

STUDY TITLE: Key Dimensions of Posttraumatic Stress Disorder and Endothelial Dysfunction

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CONSENT TO PARTICIPATE IN RESEARCH

Key Dimensions of Posttraumatic Stress Disorder and Endothelial Dysfunction

Jennifer Sumner, PhD, from the Department of Psychology at the University of California, Los Angeles (UCLA) is conducting a research study.

You were selected as a possible participant in this study because you have successfully met the eligibility requirements for participation in this study during the phone screening and have agreed to attend this in-person visit.

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We invite you to take part in this research study because you:

- Have been exposed to a traumatic event
- Are age 18 years or older
- Speak English
- Do not have cardiovascular disease (CVD)

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

We are doing this research to examine how aspects of trauma exposure and posttraumatic stress disorder (PTSD) may be related to endothelial dysfunction, a measure of heart health. PTSD is a mental health condition that is triggered by witnessing or experiencing a shocking, scary, or dangerous event. Symptoms can include having flashbacks, nightmares, and unwanted distressing thoughts about the event, startling easily, and feeling emotionally numb. Endothelial dysfunction, on the other hand, occurs when the inner lining of blood vessels fails to function normally. Both PTSD and endothelial dysfunction are associated with the onset of cardiovascular disease (CVD), one of the leading causes of death in the United States. This study will try to identify aspects of PTSD that can be targeted to reduce the risk of CVD by figuring out which aspects of PTSD are associated with endothelial dysfunction.

How long will the research last and what will I need to do?

We expect that you will be in this research study for approximately 1 month. In addition, there is an optional follow-up visit 2 years later.

For this research study, you will be asked to complete two study visits: 1) an interview assessment that asks about your emotional responses to trauma and your physical health and 2) a lab visit that will measure your blood pressure, blood vessel function, height, and weight and collect urine and blood samples (about 2-3 tablespoons of blood will be collected). In addition, you will complete tasks that collect your responses to shapes and sounds and measure your attention to faces.

You will also have the opportunity to complete an optional 2-year follow-up where you will answer questions about your emotional and physical health and repeat the lab visit procedures.

More detailed information about the study procedures can be found under ***“What happens if I say yes, I want to be in this research?”***

Is there any way being in this study could be bad for me?

There is the possibility that you might experience some feelings of distress or frustration during the study, but these are generally mild and go away quickly. In addition, there may be some discomfort when the blood pressure cuff inflates, however this feeling is usually short-lived. Drawing blood may cause temporary pain from the needle stick, bruising or swelling at the site, and rarely, infection or fainting. Loss of confidentiality (having your personal information shared with someone who is not on the study team) is also a possibility. However, the study team plans to protect your confidentiality.

More detailed information about the risks of this study can be found under ***“Is there any way being in this study could be bad for me? (Detailed Risks)”***

Will being in this study help me in any way?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include helping to prevent CVD in trauma-exposed individuals with PTSD.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate. Your alternative to participating in this research study is to not participate.

Detailed Study Information***Why is this study being done?***

We are doing this research to examine how exposure to trauma and stress may be related to physical health. Specifically, we are looking at how these experiences and aspects of posttraumatic stress disorder may play a role in heart health. PTSD is a mental health condition that is triggered by witnessing or experiencing a shocking, scary, or dangerous event. Many people who go through traumatic events may have temporary difficulty adjusting and coping, but over time usually get better. However, if the symptoms get worse, last for months or even years, and interfere with day-to-day

functioning, the individual may have PTSD. Symptoms can include having nightmares, and unwanted distressing thoughts about the event, startling easily, and feeling emotionally numb. Our measure of heart health is endothelial dysfunction, which occurs when the inner lining of blood vessels fails to function normally. It is known that both PTSD and endothelial dysfunction are associated with the onset of CVD, one of the leading causes of death in the United States. This study will try to identify aspects of PTSD that can be targeted to reduce the risk of CVD and more specifically, figure out which aspects of PTSD might trigger endothelial dysfunction. This study is sponsored by the National Institutes of Health.

What happens if I say, yes, I want to be in this research?

If you volunteer to participate in this study, the researcher will ask you to do the following:

Interview Assessment

- Complete an interview assessment via Zoom where you will be asked to:
 - Answer questions about possible PTSD, as well as other aspects of your emotional experience (e.g., depression) and information about family history (e.g., parental education, family history of CVD), medical history (e.g., diabetes, hypertension), medications (e.g., medications for high cholesterol, hypertension, and diabetes, antidepressants, vitamins), and health behaviors (e.g., cigarette smoking, physical activity, alcohol use). The interview may be recorded for research records but you can opt out if you choose.
 - Complete questionnaires about socio-demographic information (e.g., age, gender, race, ethnicity, marital status, education) and experiences in your family growing up (e.g., your relationship with your primary caregiver).

