CLINICAL DATA PROTOCOL

Title:	Stress Management and Resiliency Training (SMART) for Family Medicine Residents at Eglin AFB
IRB #:	**FWH20190021H**

Principal Investigator (PI)	Rank / Civ Rating	Branch	AD/DoD Civ/ Ctr/Civilian	Dept/Base	Phone #	E-mail
Laura Rhaney, MD	Capt	USAF	AD	FMR/Eglin	(850) 883-9501	laura.d.rhaney.mil@mail.mil

The research relevance of this protocol focuses on:					
☐	**Diagnosis**	☐	**Treatment**	☐	**Medical Utilization/Managed Care**
☒	**Prevention**	☐	**Medical Readiness**	☐	**Other:**

FOR 59 MDW PERSONNEL ONLY

Individuals must be covered under 59 MDWI 40-404, *Managing Conflict of Interest in Research*

CONFLICTS OF INTEREST:	**Do you or any of your research staff have a potential conflict of interest to disclose?** If unsure, read the below statement before proceeding.	☐Yes	☒No

If you answer YES above, you must complete the *59 MDW Form 14 – Financial Conflict of Interest Disclosure* for each individual reporting a conflict and send it via **encrypted** email to the COI Manager for an official determination **BEFORE PROCEEDING** with this protocol application. The 59th Medical Wing Conflict of Interest Office can assist you with any questions you may have regarding conflicts of interest and the COI disclosure process. Contact the COI Manager with questions or for additional guidance at: 210-292-5885 or usaf.jbsa.59-mdw.mbx.chief-scientist-hrpp@mail.mil.

1. LOCATION AND SPONSOR

Collaborating Facilities:

Nellis Air Force Base will be providing support with IRB submissions, study start up, study monitoring, study close out, etc. We will be engaged in research at Eglin AFB and travel there on a regular basis as part of the Regional Clinical Investigation Program with Dr. Nereyda Sevilla. No research is being conducted at Nellis Air Force Base nor will any regulatory documents leave Eglin AFB.

AF Sites Seeking Regional IRB:

Capt Laura Rhaney/ (612) 239-9763/ Eglin AFB/ laura.d.rhaney.mil@mail.mil

Study Sponsors: None

2. EXPEDITED REVIEW CATEGORY

☒ **SURVEYS, INTERVIEWS, OR PROGRAM EVALUATIONS**

This minimal risk study involves:

☒Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior).

☒Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

***NOTE**: Some research in this category may qualify as exempt and some may not be considered human research. See the Exempt Protocol form or the Non-research/Non-human Research form.*

3. RESEARCH PLAN

Purpose of Study:

This research seeks to identify if the practice of the SMART program mindfulness decreases stress and increase resilience in family medicine residents.

Hypotheses, Research Questions, or Objectives:

- Null Hypothesis 1: There is no significant correlation between SMART program mindfulness training program and increased resilience, decreased stress, and increased overall quality of life for residents.
- Alternative Hypothesis 1: There is significant correlation between SMART program mindfulness training program and increased resilience, decreased stress, and increased overall quality of life for residents.

Significance:

The hope is that the residents trained will be able to utilize and continue to practice the skills learned throughout their careers as physicians, and thus be able to provide sustained, compassionate care. The research could serve as a pilot project for future studies with larger numbers of residents, and possibly lead to implementation of the program in residencies.

In order to provide optimal patient care, the physician must be healthy and resilient. By practicing mindfulness, the resident should be able not only to successfully handle the everyday stressors of residency, but to enhance his or her ability to learn effectively and improve interpersonal relations.

Military Relevance:

Resilience is a valued, necessary trait for every military member. The more resilient the airman, the better able to serve the mission.

Background and Review of Literature:

Historically, mindfulness has its roots in Buddhism. The idea is to reduce stress and increase resilience by daily mindful practice. The SMART program specifically targets busy professionals who could very much use the benefits of mindfulness, but may not have a large amount of time to spend in training. The program uses techniques of joyful and kind attention, as well as a number of methods of interpreting the external world, which when practiced regularly in small increments can add up to increased quality of life.

