AWARD NUMBER: W81XWH-18-C-0331

TITLE: Effectiveness of Trauma Management Therapy and Prolonged Exposure Therapy for the Treatment of Post-Traumatic Stress Disorder in an Active Duty Sample: A Comparison Study

PRINCIPAL INVESTIGATOR: Deborah C. Beidel, Ph.D., ABPP

CONTRACTING ORGANIZATION: University of Central Florida Board of
Orlando, FL

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Deborah C. Beidel, Ph.D., ABPP

E-Mail: Deborah.Beidel@ucf.edu

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UNIVERSITY OF CENTRAL FLORIDA
BOARD OF TRUSTEES
4000 CENTRAL FLORIDA BLVD
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14. ABSTRACT

This study will provide an evaluation of performance and suitability of the compressed versions of exposure psychotherapy to support the capability gap for the treatment of active-duty service members and veterans with PTSD by comparing different exposure psychotherapy modalities. The overall objective of this study is to determine if compressed psychotherapy can be used as an effective alternative treatment for PTSD and to compare the impact of TMT and PE on social, familial, and occupational impairment. The primary objectives will be to compare 1) 3-week TMT with 12-week PE and 2) 3-week TMT with 2-week PE for the effectiveness of reducing PTSD symptoms in a gated approach or some other method to control for multiplicity. Outcomes will be determined based upon self-report, clinician ratings, as well as other aspects of psychopathology, and social/emotional functioning. The addition of the TMT group component will be assessed in particular to determine its impact on social, familial, and occupational impairment. The current status of the software and VR suite as a potential FDA-regulated medical device needs to be evaluated. The investigator or the company/supplier should request an IDE exemption for the study from the FDA. Blood samples will be collected from participants at baseline and at the end of the treatment period in order to identify PTSD biomarkers, e.g., predictors of response, biological subtypes of PTSD, and therapeutic markers. Collection, storage, and transfer of the blood samples to DoD will be performed according to standardized protocols provided by the DoD. One or more site visits may occur in order to assess adherence to standardized protocols.

15. SUBJECT TERMS **None listed.**

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Introduction

The purpose of this project is to identify an effective exposure psychotherapy paradigm for the treatment of Post-Traumatic Stress Disorder (PTSD) in active-duty service members and veterans by comparing different exposure psychotherapy modalities. The long-term goal of exposure psychotherapy is to improve the mental health of U.S. service members and veterans with military-related PTSD. Recovery from PTSD will reduce the economic burden not only for those persons experiencing PTSD, but also for the health care system and society as a whole.

Keywords

- Post-Traumatic Stress Disorder (PTSD)
- Trauma Management Therapy (TMT)
- Prolonged Exposure (PE)
- Compressed Prolonged Exposure (CPE)
- Navy Medical Center Portsmouth (NMCP)
- Eisenhower Army Medical Center (EAMC)
- Navy Medical Center Camp Lejeune (NMCCL)

Accomplishments

Major Goals/Objectives

This project will evaluate the efficacy and suitability of the compressed versions of Prolonged Exposure Therapy (PE) and Trauma Management Therapy (TMT) for the treatment of active-duty service members with PTSD. The objectives are as follows:

1. Initial goal was to determine if compressed formats of established interventions for PTSD (PE and TMT) are effective treatments for PTSD compared to PE when delivered in a standard treatment format. Due to challenges in recruitment brought about as a result of COVID-19, the goal was revised to eliminate the standard PE comparison and the study redesigned/reduced to a two group comparison (compressed PE vs TMT; see Changes/Problems below). The efficacy will be determined at the end of the active treatment phase as well as at three- and six-months post-treatment.

2. Compare the impact of TMT and PE on social, familial, and occupational impairment.

3. Examine differences in attrition and the emergence of potential adverse events that may accompany intensive treatments, such as increased suicidal ideation or increased substance use.

