Walter Reed Army Institute of Research
Consent for Research Participation

Title:	Computer-Based Cognitive Games, Personality, and Behavior Study.
Sponsor:	Center for Military Psychiatry and Neuroscience
Funder:	Military Operational Medicine Research Program RAD III, United States Medical Research and Development Command
Principal Investigator (PI):	Margeaux Auslander, Ph.D., WRAIR
Contact Info:	Phone: 301-319-7475/ Email:margeaux.v.auslander.mil@health.mil

You are being asked to take part in a research study. This study is supported by the United States Department of Defense. The box below tells you important things you should think about before deciding to join the study. We will provide more detailed information below the box. Please ask questions about any of the information before you decide whether to participate. You may also wish to talk to others (for example, your family, friends, or your doctor) about this study, before agreeing to join.

Please contact one of the investigators below if you have any questions concerning the study or if you have any other questions or concerns.

Primary: Margeaux Auslander, Ph.D. **301-319-7475**

Alternate: Phillip J. Quartana, Ph.D. **(301) 319-9777**

Key Information for You to Consider
• **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There are no penalties and you will not lose anything if you decide not to join or if after you join, you decide to quit. • **Purpose**. We are doing this research to find out if playing a computer word game can influence your decisions and performance on other cognitive and decision making tasks. We are also curious if there are individual differences on this, so you will also be asked to fill out some

personality questionnaires. We will recruit up to 200 volunteers to participate in this research study.

- **Duration.** Your part of the study will last about 90 minutes.
- **Procedures and Activities.** We will ask you to complete several personality and self-report questionnaires, three audio voice recordings, two computer-based tasks that assess your decision-making and reaction time by having you respond to words and images on the computer screen by typing or pressing computer keys, and write a personal essay. One of the computer tasks is a game that involves administering loud acoustic (noise) tones via headphones as well as selecting the intensity and duration of such tones for another player.
- **Risks.** Most studies have some possible harms that could happen to you if you join. In this study, you may experience boredom, frustration, embarrassment, and/or anger as a result of participating in the study tasks. This study also involves experiencing repeated unpleasant acoustic (noise) tones via headphones. The maximum volume you could be exposed to is 97dBs. For context, 60 dBs is approximately the volume of a normal conversation and 100dBs is approximately the volume of a car horn at 16 feet —105dBs is typically the maximum volume for personal listening devices. These tones would last up to 2 seconds each and be repeated throughout a period of about 10 minutes. Finally, there is a risk of breach of confidentiality. However, we mitigate this risk by not associating your name with any particular set of data and securely storing all files. Further, data are only published in aggregated form (only overall findings from the study are published; individual responses/data are not shared with parties outside the research team).
- **Benefits**. You will not receive any direct benefits for participating in this study. You may have the satisfaction of knowing you contributed to the understanding of psychological science and you will be given resources at the end of the study to help you better understand the science behind what we are researching. This research can also benefit society by helping psychological scientists better understand how playing cognitive games affects thinking and emotions, which can help guide better treatments for behavioral health issues.
- **Alternatives.** Participation is voluntary and the only alternative is to not participate.

What will happen if I decide to be in this research study?

If you agree to be in this research, you will complete the following research activities during your single visit:

1. Complete personality questionnaires.
2. Write a persuasive essay expressing your opinion on a topic to be shared with another person for feedback.

3. Complete mood questionnaires.
4. Complete a word completion task on the computer. For this task, you will be presented with incomplete word fragments and you will be given instructions on how to fill in the blanks to create complete words.
5. Complete a competitive reaction time game on the computer where you will compete against another player. In each round, you will respond to images on the screen by pressing a key or clicking the mouse. The slower player will receive a loud tone (white noise) administered via headphones. You will set the volume and duration of the tone for the other player.
6. Answer some basic demographic questions and questions about your perception of the study procedures.
7. Three audio recordings will be taken of you reading a standardized script.

For the computer word game, you will be randomly assigned to one of two groups, known as "randomization." Randomization is a process like flipping a coin and means that you could be assigned to either of the groups. Both groups will complete the same basic computer game, but will vary based on the types of words players are told to create in the instructions.

Research Eligibility:

You may be allowed to participate in the study if you meet the following criteria:

1. Between the ages of 18 and 39 (inclusive).
2. Of normal hearing without the use of a hearing aid.
3. Achieve a score of 100% on a comprehension quiz making sure you read and understood the material presented in this document.
4. Fluent in the English language (read, write, speak).

You are not allowed to participate in this study if any of the following criteria apply to you:

1. You wear a hearing aid or other hearing assistive device.
2. You have any condition that produces a strong sensitivity to sound (e.g., misophonia, hyperacusis) or to your knowledge are highly sensitive to sound (e.g., you are unable to listen to music through headphones with the volume on high without experiencing pain or significant discomfort).

