Increasing Resiliency in U.S. Air Force Personnel: A Multi-Site Trial

The University of New Mexico Health Sciences Center

Consent and Authorization to Participate in a Research Study

Key Information for Increasing Resiliency in U.S. Air Force Personnel: A Multi-Site Trial

(HRRC ID 22-317)

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THE STUDY?

The purpose of the study is to examine the effectiveness of the Stress Management and Resilience Training (SMART) program with increasing resilience in Air Force personnel. Information from this study may help demonstrate if the training can be effective in increasing the resilience of other military personnel.

By doing this study, we hope to demonstrate if the training is effective in increasing the resilience of military personnel. Your participation in this research will last about 36 weeks, but we estimate it will take no more than 3-4 hours of your time in total.

WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

The study will provide you the SMART training, which provides short, everyday individual practices focused on improving resilience and decreasing stress. These practices have been shown to significantly increase individuals' resilience and decrease stress in past research.

WHAT ARE THE KEY REASONS YOU MIGHT NOT CHOOSE TO VOLUNTEER FOR THIS STUDY?

Risks or discomforts from this research are minimal. It is possible your reflection on past experiences or memories during or after the SMART training may be uncomfortable. Due to this possibility, you will be provided contact information for seeking confidential mental health support through local resources or Military One Source if you so wish. Additionally, complete privacy and confidentiality of your personal information cannot be promised. To mitigate the risk of loss of privacy or confidentiality, investigators will utilize the Research Electronic Data Capture System (REDCap) to collect and store your survey data. We will enable settings in REDCap to prevent any investigator from being able to view your personal information (ex. your name and e-mail) in any other way. Once data collection is completed, the de-identified survey data will be stored on a secure server at the University of New Mexico Health Sciences Center, and only the investigators have access. Study records will be kept for 6 years after study closure, and then will be deleted and destroyed after that time.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of this study is Stephen Hernandez, PhD, RN of the University of New Mexico Health Sciences Center, College of Nursing. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, his contact information is

shhernandez@salud.unm.edu or 318-617-0020. You can also contact the study site Associate Investigator:

- **Joint Base San Antonio**: Dr. Tonya White at tonya.y.white4.mil@health.mil or 210-292-7556
- **Joint Base Andrews**: Dr. Vickie Hughes at vhughes@jhu.edu or 850-259-0648

If you have any questions or concerns about your rights as a volunteer in this research, contact staff in the University of New Mexico Health Sciences (UNMHSC) Human Research Review Committee (HRRC) between the business hours of 8AM and 5PM, Mountain Standard Time (MST), Monday-Friday at 505-272-1129.

STUDY SPONSOR.

The Tri-Service Research Program, a Department of Defense (DOD) agency that promotes scientific research, is funding this study (e.g., the study sponsor). This organization is providing money to the University of New Mexico Health Sciences Center receiving this Support, so that the researchers can conduct the study.

DETAILED CONSENT

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ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

- You are not an Active Component Air Force service member at the 59th Medical Wing, (Joint Base San Antonio-Lackland, TX [JBSA-L]), 316th Medical Group (Joint Base Andrews, MD [JBA]), 99th Medical Group (Nellis AFB, NV), or 711th Human Performance Wing (HPW), including the U.S. Air Force School of Aerospace Medicine (USAFSAM), and the 88th Medical Group (MDG) at Wright-Patterson Air Force Base, OH (WPAFB).
- You are unable to provide informed consent.
- You are less than 18 years of age.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The research will be conducted at Joint Base San Antonio-Lackland, TX, Joint Base Andrews, MD, Nellis AFB, or Wright-Patterson Air Force Base, OH. You will need to come 1 time during the study if you receive in-person or video-teleconference training, and the training visit will take about 2 hours.

The total amount of time you will be asked to volunteer for this study is no more than four hours over the next 36 weeks

WHAT WILL YOU BE ASKED TO DO (PROCEDURES)?

As a research participant, you will undergo the following research-related procedures:

- After being consented, you will complete a survey at the time you enroll in the study. The survey will ask you to provide your demographic information, e-mail contact information, and questions that measure your current levels of resilience, stress, anxiety and quality of life.
- You will be randomly assigned into either an in-person/video teleconference (VTC) SMART training or a self-paced, on-line version of the training (also called Computer-Based Training), and then be asked to complete up to three additional electronic surveys 12, 24, and 36 weeks after you complete the SMART training. Randomization will be accomplished based upon your enrollment order in the

study. For every 3 people enrolled, 2 will be selected by chance into the in-person/VTC training and 1 person will be selected by chance into the on-line version of the training. We will let you know if you have been assigned to the in-person/VTC or on-line training group. If you would like to switch your group assignment, we ask that you contact the study staff.

