Improving Resiliency in U.S. Air Force Healthcare Personnel

NCT05460663

Document IRB Approval Date: 9-1-2020

Protocol Template

Section 1: General Study Information

Instruction: The intent of this template is to guide the investigator when developing their research protocol for submission to the AFRL IRB. Please refer to the Protocol Guidance Document for additional information.

This template is unlocked to provide you with the most flexibility for completion. The overall format/layout of the document should not be altered. Insert text in the cells/rows provided. Use black, 12 point Arial font.

Title of Investigation:	Improving Resiliency in U.S. Air Force Healthcare Personnel

1.1 Principal Investigator

Name:	Jacqueline M. Killian		
Organization/Office:	711th HPW/CL	Rank/Title:	Colonel/ Senior Nurse Scientist, 711th HPW; Senior Science Advisor, United States Air Force School of Aerospace Medicine
Duty E-mail Address:	jacqueline.killian@us.af.mil	Phone:	937-255-3784

1.2 Associate Investigator(s) & Study Personnel

Will this study involve Associate Investigator(s) or other study personnel?	☒ Yes	☐ No
If **Yes**, Complete and submit the additional study personnel checklist.		

1.3 Risk Level

1.3.1 Does this study involve Minimal Risk or Greater than Minimal Risk?

☒ Minimal Risk		☐ Greater than Minimal Risk	
If **Minimal Risk**, Proceed to Section 2.			
If **Greater than Minimal Risk**, will this study enroll US DoD service members and recruit in a group setting?		☐ Yes	☐ No
If **Yes**, identify an ombudsman who will observe group recruitment of US DoD service members.	**Name:**		
If **No**, Please complete Section 2.			

Note: Research involving Greater than Minimal Risk requires a Research Monitor. Contact 711HPW/IR for additional submission requirements.

Section 2: Facility / Contractor

2.1 Please identify the following:

Sponsor:	TriService Nursing Research Program	Funding Source and Amount:	TriService Nursing Research Program, $359,258.00
Contract#; CRADA#; or Cooperative Agreement#:			
Location(s) where activity will be conducted:	Wright-Patterson Air Force Base: 711th HPW and 88th MDG		

Note: For locations outside of the 711th HPW, local Commanders must give their permission for research to be conducted on individuals under their command. Contact 711HPW/IR for additional submission requirements.

Section 3: Conflicts of Interest

Principal and Associate Investigators are responsible for disclosing any of the following that would reasonably appear to be affected by their participation in or by the outcome of the study:

- Financial Interest
  - Anything of monetary value, including but not limited to; salary or other payments for services (e.g. consulting fees or honoraria), equity interests (e.g. stock options or ownership interests).
- Intellectual Property
  - Patents, copyrights and royalties from such rights, trademarks, tradenames and trade secrets.
- Any real or perceived personal conflict
  - Membership on a board of directors or advisory committee, having a commercial interest in the products or devices that are utilized in the study.

Note: All staff must complete the Conflict of Interest (COI) checklist and file it with the PI. The PI must submit their copy of the checklist with the IR submission package.

3.1 Do any members of the study staff have a COI?	☐ Yes	☒ No
If **Yes**, Please explain in detail.		

Section 4: Background and Scientific Rationale

Although the Department of Defense (DoD) has made substantial efforts to increase service member resilience, there is limited published evidence that these efforts increase resilience.[1-3] The RAND Center for Military Health Policy Research reviewed factors related to service members' psychological resilience and interventions to enhance it. They also assessed current resilience programs and found "generally very little rigorous research […] across the different resilience factors"[1] (p. xvi), especially at family, unit, and community levels.[1] Across programs they found a lack of consistency in definitions of resilience, outcomes, and evaluation measures; they also reported that inadequate buy-in and logistical support from military leadership were barriers to program implementation.[1] The Institute of Medicine recommended the DoD utilize evidence-based resilience programs in 2013.[4] In response, the DoD "reject[ed] the recommendation to eliminate programming judged by leadership to be beneficial, although not necessarily evidence based"[5] (p. 3). Subsequent literature reviews have identified a continued lack of resilience program evaluation and inadequate evidence for the efficacy of military resilience programs.[2, 3]

The proposed study will be guided by the Defense Centers of Excellence (DCoE) Resilience Continuum (Figure 1).[1] In the DCoE Resilience Continuum, psychological resilience is conceptualized as a process associated with maintenance and recovery of psychological health. Resilience has been variously defined as "the process of coping with or overcoming exposure to adversity or stress"[1] (p. xiii) and as a process of […] negotiating, adapting to, or managing significant sources of stress or trauma"[6] (p. 152). Resilience consists of "assets and resources within the individual, their life and environment"[7] (p. 159) that promote a "capacity for adaptation and 'bouncing back' in the face of adversity"[7] (p. 152). Resilience increases an individual's ability to adapt his or her "body, mind, and spirit to current life circumstances"[6] (p.76). Resilience is considered to be a

protective factor against psychological problems for military service members and their families that is "characterized by hardiness, personal control, and positive coping strategies"[8] (p. 47). However, few Department of Defense resilience training programs aimed to increase service member resilience had been empirically evaluated for their effectiveness in increasing resiliency.[1, 3, 5]

Under the DCoE Resilience Continuum, optimal, mission-ready performance is sustained by providing supportive measures to service members and their families while engaging the support of leaders.[1] Such efforts enhance the service member's ability to maintain a positive outlook and sense of purpose in the face of challenges. As service members encounter "challenges and stressors"[1] (p. 6), they can shift into the state of 'Reacting', and possibly deteriorate to the states of becoming 'Injured' or 'Ill'.[1] Individuals experience an increasing severity and worsening symptoms of distress as they progress through these states.[1] Most service members are able to maintain a state of optimal, mission-ready functioning if they are provided "prevention and early intervention through education and training"[1] (p. 6). This training also helps service members to recover more readily to optimal performance when they experience stressors, unless the service member experiences a state of becoming 'Injured' or 'Ill', in which case medical treatment may be needed to recover to optimal performance.[1]

Stress Management and Resilience Training. The Stress Management and Resilience Training (SMART) program was developed by Dr. Amit Sood. SMART focuses on improving the practices of gratitude, mindful presence, kindness, and developing a resilient mindset.[9] The SMART program incorporates practices that focus on six individual factors that have been found to promote individual-level resilience: positive coping, positive affect, positive thinking, realism, behavioral control, and altruism.[1] In this proposed study, SMART will be provided via either a two-hour, video teleconference (VTC) training or by completion of a self-paced, on-line version completed over a period of four to eight weeks. VTC or on-line versions will be utilized in order to assure the participants and researchers remain socially distanced to prevent transmission of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). If in-person training is feasible and safe at a future time during the planned study period (Appendix A), in-person training will be used to supplement or replace VTC training.

