

Official Title: Non-Invasive Multisensory Rehabilitation of Hemianopia

NCT04963075

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Department of Neurobiology and Anatomy

MULTISENSORY REHABILITATION OF HEMIANOPIA

Informed Consent Form to Participate in Research

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SUMMARY

You are invited to participate in a research study. The purpose of this pilot research study is to determine how multisensory training can be used to change how different areas of the brain process visual information after they have been damaged by stroke or injury.

You are invited to be in this study because you have lost part of your vision as a result of a stroke or injury. Your participation in this research will involve 2 eye exams, the first is to make sure your vision is stable and the second will be after weekly visits for 3 months to see if your vision has improved. You will also be asked to keep a diary of your experiences with the training, describing what/when you can see to track progress. These visits will last about 1-2 hours.

Participation in this study will involve testing your vision with 2 different study devices. All research studies involve some risks. A risk to this study that you should be aware of is tiring during the testing sessions and unable to complete testing. You may not benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. There is no other treatment for hemianopia other than routine observation. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Dr. Benjamin Rowland. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is: [REDACTED] or after hours [REDACTED].

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [REDACTED] or the Research Subject Advocate at Wake Forest at [REDACTED].

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific

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Adult Consent Form

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knowledge that may help other people in the future. You are being asked to take part in this study because you have lost part of your vision as a stroke or injury. This is called hemianopia. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this pilot research study is to determine how multisensory training can be used to change how different areas of the brain process visual information after they have been damaged by stroke or injury.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

6 people at Wake Forest Baptist Health will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

Prior to study testing, participants will be given an eye exam to see if your vision is stable. Participants will receive a second eye exam at the end of the study to measure any changes after completion of testing with the study devices. You will also be asked to keep a diary of your experiences with the training, describing what/when you can see to track progress. The study will be conducted using two different devices. One device has little lights and speakers attached to poles that are placed in different locations. The lights and speakers will produce flashes and sounds that you will be asked to detect and point to. The other device is a virtual reality (VR) video game system (HTC Vive Pro Eye) that creates a virtual 3-D environment that has visual objects in it that make sounds you will hear over the headphones. You will point at these objects using the video game controllers. Your answers will be recorded by the computer. The computer will not record your name but will assign you an ID number instead.

As part of this research study, you will be videotaped. This is being done to monitor how you perform the test and any movements made during testing. You understand that you may request the filming or recording be stopped at any time during the course of the research study. You can also withdraw your consent to use and disclose the photograph/videotape/audiotape before it is used. You should also understand that you will not be able to inspect, review, or approve the photographs, videotapes, audiotapes or other media (including articles containing such) before they are used in this study.

Please choose one of the following regarding the use and disclosure of the videotape used in this research study:

I would like the videotapes of me to be destroyed once their use in this study is finished.

The videotapes of me can be kept for use in future studies provided they are kept secure and any future study will be reviewed by an IRB. I understand that I will not be able to inspect, review or approve their future use.

We can send copies of your test results to your personal physician. Even if you do not wish to have any of your medical information sent to your physician, you can still participate in this research study.

Do you request that we send important medical findings from your study tests/exams to your personal physician?

Yes No _____ Initials

HOW LONG WILL I BE IN THE STUDY?

Your performance in the task may change with each test session. Thus, we will ask you to commit to come back for weekly sessions for 3 months. We expect that each study will take approximately 1-2 hours. You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

WHAT ARE THE RISKS OF THE STUDY?

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

The ability of your brain to process visual information may change during this study. You may be able to sense visual stimuli in areas in which sight has been lost. However, this is not guaranteed, and your vision may not change at all. We hope the information learned from this study will benefit other people in the future.

WHAT OTHER CHOICES ARE THERE?

This is not a treatment study. Your alternative is to not participate in this study. There is currently no other treatment for hemianopia other than observation by your primary health care provider or eye doctor.

WHAT ARE THE COSTS?

All study costs, related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published

in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive \$100 if you complete the study.

To receive payment, you must provide your social security number, name and address so that we can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not let them know what the payment is for, only that you have been paid. If you do not wish to provide this information you can still take part in this study but you will not be paid.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the Neuroscience Clinical Trials and Innovation Center (NCTIC) at Wake Forest University Health Sciences. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you and information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes current medical history and treatment related to your stroke or injury.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you (“your health information”) may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis

centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Only the following people or organizations will be granted access to your Protected Health Information:

- 1) The study investigator and his/her staff, or others at Wake Forest University Health Sciences who oversee research.
- 2) Other people or laboratories providing services for this research project on behalf of Wake Forest University Health Sciences and Wake Forest University Baptist Medical Center.
- 3) If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state law.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified.

You can tell Dr. Ben Rowland that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Benjamin Rowland



However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best medical interest, you failed to follow instructions, or because the entire study has been stopped. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Ben Rowland [REDACTED], after hours: [REDACTED].

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [REDACTED] or the Research Subject Advocate at [REDACTED].

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

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed): _____

Subject Signature: _____ Date: _____ Time: _____ am pm

Person Obtaining Consent: _____ Date: _____ Time: _____ am pm