- We will send you information to access the in-person/VTC or on-line SMART training. We ask that you complete the assigned training.
  - In-person/VTC SMART Training: We will contact you with the dates and times of scheduled in-person/VTC classes and schedule you for the class you would like to attend. In-person/VTC SMART training will be conducted as a group training with a maximum of 10 Air Force personnel over approximately two hours. If in-person training is feasible and safe during the study period, in-person training will be used to supplement or replace VTC.
  - On-line Training: The on-line version of SMART is self-paced and can be completed over a period of four to eight weeks. We will contact you to provide instructions to access this training.
- After you complete the SMART training, we will provide you a copy of *The Resilience Journal: A 2-Minute Commitment to Lift Your Entire Day* at no charge. This book can help you review SMART practices and track your usage of these practices for improving gratitude, mindful presence, kindness, and developing a resilient mindset.
- We will send an e-mail asking you to complete an on-line follow-up survey 12 weeks after you complete the SMART training.
  - The survey will take approximately 10 to 15 minutes for you to complete.
  - If you don't complete the survey within a week after we send the initial e-mail request, a maximum of three e-mail reminders (one reminder per week) will be sent to ask you to complete the survey.
  - If you don't complete the 12 week survey after all e-mail requests, no further attempts will be made to contact you to completed the 12 week survey.
- We may send an e-mail asking you to complete an additional on-line follow-up survey 24 and 36 weeks after you complete the SMART training.
  - The survey will take approximately 10 to 15 minutes for you to complete.
  - Your responses to this survey will help show if the training continues to help improve your resilience over time.
  - If you don't complete the survey within a week after we send the initial e-mail request, a maximum of three e-mail reminders (one reminder per week) will be sent to ask you to complete the survey.
  - If you don't complete the 24-week and/or 36-week survey after all e-mail requests, no further attempts will be made to contact you to complete the 24-week and/or 36-week survey. .

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

- Risks or discomforts from this research are minimal. It is possible your reflection on past experiences or memories during or after the SMART training may be uncomfortable. Due to this possibility, you will be provided contact information for seeking confidential mental health support through local resources or Military One Source if you so wish.
- Additionally, complete privacy and confidentiality of your personal information cannot be promised. To mitigate the risk of loss of privacy or confidentiality, investigators will utilize the Research Electronic Data Capture System (REDCap) to collect and store your survey data. Once data collection is completed, the survey data will be stored on a secure server in which only the investigators have

access. We will enable settings in REDCap to prevent any investigator from being able to view your personal information (ex. your name and e-mail) in any other way. Once data collection is completed, the de-identified survey data will be stored on a secure server at the University of New Mexico Health Sciences Center, and in which only the investigators have access. Study records will be kept for 6 years after study closure, and then will be deleted and destroyed after that time.

- If you are randomly assigned to participate in a study group, there is a risk that the group you are assigned to may not see the same impact as someone assigned to another group.
- In addition to risks described in this consent, you may experience a previously unknown risk.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

We do not know if you will get any benefit from participating in this study. However, some people have experienced significant improvements in resilience and decreased stress and anxiety when they completed the Stress Management and Resilience Training (SMART) program. Information from this study may help demonstrate if the training is effective in increasing the resilience of military personnel.

WHAT WILL IT COST YOU TO PARTICIPATE?

There are no costs associated with taking part in the study.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

REDCap is a secure, web-based program to capture and store data at the University of New Mexico Health Sciences Center (UNM HSC). Please be aware, while we make every effort to safeguard your data once received on servers via REDCap, given the nature of online surveys, as with anything involving the internet, we can never guarantee the confidentiality of the data while still in route to the server.

Any paper study documents will be maintained in a locked cabinet located in a study member's office and properly disposed of after the completion of the study. All data files used during the data analysis will be password protected. Any printouts from software will be de-identified. Printed study documents will be locked in a secure area located in an authorized study member's office.

Identifiers (ex. your name and e-mail contact information) will be removed from the data. The de-identified data will be placed in a central storage location at the UNM HSC to complete an analysis of all responses in order to be able to report the results of this study. These data will not include your name or other information that can identify you.

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave information, or what the information is.

The study members advise that you protect your copy of the informed consent document. A breach of confidentiality could occur if you inadvertently lose this document or allow others to view the document. In the unlikely event that you experience a loss of confidentiality, the study staff will take appropriate action to assist you in contacting the UNM Privacy Office for assistance.

Complete confidentiality cannot be promised, particularly for military personnel, because information regarding potential Uniformed Code of Military Justice (UCMJ) violations or concerns regarding fitness for duty may be reported to appropriate medical, law enforcement, or command authorities.

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CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

If you choose to leave the study early, your de-identified data collected until that point will remain in the study database and may not be removed. Your name and e-mail contact information will be destroyed.

POTENTIALLY BENEFICIAL ALTERNATIVES TO STUDY PROCEDURES OR INTERVENTIONS.

If you choose not to participate in this study, you can find additional information about resilience and local resources at https://www.resilience.af.mil/

WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?

You will not receive any rewards or payment for taking part in the study.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

You will be informed if the investigators learn new information that could change your mind about staying in the study. You may be asked to review a new informed consent form with a study member if the information is provided to you after you have joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESARCH TESTS?

Generally, surveys done for research purposes are not meant to provide clinical information information/diagnoses and cannot be used to make decisions about standard medical care.

A description of this clinical trial will be available on 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.

WHAT ELSE DO YOU NEED TO KNOW?

If you volunteer to take part in this study, you will be one of about 500 people to do so at 4 different study locations.

FUTURE USE OF YOUR INFORMATION.

Identifiers (ex. your name and e-mail contact information) or other information that can identify you will be removed from the data and your data will not be used for future, unspecified research. Study records will be kept for 6 years after study closure, and then will be deleted and destroyed after that time.

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- **Nellis Air Force Base**: Dr. Jackie Killian at jacqueline.killian@unlv.edu or 757-810-0686
- **Wright-Patterson Air Force Base**: Dr. Theresa Bedford at theresa.bedford@us.af.mil or 678-360-4725

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- You are unable to provide informed consent.
- You are less than 18 years of age.
- You are a Basic Military Trainee (BMT)

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