Fostering Resilience to Race-Based Stress: A Pilot Study

NCT05422638

November 9, 2022

Study Title: Fostering Resilience to Race-Based Stress

Principal Investigator: Ariel J Lang, PhD, MPH

VA Facility: VA San Diego HCS

Participant Name:	Date:

STUDY SUMMARY

You are being asked to participate in a research study. This section summarizes key information about this study to assist you, or your legally authorized representative, in understanding the reasons why you may or may not want to participate in the research. Your participation is voluntary. You may refuse to participate or withdraw at any time. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer. Carefully review this section and the detailed information that follows before you agree to participate.

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?
This study is about promoting wellness and empowerment among Veterans who have experienced race-based stress. It is being funded by the Department of Veterans Affairs. By doing this study, we hope to learn about Veterans' reactions to interventions that are intended to reduce the physical and emotional toll of race-based stress.

WHAT DOES THE STUDY INVOLVE AND HOW LONG WILL IT LAST?
You will be asked to complete a set of questionnaires and give blood, urine and saliva samples before and after attending an 8-week group in which coping with race-based stress will be discussed. Your participation in this research will last about 3 months.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?
There may or may not be any benefit to you from participating this study. Your participation, however, will help the researchers understand the best ways to help Veterans maintain wellness under difficult circumstances.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?
Talking about experiences of discrimination and giving samples of bodily fluids can be uncomfortable. A complete description of risks is included in the Research Details Study Risks section.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?
The person in charge of the study is Dr. Ariel Lang of the VA San Diego Healthcare System. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is: 858-552-8585 x5359.

RESEARCH DETAILS

WHO IS CONDUCTING THIS RESEARCH AND WHY?

Study Title: Fostering Resilience to Race-Based Stress

Principal Investigator: Ariel J Lang, PhD, MPH

VA Facility: VA San Diego HCS

Ariel J Lang, PhD, MPH and Clarice Wang, PhD are asking for your consent to this research. They are conducting this study in collaboration with Dr. Maurice Endsley of the Northern California VA and Dr. Keisha Ross of the St. Louis VA. This study is being sponsored by the VA Office of Research and Development.

The purpose of the research is to examine interventions to help Veterans care for and empower themselves in the face of race-based stress. You are being asked to participate because you identify as coming from a racially/ethnically minoritized group and may be experiencing stress related to discrimination. Approximately 60 people will take part in this research at this facility.

FOR HOW LONG WILL I BE IN THE STUDY?

Your individual participation will take approximately 3 months. This will include an initial evaluation that will take 60-90 minutes, 8 weekly group meetings of 90 minutes each and a final evaluation that will take 60-90 minutes.

WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?

1. You will be assessed for eligibility for the study based on your responses to a set of questionnaires. If you are eligible, you will continue to step 2. If not, your participation will be end.
2. You will complete an initial evaluation on a computer at home or at the VA that includes questions about your lived experiences and physical and mental health. You will also give a blood, urine and saliva samples at the VA laboratory. This step generally takes 60-90 minutes. You can skip any question that makes you uncomfortable and you can stop at any time.
3. You will be randomly (as if by the flip of a coin) assigned to one of two types of interventions to help people cope with the stress of discrimination. The intervention will be led by a trained professional using videoconferencing. It will consist of 8 weekly 90-minute sessions with some between-session activities to complete on your own. The groups will be audio-recorded for review by experts in these types of interventions.
4. You will complete a second evaluation on a computer at home or at the VA that includes questions about your lived experiences and physical and mental health. You will also give a blood, urine and saliva samples at the VA laboratory. As in step 2, this generally takes 60-90 minutes, and you can skip any question and can stop at any time.

If you are pregnant, please let us know. There is no known risk to you or your unborn child, but we will not collect blood, urine or saliva samples because pregnancy-related changes in your body will change the lab values.

If you choose to participate, you will be asked to:

-Keep your study appointments. If you miss an appointment, please contact the investigator or research staff to reschedule as soon as you know you will miss the appointment.
-Tell the investigator or research staff if you believe you might be pregnant.
-Complete your questionnaires as instructed.
-Be actively involved in the group meetings, be respectful of your peers' opinions, and complete between-session assignments.

-Ask questions as you think of them.
-While participating in this research study, do not take part in any other research project without approval from the investigators. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

WHICH PROCEDURE/S OR TREATMENT/S ARE DONE FOR RESEARCH?

