

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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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. Outcomes will be determined based upon self-report and clinician ratings, as well as other aspects of psychopathology, and social/emotional functioning. The addition of the TMT group component will be assessed to determine its impact on social, familial, and occupational impairment. Blood samples will be collected from participants at baseline, post-treatment, and 3-and 6-month post assessments 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. Site visits will occur on a quarterly basis 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

- The study personnel at the Navy Medical Center Portsmouth (NMCP) have been on-boarded and credentialing of the clinicians is complete.
- The study site personnel at Eisenhower Army Medical Center (EAMC) and Navy Medical Center Camp Lejeune (NMCCCL) have been identified and are in various stages of the onboarding and credentialing process.
- The electronic assessments and questionnaires in Qualtrics have been completed. Clinicians at UCF have administered the interviews/questionnaires in mock patient interviews to pilot functional utility as well as clinical consistency.
- Individual accounts to access Qualtrics have been established for the clinicians and research coordinators at NMCP and EAMC who have been on-boarded or who are in the process of being on-boarded.
- iPads have been distributed to the study site personnel at NMCP who are also testing the electronic questionnaires/assessments.
- The Empatica E4 wristbands that will be used to measure heartrate and skin conductance during exposure sessions have been received at UCF. The devices have been tested and shown to measure these variables reliably.
- The Fatigue Science Readiband sleep actigraphy devices have been received at UCF and are in the process of being tested. Several staff members and graduate students have worn the device to test their accuracy. Initial results show that the devices will meet the needs of the study. The project manager is also reviewing the data and getting familiar with the data collection software platform.
- Two virtual reality systems have been delivered to NMCP and have been assembled and ready for use. The other study sites will have two VR systems delivered and assembled in the next quarter.
- The IRB at NMCP is ready to approve the study protocol pending the approval of the CRADA by the legal department at EAMC. It is anticipated that this will take place in the first month of the next quarter

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 CMR was submitted as required and the submission was verified

- 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: In Process

- 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: Completed

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: IRB submission was delayed due to delays in completion of CRADA. However, the protocol was submitted to the Portsmouth IRB, acting as IRB of record for all three sites. We anticipate that this approval will occur quickly as we worked in advance of formal submission to clarify IRB questions.

- 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: The study protocol was submitted to the contracting agency (completed). As noted above, IRB approval is in process.

- 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: In process - IRB submission was delayed due to delays in completion of CRADA. However, the protocol was submitted to the Portsmouth IRB, acting as IRB of record for all three sites. We anticipate that this approval will occur quickly as we worked in advance of formal submission to clarify IRB questions.

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: Completed

- 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: In process – we had two individuals (one at Eisenhower and one at Camp Lejeune) who accepted positions and then later withdrew, forcing us to re-open the search for these two positions. All other positions have been filled and training is ongoing.

- 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: The first training was completed in March of 2019. The second training was completed on May 21-23. The third training will occur June 4-7, 2019.

- **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 need to complete the phlebotomy course as the labs at each of the three study sites have agreed to perform the blood draws. They will however receive training during the next quarter on how to process 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: Training of study procedures and assessments was held at NMCP February 11-13; training at other sites will take place as new personnel are on-boarded. Training at EAMC took place May 21-23. Training at NMCCCL occurs June 4-7.

- **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: As stated above, the Project Coordinators will not be collecting the blood samples but will be trained during the next quarter on how to process and ship the samples.

- **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: The 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: The first training took place from March 4-8, 2019. Other trainings will occur as equipment is installed

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: Pending IRB approval

- **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: Pending

- Finish 6-month follow-up assessments: Project coordinators will arrange final 6-month follow-up assessments.
Timeline: Year 05, Month 06
Status: Pending

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 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: Pending

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

Training of study procedures and assessments was held at NMCP February 11-13. Training of TMT, CPE and PE treatment protocols was held at NMCP April 4-8. Training of study procedures and assessments occurred on May 21-23 at EAMC and will occur on June 4-7 at NMCCCL. Training will continue to take place as new personnel are on-boarded.

Results disseminated to communities of interest

Nothing to report

Plans to accomplish the goals in the next reporting period

Complete IRB approval process

Complete the onboarding, credentialing and training of study site personnel.

Obtain all supplies and equipment necessary to fully implement the study protocol at each site. This includes laboratory supplies to collect and process blood samples and the virtual reality systems.

