The Impact of Modifiable Psychosocial Factors on Veterans' Long-term Trajectories of Functioning and Quality of Life: Promoting Recovery by Targeting Mindfulness and Psychological Flexibility (Study Evaluating Returning Veterans Experienced: Post-Deployment Functioning (Project SERVE))

NCT03615222

v. 08/05/2020

Department of Veterans Affairs	RESEARCH CONSENT FORM		
SUBJECT NAME		DATE (MM/DD/YYYY)	
TITLE OF STUDY	*Project SERVE: Post-Deployment Functioning Phase 3 (Project SERVE: FX3)*		
PRINCIPAL INVESTIGATOR	**Suzannah Creech, Ph.D.**	VAMC	**CTVHCS**

DESCRIPTION OF RESEARCH BY INVESTIGATOR **1.** Purpose of study and how long it will last: **2.** Description of study including procedures to be used: **3.** Description of procedures that may result in discomfort or inconvenience: **4.** Expected risks of study: **5.** Expected benefits of study: **6.** Other treatment available: **7.** Use of research results: **8.** Special circumstances:

The study you are being asked to volunteer to take part in involves research. This research study takes place at the Central Texas Veterans Health Care System (CTVHCS). It is important that you read and understand the information on this form. Project SERVE (Study Evaluating Returning Veterans' Experiences) is a research program conducted at the VA Veterans Integrated Service Network 17 (VISN 17) Center of Excellence (CoE) for Research on Returning War Veterans. You are being offered the opportunity to volunteer to take part in Project SERVE: Post-Deployment Functioning Phase 3 (Project SERVE: FX3), which is part of a family of studies that make up the Project SERVE program. This research program has been following returning post-9/11 war Veterans since 2009 and aims to better understand the experiences of retuning war Veterans over time.

PURPOSE

The purpose of this research is to advance our scientific understanding of how Veterans who were previously deployed to Iraq and/or Afghanistan as part of Operations Enduring or Iraqi Freedom or New Dawn (OEF/OIF/OND) adapt to general stress and potentially traumatic events encountered in theatre (circumstances involving actual or threatened death or serious injury) after they return to civilian life. The research team aims to understand factors that influence long-term functioning and recovery from stress reactions. We are particularly interested in studying factors that will help us and other research teams develop and adapt improved treatments and programs to help Veterans. This research study is a local research project for which approximately 600 Veterans will be asked to participate. This study will last approximately 2 years and involve multiple contacts, as described in detail below.

DESCRIPTION OF THE STUDY

This research project is being conducted by Dr. Suzannah Creech and other investigators in the VISN 17 Center of Excellence for Research on Returning War Veterans in Waco, Texas. To participate, you must:

1) be at least 18 years of age;
2) have been deployed in support of Operation Enduring Freedom/Operation Iraqi Freedom/Operation New Dawn;
3) be enrolled in the CTVHCS;
4) be able to understand and sign this informed consent form;

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5) be able to complete the interview and questionnaires;
6) be willing to be contacted for follow-up assessments;
7) if you are receiving treatment for emotional of psychological difficulties (i.e., medication, therapy), you must be stable on those treatments.

PROCEDURES

If you consent to participate in this research study, the following assessments and procedures will occur:

1) Baseline (initial assessment). You will begin by completing an interview and questionnaire packet. The interview will be video-recorded for training, quality assurance, and behavioral coding purposes. The questionnaires will assess how you are functioning in different areas of your life, how satisfied you are in these areas, medical history, mental health symptoms, risk for self-directed violence, and coping strategies. The baseline assessment will take about 2-3 hours to complete and will confirm your final eligibility.
2) 8- and 16-month assessments. You will be asked to complete follow-up self-report questionnaires 8 and 16 months after you begin the study. We will ask you questions about changes in your experiences over time using some of the same questionnaires that were used during the initial assessment. These follow-ups will take approximately 45 minutes each. You may complete these online. You will also be given the option of completing them via paper-and-pencil and returning them using a self-addressed, stamped envelope that will be provided to you.
3) Two-year follow-up assessment. A two-year follow-up assessment will consist of an interview and questionnaires, many of which will be repeated from prior assessments. This assessment may be completed in person, over the phone, or video and will take approximately 1-2 hours.
4) Saliva and Blood Samples. In order to perform genetic and other studies involving biological markers, we will ask you to make a donation of saliva and blood at the in-person baseline and two-year follow-up assessments to obtain DNA, genetic, and other biological materials. We will use these materials to investigate whether there are genes or other markers that predict a person's stress responses over time, PTSD, other health issues, or any diseases, illness or condition. You can decline to participate in the saliva and/or blood sample and still participate in the rest of the study. If you choose to participate, you will be asked to spit in a test tube and donate approximately 43mL, or 3 tablespoons, of blood. These procedures will take approximately 10-15 minutes.
5) Full participation in the research will require a commitment of about 5-7 hours over the two-year timeframe. During this time, you may be invited to participate in additional studies, including studies that extend beyond the 2-year period of this study. You are not required to participate in any additional research studies, and your participation in this present research will not affect your participation in other research projects approved by the CTVHCS IRB.

