CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Efficacy of Biofeedback Training for Visual Function and Quality of Life in Glaucoma: A Randomized Controlled Trial

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Introduction:

You are invited to participate in a research study. Please read the information about the study presented in this form. The form includes details on study's risks and benefits that you should know before you decide if you will participate. You should take as much time as you need to make your decision. You should ask the study investigator or study staff to explain anything that you do not understand and make sure that all your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish including your friends, family, and family doctor. Participation in this study is voluntary.

Background:

You are being asked to take part in this study because you have glaucoma and are doing vision rehabilitation at the low vision service at the UHN.

Newer therapies in Low Vision Rehabilitation include eye movement training methods which hope to reduce the impact from vision impairment due to central visual field defects. One such method is called Biofeedback training. Biofeedback training is a

method for training eye movements with the help of visual targets along with noise clues to help improve eye movement performance. The training is done in the office with the help of an instrument called microperimeter. Microperimeters are instruments which can show the patient visual images, monitor eye movements and produce sounds to help eye movements. Microperimeters are approved devices for use by Health Canada, including performing Biofeedback training.

Biofeedback training (BT) aims to improve eye movements by training attention. As a result from training the eye movements, the vision for near and distance improve. Audio biofeedback is a therapy used in low vision rehabilitation for more than ten years and helps improve near and distance vision in macular degeneration and other eye conditions. Previous studies have shown that BT benefits patients with glaucoma.

Purpose of study:

BT is the standard of care for patients with low vision, and studies have shown that it improves the reading speed and the light perception on the retina in patients with glaucoma. We have delivered BT for patients who have glaucoma with central visual loss, noticing that they see sharper after training. This study will show in more detail how BT has helped the patients see better.The purpose of this study is to analyze all visual functions that may be improving from BT, including how the eyes are moving post-BT, and quality of life. The study will last 1 year. Seventy patients will be invited to participate in the study.

Study Design

This study is a prospective randomized controlled study, which means the participants will be randomized into treatment and control groups by chance. It is like flipping a coin. You have a 50% chance of being in the treated group and a 50% chance of being in the control group. The treatment group will receive the BT right away during the study and the control group will receive BT after the study, and this will be 9 weeks later than the treatment group. Neither you nor your doctor can choose what group you will be in, however, due to the availability in the clinical research unit that will host the study, the patients who will wait for 9 weeks will still be receiving the BT at the same time as in our regular clinic. The research clinic has an exclusive device, so this group will be treated on the same schedule as the patients who do not participate in the study and schedule it in the regular clinic because there is a waitlist there.

Study Visits, training, and randomization

To participate in this study, you need to sign this written consent. If you consent to participate, we are going to collect data from tests that you perform as a routine

during your visits to our service. Also, your year of birth, sex, and race information will be collected. The visits will take place at the Toronto Western Hospital on the low vision rehabilitation clinic from the Department of Ophthalmology.

Visit 1: This visit will take approximately one hour, just like any low vision visit. During visit 1 you will do the tests below to determine your initial visual function. All these tests are performed in the low vision clinic for glaucoma vision rehabilitation as a standard of care:

- Visual test for distance vision - is assessed using letters charts at a distance of 4 meters, the examiner will ask you to read the letters with each eye separately.
- Near vision visual acuity test - tested with a “sentences reading card”, you will read the sentences at a close distance.
- Reading speed test - you are going to read paragraphs on the iPad as fast as possible, that will measure your speed.
- Contrast sensitivity using a light stripes chart - you will tell the doctor the direction of these stripes on the chart to determine if you can sense contrast differences
- Eye movements with RightEye device - you will be looking at a laptop screen for a few moments and it will determine the pattern of your eye movements and eventual abnormalities
- Quality of life questionnaire - you will answer on the paper 48 questions about your activities of daily living to assess eventual visual difficulties..For example, you will answer if you have difficulty shaving, walking around, reading, signing a check, seeing money, going to the movies, and other questions.
- Microperimetry, - a more accurate visual field testing used in low vision to determine how you use your vision and plan interventions for rehabilitation. It takes 5 minutes for each eye. You will look at a central circle while pressing a button if you notice any lights around.
- Regular visual fields for glaucoma - you will also press a button every time lights are noticed on your visual fields. This one determines a more peripheral test of your fields of vision than microperimetry and is used to follow the progression of the glaucoma. It takes the same amount of time as microperimetry.
- OCT test - scansyour optic nerves,and it is also done seated in front of a similar device. You will look at a target and the machine will scan and take pictures from the back of your eyes. It takes 2 mintus for each eye.