To date, ten studies, most with small sample sizes, have been published to report the effectiveness of SMART in increasing resilience and/or decreasing stress.[10-19] Four of these studies were experimental, and six were quasi-experimental designs. A majority of the studies examined the SMART intervention with physicians or nurses; however, non-healthcare personnel were included in three studies. Five published studies incorporated a two-hour version of the in-person SMART training.[10-13, 15] Of these studies, three showed a 7.7% to 10.6% increase in CD-RISC scores, with a large effect (d = 0.82 – 1.16), eight to twelve weeks after training was completed and a significant decrease in self-reported stress.[10-12] Four of the six studies which utilized alternate forms of the SMART program showed that participant resilience significantly increased by 6.3% to 13.2% between twelve and thirty-six weeks after the program was completed.[14, 17-19]

The SMART program has shown evidence of short duration efficacy when delivered via an in-person setting, but has not been tested with military personnel. To date, the effectiveness of the on-line

training, as well as, its equivalency with the in-person training has not been evaluated. This proposed investigation is necessary to determine if the training is as relevant to and effective with AF service members using an appropriately powered, quasi-experimental design. If the SMART program has similar effectiveness to that reported in studies with civilians, it would have the potential to be the kind of evidence-based resilience intervention that has, thus far, been lacking for military service members.

Section 5: Study Objective(s) and Purpose

5.1 Purpose

The purpose of this proposed study is to examine the effectiveness of the Stress Management and Resilience Training in increasing resilience in U.S. Air Force (USAF) healthcare personnel.

5.2 Primary Objective

The specific aim of this proposed quasi-experimental study is to examine the effectiveness of SMART in increasing levels of resiliency in active component USAF healthcare personnel (any 4XXX Officer or Enlisted Air Force Specialty Code [AFSC]) assigned to 88th Medical Group (MDG) or U.S. Air Force School of Aerospace Medicine (USAFSAM) at Wright Patterson Air Force Base (WPAFB), OH.

To accomplish this aim, the following research question will be asked: Does SMART increase levels of resiliency in active component U.S. Air Force healthcare personnel?

5.3 Secondary Objective(s)

N/A

Section 6: Study Design

6.1 Description of Study Design

A pre/post-training quasi-experimental study is proposed to examine the effectiveness of the Stress Management and Resilience Training in increasing the levels of resiliency in healthcare personnel serving in the U.S. Air Force.

Intervention Group Assignment. Simple randomization will be utilized for participant assignment into the intervention delivery type (i.e. VTC group sessions or on-line SMART program). However, participants will be allowed to switch to their desired delivery type. We will track those individuals who chose to switch their randomized assignment. This will enhance our recruitment process and permit a component of randomized trial within a quasi-experiment. If in-person training becomes feasible and safe during the planned study period, in-person training will be used to supplement or replace VTC. Based on our estimation of the sample size needed and potential attrition, we will seek to enroll at least 60 participants into both the VTC and on-line training groups. We will assess the participants' level of resilience at baseline (enrollment) and at 12 weeks post SMART training. A second post-test will be attempted for participants who completed the SMART training no later than the end of February 2021 to test for longer-term changes in resilience.

Variables and Measures. Baseline data will be collected from each participant prior to the delivery of the intervention. The baseline survey will include nine demographics questions to attain information for participant age, gender, marital status, race, ethnicity, previous deployment, military grade/rank, duty location, and military job duty (i.e. AFSC). Participants' names and preferred e-mail and phone contact information will be requested. This information is necessary to arrange a follow-up phone call for each participant approximately four weeks after completing the SMART training and to send follow-up surveys via the Research Electronic Data Capture System (REDCap™; see Intervention) at weeks 12 and 24 (if applicable) after participants complete SMART. The baseline and follow-up surveys will also include the Connor Davidson Resilience Scale (CD-RISC)[20-21], Perceived Stress Scale (PSS)[22-13], Generalized Anxiety Disorder Scale (GAD-7)[24], and five-item Quality of Life (QoL) measures.[25]

Change in resilience scores on the CD-RISC will be the primary endpoint of the study; secondary endpoints include changes in PSS, GAD-7, and the five-item QoL measure. Although stress, anxiety, and QoL are not primary outcome variables in this study, a decrease in stress and anxiety and an increase in QoL have been reported in past studies by participants who completed SMART, in addition to changes in resilience. Including the PSS, GAD-7, and QoL measure will offer an additional opportunity, with minimum response burden, to compare participant outcomes from this study with outcomes reported in previous studies.