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Please indicate your willingness to be contacted about additional research studies and quality improvement projects.

_____/DATE:_____ I agree to be contacted about additional studies and quality improvement projects.

_____/DATE:_____ I DO NOT want to be contacted about additional studies or quality improvement projects.

DISCOMFORT AND RISKS

1) Only minor, transient side effects are expected as part of this study.
2) There is a slight risk that recollections of prior experiences during interviewing or filling out forms could affect your mood or make symptoms of mental stress worse. Expected minor reactions include sadness or anxiety in remembering past experiences. These discomforts are usually short-lived and usually resolve without treatment. Everyone will be provided with a referral sheet with information about how to access local VA and non-VA mental health care for a variety of mental health needs. If you are in distress and need or request counseling, you will be offered immediate access to counseling.
3) We will guard your personal health information to prevent it from being inadvertently revealed to anyone other than the researchers. However, because of the need to give certain information to review boards, absolute confidentiality cannot be guaranteed, and there is a slight risk that information used in this study could inadvertently be revealed to someone who does not have a right to see it.
4) You may feel uncomfortable providing a saliva sample by spitting in a test tube in front of research staff. Research team members have been trained to avert their eyes when samples are provided.
5) The risks of having blood taken from a vein in your arm are pain, bleeding, bruising, and rarely, infection at the site where the needle is inserted. Fainting or light-headedness may occur, but they seldom happen. If you are injured as a result of having blood drawn, VA will provide medical treatment for your research-related injury at no cost to you.
6) There are no other known physical, psychological, social, financial, employment, privacy or legal risks of participating in the study.
7) There may be other risks to the participant that are currently unforeseeable.

BENEFITS

1) You may not personally be helped by taking part in this study, but your participation may lead to knowledge that will help others.
2) Our research team members are available to help connect you with mental health services that are not part of the study but from which you may benefit.

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3) If we discover a previously unknown condition that may require medical attention we will provide information to you or your physician. Many research results of the study do not currently have valid clinical interpretation, and we will not inform you about these research results.

OTHER TREATMENT AVAILABLE

This research project does not involve providing treatment. Thus, there are no treatment alternatives. Study staff will be available to assist you with a referral for treatment as needed.

RESEARCH RESULTS

1) We will let you know of any important discoveries made during this study, which may affect you, your condition, or your willingness to participate in this study.
2) Identifiable data. Identifiable data that we are collecting on you include: name, social security number, date of birth, address including zip code, biometric identifiers (voiceprint), and dates of care. All study materials that identify you such as keys linking your name with your study ID number, contact information, informed consent documents and forms with personally identifiable information will be stored in a locked office at Waco campus of the CTVHCS in a physically secure environment that includes controlled access and locking the materials in file cabinets. Interview and questionnaire data will be marked with a code number. Should you choose to complete follow-up questionnaires online, the website that is used will not record your IP address or any identifiable information about you. The coded data will be stored separately from where the master list linking names and code numbers is stored. Identifiable data from the study will not be transferred to another entity outside the VA. Under normal circumstances, only the PI and designated research team members have access to these materials. By signing this document, you are agreeing to allow VA research team members to store and analyze data obtained in this study.
3) De-identified data. Data that has been coded so that it cannot be identified with you will be compiled into an electronic database and analyzed to produce scientific results. So that scientists may learn as much as possible from the information you provide us, de-identified data collected in this research study may be shared with research collaborators from other institutions outside of the VA. By signing this document, you are agreeing to allow research team members to store, analyze, and share de-identified data obtained in this study. IRB and other committees will monitor and approve this future use of the data, and IRB approval to send the de-identified data to other sites will be obtained before data is transferred to collaborators outside of the VA. The de-identified data will be used by research team members for an indefinite time period after the study is completed.