4. Using blood samples collected at baseline, end of treatment, and three- and six-months post-treatment, identify PTSD biomarkers (e.g., predictors of response, biological subtypes of PTSD, and therapeutic markers).

Major activities

- Participant accrual is ongoing.
- We continue to be challenged by resignations of study personnel but continue to recruit and replace clinicians.
- Closure of Camp Lejeune site due to ongoing difficulties with integration of the project into the mental health service on the base (see Changes/Problems section below).
- To date, 81 participants have been assessed for the project and 69 have been randomized into one of the two groups – one additional participant is pending randomization (see CONSORT chart). Forty-two participants (42) were randomized to Compressed PE – 30 have completed treatment, 11 dropped out, and 1 is currently in treatment. Twenty-seven participants (27) have been randomized to TMT – 18 have completed treatment, 4 participants dropped out, and 5 are waiting to begin treatment (see CONSORT chart).

Specific Objectives/Deliverables

Reporting

• Develop and Submit Quarterly Reports.
The researchers will create a quarterly report that documents the project's activities.
Deliverable: Quarterly Reports.
Timeframe: Years 01-05, quarterly
Status: Quarterly reports have been submitted as required

• Submit Contractor Manpower Report (CMR): The researchers will create and submit a CMR annually.
Deliverable: Verification of Submission.
Timeframe: October 31 for the previous fiscal year
Status: The first and second CMRs were submitted as required and the submission were verified. The next CMR was due on 10.31.2020 (with an extension to 1.31.2021) and despite significant effort (see previous annual reports), we were not able to submit for 2020 or 2021. . The new contract specialist assigned to this contract provided us with a different website and we plan to submit September 2022 as required.

• Develop and deliver a Contractor Recommended Surveillance Plan.
The researchers will develop a recommended plan to evaluate the quality of the research effort within 5 days of contract award. This plan will include program metrics and success indicators.
Deliverable: Contractor Recommended Surveillance plan.
Timeframe: Year 01, Month 01
Status: Completed

• Provide Case Report Forms.

The researchers will provide a Case Report Form Template for review within 3 months from contract award. The government will review to ensure appropriate and complete phenotypic information for each patient is being collected for correlation with the blood samples that USACEHR will analyze.
Deliverable: Case Report Forms.
Timeframe: Year 01, Month 03
Status: Completed

• Develop and deliver an Annual Progress Report.
The researchers will create an Annual Progress Report that details the efforts related to the project for the year.
Deliverable: Annual Progress Report.
Timeframe: Year 01, Month 12
Status: Completed for Years 01, 02, 03, and 04

• Provide notification of contact with other agencies: The researchers will provide written notice of any anticipated meetings between research staff (including sub-contractors) and other government agencies.
Deliverable: Notifications of contact
Timeframe: As needed/as appropriate
Status: Will complete as needed

• Provide written communications related to the project: The researchers will provide copies of written communications between project staff (including sub-contractors) and other government agencies.
Deliverable: Copies of written communications
Timeframe: As needed/as appropriate
Status: Will complete as needed

Agreements, Subcontracts, and Surveillance

- Initiate and complete subcontracts: UCF will complete the subcontract agreement with the Geneva Foundation and with Peter Tuerk, Ph.D.

Deliverable: Completed subcontracts
Timeframe: Year 01, Month 04
Status: The subcontract with Geneva was terminated (03/10/21) due to poor performance and a new subcontract with The Staffing Resource Group (SRG) was initiated on (03/11/21). SRG has been extremely accessible to UCF personnel as well as clinicians and research coordinators on the project. SRG has identified and hired the remaining personnel needed in this short period of time. Overall, we are pleased with SRG's performance thus far.

Data Analysis Plan

• Develop a Data Analysis plan: The researchers have developed a data analysis plan (included with the original proposal).
Deliverable: Data Analysis Plan (included with proposal)
Timeframe: Year 01, Month 01
Status: Completed.