Connor Davidson Resilience Scale. The CD-RISC has been utilized to measure service member resilience in multiple studies.[21, 26-30] The 25-item scale was developed from multiple studies of the characteristics of resilient individuals.[6] Respondents can answer each item using a five point Likert scale ranging from not true at all (0) to true nearly all the time (4).[6] A total CD-RISC score is calculated by summing the score of all 25 items for a total possible score of 100, with a higher score reflecting a greater level of resilience.[6]

During the scale's development, an intraclass correlation coefficient of 0.87 was reported for test-retest reliability.[6] The convergent validity of the scale was demonstrated by a strong positive correlation to the Kobasa Hardiness measure (r = .83, p <.0001), a strong negative correlation with the perceived stress scale (r = – .76, p <.001), and a modest negative correlation with the Sheehan Stress Vulnerability scale (r = –.32, p <.0001).[6] The psychometric properties of the CD-RISC were favorable in a large sample of AF personnel (N = 57,692),[21] in which the reported CD-RISC mean score was 83.66 (SD = 11), and Cronbach's alpha was .91.[21]

Perceived Stress Scale. The PSS was developed to provide a global measure and measure for current levels of perceived stress.[22] The PSS is a 14-item instrument, and respondents answer each item on a four point Likert scale ranging from never (0) to very often (4).[22] An individual's score is calculated by reverse scoring seven items and then summing all item scores, resulting in a score range of 0-56.[22]

The test-retest reliability of the PSS has been reported to be .55 and .85.[22] Concurrent and predictive validity of the PSS has been reported. The PSS and Center for Epidemiological Studies

Depression Scale were shown to concurrently and independently predict psychosomatic symptoms.[22] The PSS has predictive validity for utilization of health services (r = .20, p <.001), social anxiety (r = .37, p <.001) and smoking cessation rates (r = .39, p <.001).[22]

Generalized Anxiety Disorder Scale. The GAD-7 is a brief measure of anxiety. Respondents can answer each item using a four point Likert scale ranging from not at all (0) nearly every day (3).[24] A total score is calculated by summing the scores of the seven items with possible scores ranging from 0-21.[24] Scores between 5-9 are indicative of mild anxiety, and score between 15-21 are indicative of severe anxiety.[24]

During the scale's development, an intraclass correlation coefficient of 0.83 for test-retest reliability was reported.[24] Construct validity for the GAD-7 scale was demonstrated by a significant (p <.05 for all comparisons) positive correlations to disability days (r = .27), physician visits (r = .22), and symptom related disability (r = .63).[24] The convergent validity of the scale was demonstrated by a statistically significant, positive correlations to the Beck Anxiety Inventory (r = .72) anxiety subscale of the Symptom Checklist (r = .74), and Patient Health Questionnaire for Depression (r = .75).[24] In a previous study, the SMART program demonstrated a decrease in participants' reported levels of general anxiety (*Estimated Treatment Effect* =–1.74, 95% CI = –4.7, +1.22).[13]

Linear Analogue Self-Assessment (LASA) Quality of Life. A five-item LASA QoL measure will be used for this study. The 5-item LASA QoL measure includes the overall QoL measure, as well as, measures of physical, emotional, spiritual, and intellectual QoL.[25] Participants will respond to each item using a 10-point Likert scale ranging from as bad as it can be (0) as good as it can be (10).[31] Although each item is scored separately and represents a distinct aspect of quality of life, the reported Cronbach's α for all five items suggests they share a common underlying construct.[25]

The LASA overall quality of life item has been utilized as a brief, minimal burden assessment of QoL in clinical practice and clinical trials.[31] The LASA overall QoL mean score for an healthy individual has been reported as 8.3 (SD = 10.2), and a score ≤ 5 can indicate a clinical concern.[31] A lower LASA overall QoL scores is correlated with a worse performance status, and an increased likelihood of reporting a clinically meaningful deficit.[31] In a previous study, the SMART program demonstrated a positive effect on participants' QoL (*Treatment Effect* = +1.2, *95% CI* = 0.0, 2.4, p = .044, d = .83).[12]

Intervention. SMART is focused on improving the practices of gratitude, mindful presence, kindness, and developing a resilient mindset.[9] In this study, SMART will be offered via a two-hour VTC training provided by Dr. Hernandez or Col Killian or via a self-paced on-line course. The two-hour VTC will be provided synchronously to a maximum of 10 individuals. A study team member will contact participants in the VTC group to provide available dates and times of scheduled classes, and these participants will be scheduled for a class they would like to attend. Participants in the VTC group will be provided a web-link prior to the session, and each session will have a unique password to access the training. Participants in the on-line training group will be provided a code to access the training website. If local conditions permit in-person group meetings (i.e. Health Protection Condition

[HPCON] Alpha or Bravo), in-person group SMART training in a classroom will be offered as an alternative to VTC sessions.

In order to provide the in-person or VTC SMART training, instructors must complete the Transform course in Rochester, MN or at another designated location. The Transform course consists of two days of initial classroom training, at least three months of distance-learning with Dr. Amit Sood, the developer of the SMART training, and a one-day, end-of-course classroom training.[32] Dr. Hernandez (PI) has completed the Transform course, and Col Killian attended the two day classroom training July 17 and 18. She is in process of completing the distance-learning portion with Dr. Amit Sood.

In order to assure fidelity, Dr. Sood provides a standardized presentation, which is customizable by presenters. Dr. Hernandez has completed the Transform course and is approved to provide SMART training. During the initial delivery of the SMART training in month 3, Dr. Hernandez and Col Killian will make notations and jointly agree to incorporate recommendations for improving training delivery. At the end of the course, participants will be offered a copy of *SMART with Dr. Sood: The Four-Module Stress Management and Resilience Training Program* at no charge to the participants. This book will serve as a review of the practices and course content for improving gratitude, mindful presence, kindness, and developing a resilient mindset.

Additionally, in previous studies, individual participants were contacted by phone four weeks after attending the SMART course. These phone calls were offered to provide participants the opportunity to ask questions and to provide reinforcement of the principles presented during the SMART training.[12, 15, 33-35] Therefore, study participants will be contacted by the PI two weeks after completing the SMART training by e-mail or phone and asked if they would like to schedule a follow-up phone meeting. If so, the PI will work to schedule a 30-minute follow-up phone call with participants. At the end of this follow-up session, participants will be provided the option to schedule a final 30-minute follow-up phone call. All phone consultations will be completed before the 12-week follow-up survey. These consultations will be a budget item for the proposed study and provided at no cost to participants.

Procedures. Letters of support have been received from the 88th MDG and USAFA Commanders. These letters of support includes permission to recruit potential participants with posted flyers, newspapers, social media, and informational e-mail announcements. Recruitment materials will be distributed in accordance with any limitations set by the governing IRBs and any future Commander instructions. Study information will be distributed as broadly as possible.