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.

Personnel from UCF will conduct quarterly visits at each study site.

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 for processing and analysis monthly.

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 completed in Qualtrics will be uploaded daily and reviewed by the project manager for quality.

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

Impact

What was the impact on the development of the principal discipline(s) of the project?

Nothing to report.

What was the impact on other disciplines?

Nothing to report.

What was the impact on technology transfer?

Nothing to report.

What was the impact on society beyond science and technology?

Nothing to report.

Changes/Problems

Changes in approach and reasons for change.

Nothing to report.

Actual or anticipated problems or delays and actions or plans to resolve them.

Nothing to report.

Changes that have a significant impact on expenditures.

Nothing to report.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents.

Nothing to report.

Products

Publications, conference papers, and presentations

Nothing to report.

Website(s) or other Internet site(s)

Nothing to report.

Technologies or techniques

A database has been developed in Qualtrics that is comprised of electronic versions of the assessment instruments and questionnaires that will be utilized to gather data on iPads. These include: the Clinician-Administered PTSD Scale for DSM-5, the Posttraumatic Stress Disorder Checklist for DSM-5, the Traumatic Life Events Questionnaire, the Trauma-Related Guilt Inventory, Posttraumatic Cognitions Inventory, the Moral Injury Event Scale, the World Health Organization Disability Assessment Schedule 2.0, the Quality of Life Scale, the Connor-Davidson Resilience Scale, the Structured Clinical Interview for DSM-5-Clinician Version,

Structured Clinical Interview for DSM-5, Personality Disorders, the Patient Health Questionnaire-9, the Generalized Anxiety Disorder-7, Dimensions of Anger Reactions-5, and Clinical Global Impressions Scale.

Inventions, patent applications, and/or licenses

Nothing to report.

Other products.

Nothing to report.

Participants & Other Collaborating Organizations

The following individuals have worked on the project for at least one person month in the last year.

Name:	Deborah C. Beidel, Ph.D., ABPP
Project Role:	Principal Investigator
Contribution to Project:	Dr. Beidel is overseeing the implementation of the project.
Nearest Person Month Worked	2.3

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.
Nearest Person Month Worked	7.82

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.
Nearest Person Month Worked	1.6

Name:	Amie Newins, Ph.D.
Project Role:	Co-Principal Investigator
Contribution to Project:	Dr. Newins will aid in supervision of treatment.
Nearest Person Month Worked	2.05

Name:	Stephen Dalsemer, MPA
Project Role:	Project Manager
Contribution to Project:	Implementation of day to day operations of the project; coordination with research coordinators at each site; purchase, test, and distribute all research equipment necessary to implement protocol; coordinate travel and DSMB meetings; completion of the deliverables and reports.
Nearest person month worked:	8

Name: Erynne Shatto, Ph.D.
Project Role: NMCP Clinician
Contribution to Project: Assessment and Treatment
Nearest person month worked: 6.75

Name: Ladonna Hankins, Ph.D.
Project Role: NMCP Clinician
Contribution to Project: Assessment and Treatment
Nearest person month worked: 3.36

Name: Monique Carter
Project Role: NMCP Research Coordinator
Contribution to Project: Oversee study site operations
Nearest person month worked: 7.35

Name: Kashana Gaines, LCSW
Project Role: EAMC Clinician
Contribution to Project: Assessment and Treatment
Nearest person month worked: 2.08

Name: Cynthia Gilley
Project Role: EAMC Research Coordinator
Contribution to Project: Oversee study site operations
Nearest person month worked: 4.49

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to report

What other organizations were involved as partners?

Organization Name: Geneva Foundation
Address: 917 Pacific Ave, Tacoma, WA 98402
Contact: Miranda Bethay
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: Heather Hauck, MD, LCDR, FAPA
Project Role: Study Site Co-PI
Contribution of Project: Human subject participation site

Organization Name: Eisenhower Medical Center, Fort Gordon
Neuroscience/Rehabilitation Center
Dwight David Eisenhower Army Medical Center
Address: 300 E. Hospital Road, Fort Gordon, GA 30905-5650
Contact: Demetrious L. Pittman, MAJ
Project Role: Study Site Co-PI
Contribution of Project: Human subject participation site

Special Reporting Requirements

Quad Chart

Appendices

None