Regulatory

• Initiate Human Subjects Approval.

UCF will work with the three sites to submit all necessary Human Subjects documentation, and once IRB approval is granted at the sites, will submit that information to UCF IRB and HRPO for second-tier review.
Timeframe: Year 01, Month 01 through Year 01, Month 12
Status: Completed.

• Develop a Draft Study Protocol.
Within 2 months of contract award, the researchers will submit a draft research protocol to the government. After IRB approval, the final protocol will be submitted to HRPO. HRPO approval will be obtained prior to initiation of study recruitment.
Deliverable: Draft Study Protocol.
Timeframe: Year 01, Month 02
Status: Completed. HRPO approval is no longer required for studies with DOD IRBs.

• Determine and if necessary, obtain FDA device exemption.
If the IRB makes the determination that the virtual reality system will require a device exemption from the FDA, the researchers will work with the FDA to obtain an IDE exemption. The exemption will be documented in the official meeting minutes from an FDA meeting.
Deliverable: Meeting minutes or notice from FDA, if deemed necessary by IRB.
Timeframe: Year 01, Month 01-09
Status: Completed.

Personnel Management and Hiring

• Develop and submit job descriptions: Provide Geneva Foundation with job descriptions to begin clinical personnel recruitment at three performance sites.
Deliverable: Job descriptions.
Timeframe: Year 01, Month 02
Status: As stated above, the sub-contract with Geneva Foundation has been terminated. The new sub-contractor (SRG) has been given all job descriptions and hires personnel as needed.

• Complete Hiring of Clinical Personnel: Personnel decisions for project personnel at the three treatment sites will be finalized.
Timeframe: Year 01, Month 03 through Year 01, Month 09
Status: There are currently two vacancies at Portsmouth (study clinicians). Identified candidates have been interviewed by the PI. The site PI at Portsmouth has requested the ability to interview potential therapists, which is a reasonable request. We are arranging the interviews and hope to extend offers very soon.

• Complete Hiring of Support Personnel at UCF: Personnel decisions for project personnel at UCF finalized.
Timeframe: Year 01, Month 03 through Year 01, Month 09
Status: Completed

Study Preparation

• Develop a DSMB Charter: The researchers will provide a charter for the DSMB. This charter will include a plan or scheduled and unscheduled reviews of adverse events.
Deliverable: DSMB Charter.
Status: Completed

Timeframe: Year 01, Month 02

• Provide Training Manuals: The researchers will provide drafts of the training manuals associated with the proposed study within two months of contract award. The manuals will include recommendations for assessing treatment fidelity.
Deliverable: Draft Training Manuals
Timeframe: Year 01, Month 02
Status: Completed

• Develop a Randomization Plan: The researchers will develop a randomization plan that will describe the method by which random assignment will be achieved. This plan will be submitted within 3 months of contract award.
Deliverable: Randomization Plan
Timeframe: Year 01, Month 03
Status: Completed. The plan did not change even though we developed a new randomization schedule consistent with changes in study design (2/2022). See below.

• Develop a Data Management Manual: The researchers will develop and deliver a data management manual within 3 months of contract award. This manual will include a description of all phases of data management, including informed consent, data accuracy, and database audit plan.
Deliverable: Data Management Manual
Timeframe: Year 01, Month 03
Status: Completed

• Train Therapists in PE and TMT: Therapists will complete training in both Prolonged Exposure and Trauma Management Therapy and reach approved criteria.
Timeframe: Year 01, Month 10 through Year 01, Month 12
Status: 4 of 6 therapists are fully trained and are providing treatment. Candidates for the two open positions at Portsmouth have been interviewed by the PI. Additionally, with the closing of the Camp LeJeune site, one additional therapist will be hired at Eisenhower. A candidate for this position has been interviewed by the PI. Candidates who are hired for the study will be trained in assessment and treatment protocols.