Initial recruitment and randomization will be completed during months 3 through 10 of the study. However, if the study team determines the need to recruit additional participants to ensure adequate statistical power, additional participants will be recruited in month 11 and 12. The study team will work with identified local points of contact to develop a schedule to assure the maximum number of participants can receive information about SMART during a variety of times. If approved by the chain of command, SMART could be completed during the participants' scheduled period of work. The study team will assure an IRB approved ombudsman will be present if informed consent is obtained in a group setting.

After informed consent is obtained and prior to the delivery of the intervention, a survey will be administered to collect demographic information and baseline measurements with the CD-RISC, PSS, GAD-7, and QoL measures. Participant demographic data, e-mail and phone contact information, and responses to survey items will be initially completed using a paper survey prior to the delivery of SMART and manually entered into the Research Electronic Data Capture System (REDCap™; DHHS/NIH/NCRR #8UL1TR000041) by a study team member. If a participant prefers, they will be provided a web-link to enter the initial information directly into REDCap™.

REDCap™ is a secure and encrypted, web-based platform licensed to and managed by the University of New Mexico Health Sciences Center Clinical and Translational Science Center (UNM HSC CTSC).[36] REDCap™ includes a suite of research tools for project management, survey administration, encrypted database storage and retrieval, and reporting.[36] REDCap™ will be utilized to administer follow-up surveys at week 12 and 24 (if applicable) after participants complete SMART. We propose to collect the 24-week follow-up survey responses in order to conduct an exploratory analysis to assess the longevity of the effect of SMART on resilience and stress.

Study team members will verify participant data has been entered correctly. Participant e-mail and phone contact information will be used to schedule a follow-up phone call two weeks after completing the SMART training (see intervention). Participants' e-mail contact information will be used be utilized to send follow-up surveys through REDCap™. Each survey will take approximately 10 to 15 minutes for participants to complete. If the participant does not respond to the initial REDCap™ invitation, a maximum of three e-mail reminders (one reminder per week after the initial e-mail is sent) will be sent to complete the survey.[37] If a participant does not complete the survey after all e-mail requests have been sent, a study team member may call the participant to verify their e-mail information and offer to assist the participant with accessing the survey. Because participants' demographic information will be associated with an individual's contact information in REDCap™, demographic information will not be requested as part of the surveys at weeks 12 or 24. All data will be de-identified prior to exporting the data for analysis.

Data Analysis. IBM® SPSS® Statistics (version 26) and R (survey package, version 3.61) will be used for the statistical analysis. Initial analysis will include descriptive statistics, including means or medians, frequencies and percentages, as appropriate, to characterize demographic status, military grade, duty location, military occupation, and previous deployment status. Cronbach's α will be calculated for each multi-item scale.

The objectives of our analysis include testing and estimating the efficacy of the intervention by comparing pre-post intervention changes (improvements) in the outcome measurements of interest. Analyses will be reported as point estimates with 95% confidence intervals and appropriate estimates of effect size. In this analysis, both the VTC and on-line groups will be analyzed separately and scores will also be pooled together to test for overall intervention effects.

To better understand factors that can impact the intervention effects, we will conduct regression models on the pre-post intervention difference while controlling for demographic characteristics,

AFSC, and previous deployment. We will also take into consideration potential clustering effects among the participants from the same organizational unit using random effects (e.g. in regression models).

Changes in resilience, stress, anxiety, and QoL over time will be assessed by separately analyzing changes from baseline to week 12 and to week 24. A joint analysis of the longitudinal trend over the three time points at baseline, 12-week, and 24-week will be completed. We will also consider a joint analysis of resilience, stress, anxiety, or QOL, as well as, analysis for subscales of any specific domain of interest.

Section 7: Subject Selection		
7.1 Do you plan to target a specific population for your study?	☐ Yes	☒ No
If **Yes**, please complete 7.2		

7.2 Equitable Subject Selection Rationale

7.3 Inclusion & Exclusion Criteria

A subject who has met all of the following criteria is eligible for participation in the study:

Participants must be active component healthcare personnel (any 4XXX Officer or Enlisted AFSC) serving in the U.S. Air Force, assigned to 88th MDG and USAFA at WPAFB, OH. Participants must be ≥ 18 years of age to participate.

A subject who meets any of the following criteria is disqualified from participation in the study:

Adults unable or unwilling to provide consent and individuals who are not yet adults will be excluded from this study. Active component Air Force service members without a healthcare AFSC will be excluded from the study.

7.4 Recruitment Plan

Study team members will work to recruit a sample of active component Air Force healthcare personnel. The 88th MDG and USAFA Commanders have provided letters of support to recruit potential participants with posted flyers, newspapers, social media, and informational e-mail announcements.

If allowed by University of New Mexico and WPAFB guidelines, study team members will travel to WPAFB to provide scheduled informational sessions and to attain participant consent. VTC informational sessions will also be scheduled and provided. For in-person recruitment sessions, all infection control practices and guidelines required by the installation will be enforced. Informational sessions will be coordinated at the 88th MDG and USAFA to occur at unit or staff meetings and open sessions in prearranged locations. The purpose of these sessions is to maximize study recruitment by providing information regarding the proposed research and answering any questions that potential participants may have. The location, number, and timing of these sessions will be designed to make information about the study accessible to service members on all shifts. On-site

liaisons will assure an IRB approved ombudsman will be present for all group informational sessions.

Team members will be attired in civilian clothing during these meetings. Although Col Killian is a Colonel in the active component Air Force and Dr. Hernandez is a Colonel in the Air Force Reserve, neither individual is in the chain of command of any of the potential participants. Therefore, the PI and AI cannot order a potential participant to complete the proposed study or affect any of the potential participant's careers.

7.5 Informed Consent

7.5.1 Waiver of Documentation of Consent

7.5.1.1 Indicate whether either of these apply

☐ Yes	The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research and the subject's wishes will govern.
☒ No	

OR

☐ Yes	The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
☒ No	

If **Yes to either**, this study qualifies for a Waiver of Documentation of Consent. Please use the Abbreviated Consent template.