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4) Saliva and Blood sample. Saliva and blood materials such as DNA collected in this study will be coded at the site of where the saliva/blood sample is obtained and stored during the duration of this study at the VA. For the purposes of conducting additional genetic testing, coded samples may be sent to other VA and academic laboratories. At this time, we anticipate that one of the sites where we will send coded samples to have additional genetic and epigenetic work completed will be the VA Pharmacogenomics Analysis Laboratory, which is located at the Central Arkansas Veterans Healthcare System in Little Rock, AR. Other potential sites could be at our academic affiliates, Texas A&M and Baylor Universities, or UT Southwestern or other academic laboratories that process coded samples to support research. All biological samples will be shipped to the laboratory via delivery service with a chain of custody and will only be identified by a code number which will be assigned by researchers at the CoE prior to shipping. The information necessary to decode the samples will remain at the CoE. Thus, researchers at other laboratories should not be able to personally identify you. You also have the option of allowing the materials to be transferred to a tissue bank and used by other research teams (see below). If the materials are transferred to another site, the IRB will approve the transfer and the transfer will only occur to a VA-approved site. The materials will be used by the investigators for an indefinite time period, and will be destroyed when they are used up or when they decompose. There is a very remote risk that your DNA sample might be obtained by someone who has no right to examine it, and enough information might be determined from your DNA to identify you even if only a code is attached to the sample. There might be identity risks involved if this information falls into the wrong hands (e.g. you could be denied insurance coverage or employment because of certain genetic information about you).
5) Video recordings. Only research team members directly involved in the study will have access to the recordings. Recordings will be either recorded directly or transferred on to a secure VA server and will be disposed/ destroyed according to current VA regulations at the time of disposal/destruction of documentation.
6) Your medical and research records will be maintained according to this medical center's requirements. Records of your participation in this study may only be disclosed in accordance with federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing regulations. There is a possibility that the Office for Human Research Protections (OHRP), Food & Drug Administration (FDA), Government Accounting Office (GAO), VHA, other U.S. government agencies, the Research Compliance Officer, IRB members or other research staff may have access to your records or may inspect your records. Every effort will be made to keep information about you both private and confidential. To help maintain your confidentiality, codes (not your name and social security number) will be used for all reports generated.
7) Information you give us and information from your medical record will be recorded in research records and used to perform the research study. Your research records will be maintained according to this medical center's requirements.

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8) Per regulation 38 USC 7332, information about alcohol and drug use is highly protected. This information is obtained because it is important to understand the relationships between warzone stress, substance use, and functional recovery. Therefore, the collection of this information is crucial to the research project. As part of this study, you are consenting for your drug and alcohol information history to be reviewed and released to the research team as stated in this consent form.
9) To help us further protect your confidentiality, the investigators have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). With this Certificate, it is very unlikely that the researchers could be forced (for example, by court subpoena) to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you identify yourself as a participant in this research, or if an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. This means you and your family must also actively protect your own privacy. Finally, you should understand that the investigator is not prevented from taking steps to prevent serious harm to yourself or others. Specifically, this Certificate permits an investigator's voluntary disclosure if you report information that indicates that you are a danger to yourself of others, or any instances in which the current health and safety of a child, elderly person, or person with disabilities needs to be protected. This Certificate of Confidentiality does not represent an endorsement of this research project by the Secretary of Health and Human Services.
10) Data repository. If you agree, coded protected health information, such as your age, gender, ethnicity, medical history, genetics, and the results of the research procedures will be added to the Project SERVE Data Repository if you agree to this. Project SERVE Data Repository is maintained indefinitely so that scientists can study the association between mental health and functional recovery in Veterans. This study is part of the larger Project SERVE family of studies. As such, this study will serve as one of several sources of data for the Project SERVE Data Repository, which is a database of information that will be used in future research.

Please indicate your level of willingness to participate in the data repository by affixing your signature and date to the left of the statement below that most accurately reflects your level of consent to this study procedure.