• All Research and Clinical Staff Trained in Study Protocol: All clinical staff will be trained in all aspects of the protocol, including all procedures and timelines, study assessments, and data handling.
Timeframe: Year 01, Month 10 through Year 01, Month 12
Status: All therapists are trained in the study protocol as they are being onboarded and credentialed.

• Establish clinic space at each treatment site and begin recruitment: PI will travel to each site to assure project implementation. This will include meetings with leadership, site investigators, and research staff to assure that adequate space and all office equipment/computer equipment has been delivered and that clinicians have completed all necessary training at the site.
Timeframe: Year 02, Months 01 and 02
Status: Clinic space at all 3 sites has been established. The Camp Lejeune site closes on June 3, 2022.

• VR equipment installed at each site and clinicians trained on use: Working with distributor, PI will ensure that VR systems are established at each site and clinicians are thoroughly trained in their use.
Deliverable: Documentation of training completion.
Timeframe: Year 02, Months 01 and 02

Status: VR training occurs on site or at UCF (depending on availability and scheduling) at the same time as all other clinical training.

Study Execution

• Admit and initiate treatment protocol: Each site will admit a minimum of three participants per month. Thus, a minimum of nine participants per month will be admitted to the study, as shown in the included Gantt chart.
Timeline: Year 02, Month 03 through Year 05, Month 12
Status: As delineated below, changes in the study design will allow for accelerated recruitment into the two intensive treatment groups. At this point, we believe that we will achieve our revised treatment goal (144 patients randomized to one of two treatments) by month 06 of year 06, allowing for completion of follow-up by the end of the contract.

• Initiate and continue patient follow-up: Project coordinator will track participants and arrange for 3- and 6-month follow-up assessments.
Timeline: Year 02, Month 07 through Year 05, Month 12
Status: Three-month follow-up assessments are ongoing.

• Finish 6-month follow-up assessments: Project coordinators will arrange final 6-month follow-up assessments.
Timeline: Year 06, Month 06
Status: Six-month follow-up assessments are ongoing..

Shipment of Blood Samples

• Work with the USACEHR Director of Systems Biology to develop blood sample collection and shipment protocol. This will be completed by 30 days prior to recruitment commencement.
Deliverable: Blood Sample Protocol
Timeframe: Year 01, Month 11
Status: Completed

• Send blood samples to USACEHR Director of Systems Biology (Marti Jett-Tilton, Ph.D., Senior Scientist ST/SES, US Army Medical Research and Development Command, Walter Reed Army Institute of Research) and Notify Government of Shipment: On the last day of the month, samples will be sent to USACEHR Director of Systems Biology per protocol established in Year 01. This will include a detailed description of the data identifiers (as documented in the Case Report Form for each subject) as well as collection techniques. Notification of number of blood samples sent will be sent to the government with each monthly batch that is sent to USACEHR.
Deliverable: Blood samples and notification of shipment.
Timeframe: Monthly, Year 02, Month 03 through Year 06, Month 12
Status: Shipping procedures have been established and data collection is ongoing

Data Analysis

• Develop and deliver a Top Line Results report: Depending on the date of the final 6 month follow up assessment, this report will be delivered in month 07 or 08. The researchers will create a Top Line Results report within 30 days of database lock. This report will provide a high-level summary of the research outcomes based on preliminary data analyses of the study.
Deliverable: Top Line Results report.
Timeframe: By Year 06, Month 08
Status: Pending

• Conduct data analyses: The statistician will conduct data analyses to examine the primary and secondary hypotheses per the Data Analysis Plan.
Timeframe: Year 05, Month 06 through Year 06, Month 09
Status: Pending

• Develop and deliver a final clinical results report: The researchers will create a final report that details all clinical results resulting from the study described in Task 12. The report will be submitted within 6 months of database lock.
Deliverable: Final Clinical Results

Status: Year 06, Month 12.