7.5.2 Consent Plan

Informed consent will be completed by a study team member after the completion of the described information sessions with individuals or groups. Any potential participant who wishes additional time to review the study information before providing consent will be able to do so. Participants will be provided with a copy of the consent document and will be informed that they may withdraw from the study at any time. Informed consent will be obtained from participants prior to baseline data collection.

7.6 Protected Health Information (PHI)

7.6.1 Does this research involve the use of PHI?	☐ Yes	☒ No

If **Yes**, and subjects will provide written consent to participate in this study, a HIPAA Authorization should be signed.

If **Yes**, and you are requesting a waiver of documentation of consent, you should also submit a request for waiver of HIPAA Authorization.

7.7 Compensation

Per Department of Defense guidance, participants will not receive incentives.

Section 8: Experimental Plan

8.1 Equipment

N/A

Section 9: Risk/Benefit Analysis

9.1 Benefits

The SMART training provides short, everyday individual practices, which have been shown to increase individual's resilience in past research with healthcare personnel and other participants. However, the effectiveness of the training has not been evaluated in military personnel. The information learned from this study may help demonstrate if the training is effective in increasing the resilience of military personnel.

9.2 Risks

There are no known risks to participating in this study. It is possible a participant's reflection on past experiences or memories during or after the SMART training may be uncomfortable. Due to this possibility, all participants will be provided contact information for seeking confidential mental health support through local resources or Military One Source.

Section 10: Statistical Consideration and Plan

10.1 Sample Size

We have conducted a thorough analysis to determine a sample size for this proposed study using information derived from the available literature (see Background and Significance: Stress Management and Resilience Training). We considered changes in CD-RISC scores, the primary outcome, from baseline to 12 weeks post-intervention after receiving SMART training (efficacy). We assumed a pre-post intervention change in CD-RISC scores of 7.7 (*SD* = 8.7) to be achievable and meaningful.10 This corresponds to a standardized mean difference between 0.8 and 0.9 *SD*. Sample size estimates specified a two-tailed alpha error of .05 for either paired or two-sample *t*-tests or corresponding nonparametric tests (i.e. Wilcoxon signed ranks or rank sum tests) using a range of effect size and power specifications for mean difference.

Based on this analysis, we propose to recruit 120 active duty service members in total. Assuming up to 25% attrition between enrollment and 12 weeks post-intervention follow-up (i.e. a final sample of 90 or 45 per group), this would be sufficient to achieve 90% power to detect a standardized mean difference of 0.5 *SD* in either a paired *t*-test or Wilcoxon signed ranks test.

Section 11: Subject Re-Contact

11.1 Do you wish to re-contact participants for possible participation in future research protocols?	☐ Yes	☒ No

If **Yes**, Permission to re-contact participants for future research projects must be sought via a separate re-contact registry. Contact the IR Office.

Section 12: Samples		
12.1 Will this activity involve the use of biological samples/tissue?	☐ Yes	☒ No
If **Yes**, Choose one: ☐ Identifiable Specimens	☐ De-identified Specimens	
If **No**, Proceed to Section 13.		
12.2 How will samples will be provided to the investigator, labeled, stored, maintained or destroyed, etc.?		
N/A		
12.3 Do you wish to use blood, cells, bodily fluids, tissues and/or other identifiable health information and personal identifiers from patient records (medical, research, hospital, etc.) for use in more than one protocol?	☐ Yes	☒ No
If **Yes,** a tissue/health information registry must be approved if you intend to collect and use tissue and/or health information outside of the parameters of a single IRB approved protocol.		
12.4 Will you be shipping ANY bodily specimens?	☐ Yes	☒ No
If **Yes** and your protocol includes shipping of blood or other potentially infectious material (OPIM), please ensure that the protocol includes a plan for shipment. Additionally, the protocol and transport plan should be sent to Biosurety (711HPW.IR.Biosurety@us.af.mil) to ensure that it meets all required regulations.		
12.5 Does your protocol include the manipulation of blood or other potentially infectious material beyond collection and/or direct analysis?	☐ Yes	☒ No
If **Yes**, the protocol must also be submitted to Biosurety (711HPW.IR.Biosurety@us.af.mil) for review and approval. If **No**, personnel must complete annual Blood borne Pathogens (BBP) training and the laboratory must have an Exposure Control Plan.		

Section 13: Safety Monitoring

The PI will ensure that mishaps or injuries sustained during research will be reported as required pursuant to AFI 91-204.

- The Principal or Associate Investigator will provide the test subject(s) a short safety briefing explaining what to do in the event of an emergency. Briefing will include where the exits are located, tornado and shelter-in-place locations, and building evacuation assembly location(s). A mishap is an unplanned occurrence, or series of occurrences, that results in damage or injury, as described in AFI 91-204. In the event of a mishap involving government personnel or property, an AF Form 978, Supervisor Mishap Report, will be completed for property damage, or by the injured personnel's supervisor, and returned to the appropriate government safety office within five (5) workdays following the mishap, or notification of the mishap, whichever is earlier.

Established local infection control practices to minimize the risk of SARS-CoV-2 infection will be followed. Possible examples of these practices include:

- Wearing a cloth mask at all times.

- Maintaining physical distancing (6').
- Reducing the number of people in a room to no greater than five at a time.
- Minimizing the number of staff who have "face to face" contact with study participants.
- Washing hands before and after any in person contact with participants.

Section 14: Data Management and Confidentiality

All data will be collected from participants specifically for research purposes. This study will involve minimal impact, risk, and approximately three hours of time commitment for participants.

Participants will be asked to complete a baseline survey and provide phone and e-mail contact information. This information will be collected by paper after consent is provided and manually entered into REDCap™ by an authorized study member. If desired, participants will be provided a web-link to directly enter their information into the REDCap™ system. Participants names, phone numbers, and e-mail contact information will be coded as a protected identifier to prevent unintentional export of the information from the REDCap™ system.

