ATLANTA VA HEALTH CARE SYSTEM
Consent to be a Research Subject

TITLE: Spatial Cognitive Training in Visual Impairment

PRINCIPAL INVESTIGATOR: April Maa, MD

SPONSOR'S NAME: Department of Veterans Affairs

INTRODUCTION/PURPOSE:
You are being asked to be in this research study because you are an adult who is blind, or have low vision, aged 50 or older. There will be about 60 people volunteering for this study.

This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. Please read this consent form before you decide to take part. Talk over any questions or concerns with the research team. If you agree to be in this study, you will need to sign this consent form and a HIPAA form before starting in the study. It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study. The decision to join or not join the research study will not cause you to lose any medical benefits. All procedures are experimental and done for study purposes only.

The purpose of this research study is to see if doing regular training on a spatial imagery task leads to improvements in your ability to do the trained spatial imagery task and in your ability to get around in everyday activities.

This study requires 3 visits to the Atlanta VA Health Care System and 2 visits to Emory University for study testing, and 3 weeks of home-training you will do on a computer linked to the internet. If needed, transportation may be provided. (Please see Table 1 for an overview of the study activities.)

Table 1: Overview of study activities

STUDY VISIT #	ACTIVITY	LOCATION	TIME
Visit 1: SCREENING	• Consenting • Cognitive Screening and Hearing test	Atlanta VA	3 hours
Visit 2: PRE-TRAINING	• Behavioral testing • MRI scanning	Atlanta VA & BITC at Emory University Hospital	6 hours
HOME TRAINING	• Study training on IPad	Your home	1 hour per day, 5x week for 3 weeks
Visit 2: POST-TRAINING	• Behavioral testing • MRI scanning	Atlanta VA & BITC at Emory University Hospital	6 hours

PROCEDURES:

Screening

Visit 1: You will come to the Atlanta VA Health Care System. Prior to any study testing, the study team will obtain your consent to participate after all your questions are answered. You will be screened for cognition and hearing using questionnaires and a hearing test. This visit will take about 3 hours.

Pre-training Testing

Visit 2 – Atlanta VA
You will be asked to perform neuropsychological tests, behavioral tasks on a computer, and a "real world" task of walking around and pointing on a specially designed grid on the floor.

Visit 2 – Emory
Next, you will go to the Biomedical Imaging Technology Center at Emory University Hospital where you will have a Magnetic Resonance Imaging (MRI) scan. During the scan you will lie on a bed that slides into the scanner. Pictures of your brain will be taken to show its structure as well as its function during study tasks. These pictures will allow investigators to study changes occurring in brain blood flow during the tasks and compare it with how you performed on the tasks. You will be interacting with the investigator(s), trained research assistant(s), and MRI technician(s) during these sessions. We will then return to the VA for your home training instructions and transportation home. This visit may take up to 6 hours of your time. You may take breaks as needed.

Intervention - Home Training

You will be randomly assigned (like flipping a coin) to one of two training groups. One group will do the spatial cognitive training, the other group will do a letter-number matching training. If you are put in the letter-number matching training group to begin with, you will be offered the opportunity to undergo the spatial cognitive training after you complete participation.

Both groups will do home-training, 5 days a week, Monday through Friday between the hours of 9 am and 5 pm. Each home-training session lasts about 1 hour. You will be given an IPad to take to your home. We will show you how to use the IPad and do the training on Visit 2. Please note: You will need to return the IPad when you come back for Visit 3. If the IPad is not returned, we will withhold final payment until it is returned to us.

Post-training Testing

Visit 3 – Atlanta VA and Emory
Please refer to the Visit 2 descriptions for the activities you will do during this visit. Total time for Visit 3 is about 6 hours.

RISKS:
Neuropsychological and Behavioral testing - There are no known risks for these procedures. They are entirely non-invasive and painless. It is possible that you will become frustrated during these tasks or while completing questions about your mood or past emotional events. If this occurs, you may request a break from the procedure(s). If you become so upset that you cannot continue, you may ask to be withdrawn.

Real-world testing - As a blind participant, you may be at somewhat higher risk of falling, compared to sighted people, during the real-world assessment. However, a trained member of the research team (the research assistant) will be present at all times to closely watch your performance and ensure you do not fall.

Magnetic Resonance Imaging (MRI): MRI is a very common test used by physicians. Its only known risk is that it can cause a metal implant or foreign body in the eye, brain or other organ (including pacemakers, aneurysm clips, shrapnel, metal fragments, orthopedic pins, screws, or plates, IUDs, or piercings that you cannot remove) to move, which could cause serious harm and even be fatal. **It is very important to know if you have any metal in your body**. If there is, you will not be allowed to undergo the MRI scan. If this precaution is taken, MRI scanning is safe. A small percentage of people are unable to tolerate MRI scanning because they are claustrophobic (they become uncomfortable in the enclosed space of the scanner). If you have a history of this, you will not participate in this study. If you become uncomfortable while in the scanner, you will be removed at once.

The scanner used in this study is approved by the Food and Drug Administration (FDA) for diagnostic purposes. There is no evidence that it is harmful.

The scanner makes a loud noise. To protect your hearing, we will supply you with ear inserts as well as noise-canceling headphones. These measures will dampen the noise to a level that is safe for your hearing. The headphones will also be used to deliver instructions during the scan session.