Lab Visit

- Complete a lab visit at the UCLA Department of Psychology that includes the following:
 - Research personnel will measure your height, weight, and hip, waist, and arm circumference, obtain a resting clinic blood pressure from you, and collect a blood sample. The blood sample will be taken by research personnel trained in phlebotomy from a vein in your arm and will total approximately 2-3 tablespoons. You will also be asked to collect a urine sample at home on the morning of this visit. The blood and urine samples will be used to examine cardiovascular risk markers, such as inflammation and oxidative stress.
 - A flow-mediated dilation (FMD) test will be done. Developed in 1992, the FMD test is the most commonly used non-invasive assessment of vascular endothelial function in humans, using ultrasound to create images of the inner lining of your blood vessels. (Ultrasound is a safe and painless scan that uses sound waves to create pictures of your organs or internal body structure.) To complete this assessment, you will be asked to lie down on an exam bed and an appropriate-sized blood pressure cuff will be placed around your right forearm. After a 15-minute rest, an ultrasound scan of an artery in your upper arm will be taken. Next, the blood pressure cuff will be inflated slightly for 5 minutes. The ultrasound image of the artery will be recorded continuously until 5 minutes after cuff deflation.

- You will be given a snack.
- Your heart rate will be measured with an electrocardiogram (ECG). An ECG is a quick, safe, and painless test that records the electrical activity of your heart through small electrode patches that research personnel will attach above your right collarbone and left wrist. You will then rest for 5 minutes and do a breathing task.
- You will complete two tasks. One task will examine your responses to shapes and sounds. You will be asked to sit in front of a computer screen and wear headphones. Colored shapes will appear on the computer screen, and you will be asked to focus on the images while also listening to sounds through the headphones. At specified times, the sound may become louder, and you will also sometimes experience a sudden puff of air directed toward your throat. The response of your body to the sudden sound or puff of air will be assessed via electromyography (EMG) and electrodermal activity (EDA), which evaluate and record the electrical activity produced by the skeletal muscles in your face (EMG) and by your skin (EDA).
- You will also be asked to complete an attention task. Once again, you will be seated in front of a computer screen and asked to view groups of happy and sad faces. A remote high-speed eye-tracker will be used to measure your level of attention. Upon finishing this task, the lab visit is considered complete.

Optional 2-Year Follow-up Lab Visit

- You will have the opportunity to return to the UCLA Department of Psychology in 2 years for a follow-up lab visit to undergo questions and repeat all of the lab procedures. This follow-up visit is completely optional and not a mandatory part of the overall study.

How long will I be in the research study?

Participation in the interview assessment will take approximately 2-3 hours and participation in the lab visit will take approximately 4 hours. The interview assessment and lab visit will take place on separate days about 2-3 weeks apart.

Participation in the optional 2-year follow-up lab visit will take approximately 4 hours.

Is there any way being in this study could be bad for me? (Detailed Risks)

- There may be risks or discomfort if you take part in this study. These may include some feelings of distress or frustration, but these are generally mild and go away quickly. If you feel upset, or continue to feel upset, a member of the research team will be available to talk to you and discuss appropriate care.
- The risk of blood pressure measurement may include discomfort when the blood pressure device inflates, however this feeling is usually short-lived. In rare cases, bruising can occur as a result of cuff inflation.
- Drawing blood may cause temporary pain from the needle stick, bruising or swelling at the site, and rarely, infection or fainting.
- The computer task involving the sudden puff of air is intended to be startling but not painful, and it has safely been used in multiple prior studies with both children and adults.

- A risk of taking part in this study is the possibility of a loss of confidentiality. Loss of confidentiality includes having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your confidentiality. These plans for keeping your information private are described below under ***“Will information about me and my participation be kept private?”***

Are there any potential benefits if I participate?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include helping to prevent CVD in trauma-exposed individuals with PTSD.

What other choices do I have if I choose not to participate?

Participation in research is completely voluntary. Your alternative to participating in this research study is to not participate.

Will I be paid for participating?

- You will receive \$50 for completion of the interview assessment and \$175 for completion of the lab visit. Reimbursement for travel to UCLA (\$20) is available for the in-person visit.
- If you agree to the optional 2-year follow-up lab visit, you will receive \$175 for completion of that lab visit. Again, reimbursement for travel to UCLA (\$20) is available.