What happens to the information collected for this research?

Information collected from you for this research will be analyzed by scientists to help answer our research hypotheses.

We may use the data collected as part of this study in future research. In such instances, these data would be reanalyzed as secondary data analysis to test hypotheses (scientific ideas) that were not considered during the original design of the research study. It is possible we may share this data with other institutions and/or researchers as a part of this process. In such instances, we would first establish

agreements with those institutions/researchers to protect your confidentiality. Personally identifiable information will not be shared. We will not attempt to notify you if any of the activities described in this paragraph occur.

We may share your research data with other investigators without asking for your permission; it will not contain information that could directly identify you.

The overall results and findings from this study may, at your request, be shared with you if they are part of a publicly released publication. You may contact the principal investigator to receive a copy of this report if/when it is produced.

We plan to submit the findings of this research for publication in scientific journals and scientific presentations. Individual responses and data will not be shared. These reports and/or presentations will only contain anonymized aggregated data.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. Additionally, a copy of the informed consent form may be posted to a public website no later than 60 days after enrollment is completed.

With your consent, we may use your contact information to reach out to you about future opportunities to participate in research.

How will my privacy and data confidentiality be protected?

We will take measures to protect your privacy. Even with these measures, we can never fully guarantee your privacy will be protected. We will try our best to protect your privacy by doing the following:

The only document that will have your name and link you to this study is this document (the informed consent document) and a form we are required to complete to process your payment. This form requires us to collect your Social Security Number or tax payer ID in order for our bank to issue your compensation payment.

With your permission, we may also add your contact information to a registry to contact you about other opportunities to volunteer for research studies with us.

However, these documents will not be connected to any specific set of data from this study. Further, these documents will remain confidential. Data files and study documents will not contain your name. Instead your data will be identified only by a number that is not linked to your name or based on any personally identifiable information.

While we will do our best to protect your information, we can never guarantee that a breach of confidentiality cannot occur.

Once the study is complete, your records will be kept in a safe and secure storage for at least five years, at the Walter Reed Army Institute of Research. Records will be

maintained until it has been deemed no longer necessary to retain them by the study Sponsor, the Center for Military Psychiatry and Neuroscience at the Walter Reed Army Institute of Research, and then destroyed as per applicable regulations. Any future research using your data will require a research protocol and approval by an Institutional Review Board (IRB) (a committee responsible for protecting research participants) or other authorized official responsible for protecting human subjects in research studies. For instance, an IRB reviewed and approved this current study that you are taking part in. The data protections for privacy and confidentiality described in this document will apply to any future use of your stored data and samples.

As all data will be de-identified following volunteer participation, it will not be possible for us to identify and delete your specific data after you complete your participation. If, for any reason, you decide today that you do not want us to use your data for research purposes, please inform the experimenter before leaving today. You will be offered a formal opportunity to withdraw your data at the end of today's session.

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

Yes, for your participation, you will receive $100. In order for our bank to process this payment, you will need to provide a social security number or tax payer ID number. This is because the bank is required to report payments over a certain amount to the IRS and issue you a tax form.

Other than payment specifically stated in this informed consent, there is no other compensation available for your participation in this research study; however, you should also understand that this is not a waiver or release of your legal rights.

Are there costs for participating in the research?

No, there are no costs to you for taking part in this research study.

Are there disclosures of financial interests or other personal arrangements from the research team?

No.

What happens if I withdraw from this research?

You may withdraw from this study at any time. If you choose to leave the study, data collected prior to your withdrawal may, with your permission, be used by the study. You will be asked for your permission to use any data that you have provided up to that time. You must make your decision at that time as we would be unable to identify your data for deletion after you leave the laboratory (as no personally identifiable information will be stored with data).

You may withdraw your consent at any time and stop participating in this research study. Leaving the study will not impact your ability to receive benefits that you would have received otherwise. Should you choose to withdraw, you should inform the experimenter.

The principal investigator, CPT Margeaux Auslander, or another study staff member assisting you during the study, may decide not to allow you to continue participating in this study under the following conditions:

- If you disclose health conditions that would make it dangerous to you or others if you were to continue participating
- If other situations or conditions arise that would make participation harmful to your own health or wellbeing,
- If you fail to comply with the procedures as outlined in this form.
- At the discretion of the study staff.

Who can I contact if I have questions about my rights as a research participant?

If you have questions about your rights as a research volunteer in this study, you may contact the Human Subjects Protection Branch, Walter Reed Army Institute of Research 503 Robert Grant Avenue, Silver Spring, MD 20910, phone number 301-319-9940 and email usarmy.detrick.medcom-wrair.mbx.hspb@health.mil.

SIGNATURE OF PARTICIPANT

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT
(Can only be signed by an investigator or staff approved to administer consent)

_____
Printed Name of Administering Individual

_____ _____
Signature of Administering Individual Date