All procedures are done for research purposes only.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Any study has possible risks and discomforts. The procedures in this study may have all, some, or none of the risks listed. Rare, unknown, or unexpected risks also may occur.

- Some people become uncomfortable at being asked questions about their lived experiences and health. If, for any reason, you wish not to answer specific questions or you wish to terminate the session, you will be able to do so.
- Having blood drawn and providing urine samples can be uncomfortable. There may be some discomfort, bruising, or bleeding at the site where the blood is drawn. Rarely, fainting occurs because of drawing blood. VA providers, however, are trained to maintain your safety and to help you feel as comfortable as possible.
- Engaging in group discussions about the stress of racism can be uncomfortable. A trained provider will be present to help with the conversation. If you have any concerns about the group, please raise them with your group leader.
- Loss of confidentiality is always possible when participating in research. The study team will take a number of steps to protect your privacy, including identifying your responses by code numbers and storing all records behind the VA firewall.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

The study team has explained that by signing this Informed Consent Document, you voluntarily and without separate compensation authorize voice recordings to be made of you by the study team while you are participating in this study. You also authorize disclosure of the voice recording to Dr. Maurice Endsley of the Northern California VA and Dr. Keisha Ross of the St. Louis VA. The said voice recording is intended for these experts to ensure that the groups are being led appropriately. The recordings will be destroyed following VA procedures after they are reviewed.

The study team has also explained that you will not receive any royalty, fee or other compensation for such use. If you refuse to grant consent, there will be no effect on any VA benefits to which you may be entitled. You may at any time exercise the right to cease being recorded.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this research study. However, a possible benefit is that it may be helpful to discuss stressful experiences with other Veterans who have had similar experiences. The information we get from this study might help to create programs to help other Veterans who have experienced racism.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

While you are a participant in this study, you will be notified if any important new information is found that may affect your willingness to continue.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

The VA will provide necessary medical treatment should you be injured as a result of participating in this study and following study procedures. You will be treated for the injury by the VA at no cost to you or your insurance but no additional compensation is available.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

Dr. Ariel Lang at 858-552-8585 x5359 or Dr. Clarice Wang at 760-643-4485.

DO I HAVE TO TAKE PART IN THIS STUDY?

Taking part in this research study is your decision. Your participation in this study is voluntary. You do not have to take part in this study, but if you do, you can stop at any time. You have the right to choose not to participate in any study activity or completely withdraw from continued participation at any point in this study without penalty or jeopardy to the medical care you will receive at this institution or loss of benefits to which you are entitled.

If you are a VA employee or student, refusal to take part in the study will in no way influence your employment, ratings, subsequent recommendations, or academic progress as applicable.

If you withdraw from the study, the investigator may continue to review the data already collected for the study but cannot collect further information, except from public records. Specimens already used cannot be withdrawn.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

The investigator may end your participation if you do not keep appointments or if you do not respect group rules, such as being respectful and keeping the discussions private.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

There will be no costs to you or your insurance for any procedures or testing done only as part of this research study. If you receive a bill for services that you think could be related to your participation in this study, you should contact Dr. Lang.

Medical care and services provided by the VA that are not part of this study (e.g., normal hospital and prescription expenses which are not part of the research study) may require co-payments if your VA-eligibility category requires co-payment for VA services.

WHAT COMPENSATION WILL I RECEIVE IF I TAKE PART IN THIS STUDY?

You will receive $50 for the initial evaluation and $50 for the second evaluation. This payment will be made directly to your bank account using electronic funds transfer. If you currently have a debt to the Federal Government, your debt may be subtracted from your funds transfer payment for study participation.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have any questions, complaints, or concerns about the research or other related matters, you may contact Dr. Lang at 858-552-8585 or the Research Team at 619-306-9476.

If you have any questions or concerns about your rights as a research subject, the validity of a research study, or research personnel you can contact the Research Compliance Officer at 858-642-3817, VA Research Service at 858-642-3657, VA Regional Counsel at 858-642-1540, or the VASDHS Institutional Review Board at 858-642-6362. This is the Board that is responsible for overseeing the safety of human participants in this study.

HOW WILL MY SPECIMENS BE USED?

