

UNIVERSITY OF WISCONSIN - MADISON

**Subject CONSENT to Participate in Research
And
AUTHORIZATION to Use and/or Disclose Identifiable Health information for
Research**

Protocol Title: Measuring Experience Dependent Changes in Brain Structure

Principal Investigator: Andrew L. Alexander, PhD

Phone: (608) 265-8233

Email: alalexander2@wisc.edu

Mailing Address: Waisman Center, 1500 Highland Ave., Madison, WI 53705

Invitation

You are being invited to participate in a research study that uses magnetic resonance imaging (MRI) to look at brain changes from playing a computer game. You are being invited because you were determined to be eligible based upon your responses to our recruitment materials. In particular, you are a healthy adult 18-24 years old, with no known visual or cognitive impairments, no experience with racecar or music video games over the past 4 years, and no musical experience over the past 4 years. This study will involve up to 80 individuals at the University of Wisconsin-Madison.

Your participation in these procedures is completely voluntary. If you decide not to participate, any relationship you have with the University of Wisconsin-Madison (UW-Madison) or the University of Wisconsin Hospitals and Clinics (UWHC) will not be affected in any way.

The procedures and the possible risks, discomforts and benefits of participation are described below. If you participate, you will receive a copy of this consent form to keep for your records.

What is the purpose of this study?

Recent studies suggest that MRI can detect changes in the brain after playing a computer game for roughly 90 minutes and these changes are affected by frequency and duration of training. This study will investigate how computer game training leads to brain changes over time. It will also assess new investigational brain imaging techniques for detecting changes in the brain.

What will my participation involve?

Participation in this study will require multiple sessions over roughly 4-6 weeks. All participants will undergo two cognitive testing sessions and three MRI brain exams. Some participants will be randomly assigned (like by a coin flip) to undergo multiple video game training sessions, while other participants (controls) will only do the brain imaging and cognitive testing.

Before you do any scans or cognitive testing, you will be asked a series of medical history questions to make sure you are safe to go into the scanner. If your medical history indicates that you are not safe to go into the scanner, you will not be allowed to continue in the study and your responses to the medical history questions will be destroyed. However, you will be compensated with one research point for your time.

Study Procedures:

MRI Scans: The MRI scanner will be used to collect detailed pictures of your brain. You will receive three MRI exams in total. The total time for each MRI exams will take 30-60 minutes. During the scanning it is essential for you to remain as still as possible to avoid blurring of your brain pictures. Your head may be held in place by foam padding to help you keep still. We will take several different types of brain pictures and each scan will take approximately 1-15 minutes. In some scans there is nothing for you to do or look at. You simply need to keep still. In other scans you will view short videos of video game play. Here you will need to pay attention to the videos. In between scans, you will be able to communicate to the scan operator through an intercom. The MRI will be performed at one of following University of Wisconsin locations: the Waisman Center, the Wisconsin Institutes for Medical Research (WIMR), or the UW Hospital.

Some of the MRI data will be acquired using investigational software and hardware in addition to the standard MRI technology. The investigational software and hardware enables newly developed features that are not yet FDA approved for clinical use.

Cognitive Testing: You will be asked to view visual stimuli (such as black and white lines, letters, digits, simple shapes like triangles, circles, and squares, photographs of real-world scenes, or video game scenes) presented on a computer or television screen and make some simple judgments about the stimuli (such as indicating whether the stimulus you observed is the same or different from that on a previous trial), by a button press on a keyboard, a mouse click, or a movement of the mouse.

Computer Game Playing: If you are in one of the video game groups, you will be asked to come into the lab and play a video game for roughly 90 minutes at 10 different sessions over the course of 4 weeks. You will be assigned to a specific game. Game performance may be recorded periodically over this period. You should try to do your best and improve your performance over this period. If you become tired while playing the game, it can be paused or stopped at any point.

Control Group: You will not have to come into the lab to play any of the video games. You should refrain from playing video games during the study period.

You will be informed whether or not you will play a video game before your first session.

Session Overview:

Video Game Participants:

Session 1 (Roughly 90 minutes):

- Consent process (explanation of the study – 30 minutes)
 - Cognitive Testing (60 minutes)
- Session 2 (Roughly 3 ½ hours)
- MRI Scan 1 (60 minutes)
 - Video game (90 minutes)
 - MRI Scan 2 (60 minutes)
- Sessions 3-11 (Roughly 90 minutes each spread over 4-5 weeks)
- Video game (90 minutes)
- Session 12 (Roughly 60 minutes)
- MRI Scan 3 (60 minutes)
- Session 13 (Roughly 60 minutes)
- Cognitive Testing (60 minutes)

Control Participants:

- Session 1 (Roughly 90 minutes):
- Consent process (explanation of the study – 30 minutes)
 - Cognitive Testing (60 minutes)
- Session 2 (Roughly 2 hours)
- MRI Scan 1 (60 minutes)
 - MRI Scan 2 (60 minutes)
- Session 3 (Roughly 60 minutes)
- MRI Scan 3 (60 minutes)
- Session 4 (Roughly 60 minutes)
- Cognitive Testing (60 minutes)

We will also collect the following additional information about you for this research study:

From You: We will need your birth-date, home address, phone number, e-mail address, race, sex, education. This information will be used to determine age, demographic information and also to be able to contact you if necessary. By signing this form, you are giving us permission to collect the information described above.

