being in this research study?

Foreseeable risks and discomforts include the following:

Vision testing:
The vision testing includes standard clinical tests carried out in an eye doctor's office. There may be some slight discomfort from sitting with your chin in a chin rest.

Pedestrian detection:
There is a very slight chance that you might experience some temporary discomfort when viewing motion video backgrounds that simulate walking on a large TV screen. Should you feel any discomfort or tiredness, you may take breaks whenever you need to, or stop the test altogether.

Prism glasses:
There may be a period of adjustment to using the prism glasses, similar to the adjustment when first wearing new bifocal or progressive addition lenses. There is a chance that some people may experience headaches during the adjustment period. Until you become accustomed to the prism glasses you may encounter some difficulties in navigating your surroundings comfortably. At the study visit when we fit the prism glasses, we will start with you wearing the prism glasses when sitting down. We will only ask you to stand up and try walking with them once you feel comfortable enough to do so. You will have a member of the research team with you at all times to provide directions and ensure your safety while walking around at the study visit.

Home use of prism glasses:
As explained above, until you become accustomed to the prism glasses you may encounter some difficulties in navigating your surroundings comfortably. Therefore, at first you should only wear the prism glasses at home or in places with which you are extremely familiar until you become comfortable using them. **You should not drive a car or any other moving vehicle, or operate any heavy equipment while wearing the prism glasses.** If you experience extreme difficulties in using the prism glasses, you should stop using them and wear your regular glasses, and contact the person listed on the instructions sheet given to you (or) Dr. Eliezer Peli at 617-912-2597. After extended use of the prism glasses, you should not experience any additional risks/discomforts as you switch back to your regular glasses.

Unforeseeable risks
There may be other risks that are currently unknown.

What are the possible benefits from being in this research study?

We cannot promise any benefits to you from taking part in this research study. However, possible benefits may include improved ability to detect objects on the side of your visual field loss when wearing the prisms, which may help you to avoid bumping into objects or people when walking around.

The results of the study will help us to improve the functionality of prism glasses for people with visual field loss. Ultimately improved functionality of the devices may result in improved mobility and quality of life for people with visual field loss.

What other treatments or procedures are available for your condition?

Other treatments for hemianopia are available, including alternative prism designs, visual scanning training and vision restoration therapy.

Can you still get medical care within NECO Center for Eye Care, Commonwealth if you don't take part in this research study, or if you stop taking part?

Yes. Your decision won't change the medical care you get within NECO Center for Eye Care, Commonwealth & Roslindale or any NECO-affiliated Community Health Centers now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should you do if you want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will you be paid to take part in this research study?

You will be offered reimbursement for your travel expenses, of up to a maximum of $50.00 per visit, for travel specifically for the study to the NECO Center for Eye Care, Commonwealth. You will not be paid for your time taking part in this study.

We may use your information to develop a new product or medical test to be sold. The Sponsor, hospital, and researchers may benefit if this happens. There are no plans to pay you if your samples or information are used for this purpose.

What will you have to pay for if you take part in this research study?

Study funds will pay for the prism glasses that you try during the study and for other study-related items. We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

What happens if you are injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the beginning of this consent form.

If you take part in this research study, how will we protect your privacy?

Federal law requires New England College of Optometry and Mass General Brigham to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information."

In this study, we may collect identifiable information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable information and why:

- New England College of Optometry and Mass General Brigham researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Mass General Brigham ethics board or an ethics board outside Mass General Brigham that oversees the research
- A group that oversees the data (study information) and safety of this study

- Non-research staff within New England College of Optometry who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other researchers within or outside New England College of Optometry, for use in other research as allowed by law.

Certificate of Confidentiality

A federal Certificate of Confidentiality (Certificate) has been issued for this research to add special protection for information and specimens that may identify you. With a Certificate, unless you give permission (such as in this form) and except as described above, the researchers are not allowed to share your identifiable information or identifiable specimens, including for a court order or subpoena.

Certain information from the research will be put into your medical record and will not be covered by the Certificate. This includes records of medical tests or procedures done at the hospitals and clinics, and information that treating health care providers may need to care for you. Please ask your study doctor if you have any questions about what information will be included in your medical record. Other researchers receiving your identifiable information or specimens are expected to comply with the privacy protections of the Certificate. The Certificate does not stop you from voluntarily releasing information about yourself or your participation in this study.

Even with these measures to protect your privacy, once your identifiable information is shared outside NECO Center for Eye Care, Commonwealth, we cannot control all the ways that others use or share it and cannot promise that it will remain completely private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.

The results of this research may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my identifiable information to be used and shared as described above.

_____	_____	_____
Subject	Date	Time (optional)

Signature of Parent(s)/Guardian for Child:

I give my consent for my child to take part in this research study and agree to allow his/her identifiable information to be used and shared as described above.

_____	_____	_____
Parent(s)/Guardian for Child	Date	Time (optional)

Assent

Statement of Person Giving Assent

- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions, and my questions have been answered.

Signature of Child:

I agree to take part in this research study and agree to allow my identifiable information to be used and shared as described above.

_____	_____	_____
Child, Ages 14-17	Date	Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

_____	_____	_____
Study Doctor or Person Obtaining Consent	Date	Time (optional)

Consent Form Version Date: 20 July 2022