To ensure confidentiality, the collected data will be entered into and stored on the secure REDCap™ server at the University of New Mexico (UNM) Health Sciences Center (HSC) Clinical and Translational Science Center (CTSC). Paper surveys will be maintained in a locked cabinet located in Dr. Hernandez's office. No other individuals utilize the same office space. UNM HSC IRB approval is required to use REDCap™ for data collection related to human subjects research. Researchers must provide the approved protocol number and study closure date prior to putting a REDCap™ database or survey into production status. The CTSC's implementation of REDCap™ is not intended to be a long-term repository or warehouse for personal health information, and the PI will be required to provide the study's IRB expiration date. As the expiration date approaches, the system administrator we will contact the Dr. Hernandez for proper disposition of the REDCap™ data.

Participants will be made aware that the SMART course may be provided in a group setting. During any interactive portion of the course, participants may volunteer to provide information, thoughts, and feedback; however, they are not required to provide any information. All follow-up phone calls will be scheduled at a time and location of the participants' choosing. For all baseline and follow-up surveys, participants may choose which items they complete.

All data files used during the data analysis will be password protected. Any printouts from software (e.g. IBM® SPSS® Statistics) will be de-identified. Settings in REDCap™ will be enabled to ensure that only Dr. Hernandez will be able to identify a specific participant and their survey responses based upon a linked number assigned by REDCap™ when the surveys are completed.

Section 15: Data Sharing Plan

Collected data will be stored in the REDCap™ project database hosted by the UNM HSC CTSC Informatics behind the firewall of the HSC. Access from outside of the UNM HSC will require the use of a secure UNM HSC Net ID. Dr. Hernandez and other team members who are employees of the

UNM HSC will complete the planned data analysis. Printed study documents will be locked a filing cabinet located in Dr. Hernandez's office.

After the study is completed, the de-identified data may be placed in a central storage location at the UNM HSC. Identifiers (i.e. name, phone and e-mail contact information) will be removed from the data and non-identifiable data could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from participants. The purpose is to make study data available to other researchers.

Study findings will be disseminated to the chain of command and research site locations at WPAFB. Dissemination at WPAFB will be aided by the on-site liaisons to coordinate leadership and PI communication either by email or video teleconference/telephone briefings. Presentations of study findings are planned at the Military Health System Research Symposium and TriService Nursing Research Program Dissemination Course. Manuscripts of study findings may be submitted to Nursing Research and Military Medicine. Study results will be presented in summary form only.

Section 16: References

1 Meredith, L., Sherbourne, C., Gaillot, S., Hansell, L., Ritschard, H., Parker, A., & Wrenn, G. (2011). Promoting psychological resilience in the U.S. Military. Retrieved from http://www.rand.org/content/dam/rand/pubs/monographs/2011/RAND_MG996.pdf

2 Thompson, S. R., & Dobbins, S. (2018). The applicability of resilience training to the mitigation of trauma-related mental illness in military personnel. *Journal of the American Psychiatric Nurses Association, 24*(1), 23-34. doi:10.1177/1078390317739957

3 Rocklein Kemplin, K., Paun, O., Godbee, D. C., & Brandon, J. W. (2019). Resilience and suicide in special operations forces: State of the science via integrative review. *Journal of Special Operations Medicine: A Peer Reviewed Journal for SOF Medical Professionals, 19*(2), 57-66.

4 Committee on the Assessment of Resiliency and Prevention Programs for Mental and Behavioral Health in Service Members and Their Families (2014). *Prevention of psychological disorders in service members and their families: An assessment of programs*. Washington, DC: Institute of Medicine.

5 Department of Defense. (2015, July). *Report to Congressional Armed Services Committees: Implementation of recommendations of Institute of Medicine on improvements on certain resilience and prevention programs of the Department of Defense*. Retrieved from https://www.pdhealth.mil/report-implementation-recommendations-institute-medicine-improvements-certain-resilience-and

6 Connor, K. M., & Davidson, J. R. T. (2003). Development of a new resilience scale: The Connor-Davidson Resilience Scale (CD-RISC). *Depression & Anxiety, 18*(2), 76-82.

7 Windle, G. (2012). The contribution of resilience to healthy aging. *Perspectives in Public Health, 132*(4), 159-160. doi: 10.1177/1757913912449572

8 Committee on the Assessment of Resiliency and Prevention Programs for Mental and Behavioral Health in Service Members and Their Families (2014). *Prevention of psychological disorders in service members and their families: An assessment of programs*. Washington, DC: Institute of Medicine.

9 Resilient Option. (n.d.). Resilient option on-line program. Retrieved June 30, 2020 from https://www.resilientoption.com/online-program

10 Loprinzi, C. E., Prasad, K., Schroeder, D. R., & Sood, A. (2011). Stress Management and Resilience Training (SMART) Program to decrease stress and enhance resilience among breast cancer survivors: A pilot randomized clinical trial. *Clinical Breast Cancer, 11*(6), 364-368. doi:10.1016/j.clbc.2011.06.008

11 Sood, A., Prasad, K., Schroeder, D., & Varkey, P. (2011). Stress Management and Resilience Training among Department of Medicine faculty: A pilot randomized clinical trial. J*ournal of General Internal Medicine, 26*(8), 858-861. doi:10.1007/s11606-011-1640-x

12 Sood, A., Sharma, V., Schroeder, D. R., & Gorman, B. (2014). Stress Management and Resiliency Training (SMART) program among Department of Radiology faculty: A pilot randomized clinical trial. *Explore (NY), 10*(6), 358-363. doi:10.1016/j.explore.2014.08.002

13 Chesak, S. S., Bhagra, A., Schroeder, D. R., Foy, D. A., Cutshall, S. M., & Sood, A. (2015). Enhancing resilience among new nurses: Feasibility and efficacy of a pilot intervention. *Ochsner Journal, 15*(1), 38-44.