Are there any benefits to me?

There will be no direct benefit to you for your participation; however, the information gathered from this study will improve the understanding of how memory and learning are affected by training.

Will I be compensated for participating?

You will receive \$150 for completing the three MRI brain scans and final cognitive testing session. If you are randomly assigned to a video game playing condition, you will receive an additional \$10 for each video game session. The video gaming group participants will earn up to \$250, while control participants will earn up to \$150. If you decide to discontinue your participation in the study, you will be paid a prorated value based upon what you have completed.

Are there any risks involved?

Risks of MRI: Some people should not participate in MRI studies. These include persons with shrapnel or certain metallic implants, such as prostheses, or aneurysm clips, or persons with electronic implants, such as cardiac pacemakers or implanted hearing devices. You will be screened for metal or electronic implants. There are no other known risks to body tissues associated with the magnetic field strength used in this study. Some participants report some anxiety or claustrophobia in the MRI scanner since the head must be placed fully inside the scanner tube. If anxiety or claustrophobia occurs, please let us know and we will stop the scan and bring you out of the scanner. In addition, fatigue and physical discomfort are possible. The MRI scanner makes a great deal of noise and can also vibrate when taking images. To minimize the level of noise, you will be fitted with disposable earplugs or headphones to wear during the procedure. These may be a bit uncomfortable to wear, and will not eliminate all sound, so that communication with you is still possible.

Although there is no evidence that MRI scans can cause harm to a fetus, there may be risks to a fetus that are not known at this time. For these reasons, this study is not approved for the enrollment of pregnant women. You should only take part in this study only if you are certain you are not pregnant.

Female Participants: I confirm that I am not pregnant.

Signature

Risks of Video Game Playing: If you play the computer game, you may become fatigued or frustrated by difficulty. Some individuals may become nauseous, dizzy, or experience eye stress when viewing and/or interacting with simulated 3D objects on a large screen. Please remember that you may interrupt or terminate your participation for any reason, including discomfort, and can do so at any time.

Risks of Cognitive Testing: Some participants may find the cognitive tests stressful or frustrating. If this occurs, breaks in testing will be provided.

Risk of Breach of Confidentiality: Because your personal information will be retained, there is a small possibility that your information could become available to unauthorized persons. This risk is a concern because of the sensitivity of some of the study data, such as either incidental brain imaging findings or other health information. This could affect your employment or insurability. While there are laws against this, the laws do not apply to everyone and are difficult to enforce.

This is NOT a Substitute for a Clinical MR Exam:
These MRI exams will not be used to diagnose medical problems. This MR exam should not be used to replace a visit to your primary physician. If you are having

physical symptoms that you believe may be related to some disease, you should see your primary physician, who will then direct the order and types of studies required to arrive at a diagnosis. The images from your MR exam will NOT be placed in your medical record and a copy of the images will NOT be provided to you.

Possible Discovery of Unanticipated Findings

Whenever an MRI of the brain is conducted, there is the chance of an unexpected finding. You will be informed of all findings of clear clinical significance that may be revealed during the imaging procedure. Findings of clear clinical significance are those for which we generally know the risks of non-treatment and for which treatment may be available. In order to assist us in interpreting the results of your MRI, we are also seeking your permission to review your medical records, if available, for review by our clinical reader. You will not be informed of findings judged as not clinically significant by our clinical reader, thus you should not expect to receive any results.

There may be benefits to learning such results (early detection and treatment of a medical condition), but there are risks as well (problems with getting insurance or a job, or feeling worried about a finding for which no treatment is required or appropriate).

In the case of a detected finding of potential clinical significance, you will be contacted by the PI, who will advise you that a clinician will be in contact to discuss the findings. At that time, you may choose to have your physician informed of any findings of clinical significance that we report to you. You may provide the contact information for your primary physician below. Please note, however, that if you choose to have your physician informed of findings of clinical significance, that report will likely be placed in your medical records. We will discuss this with you at the time you are informed.

Physician Contact Information (Optional):

Name of primary physician

City or clinic

Health Care Provider

Are there any costs to participating?

You will not be charged for any procedures relating to your participation in this study.

Will compensation be made for any injury resulting from this research?

In the event that you are physically injured as a result of participating in this research, emergency care will be available. You will, however, be responsible for the charges for the emergency care. There is no commitment by the University of Wisconsin to provide any compensation for research-related injury. You should realize, however, that you have not released this institution from liability for negligence. Please contact Dr. Andrew

Alexander at (608) 265-8233 if you are injured as a result of participating in this research.