Residents are pushed to excel in academic and clinical settings, and when combined with their extracurricular responsibilities, this can result in a great deal of stress. Their time is limited, and therefore SMART training may be well suited for their needs. John Kabat-Zinn is generally recognized as one of the foremost authorities on mindfulness, and his article “Mindfulness in Medicine” notes that premedical and medical students benefited from training, showing “reduced psychological distress and increased empathy”. He also mentioned a possible link in reduction of medical errors and increased attention[1].

There is a physiological basis of mindfulness training. Research shows impact in areas of memory, learning, and emotion, as well as visual and auditory sensory regions. The article “Mindfulness Practice Leads to Increases in Regional Brain Gray Matter Density” shows just that, with increased density in areas of the left hippocampus, posterior cingulate cortex, temporo-parietal junction, and cerebellum [2]. Another article claims “enhanced attentional regulation of alpha in primary somatosensory cortex”, in other words more control over mind wandering[3].

Used well, the SMART tool would ideally decrease rates of burnout and increase patient safety. Decreased burnout has been linked to mindfulness, and “it has been suggested that increased clinician mindfulness could also reduce medical errors, but there has been no empirical test of this hypothesis”[4]. Dr. Sood at Mayo Clinic, the creator of the SMART method, notes “in general, peace, joy, and resilience correlate with increased activity in the higher cortical center of your brain, especially the pre-frontal cortex”[5]. Mindfulness training can effectively retrain the brain to think differently, to experience life in a more optimistic manner and increase the ability to handle stressors[5]. There are many existing studies evaluating various methods of mindfulness, however the SMART method has not yet been tested on military medical residents.

Bibliography:

1. Ludwig DS, Kabat-Zinn J. Mindfulness in medicine. *JAMA*. 2008;300(11):1350-1352.
2. Holzel BK, Carmody J, Vangel M, et al. Mindfulness practice leads to increases in regional brain gray matter density. *Psychiatry Res*. 2011;191(1):36-43.
3. Kerr CE, Sacchet MD, Lazar SW, Moore CI, Jones SR. Mindfulness starts with the body: Somatosensory attention and top-down modulation of cortical alpha rhythms in mindfulness meditation. *Front Hum Neurosci*. 2013;7:12.
4. Sibinga EM, Wu AW. Clinician mindfulness and patient safety. *JAMA*. 2010;304(22):2532-2533.
5. Sood, Amit. *Train Your Brain....Engage Your Heart....Transform Your Life: A Course in Attention & Interpretation Therapy (AIT).* Morning Dew Publications, LLC; 2009, 2010.

4. RESEARCH DESIGN AND METHODS

Research Design and Methods:

The study design will be a one-arm case study, pre and post test design. Active Duty Family Medicine Residents age 18 years or older will be recruited at Eglin AFB. Subjects meeting the inclusion/exclusion criteria will be offered an opportunity to participate.

Screening:

- Obtain and document signed Informed Consent document and HIPAA Authorization.
- Record: name, age, gender, current email address, phone number, and post graduate year in training.

The Research staff will then contact the subjects to have them complete a follow-up questionnaire. All information collected on the questionnaires will be coded with an identifier and only the research staff will have the Master Key that can be linked back to each individual.

Visit 1-Baseline (can be the same day as Screening Visit):

- Participants will be handed the following questionnaires in a plain manila envelope to complete prior to the SMART 1 Hour Session and will be asked to return them to the study staff:
  - Stress Scale
  - Mindful Attention Awareness Scale
  - Connor-Davidson Resilience Scale
- Particpants will participate in the 1 hour SMART Program training conducted by the PI, who is certified to teach this method.