Your bodily fluids will be used to study "allostatic load," which is a term for stress-related bodily changes. The VA laboratory will run an A1C test (this is a standard blood test that measures your average blood sugar levels over the past 3 months), a complete blood count (CBC) and a lipid panel (cholesterol test). If any critical values (abnormally high or low) are found, your primary care provider will be notified, and you will be advised to follow-up with them. Additionally, your blood, urine and saliva will be coded with a label that does not directly identify you and will be transported to our collaborator's laboratory at UCSD for additional testing. Once tests are completed on these samples, any remaining fluids will be safely disposed.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Participation in this study may involve a loss of privacy, but information about you will be handled as confidentially as possible. If you are not already a VA patient, a medical record including your name and Social Security number will be entered in the VA Computerized Patient Record System.

Your social security number will be collected to access your medical chart and so that we may provide payment to you.

Your research records will be labeled with a code number. The list that matches your name with the code number will be kept in a locked file in the research team's office. Any research records that identify you will be kept only as paper records in a secure VASDHS location, or as files behind the secure VASDHS computer firewall.

Your information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

We will include information about your study participation in your medical record. These chart notes will state that you have completed in an assessment or intervention session but will not describe your responses, experiences or opinions except in cases of safety concerns or mandated reporting. These chart notes will not affect your VA healthcare.

We will keep confidential all research and medical records that identify you to the extent allowed by law. However, you should know that there are some circumstances in which we may have to show your information to other people. For example, the Federal Office of Human Research Protections, the General Accounting Office, the VASDHS R&D Committee, the VASDHS Institutional Review Board, the VA Office of Research and Development, and federal compliance officers may look at or copy portions of records that identify you.

While this study is being conducted, you will have access to your research related health records. This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

Any presentations or publications from this information will not identify you.

Study Title: Fostering Resilience to Race-Based Stress

Principal Investigator: Ariel J Lang, PhD, MPH

VA Facility: VA San Diego HCS

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

You have been informed that you do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled.

The study coordinator or clinical research associate has explained the study to me. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

By signing this document below, I voluntarily consent to participate in this study. I also confirm that I have read this consent, or it has been read to me. I will receive a copy of this consent after I sign it. A copy of this signed consent will also be put in my medical record.

I agree to participate in this research study as has been explained in this document.

_____ _____
Participant's Signature Date

_____ _____ _____
Signature of Researcher obtaining consent Name (print) Date

A copy of this document will be provided to the research participant.

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Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this document, you provide your permission called your 'authorization,' for the access, use, and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect and use information learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, information from your medical records such as lab results, and voice recording of group meetings in which you participate.

The research team may also need to share your health information and the information it collects to other entities as part of the study progress. This includes sharing the voice recording of your group meetings with VA providers who are experts in each group type. Other VA entities may include the VA Office of Research Oversight (ORO).

Your health information disclosed outside the VA as described in this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you may (a) write to the Release of Information Office at this facility; (b) ask a member of the research team to give you a form to revoke the authorization; or (c) send your written request to the Principal Investigator for this study at the following address: 3350 La Jolla Village Dr. (MC 111N1), San Diego, CA 92161.

If you revoke this authorization, Dr. Lang and her research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

While this study is being conducted you will have access to your research-related health records.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization.

Unless you revoke (take back) your permission, your authorization to allow us to use and/or disclose your information will expire at the end of this research study.

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AGREEMENT TO AUTHORIZE USE AND RELEASE OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION

By signing this document below, I give my authorization (permission) for the use and disclosure of my individually identifiable health information as described in this document. This authorization has been explained to me and I have been given the opportunity to ask questions. If I believe that my privacy rights have been compromised, I may contact the VHA facility Privacy Officer to file a verbal or written complaint. I will be given a signed copy of this document for my records.

_____	_____	_____
Participant's Signature	Last 4 of SSN	Date

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EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

You have been asked to participate as a subject in medical research.
You have the right to know:

1) The nature and purpose of the study.
2) The procedures in the study and any drug or device to be used.
3) Discomforts and risks reasonably to be expected from the study.
4) Benefits reasonably to be expected from the study.
5) Alternative procedures, drugs, or devices that might be helpful to you and their risks and benefits.
6) Availability of medical treatment should complications occur.
7) You may ask questions about the study or the procedure.
8) You may quit the study at any time without affecting your future care at the VA.
9) You should be given a copy of the signed and dated written consent form for the study.
10) Your consent to participate must be given freely, without being obtained through deceit, force, or coercion.

If you have any questions or concerns about your rights as a research subject please contact the VASDHS Research Compliance Officer at (858) 642-3817 or RCO@vapop.ucsd.edu. You may leave an anonymous comment at the VASDHS research compliance hotline at 858-642-6311.

REF: California HSC 24170-24179.5