Randomization:
Following the visit 1 assessment you will then be randomized in a ratio 1:1 between BT Treatment and Control group::

- Group A (Treatment): Participants will promptly receive the biofeedback training. After BT, 1 month (visit 7), 6 month (visit 8), and 1 year (visit 9) follow up visits will take place and the patients will end the participation in the study, continuing this regular care at the clinic. The standard of care includes the same visits and procedures as the study.

- Group B (Control): Participants will undergo visit 1 and visit 2t (9 weeks later), out of the study. This means that your treatment will be 9 weeks later than group A and that you will perform 1 visit exclusively for the study for tests. After that, you will end your participation in the study and will continue having the same procedures as group A patients as a standard of care.

Group A Visit 2- 6 - BT Training Procedure:
The BT procedure (Visits 2-6) for group A will take place during weekly 20-minute office visits. You will be seated in front of the instrument, and an LED circle will be presented. A beep sound will start and you will be guided to move your eye in a direction that makes the beep sound faster until it becomes continuous, when also a light will show up. The beep will depend on your eye position, and you will be training for 20 minutes how to keep it longer on that “long beep” eye position. You will be allowed to rest as many times as you need during the BT.

Group A Follow Up Visits - Visits 7-9:
These visits will be1 hour long each. All the tests performed during visit 1 will be repeated in visits 7, 8, and 9. This corresponds to the standard of care follow up post-BT done 1 month after the procedure and followed every 6 months regularly..

Group B Visit 2:
This visit will be 1 hour long. All the tests performed during visit 1 will be repeated in visit 2.This consists of an extra-visit that the patients in the control group will perform as a research procedure exclusively, not part of standard of care.

Group A schedule and duration in hours (h):

Group A - time from V1	Biofeedback	Microperimetry	OCT	Visual acuity	Reading	Contrast	Visual fields	Saccades and pursuit	Questionnaire
V1-Initial		X	X	X	X	X	X	X	X
V2-1 week	X								
V3- 2 weeks	X								
V4-3 weeks	X								
V5- 4 weeks	X								
V6- 5 weeks	X								
V7- 9 weeks		X	X	X	X	X	X	X	X

V8- 6 months		X	X	X	X	X	X	X	X
V9-12 months		X	X	X	X	X	X	X	X

Group B Schedule:

Group B - Time from V1	**Biofeedback**	**Microperimetry**	**OCT**	**Visual acuity**	**Reading**	**Contrast**	**Visual fields**	**Saccades and pursuit**	**Questionnaire**
V1- Initial		**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
V2- 9 Weeks		**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**

As we said, we have a machine that is dedicated to the research, so there will be no delays or waitlist for the control or treated group to receive the BT, except in case of technical problems. If any unforeseen events happen, you will be informed right away.

Risks:

About 80% of the patients experience some eye straining from BT. The patients may experience fatigue for a few moments after training. This discomfort disappears spontaneously. Besides that, there is always a small risk from being in an ophthalmology office regarding contamination and infection from the equipment and, also, from being in a hospital.

Benefits:

You will not benefit directly from participating in this study. We hope that the information learned from this study can be used in the future to help other people with a similar disease and/or health condition.

Alternatives to Being in the Study:

Regardless of participation in this study, you will continue to receive the standard of care for your condition in our service.This may include low vision assessment, low vision glasses, aids, and others. Even if you decide not to be in the study, you will still receive the same BT.