_____/DATE:_____ I agree to include my data in the data repository.

_____/DATE:_____ I DO NOT want my data included in the data repository.

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11) Any and all paper AND electronic documentation containing confidential, personally identifiable information, protected health information, and any other sensitive information will be disposed/destroyed according to current VA regulations at the time of disposal/destruction of documentation. The required records, including the investigator's research records, must be retained until disposition instructions are approved by the National Archives & Records Administration and published in VHA's Records Control Schedule (RCS10-1).
12) If results of this study are reported in medical journals or at meetings, you will not be identified by name, by voice recording, by recognizable photograph, or by any other means without your specific consent. Your private information will be maintained according to this medical center's requirements.

SPECIAL INFORMATION

1) You are not required to take part in this study: your participation is entirely voluntary. You can refuse to participate now or you can withdraw from this study at any time after giving your consent. Refusal to participate or withdrawal will involve no penalty or loss of benefits to which you are otherwise entitled.
2) Veteran participants and non-Veteran participants do not pay for treatment associated with participation in a VA research project except in accordance with federal law. There will be no costs to you for any of the treatment or testing done as part of this research study. Some Veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.
3) VA must provide necessary medical treatment to a research subject injured by participation in a research project approved by a VA R&D Committee and conducted under the supervision of one or more VA employees. Except in limited circumstances, the necessary care must be provided in VA Medical facilities. Exceptions include: situations where VA facilities are not capable of furnishing the care or services required; and situations involving a non-veteran research subject. Under these circumstances, Directors may contract for such care. This requirement does not apply to treatment for injuries that result from non-compliance by a research subject with study procedures. All regulations pertaining to the participation of veterans as participants, including requirements for indemnification in case of research-related injury, pertain to non-veteran participants enrolled in VA-approved research. (For additional information on research related injuries, see 38 CFR 17.85).
4) In case there are medical problems, research related injuries, or questions, you may call Dr. Suzannah Creech at 254-297-3025. If any medical problems occur in connection with this study, the VA will provide emergency care.
5) Termination of Subject's Participation. In rare cases, the PI may end your participation from the study without your consent. This would only be if we believed that the study was no longer in your best interest.

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6) To compensate you for your time spent completing the research procedures, which includes being interviewed, filling out forms, and traveling to the research site, you will be paid as follows: $75 for the baseline assessment, $25 for the 8-month follow-up, $25 for the 16-month follow-up, and $75 for the 2-year follow-up ($200 for completing each of these assessments). Payments will be made by cash or electronic payment after all procedures for each assessment time-point are completed and all forms are turned in. Thus, the total amount of compensation for completing all procedures is $200.
7) Approval for VA biological studies. As a participant in this research project, you will be asked to voluntarily donate DNA and biological materials obtained from saliva and blood samples. Studies of biological markers including genetic studies using your DNA and other genetic material hold promise for understanding the causes and treatments for stress-related disorders and other conditions. Specifically, we predict that genetic profiles will help us explain the course and outcome of exposure to potentially traumatic situations. Your saliva and blood samples will be used for studies of any major disease or health condition, including genetic studies. Your saliva and blood (collected by venipuncture) samples will be labeled with a code number (no identifying information) that is used to match your saliva/blood sample to the other assessment data you provide as part of this study. The saliva/blood and materials will be processed by VA research study team members and stored at the VA. You can decline to participate in the saliva/blood samples and continue to participate in the rest of the study. At the current time, we are in the preliminary stages of research examining these biological samples. We will keep your saliva, blood and DNA samples indefinitely so that additional tests may be performed in the future, potentially using new procedures that do not exist at this time. The storage of saliva and blood materials and DNA will allow us to re-examine them at a later date without having to contact you to request another sample. We will not be performing genetic testing for diseases that have valid clinical tests (such as Huntington's disease or breast cancer). We do not plan to share with you the results of the genetic or saliva/blood material research because it is unclear at this time what these results mean. There is a possibility that the samples donated under this study may contribute to the development of products that have commercial value, such as a saliva/blood test for stress responses. Should your donated sample lead to the development of a commercial product, the U.S. Government and academic institutions working on this project will own it and it is possible that it will be patented and licensed by one or more of these institutions. The institutions do not intend to provide any compensation for this use and will not give you any notice of future uses of your sample. You may ask the researchers to stop using your saliva, blood, genetic materials or data at any time (Contact Dr. Suzannah Creech at 254-297-3025). If you inform us to stop using the material, the research team will destroy the keys linking you to the data to ensure the integrity of the research, and no more data will be collected using the samples.