14 Magtibay, D. L., Chesak, S. S., Coughlin, K., & Sood, A. (2017). Decreasing stress and burnout in nurses: Efficacy of blended learning with stress management and resilience training program. *Journal of Nursing Administration, 47*(7-8), 391-395. doi:10.1097/nna.0000000000000501

15 Kashani, K., Carrera, P., De Moraes, A. G., Sood, A., Onigkeit, J. A., & Ramar, K. (2015). Stress and burnout among critical care fellows: Preliminary evaluation of an educational intervention. *Medical Education Online, 20*. doi:10.3402/meo.v20.27840

16 Stonnington, C. M., Darby, B., Santucci, A., Mulligan, P., Pathuis, P., Cuc, A., . . . Sood, A. (2016). A resilience intervention involving mindfulness training for transplant patients and their caregivers. *Clinical Transplantation, 30*(11), 1466-1472. doi:10.1111/ctr.12841

17 Werneburg, B. L., Jenkins, S. M., Friend, J. L., Berkland, B. E., Clark, M. M., Rosedahl, J. K.,… Sood, A. (2018). Improving resiliency in healthcare employees. *American Journal of Health Behavior, 42*(1), 39-50. doi:10.5993/ajhb.42.1.4

18 Dyrbye, L. N., Shanafelt, T. D., Werner, L., Sood, A., Satele, D., & Wolanskyj, A. P. (2017). The impact of a required longitudinal stress management and resilience training course for first-year medical students. *The Journal of General Internal Medicine, 32*(12), 1309-1314. doi:10.1007/s11606-017-4171-2

19 Sharma, V., Sood, A., Prasad, K., Loehrer, L., Schroeder, D., & Brent, B. (2014). Bibliotherapy to decrease stress and anxiety and increase resilience and mindfulness: A pilot trial. *Explore (NY), 10*(4), 248-252. doi:10.1016/j.explore.2014.04.002

20 Connor, K. M., & Davidson, Jonathan R. T. (2003). Development of a new resilience scale: The Connor-Davidson Resilience Scale (CD-RISC). *Depression & Anxiety, 18*(2), 76-82. doi: 10.1002/da.10113

21 Bezdjian, S., Schneider, K. G., Burchett, D., Baker, M. T., & Garb, H. N. (2017). Resilience in the United States Air Force: Psychometric properties of the Connor-Davidson Resilience Scale (CD-RISC). *Psychological Assessment, 29*(5), 479-485. doi:10.1037/pas0000370

22 Cohen, S., Kamarack, T., & Mermelstein, R. (1983). A global measure of perceived stress. *Journal of Health and Social Behavior, 24*(4), 385-396.

23 Cohen, S., & Williamson, G. (1988). Perecived stress in a probablility sample of the United States. In S. Spacapan & S. Oskamp (Eds.), *The social psychology of health* (pp. 31-67). Newbury Park, CA: Sage.

24 Spitzer, R. L., Kroenke, K., Williams, J. W., & Löwe, B. (2006). A brief measure for assessing generalized anxiety disorder: The GAD-7. *Archives of Internal Medicine, 166*(10), 1092-1097. doi:10.1001/archinte.166.10.1092

25 Locke, D., Decker, P., Sloan, J., Brown, P., Malec, J., Clark, M., . . . Buckner, J. (2007). Validation of single-item linear analog scale assessment of quality of life in neuro-oncology patients. *Journal of Pain and Symptom Management, 34*(6), 628-638. doi:10.1016/j.jpainsymman.2007.01.016

26 Pietrzak, R. H., Goldstein, M. B., Malley, J. C., Rivers, A. J., Johnson, D. C., & Southwick, S. M. (2010). Risk and protective factors associated with suicidal ideation in veterans of Operations Enduring Freedom and Iraqi Freedom. *Journal of Affective Disorders, 123*, 102-107.

27 Hernandez, S. H. A., Parshall, M. B., & Morgan, B. J. (2017). Treatment-seeking beliefs and behaviors in Air Force nursing personnel. *Military Medicine, 182*(7), e1687-e1692. doi:10.7205/MILMED-D-16-00397

28 Hernandez, S., Morgan, B., & Parshall, M. (2016). Resilience, stress, stigma, and barriers to mental health care in Air Force nursing personnel. *Nursing Research, 65*(6), 481-486. doi:10.1097/NNR.0000000000000182

29 Maguen, S., Turcotte, D. M., Peterson, A. L., Dremsa, T. L., Garb, H. N., McNally, R. J., & Litz, B. T. (2008). Description of risk and resilience factors among military medical personnel before deployment to Iraq. *Military Medicine, 173*(1), 1-9.

30 Pietrzak, R. H., & Southwick, S. M. (2011). Psychological resilience in OEF–OIF veterans: Application of a novel classification approach and examination of demographic and psychosocial correlates. *Journal of Affective Disorders, 133*(3), 560-568. doi: 10.1016/j.jad.2011.04.028

31 Singh, J. A., Satele, D., Pattabasavaiah, S., Buckner, J. C., & Sloan, J. A. (2014). Normative data and clinically significant effect sizes for single-item numerical linear analogue self-assessment (LASA) scales. *Health and Quality of Life Outcomes, 12*, 187. doi:10.1186/s12955-014-0187-z

32 Sood, A. (n.d.). Transform course. Retrieved June 30, 2020 from https://www.resiliencetrainer.com/transform-course

33 Chesak, S. S., Bhagra, A., Schroeder, D. R., Foy, D. A., Cutshall, S. M., & Sood, A. (2015). Enhancing resilience among new nurses: Feasibility and efficacy of a pilot intervention. *The Ochsner Journal, 15*(1), 38-44.

34 Loprinzi, C. E., Prasad, K., Schroeder, D. R., & Sood, A. (2011). Stress Management and Resilience Training (SMART) Program to decrease stress and enhance resilience among breast cancer survivors: A pilot randomized clinical trial. *Clinical Breast Cancer, 11*(6), 364-368. doi:10.1016/j.clbc.2011.06.008

35 Sood, A., Prasad, K., Schroeder, D., & Varkey, P. (2011). Stress Management and Resilience Training among Department of Medicine faculty: A pilot randomized clinical trial. *Journal of General Internal Medicine, 26*(8), 858-861. doi:10.1007/s11606-011-1640-x

36 Harris, P. A., Taylor, R., Thielke, R., Payne, J., Gonzalez, N., & Conde, J. G. (2009). Research electronic data capture (REDCap): A metadata-driven methodology and workflow process for providing translational research informatics support. *Journal of Biomedical Informatics, 42*(2), 377-381.