Visit 2-12 Weeks from Baseline:

- Participants will be handed the following questionnaires in a plain manila envelope to complete and will be asked to return them to the study staff:
  - Stress Scale
  - Mindful Attention Awareness Scale
  - Connor-Davidson Resilience Scale

Visit 3-12 Months from Baseline:

- Participants will be handed the following questionnaires in a plain manila envelope to complete and will be asked to return them to the study staff:
  - Stress Scale
  - Mindful Attention Awareness Scale
  - Connor-Davidson Resilience Scale

Subjects' participation ends at 12 months.

a. Interventions and Observations:

Identify if the practice of the SMART 1 hour training lecture program mindfulness in family medicine residents decreases stress and increases resilience.

b. Setting:

Eglin Family Medicine Residency Conference Room

c. Date(s):
September 2018 through September 2020

d. Subjects:
Male and Female Active Duty military Family Medicine Residents age 18 years or older at Eglin Air Force Base.

e. Inclusion/Exclusion Criteria:	
Inclusion Criteria	Male and female active duty military family medicine residents age 18 or older, amenable to participation in training and filling out questionnaires
Exclusion Criteria	Unwilling to participate

f. Source of Research Material:

Will you be using private information in this study? ☒ Yes name, email address, phone number

Use of identifiers with private information

Identifiers to be Used?	**Column A** Looked at by research team	**Column B** Recorded on enrollment log, subject list, or key list	**Column C** Recorded on data collection tool (survey, spreadsheet, etc.)	**Column D** Recorded on specimen containers	**Column E** Shared w/ others not on research team	**Column F** Stored after study ended
Names	☒	☒	☐	☐	☐	☐
Study codes linked to individuals' identities using a key only accessible by the researcher		☒	☒	☐	☐	☐
Dates (except year)	☒	☒	☐	☐	☐	☐
E-mails	☒	☒	☐	☐	☐	☐
Phone numbers	☒	☒	☐	☐	☐	☐

Coding Plan?	
Describe the method that will be used to create and assign unique study codes to data.	All information collected on the questionnaires will be coded with an identifie. The code will be placed in a Master Key of identifiable PHI/PII for each subject.The key is linked to a participant's name, email address, and phone number and will be used only to contact subjects to complete their follow-up questionnaires and merge their baseline and post-questionnaire results. Only the research staff will have direct access to the Master Key and be able to link a subject's response to their questionnaire information.
Describe the method that will be used to create and assign unique study codes to specimens.	☒N/A, not collecting specimens
What is the format of the key?	☒Electronic
Who will have access to the key?	Research Staff listed on this study
Where will the key be stored and how will it be protected?	Location(s): We will maintain a Master Key of identifiable PHI/PII that will be kept in an electronic database, which will be encrypted, double password protected and the access will be restricted. The Master Key will be electronically stored separately from the coded de-identified research data. The Master Key will not be stored on any non-government or personal computers or laptops. At the conclusion of the study, the data from Eglin will be de-identified prior to review and analysis. Confidentiality measures: The coded research data will be kept in a locked cabinet in a locked office and only the research department has the key. The coded research data will be retained until the conclusion of the research study. Once a Final Report has been approved by the IRB, all the paper records will be de-identified and any key linking the subject to their records will be destroyed, based on AFI 33-332, "The Air Force Privacy and Civil Liberties Program" and the National Institute of Standards and Technology Special Publication (NIST SP 800-88) for the approved methods to destroy PII. The anonymized

	research data will not be utilized for further research activity beyond the protocol stipulations without additional IRB approval and research subject authorization.

Complete the table.

Source of Research Material per Participant (Procedures)	# Routine Care	# Research Driven	# Total Procedures
Mindful Attention Awareness Scale	0	3	3
Perceived Stress Scale	0	3	3
Connor-Davidson Resilience Scale	0	3	3

Instrumentation:

- Mindful Attention Awareness Scale: Dispositional mindfulness, i.e. open or receptive awareness of and attention to what is taking place in the presentPerceived Stress Scale: Measures perception of stress as related to life situations.
- Connor-Davidson Resilience Scale: Measure of stress coping ability.

5. HUMAN SUBJECT PROTECTION

Recruitment and Consent Processes:

Male and Female Active Duty military Family Medicine Residents will be recruited through announcements at morning meetings. All potentially eligible patients, will be offered an opportunity to participate.

Consent Processes:

Informed Consent (ICD) and HIPAA Authorization (HIPAA) will be sought in advance from each prospective subject and appropriately documented in accordance with 32 CFR 219.117. The research staff will provide a written copy of the Informed Consent Document and HIPAA Authorization. The subject may decline to consent without prejudice. At the subject's discretion, they may take the ICD and HIPAA home to discuss further prior to making a decision. If the subject consents, a copy of the ICD will be given to the subject. No vulnerable populations are included in this research study. Subjects who cannot provide Informed Consent will not be allowed to participate. No Legally Authorized Representatives (LAR) will be utilized.