How will my privacy be protected and who will use my health information?

We have taken precautions to protect your information from a breach of confidentiality with the use of electronic security measures (e.g., passwords and file encryption). Additionally, paper files will be stored in a locked cabinet when not in use. Your data will be coded with a specific study number and only authorized study personnel will have access to individually identifiable information. To the extent permitted by law, your identity and your participation in this study will remain confidential.

The information collected from you during this study will be used by the researchers and research staff of the UW-Madison and its affiliates for this study. It may also be shared with others at the UW-Madison and outside the UW-Madison. Whenever possible your health information will be kept confidential.

Others at the UW-Madison, and its affiliates who may need to use your information in the course of this research:

- UW-Madison regulatory and research oversight boards and offices
- Accounting and billing personnel at the UW-Madison
- Research support services staff at the UW-Madison and its affiliates

Others outside of UW-Madison and its affiliates who may receive your information in the course of this research:

- Other researchers developing image analysis tools or conducting research relevant to dementia or aging
- Research oversight and regulatory agencies, such as the FDA.
- Companies associated with the MRI scanner hardware (e.g., General Electric Healthcare, Nova Medical)

People outside of the UW-Madison and its affiliated who receive your health information may not be covered by privacy laws and may be able to share your health information with others without your permission. This study, however, does not involve sharing any of your health information with individuals outside of the UW-Madison and its affiliates.

Data Banking

The data collected for this study will be banked for use in future research projects. Research data (including brain images, cognitive assessments, survey measures, and game performance measures) may be used for educational or training purposes by trainees or staff at UW-Madison. It may also be shared with academic, nonprofit developers of software tools for brain imaging or computer games, to allow for analyses to be replicated, or for unspecified future research. The results of this study may also be used for future medical and scientific publications. To protect your confidentiality data will be coded and identifiable information will be stored separately from the study data. Study data will be stored in secure offices and using secure electronic storage. Only de-identified data will be shared with outside researchers. Data sent to outside

researchers will be coded again so that it cannot be linked back to your identifiable information. There is no end date for the use of this data for these purposes. You can withdraw your data from this research at any point by contacting the PI.

Will commercial products be developed from my data?

Commercial products may be developed from the data collected from and about you for this research study. However, it is not expected that you will be able to share in the profits from commercialization of products developed from your data.

Is my permission voluntary and may I change my mind?

Your permission is voluntary. You do not have to sign this form and you may refuse to do so. If you refuse to sign this form, however, you cannot take part in this research study.

You may completely withdraw from the study at any time.

IF YOU DECIDE NOT TO PARTICIPATE IN THIS STUDY OR IF YOU STOP WHILE THE STUDY IS UNDERWAY, YOUR RELATIONSHIP WITH THE UW-MADISON AND ITS AFFILIATES WILL NOT BE AFFECTED IN ANY WAY.

How long will my permission to use my health information last?

By signing this form you are giving permission for your health information to be used by and shared with the individuals, companies, or institutions described in this form. Unless you withdraw your permission in writing to stop the use of your health information, there is no end date for its use for this research study. You may withdraw your permission at any time by writing to the person whose name is listed below:

Andrew Alexander, PhD

Professor
Department of Medical Physics
University of Wisconsin
School of Medicine and Public Health
Waisman Laboratory for Brain Imaging
1500 Highland Ave
Madison, WI 53705
(608) 265-8233
<http://www.waisman.wisc.edu/pi-alexander.htm>

Beginning on the date you withdraw your permission, no new information about you will be used. Any information or tissue that was shared before you withdrew your permission will continue to be used. If you withdraw your permission, you can no longer actively take part in this research study.

WHO SHOULD I CONTACT IF I HAVE QUESTIONS?

Please take as much time as you need to think over whether or not you wish to participate. If you have any questions about this study at any time, contact the Principal Investigator Andrew Alexander at (608)265-8233.

If you are not satisfied with response of research team, have more questions, or want to talk with someone about your rights as a research participant, contact the UWHC Patient Relations Representative at 608-263-8009 or University of Wisconsin Medical Foundation Patient Relations Representative at 800-552-4255 or 608-821-4819.

**AGREEMENT TO PARTICIPATE IN THIS STUDY
AND
PERMISSION TO USE AND/OR DISCLOSE MY HEALTH INFORMATION**

I have read this consent and authorization form describing the research study procedures, risks, and benefits, what health information will be used, and how my health information will be used. I have had a chance to ask questions about the research study, including the use of my health information, and I have received answers to my questions. I agree to participate in this research study, and permit the researcher to use and share my health information as described above.

YOU WILL RECEIVE A COPY OF THIS FORM AFTER SIGNING IT.

Please write in the date at the same time you sign your name.

Name of Participant (please print): _____

Signature of Participant

Date

Signature of Person Obtaining Consent

Date