You may experience some muscle discomfort from lying in the scanner. You may also become too hot or too cold, in which case you may ask for an adjustment of room temperature or a blanket. Some people become nervous or claustrophobic in the scanner. If this happens to you, you may ask to be withdrawn immediately. You may also experience sensations of dizziness or vertigo, nausea, metallic taste, tingling or muscle twitching. These are due to the strong magnetic field. If you experience any of these sensations and they disturb you, you may ask to be withdrawn.

There are no known risks to pregnant women from magnetic resonance imaging. However, if you believe there is a possibility that you may be pregnant, you should not participate in this study because it is possible that in the future some risk to pregnancy may be identified.

This MRI scan is for research purposes only and is not designed to detect problems of the brain. A radiologist will not be reading the scan. Do not rely on the scan for clinical or diagnostic purposes. However, if the researchers have a question about something they see on the scan they will tell you, and ask you if you want the scan sent to a qualified health professional for review and any further medical treatment. You or your insurance company may have to pay for the review and any such treatment.

There may be risks, discomforts or side effects that are not yet known.

BENEFITS:

There is no direct benefit to you from taking part in this study. However, this research study may help us learn new things that may help other people in the future.

CONFIDENTIALITY:

We will keep information about you, including any research records we create, strictly confidential to the extent required by law.

We may be required to release your record if we receive a subpoena or a court order. The study staff will keep your study files locked in a file cabinet in a private office. We will use a study number rather than your name on study records when we can. Your name and other facts that might point to you will not appear when we present this study or publish its results. People other than those doing this research study may have access to your medical and study records including:

- Department of Veterans Affairs
- The Food and Drug Administration
- The Office for Human Research Protections (OHRP)
- The Government Accountability Office (GAO)
- The Office of Research Oversight (ORO)
- The Inspector General
- The Emory University Institutional Review Board and other offices in Emory University that help run and/or oversee studies
- The Atlanta VA Research Compliance Officer
- VA research staff within the VA Hospital or at Emory University (when data is stored at Emory)
- Any appropriate state or federal government agencies that make rules and policy about how research is done that are not listed above

If you are participating in a study where a test and/or procedure may be performed at Emory and you are not and have never been an Emory patient, you do not have an electronic medical record. Please note that an Emory medical record will be created if you have any services or procedures done by an Emory provider or facility for this study.

All research records and/or identifiers will be destroyed in accordance with the VA record retention schedule.

If you are a veteran who is a patient at the Atlanta VA Health Care System, a copy of your signed and dated consent and HIPAA forms may be placed in your medical record(s). If you are a non-veteran receiving clinical services (i.e., use of the laboratory, radiology, audiology, etc.) as part of this study, you will have an electronic medical record created for you. You will also be given a VA Notice of Privacy Practices (NOPP) and we will ask you to sign a form saying that you have received this notice.

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

COMPENSATION:

You will be compensated for your time to participate in this study. Payment will be made by direct deposit as follows: Visit 1 - $25, Visit 2 - $50, Visit 3 $75. If you have not set up direct deposit with the Atlanta VA, we will assist you to do so. You will be compensated $150 if you complete all sessions of the study. An extra $20.00 will be provided for sessions in which you provide your own transportation. If you drop out, are withdrawn by the investigator, or are otherwise unable to complete the study, compensation will be prorated for the number of sessions in which you participate.

You will get emergency medical care if you get injured from being in this study. Under Federal Law, you will qualify for follow-up treatment if the injury was related to the research study. You may or may not get further compensation if you are injured in this study. This rule would not apply if you do not

follow study procedures. If you believe you have been injured by this research, you should contact Dr. April Maa at (404) 321-6111 x 206660.

COSTS:
There will be no cost to you to participate in this study. Some Veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services that are not part of this study.

CONFLICT OF INTEREST:
None

CONTACT PERSONS: If you have any questions, concerns, or complaints about this study you can call a member of the study staff:

Kyle Hortman at (404) 321-6111 x 206566

If you have been harmed from being in this study call: Dr. April Maa at (404) 321-6111 x 206660

If you want to speak to someone who is not a member of the study to discuss problems, ask questions or voice concerns, you can call:

The Emory University Institutional Review Board (404) 712-0720 or toll free at 1-877-503-9797

Or

The Research Compliance Officer at (404) 321-6111 ext. 206964 or the Clinical Studies Center Director at (404) 321-6111 ext. 206933

If you have any questions about your rights as a participant in this research study, call the Emory University Institutional Review Board at (404) 712-0720 or toll free at 1-877-503-9797.

NEW FINDINGS:
We may learn new things during the study that you may need to know. We can also learn about things that might make you want to stop participating in the study. If so, you will be notified about any new information.

VOLUNTARY PARTICIPATION AND WITHDRAWAL:
Your participation is voluntary and you have the right to refuse to be in this study. You can stop at any time after giving your consent. This decision will not affect in any way your current or future medical care or any other benefits to which you are otherwise entitled. The study doctor, investigator, or sponsor may stop you from taking part in this study at any time if they decide it is in your best interest or if you do not follow study instructions.

(Continued on the next page.)

We will give you a copy of this consent form to keep. If you are willing to volunteer for this research, please sign below.

RESEARCH PARTICIPANT'S SIGNATURE AND DATE:

_____
Research Participant's name

_____ _____ _____
Research Participant's Signature Date Time
(to be entered by participant)

_____
Name of Approved Individual Obtaining Consent

_____ _____ _____
Signature of Approved Individual Obtaining Consent Date Time
(to be entered by Approved Individual)

An Approved individual is one who has completed HRPP training and is officially approved to consent subjects for this specific study. The signature and date of this individual certifies that this is the most current approved consent document for this study.