Recruiting Service Members	Will you be recruiting service members in a group setting?	☒Yes	☐No

Participation Compensation:

☒	Subjects will not be paid for participation in this study.

Assent Process: N/A

Benefits:

The benefits to the participant are increased resilience and decreased stress, and an increased ability to handle issues in both professional and personal life. Long term benefits for research community include data about the effectiveness of the SMART program, and mindfulness training effectiveness among family medicine residents.

Risks:

There is a minimal risk of psychological discomfort that may arise during group sharing. Additionally, a slight risk of inadvertent breach of confidentiality is present. The risks of the study are no more than those encountered in daily life.

Costs: N/A

Safeguards for Protecting Information:

Data and Specimen Storage Plan

How will coded or identifiable data/specimens be stored?

☒	Paper data, including completed consent forms	The surveys will only contain the subject number to mask the identity of the individual. The research consents and HIPAA Authorization Documents will be stored in a locked cabinet in a locked room with restricted access.

☒	Electronic data	All coded, de-identified research data will be electronically stored separately from the Master Key of identifiable patient demographics and PHI/PII.
☒	Long-term storage (following completion of the study and inactivation of IRB approval)	The research data will be coded and any links to identifiable data will be destroyed (an approved shredding bin) as soon as possible or no later than at the closure of the study. The anonymized research data will not be utilized for further research activity beyond the protocol stipulations without additional IRB approval. All de-identified research data will be maintained for 3 years following study closure.

Safeguards for Protecting Subjects Relative to Reasonably Expected Risks:
There is a slight chance of a breach of confidentiality since the designated research coordinator is storing a Master Key of Personally Identifiable Information (name, email address, and phone number).

Clinical Care: N/A

Injury Compensation: N/A

Data Safety Monitoring	☒N/A – none of the situations listed above apply

6. DATA ANALYSIS

Data Analysis:
All questionnaires will be scored according to the mechanism contained within. These scores are considered outcome variables and will be analyzed using paired t-test and repeated measures analysis.

Outcome Measures:
Resilience score, stress score, and mindfulness score measured at baseline, 12 weeks, and 12 months will be used as outcome measures.

Sample Size Estimation/Power Analysis:
The sample size was estimated based on the medium effect size (0.6, a resilience score mean change = 3, SD = 5) for a 2-sided paired t-test with a significance level α of 0.05. Taking 20% withdrawal into account, 35 subjects (29 completed) will achieve 80% power.

Statistical Analysis:
Continuous variables will be assessed for normality by the Shapiro-Wilks test. Normally distributed continuous data will be presented as mean and standard deviation. Paired t-tests will be performed to compare the baseline outcome scores with the 12-week outcome scores. The repeated measures analysis with a Bonferroni post hoc test will be performed to determine significant differences over time (i.e., baseline, 12 weeks, and 12 months). Non-normally distributed data will be presented as median and interquartile range (IQR) and will be analyzed using Wilcoxon signed rank test and Friedman's Rank Test (non-parametric methods). A significance level will be set to $p<0.05$. Statistical analyses will be performed by the 59MDW Biostatistician using SAS version 9.4 (Statistical Analysis Software, Cary, NC).

Number of Subjects:				
	# Planned to Enroll	# Enrolled	# Planned to Complete Study	TOTAL
Number of Subjects at Eglin AFB	35	0	29	35

7. STUDY DURATION

Duration of Study:
Approximate duration of the study: 2 years

8. LOCAL AND EXTERNAL SUPPORT SERVICES-None

9. INTRAMURAL (GME) AND EXTRAMURAL FUNDING SUPPORT- None

10. MEDICAL RESEARCH AREA

☒Family Medicine	☐Family Medicine Residency	☒Wellness

11. ATTACHMENTS

1. Form A, Signature Sheet
2. Form A-2, Study Personnel Listing
3. Informed Consent
4. HIPAA Authorization
5. Mindful Attention Awareness Scale
6. Perceived Stress Scale
7. Connor-Davidson Resilience Scale