Confidentiality:

Your data will be shared as described in this consent form or as required by law. All personal information such as your name, address, phone number, OHIP number, and family physician's name will be removed from the data and will be replaced with a number. A list linking the number with your name will be kept by the study doctor in a secure place, separate from your file.

Personal Health Information

If you agree to join this study, the study doctor and his/her study team will look at your personal health information and collect only the information they need for the study. Personal health information is any information that could identify you and includes your:

- year of birth
- sex
- race
- new medical records, that includes types, dates and results of medical tests or procedures.

The following people may come to the hospital or be given remote access to an electronic portal (via the internet) to look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study is following proper laws and guidelines. When using the electronic portal, we will share your medical record number using a secure method, so that your records are included as part of their review.

- Representatives of the University Health Network (UHN) including the UHN Research Ethics Board

These individuals have completed privacy training and signed confidentiality agreements and/or are required by law to keep your information confidential.

Whether on-site or remotely, UHN makes all efforts to ensure that your information is shared in a way that is secure and private (encrypted). However, any electronic communication carries some risk of third parties gaining unauthorized access to information.

The study doctor will keep any personal health information about you in a secure and confidential location for 10 years.

Your participation in this study will also be recorded in your medical record at this hospital. This is for clinical safety purposes.

Research Information in Shared Clinical Records

If you participate in this study, information about you from this research project may be stored in your hospital file and in the UHN computer system. The UHN shares the patient information stored on its computers with other hospitals and health care providers in Ontario so they can access the information if it is needed for your clinical

care. The study team can tell you what information about you will be stored electronically and may be shared outside of the UHN. If you have any concerns about this, or have any questions, please contact the UHN Privacy Office at 416-340-4800, x6937 (or by email at privacy@uhn.ca).

Study Information that Does Not Identify You

You will not be named in any reports, publications, or presentations that may come from this study.

Voluntary Participation

Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now, and then change your mind later. You may leave the study at any time without affecting your care. We will give you new information that is learned during the study that might affect your decision to stay in the study.

Withdrawal from the Study

You do not need to give a reason to withdraw from the study and you may leave it at any time. Withdrawal from the study will not have any effect on the care you receive in this service. If you decide to leave the study, you can contact the Principal Investigator or a member of the study team to let them know it. Please notice that upon withdrawal we will stop collecting data from your files, but all data collected during the period you were in the study will be still used in order to answer the research questions.

The principal investigator can withdraw you from the study at any moment if you stop being eligible for it.

Costs and Reimbursement:

You will not have to pay for any of the procedures, including biofeedback training, involved with this study. If you are randomized for the control group, there will be a cost of transportation for one visit. This research has no funding to cover this expense.

Rights as a Participant:

If you are harmed as a direct result of taking part in this study, all necessary measures will be made available to you at no cost.

By signing this form, you do not give up any of your legal rights against the investigators, or involved institutions for compensation, nor does this form relieve the investigators, or involved institutions of their legal and professional responsibilities.

Conflict of Interest:

Researchers have an interest in completing this study. Their interests should not influence your decision to participate in this study.

Questions about the Study:

If you have any questions, concerns or would like to speak to the study team for any reason, please call: Principal Investigator Dr. Monica Daibert Nido at 416 531 5425.

If you have any questions about your rights as a research participant or have concerns about this study, call the Chair of the University Health Network Research Ethics Board (UHN REB) or the Research Ethics office number at 416-581-7849. The REB is a group of people who oversee the ethical conduct of research studies. The UHN REB is not part of the study team. Everything that you discuss will be kept confidential.

You will be given a signed copy of this consent form.

Consent:

This study has been explained to me and any questions I had have been answered. I know that I may leave the study at any given time. I agree to the use of my information as described in this form. I agree to take part in this study.

_____	_____	_____
Print Study Participant's Name	Signature	Date

My signature means that I have explained the study to the participant 's parent named above. I have answered all the questions.

_____	_____	_____
Print Name of Person Obtaining Consent	Signature	Date