Significant results or key outcomes

Nothing to report

Major findings, developments or conclusions (both positive and negative)

Nothing to report

Results disseminated to communities of interest

Nothing to report

Other achievements

Nothing to report

Opportunities for training and professional development

Nothing to report

Results disseminated to communities of interest

Nothing to report

Plans to accomplish the goals in the next reporting period

- Continue recruitment and admission of study participants.
- Admit a minimum of four participants per month at both sites. Thus, a minimum of eight participants per month will be admitted to the study. If possible, additional subjects will be recruited to make up time lost due to pandemic.
- Personnel from UCF will conduct quarterly visits at each study site.
- Close down Camp Lejeune site and move resources to DD Eisenhower Army Medical Center, where there is a waiting list and a demand for the services provided by this project.
- Collect blood samples at baseline, post-treatment and 3- and 6-month post-treatment.

- The research coordinators will send blood samples to USACEHR Director of Systems, Dr. Marti Jett-Tilton, for processing and analysis on a monthly basis.

- Peter Tuerk, Ph.D. will provide weekly supervision for the CPE protocol and Deborah Beidel, Ph.D. will provide weekly supervision of the TMT protocol.

- Data from the assessments and treatment in Qualtrics will be uploaded on a daily basis and reviewed by the project coordinator for accuracy and quality.

- Initiate and continue patient follow-up assessments at 3- and 6-month post treatment.

Impact

We continue to experience significant therapist turnover at the treatment sites. For example, one therapist at Portsmouth cited "family problems" and resigned *effective immediately*. A second therapist, upset because the PI told her that she had to request time off and not just indicate that she was taking time off resigned *effective immediately.* We continue to recruit and train new therapists as needed but turnover is more rapid than was ever expected. This in turn, affects our ability to recruit and treat patients.

Changes/Problems

There are two significant changes that have occurred over the past year that are reported here:

Change in Study Design: After submission of the last quarterly report, it was clear that achieving the originally projected participant recruitment was not going to be possible without several addition years and additional funding, which was not possible. (see previous report Year 04 Q3 report). Consultation with the Contract Scientific Officer led to the conclusion that reducing the scope of the study to focus on a comparison of the two IOP conditions (i.e., dropping the standard PE condition) would achieve the same aims as the original project, while significantly reducing the number of participants needed. Briefly, dropping the standard PE arm is supported scientifically and statistically:

A. Scientifically: According to a recent meta-analysis [McLean et al. (2022). Exposure therapy for PTSD: A meta-analysis. Clinical Psychology Review, 91, https:doi.org/10.1016/j.cpr.2021.102115], "Exposure therapy has large effect sizes for PTSD symptoms relative to wait list and treatment as usual, a small effect relative to non-trauma-focused comparators, and negligible effect vs. other trauma treatments and medication." CPE and PE have similar effect sizes [Foa et al. (2018) Effect of Prolonged Exposure Therapy Delivered over 2 weeks vs 8 weeks vs present-Centered Therapy on PTSD symptom Severity in Military Personnel: A randomized controlled trial. JAMA, 319 (4): 354-364]. What we do NOT know is (a) whether exposure therapy with VR (as we do in TMT) would be superior to any form of PE (i.e., does adding VR enhance the effects of Exposure Therapy?) and (b) whether adding TMT's group component affects other behaviors such as sleep disruption, anger management or social isolation.

B. Statistically: Because standard PE has a dropout rate of 40% (as compared to 5-10% for compressed treatments), 42% of our participant recruitment was for the standard PR arm. If the study design was reduced to the two compressed groups, a new power analysis – based on the original data analytic strategy and these updated dropout rates - would result in a needed N of 144 (not 300) with equal randomization (based on equal dropout rates) would result in enrollment of 72 patients to the CPE and TMT groups, respectively.

The decision to make this study design change was approved by the funding agency.