37 Dillman, D., Smyth, J., & Christian, L. (2009). *Internet, mail, and mixed-mode surveys: The tailored design method* (3rd ed.). Hoboken, NJ: John Wiley & Sons.

Section 17: Attachments

Attachment 1: Timeline
Attachment 2: Letters of Support
Attachment 3: Survey

Improving Resiliency in U.S. Air Force Healthcare Personnel

NCT05460663

Document IRB Approval Date: 9-1-2020

Informed Consent Document

Protocol Title: Improving Resiliency in U.S. Air Force Healthcare Personnel

You are being asked to participate in a research study.

Key study information you should know:

- The purpose of the study is to examine the effectiveness of the Stress Management and Resilience Training (SMART) program for increasing resilience in officer and enlisted Air Force healthcare personnel. SMART training provides short, everyday individual practices, which have been shown to increase individual's resilience in past research; however, the effectiveness of the training has not been evaluated in military personnel. Information from this study may help demonstrate if the training is effective in increasing the resilience of military personnel.

- If you choose to participate, you will be asked to complete a survey at the time you enroll in the study, you will be randomly assigned into either a video teleconference (VTC) training or a self-paced, on-line version of the training, and then be asked to complete up to two additional surveys 12 and 24 weeks after you complete the training. This will take a total of approximately three to four hours of your time for the duration of study.

- Risks associated with participating in 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 RedCap to collect and store your data and it will be stored on a secure server in which only the investigators have access.

- Taking part in this research project is voluntary. You can discontinue participation at any time without penalty or loss.

- Your data will be de-identified and used for future research.

- There will be no cost to you for you to complete the SMART training or for any optional follow-up study related visits. The cost of the training is being paid for through a grant provided by the TriService Nursing Research program (https://www.usuhs.edu/tsnrp).

Please take time to read this entire document and ask questions before deciding whether to take part in this research project.

If you participate in this research, the study investigators will ask you to:

- Complete a survey.

  - The survey will ask you to provide your demographic information, e-mail and phone contact information, and questions that measure your levels of resilience, stress, anxiety and quality of life.
  - You can complete a paper survey or ask for a web-link to complete the survey on-line.

- We will let you know if you have been assigned to the VTC or on-line training group. If you would like switch your group assignment, we ask that you contact the study staff.
- We will send you information to access the VTC or on-line training. We ask that you complete the assigned training.
  - VTC Training: We will contact you with the dates and times of scheduled VTC classes and schedule you for the class you would like to attend. VTC training will be completed as a group training with a maximum of 10 Air Force healthcare 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.
  - After you complete the training, we will provide you a free copy of *SMART with Dr. Sood: The Four-Module Stress Management and Resilience Training Program* at no charge. This book can help you review practices and course content for improving gratitude, mindful presence, kindness, and developing a resilient mindset.

- Approximately two weeks after completing the SMART training, we will contact you by e-mail or phone.
  - We will ask if you would like to schedule an optional phone meeting. These phone consultations will be provided at no cost to you.
  - The purpose of the phone meeting is to provide you the opportunity to ask questions and to provide reinforcement of the principles presented during the SMART training.
  - If you would like to schedule a phone meeting, we will work to schedule a 30-minute phone call with you at a day and time of your convenience.
  - At the end of this call, you will be provided the option to schedule a second 30-minute follow-up phone meeting.

- 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 survey after all e-mail requests, we may call you to verify your e-mail information and offer to assist you with accessing the survey.

- We may send an e-mail asking you to complete an additional on-line follow-up survey 24 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 survey after all e-mail requests, we may call you to verify your e-mail information and offer to assist you with accessing the survey.
- When the study is completed, we will provide a summary of the findings to the leaders at the 88th Medical Group and the U.S. Air Force School of Aerospace Medicine. We may present the information at scientific conferences and prepare manuscripts for publication in scientific publications. All results will be summarized so that no findings can be linked to any individual's responses. You can contact the study team if you would like a copy of the summary results for this study.

The researchers will take the following precautions to maintain the confidentiality of your data:

After enrolling in the study, you will be asked to complete a survey to provide your demographic information, e-mail and phone contact information, and answer questions to measure your levels of resilience, stress, anxiety and quality of life. This information will be collected by paper and manually entered into the Research Electronic Data Capture (REDCap system by an authorized study member. If desired, you will be provided a web-link to directly enter their information into the REDCap system. Your name, phone number, and e-mail contact information will be entered as protected information to prevent unintentional export of the information from the REDCap system. REDCap is a secure web application for building and managing online surveys and databases. Settings in REDCap will be enabled to ensure that only authorized study members will be able to identify a specific participant and their survey responses based upon a linked number assigned by REDCap when the surveys are completed. Collected data will be stored in the REDCap project database hosted by the University of New Mexico Health Science Center (UNM HSC) behind a firewall. Access from outside of the UNM HSC will require the use of a secure UNM HSC Identification.

Paper surveys 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 a secure filing cabinet located in an authorized study member's office.

Identifiers (ex. your name, phone and e-mail contact information) will be removed from the data and non-identifiable data could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you. After the study is completed, the de-identified data may be placed in a central storage location at the UNM HSC. The purpose is to make study data available to other researchers. These data will

not include your name or other information that can identify you.

The data may be accessed by the Department of Defense for auditing purposes.

If you have questions regarding the study, contact the Principal Investigator: Col Jacqueline M. Killian at COMM: 937-255-3784, DSN 785-3784 or jacqueline.killian@us.af.mil or Col Stephen Hernandez at 318-617-0020 or shhernandez@salud.unm.edu. If you have questions regarding your rights as a research subject, contact the AFRL IRB: 937-904-8100 or afrl.ir.protocolmanagement@us.af.mil.