Will information about me and my participation be kept confidential?

The research team will do their best to make sure that your private information is kept confidential, and study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security. The research team will carefully follow the coding, storage, and data sharing plan explained below.

Your questionnaire responses, samples, and the data collected about you will be assigned a code number. The research file that links your name to the code number will be kept in a locked file cabinet and only the investigator and study staff will have access to the file.

The research team, authorized UCLA personnel, and the study sponsor (the National Institutes of Health) may have access to study data and records to monitor the study. Research records provided to authorized, non-UCLA personnel will not contain identifiable information about you.

The Principal Investigator plans to share de-identified data collected as part of this study on data-sharing websites used by researchers called The Open Science Framework and ClinicalTrials.gov. None of your identifiable information will be included; all shared

data will be de-identified. Additionally, publications and/or presentations that result from this study will not identify you by name.

To help us protect the privacy of your specimens and information, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to release your specimens or information about you for any legal proceeding, even if a court of law asks. The Certificate allows us to use your specimens and information about you for the purposes of this research. There are limits to this protection. The Certificate does not protect your information when:

- You or your family voluntarily release information about yourselves.
- You consent to release of information (for example, the uses described in this form, or if you sign release forms for employment, insurance, or medical care).
- A federal agency (for example, the National Institutes of Health) audits or evaluates research that it funds.
- The researchers are required by law to disclose information about incidents such as child or elder abuse or the intent to hurt yourself or others.

Mandated child or elder abuse reporting: Under California law, the privilege of confidentiality does not extend to information about sexual or physical abuse of a child or elderly adult. If any member of the research team has or is given such information, he or she is required to report it to the authorities. The obligation to report includes alleged or reasonably suspected abuse as well as known abuse.

Use of data and specimens for future research:

1. My data and/or specimens may be kept for use in future research to learn about, prevent, or treat other health-related problems (for example, PTSD, CVD).

YES	NO
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2. My blood samples may be stored for future genetic analyses. I will not be required to provide an additional blood sample for this. The samples may be used for future research on the genetic determinants of PTSD and endothelial dysfunction. The results of any future genetic analyses done on the samples will not be given to you because the tests are considered experimental and the clinical significance of the analyses is not yet known.

YES	NO
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Contact for future research:

1. I am interested in being contacted for the 2-year follow-up lab visit.

YES	NO
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2. UCLA researchers may contact me in the future to ask me to take part in other research studies.

YES	NO
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What other things should I consider before participation?

Use of specimens:

Any specimens (e.g., blood, urine) obtained for the purposes of this study will become the property of the University of California. Once you provide the specimens you will not have access to them. The University may share your specimens in the future with other researchers or outside institutions. Information that identifies you will not be shared with anyone outside of UCLA. The specimens will be used for research and such use may result in inventions or discoveries that could become the basis for new products or diagnostic or therapeutic agents. In some instances, these inventions and discoveries may be of potential commercial value and may be patented and licensed by the University. You will not receive any money or other benefits derived from any commercial or other products that may be developed from use of the specimens.

The information collected as part of this study is being obtained for research purposes only. The data are not being collected for clinical purposes and will not be provided to you.

What are my rights if I take part in this study?

- You can choose whether or not you want to be in this study, and you may withdraw your consent and discontinue participation at any time.
- Whatever decision you make, there will be no penalty to you, and no loss of benefits to which you were otherwise entitled.
- You may refuse to answer any questions that you do not want to answer and still remain in the study.

Who can I contact if I have questions about this study?

- **The research team:**

If you have any questions, comments or concerns about the research, you can talk to the one of the researchers. Please contact:

Dr. Jennifer Sumner (Principal Investigator) at jsumner@psych.ucla.edu or (310) 825-2961

- **UCLA Office of the Human Research Protection Program (OHRPP):**

If you have questions about your rights as a research subject, or you have concerns or suggestions and you want to talk to someone other than the researchers, you may contact the UCLA OHRPP by phone: (310) 206-2040; by email:

participants@research.ucla.edu or by mail: Box 951406, Los Angeles, CA 90095-1406.

Public Information about this Study

ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. A description of this research study 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.

You will be given a copy of this information to keep for your records.

SIGNATURE OF STUDY PARTICIPANT

Name of Participant

Signature of Participant

Date

SIGNATURE OF PERSON OBTAINING CONSENT

Name of Person Obtaining Consent

Contact Number

Signature of Person Obtaining Consent

Date