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Federal laws and policies provide you with protection from discrimination by health insurance companies, group health plans, and most employers based on your genetic information. A new federal law, the Genetic Information Nondiscrimination Act (GINA), will generally protect you in the following ways: 1) Health insurance companies and group health plans may not request your genetic information obtained from this research; 2) Health insurance companies and group health plans may not use your genetic information obtained from this research when making decisions regarding your eligibility or premiums; and 3) Employers with 15 or more employees may not use your genetic information when making a decision to hire, promote, or fire you or when setting the terms of your employment. Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Please indicate your level of willingness to participate in the saliva sample and genetic studies at the VA by affixing your signature and date to the left of the statement below that most accurately reflects your level of consent to this study procedure.

_____/DATE:_____ I am willing to provide a saliva sample for DNA and other genetic material research at the VA.

_____/DATE:_____ I am NOT willing to provide a saliva sample.

Please indicate your level of willingness to participate in the blood sample and genetic studies at the VA by affixing your signature and date to the left of the statement below that most accurately reflects your level of consent to this study procedure.

_____/DATE:_____ I am willing to provide a blood sample for DNA and other genetic material research at the VA.

_____/DATE:_____ I am NOT willing to provide a blood sample.

If you agree to provide a saliva and/or blood sample for genetic studies for this research project, please consider the following to determine if you agree to allow your sample to be shared with other researchers and with genetic tissue repositories.

8) Approval for outside tissue banking and sharing of biological materials. Because of the complexities of the human genome, scientists often pool samples from many research sites in order to obtain enough specimens to perform more powerful and valid genetic research. Studies using pooled samples have, for instance, been used to find genes contributing to breast cancer and diabetes. By making your sample(s)

available to a genetic repository, it may be possible to obtain additional information on stress disorders and other conditions in the future. In addition to sharing with tissue repositories, investigators inside and outside the VA working on a specific project may ask to share your sample for a single use. Donation of DNA and other genetic material will allow scientists to re-examine your materials at a later date without having to contact you for another sample of saliva/blood. In a repository, your sample will be maintained as a scientific resource that will be made available to qualified scientists for approved research projects around the world to study diseases and human traits including stress disorders. Donation of your genetic material to a tissue repository or for a single-use project would involve sending coded and de-identified samples and de-identified data to a tissue bank repository. The data will include things such as your age, gender, ethnicity, symptoms, diagnosis (if any), and medical problems (if any), with no names or identifying information included. In addition to stress responses, researchers obtain the approval of the CTVHCS IRB for each tissue bank or single-use project.

Please indicate your level of willingness to participate in sharing of genetic material by affixing your signature and date to the left of the statement below that most accurately reflects your level of consent to this study procedure.

_____/DATE:_____ My saliva and/or blood sample and genetic materials may be shared with other scientists and/or sent to a tissue repository.

_____/DATE:_____ My saliva and/or blood sample and genetic materials may NOT be shared with other scientists and/or sent to a tissue repository, and should only be used at the VA for this research project.

9) If it is determined during the course of the study that participation in the study would pose a risk to your well-being, or that you cannot fully complete the assessment procedures, your participation in the study may be stopped by the principal investigator without your consent.
10) You may withdraw from the study verbally or in writing at any time without any penalty or loss of benefits to which you are otherwise entitled.
11) As a research participant in this study, if you have a complaint about any issue regarding the study, or the research investigator; or, if you have questions about your rights as a research participant, you may contact the Institutional Review Board Chairperson, at (254) 743-2609.

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POTENTIAL CONFLICT OF INTEREST

This study is sponsored by the VISN 17 Center of Excellence for Research on Returning War Veterans and VA Rehabilitation Research and Development (RR&D). RR&D provides a fixed payment to the VA Hospital for performing the study.

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AFFIRMATION FROM SUBJECT

RESEARCH SUBJECTS' RIGHTS: I have read or have had read to me all of the above. Dr. Creech or an associated research staff member has explained the study to me and answered all of my questions. I have been told of the risks or discomforts and possible benefits of the study. I have been told that this study does not involve treatment but that study staff will be available to assist me with a referral for treatment as needed.

I understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

I understand my rights as a research participant. I understand what the study is about and how and why it is being done. I voluntarily consent to participate in this study. I know I will receive a signed copy of this consent form.

_____ _____

Research Participant's Signature Date

_____ _____

Signature of Person Obtaining Consent Date

Date Last Revised: 08/05/2020

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