NMMCL: This site has been plagued by personnel changes and only limited support from mental health. The Portsmouth IRB conducted an audit of all three treatment sites in November 2021. The audit did not reveal any patient care issues although there were some documentation and recording issues that were determined to be problematic, and the majority of those issues were at the Camp Lejeune site. Many of the deficiencies pertained to inadequate documentation with respect to the regulatory binder. Study personnel from Naval Medical Center Portsmouth traveled to Naval Medical Center Camp Lejeune to assist in getting the site up to compliance. Despite significant improvement, there continued to be issues with respect to the functioning of the project within the overall system of care.

On May 5, 2022, Dr. Beidel conducted a quarterly site visit at Camp Lejeune. The medical hospital command was fully supportive of the project but on the organizational chart, the project was situated under the Clinical Trials Unit (not the mental health unit). The immediate staff supervisor was not a clinician and, based on some of the questions that were asked, (see below) was unfamiliar with psychological clinical trials. Numerous challenges to the conduct of the were identified including:

- The hospital recently transitioned to a new EHR (Genesis) but even though it had been weeks since the transition, study personnel could not document patient encounters in the EHR.
  - One study clinician was not listed as a provider
  - The research coordinator had lost access
  - Even the other clinician, who was listed as a provider, could not input therapy notes – although able to keep a local record of all appointments, there was no official record in the EHR that patients in this protocol were in treatment with the project.
  - Patient appointments could not be listed as therapy appointments and could not be scheduled in the EHR. Every appointment had to be recorded as a walk in.
  - The immediate supervisor questioned WHY the therapists were trying to document therapy appointments, when this was a research project. She did not understand that although it was a research study, the therapies were not experimental procedures but were standard treatments that represented standard psychological therapy.
  - Five months after the IRB audit, the site still had not complied with IRB requirements to have a therapy note template.

- At a meeting with the site PI and the clinical trials supervisor, questions were raised as to why the patients had to get a diagnosis of posttraumatic stress disorder. Dr. Beidel explained that the study was funded to treat PTSD and that the study inclusion criteria required a diagnosis. There was pushback from site personnel who wanted to know why we just could not “state that patients had some symptoms reminiscent of PTSD.”

- Site personnel expressed concern about providing treatment to patients who would not be on active duty during the follow-up period, believing that providing protocol treatment to patients who then would be discharged from the military was a problem due to concerns that they would not have adequate mental health follow-up care (even though a number of patients were not in any mental treatment prior to being referred to the project). The site instructed clinicians to change study admission criteria and only admit patients who would still be on active duty during follow-up. Dr. Beidel explained that this was never part of the written protocol and that was not the way that the study had been functioning for the past three years. However, the site wanted changes to the inclusion/exclusion criteria, even though we were three years into the study. Although it is acknowledged that final decisions about patient care are the responsibility of the site, it was concerning that this site was

making decisions about study admission that were not in line with the study protocol or the IRB protocol and with no consultation from UCF.

In summary, over the past year, significant concerns about record-keeping at this site have emerged, and there was a lack of integration of the study into the mental health services at the hospital. Additionally, the request not to assign a diagnosis of PTSD and the request to change study inclusion/exclusion criteria led to a decision by the Portsmouth PI and the UCF PI to close the Camp Lejeune site and transfer support to Eisenhower Army Medical Center, where there is substantial support for the project and a 15-person waiting list. Increasing the number of therapists at Eisenhower was considered to be the best use of study resources.

UCF: No changes/problems. Dr. Neer has retired and the decision has been made not to hire/replace at this time
NMCP: No changes/only problem is difficulty in recruiting/retaining therapists at this site
EAMC: No changes/problems.

Products

Nothing new to report

Participants & Other Collaborating Organizations

Name:	Christina Alecse
Project Role:	Project Manager
Nearest person month worked:	0.62
Contribution to Project:	Ms. Alecse provides day to day coordination with study sites

Name:	Deborah C. Beidel, Ph.D., ABPP
Project Role:	Principal Investigator
Nearest person month worked:	0.98
Contribution to Project:	Dr. Beidel oversees the implementation of the project.

