

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

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# REPORT DOCUMENTATION PAGE

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| <b>14. ABSTRACT</b><br>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. |                    |                                 |                                   |   |  |
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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. 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. 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

- Although we are still recovering from the impact of COVID-19 and its related suspensions of the study at all three sites, participant accrual at treatment is ongoing.
- The sub-contract with Geneva Foundation has been terminated. A new sub-contract with The Staffing Resource Group (SRG) has been established.
- SRG has made offers to the three outstanding personnel (2 clinicians, 1 research coordinator), but onboarding and credentialing continues to take nearly 3 months. For example, the clinician hired to provide treatment at EAMC was hired 3/22/21 and is still in the process of onboarding.

## 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, we were not able to submit. **Nor have we been able to contact anyone with the contracting agency who has been able to provide us with direction.** Below are the steps that were taken to submit the CMR:

1. The internet reporting system was changed to SAM.gov for submission of the CMR and internal sources and the contract manager established an account on 10.29.2020.
2. We were then able to access the SAM.gov website but the above contract was not listed as an entity, so the CMR template was not available.
3. After several attempts, we were informed that we needed to submit the CMR only if we have a contract subject to the Service Contract Act (SCA).
4. We were also informed that for the reporting done in October (2020) there was only one contract that appeared on UCF's SAM page, and it was not for the above-named contract or our entity, UCF RESTORES.
5. It was suggested that the criteria regarding contracts that were subject to Service Contract Act has caused a lot of projects to drop-off the list of projects that are subject to CMR reporting requirements.
6. We contacted a service representative (05.10.21) at the FSD directly at: [www.fsd.gov](http://www.fsd.gov) / U.S. calls: 866-606-8220 and was told that we cannot access the CMR template at this time as it was removed following the deadline of 01.31.2021. Thus, the CMR form cannot be completed for the past reporting period.

- 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, and 03

- 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. We expect to be fully staffed in the next quarter. 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.

- Complete HRPO approval: UCF will submit approval from the sites by month 9, thereby allowing 3 months for HRPO approval.

*Timeframe:* Year 01, Month 12

*Status:* HRPO approval is no longer required for studies with DOD IRBs.

## **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 has hired all personnel needed at this time.

- 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:* Two clinicians and one research coordinator have been hired by SRG to complete project personnel. All are in various stages of onboarding and credentialing and are attending remote training for their positions.

- 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

- 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 (both forms) 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. Two additional therapists have been hired and are receiving training in assessment and treatment protocols.

- Project Coordinators Complete Phlebotomy Course: The three project coordinators will successfully complete a state approved phlebotomy course, allowing them to perform the blood draws specified in this protocol.

*Timeframe:* Year 01, Month 10 through Year 01, Month 12

*Status:* The Project Coordinators will not be collecting the blood samples but have been trained on how to ship the samples.

- 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:* Four (4) of 6 therapists are fully trained in the study protocol. The therapists who have been hired to fill the vacancies at NMCP and EAMC have been receiving training on the study protocol.

- **Project Coordinators Trained in Blood Protocol:** The project coordinator will be trained in the specific procedures necessary to collect the blood samples as well as shipping requirements. All samples shall be shipped to a storage location at a time specified and according to procedures outlined by the USACEHR Director of Systems Biology.

*Timeframe:* Year 01, Month 10 through Year 01, Month 12

*Status:* Initially, we were informed that lab personnel at the three sites would be too busy to collect the blood samples detailed in this project. However, after study initiation, individual meetings with lab personnel resulted in a reverse of that decision and currently, lab personnel are drawing and processing all blood samples. Project coordinators at each of the sites are responsible for shipping supplies to the USACEHR Director using the established shipping protocol.

- **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.

- **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:* 4 of 6 clinicians are fully trained in the use of the VR. Training with the VR system will begin for newly hired therapists at EAMC and NMCP when their access to base/post is granted.

## **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 04, Month 12

*Status:* Forty-eight participants have been consented and 43 have completed assessment for inclusion. Of the 43 assessed, 34 were randomized. Nine participants were excluded (1 did not meet criteria, 4 declined to participate, and 4 were excluded due to other reasons (e.g., medical clearance). Four (4) participants are currently in treatment and 6 (this month). Twenty-one Post assessments have been completed.

- **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 05

*Status:* Three-month follow-up assessments have been completed for 14 participants.

- **Finish 6-month follow-up assessments:** Project coordinators will arrange final 6-month follow-up assessments.

*Timeline:* Year 05, Month 06

*Status:* Six-month follow-up assessment has been completed for 4 participants. Four additional participants are scheduled for six-month follow-up this month.

## 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 05, Month 05

*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 05, Month 07

*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 05, Month 11

*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:* Pending

## 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 three participants per month at each site. Thus, a minimum of nine 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 now that UCF has resumed unrestricted travel in the U.S.

Site PIs at NMCCCL and EAMC will be changing. New site PIs have been identified (see below) and every effort will be made to ensure a smooth transition.

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.

Sandra M. Neer, Ph.D. and Peter Tuerk Ph.D. will provide weekly supervision to the clinicians to ensure each of the treatment protocols (TMT, PE, and CPE) are administered with fidelity.

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**

COVID-19 had a significant impact on participant recruitment as described in the last annual report. It also significantly impacted our staffing as 7 therapists working on the project resigned during that time – the majority of which were the direct result of COVID. Several resigned during the time that the program was shut down. Additionally, two therapists expressed extreme reluctance to return to work when the sites re-opened, instead choosing to resign their positions. This turnover significantly impacted our ability to recruit and treat patients at the rate that we originally anticipated. Another challenge is the time that it takes to onboard and credential clinical personnel. Recruitment is now occurring at all 3 sites albeit slower than anticipated due to staff replacement and training of new therapists.

## **Changes/Problems**

UCF: No changes/problems.  
 NMCP: No changes in leadership; a new therapist has been hired and has begun onboarding and credentialing.  
 NMCCCL: LCDR Pelka, current site PI, is leaving June 23; LCDR Gillespie is completing all paperwork to assume role as site PI; he will be added to IRB prior to beginning this role.  
 EAMC: LTC Pittman, current Site PI, will be leaving EAMC June 18; LTC Leslie Roberson will be added as site PI when approved by the IRB. A new therapist has been hired and is close to be onboarded and credentialed.

## Products

Nothing new to report

## Participants & Other Collaborating Organizations

Name: Deborah C. Beidel, Ph.D., ABPP  
 Project Role: Principal Investigator  
 Contribution to Project: Dr. Beidel is overseeing the implementation of the project.

Name: Sandra M. Neer, Ph.D.  
 Project Role: Co-Principal Investigator  
 Contribution to Project: Dr. Neer will supervise the day-to day-operations of the project and its development and will supervise Trauma Management Therapy treatment at all sites.

Name: Clint Bowers, Ph.D.  
 Project Role: Co-Principal Investigator  
 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  
 Contribution to Project: Dr. Newins will aid in supervision of treatment.

Name: Paige Melton, MSW, LCSW  
 Project Role: Clinician, NMCP  
 Contribution to Project: Assessment and Treatment

Name: Nicole Prosser, MSW, LCSW  
 Project Role: Clinician, NMCP  
 Contribution to Project: Assessment and Treatment

Name: Monique Carter, MBS, CCRP  
 Project Role: Research Coordinator, NMCP  
 Contribution to Project: Oversee study site operations

Name: Julia Brown, MSW, LCSW  
 Project Role: Clinician, NMCCCL  
 Contribution to Project: Assessment and Treatment

Name: Daniel Fischer, MSW, LCSW  
Project Role: Clinician, NMCCL  
Contribution to Project: Assessment and Treatment

Name: Bryana Roberts, BS  
Project Role: Research Coordinator, NMCCL  
Contribution to Project: Oversee study site operations

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

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

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: Craig Cunningham, Ph.D., CNOR, CAPT/NC/USN  
Project Role: Study Site Co-PI  
Contribution of Project: Human subject participation site

Organization Name: Naval Medical Center Camp Lejeune  
Address: 100 Brewster Blvd, Camp Lejeune, NC 28547  
Contact: Bryan M. Pelka, 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: Demetrious L. Pittman, LTC  
Project Role: Study Site Co-PI  
Contribution of Project: Human subject participation site

## Special Reporting Requirements

Nothing to report

## Appendices: None