Name:	Sandra M. Neer, Ph.D. (retired May 15, 2022)
Project Role:	Co-Principal Investigator
Nearest person month worked:	2.34
Contribution to Project:	Dr. Neer supervises the day-to day-operations of the project and its development and supervises Trauma Management Therapy treatment at all sites.

Name:	Clint Bowers, Ph.D.
Project Role:	Co-Principal Investigator
Nearest person month worked:	0.04
Contribution to Project:	Dr. Bowers is developing the project's database and data analytic procedures.

Name:	Amie Newins, Ph.D.
Project Role:	Co-Principal Investigator
Nearest person month worked:	0.12
Contribution to Project:	Dr. Newins will aid in supervision of treatment.

Name: Christine Seaver
Project Role: Graduate Student
Nearest person month worked: 1.26
Contribution to Project: Ms. Seaver provides data management

Name: Shiyang Su, Ph.D.
Project Role: Co-Principal Investigator
Nearest person month worked: 0.53
Contribution to Project: Dr. Su advises on data management issues

Name: Kathryn Sunderman
Project Role: Graduate Student
Nearest person month worked: 0.53
Contribution to Project: Ms. Sunderman conducts inter-rater reliability and treatment integrity checks

Study Personnel on Sites

NMCP
Name: Open Position
Project Role: Clinician, NMCP
Contribution to Project: Assessment and Treatment

NMCP
Name: Open Position
Project Role: Clinician, NMCP
Contribution to Project: Assessment and Treatment

NMCP
Name: Marquita Bennett
Project Role: Research Coordinator, NMCP
Contribution to Project: Oversee study site operations

NMCCL
Name: Jessica Miller, MSW, LCSW (last day of employment 5/27/2022))
Project Role: Clinician, NMCCL
Contribution to Project: Assessment and Treatment

NMCCL
Name: Daniel Fischer, MSW, LCSW (last day of employment 6/3/2022)
Project Role: Clinician, NMCCL
Contribution to Project: Assessment and Treatment

NMCCL
Name: Bryana Roberts, BS (last day of employment 6/3/2022)
Project Role: Research Coordinator, NMCCL
Contribution to Project: Oversee study site operations

DDEAMC
Name: Rebecca Facundo, LCSW
Project Role: Clinician, EAMC
Contribution to Project: Assessment and Treatment

DDEAMC
Name: Kimberley Banta, LPC
Project Role: Clinician, EAMC
Contribution to Project: Assessment and Treatment

DDEAMC
Name: Cynthia Gilley, BSN
Project Role: Research Coordinator, EAMC
Contribution to Project: Oversee study site operations

Organization Name: Staffing Resource Group
Address: 405 N Reo Street, Suite 255, Tampa, FL 33609
Contact: Britt Massing
Project Role: Sub-award
Contribution of Project: Human Resource Development

Organization Name: Naval Medical Center Portsmouth
Nursing Research & Consultation Services
Address: 620 John Paul Jones Cir, Portsmouth, VA 23708
Contact: Shawna Grover, Ph.D., ANP-BC, LCDR/NC/USN
Project Role: Study Site Co-PI
Contribution of Project: Human subject participation site

Organization Name: Naval Medical Center Camp Lejeune (discontinuation effective 06/03/2022)
Address: 100 Brewster Blvd, Camp Lejeune, NC 28547
Contact: John Gillespie, M.D., LCDR
Project Role: Study Site Co-PI
Contribution of Project: Human subject participation site

Organization Name: Eisenhower Medical Center, Fort Gordon
Dwight David Eisenhower Army Medical Center
Address: 300 E. Hospital Road, Fort Gordon, GA 30905-5650
Contact: Leslie Walker Roberson, LTC
Project Role: Study Site Co-PI
Contribution of Project: Human subject participation site

Special Reporting Requirements
Nothing to report

Appendices
None