**AWARD NUMBER:** W81XWH-17-C-0236

**TITLE:** Targeted Strategies to Accelerate Evidence-Based Psychotherapy (EBP) Implementation in Military Settings

**PRINCIPAL INVESTIGATORS:** Craig Rosen, PhD.; Carmen McLean, PhD.

**CONTRACTING ORGANIZATION:** Palo Alto Veterans Institute for Research
Palo Alto, CA 94304

**REPORT DATE:** October 2018

**TYPE OF REPORT:** Annual

**PREPARED FOR:** U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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Targeted Strategies to Accelerate Evidence-Based Psychotherapy Implementation in Military Settings

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W81XWH-17-C-0236

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**6. AUTHOR(S)**
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**5d. PROJECT NUMBER**

**5e. TASK NUMBER**

**5f. WORK UNIT NUMBER**

**7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)**
Palo Alto Veterans Institute for Research (PAVIR)

**AND ADDRESS(ES)**
3801 Miranda Ave, Bldg 101 A2-210, Palo Alto, CA 94304-1207

**8. PERFORMING ORGANIZATION REPORT NUMBER**

**9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)**

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

**10. SPONSOR/MONITOR'S ACRONYM(S)**

**11. SPONSOR/MONITOR'S NUMBER(S)**

**12. DISTRIBUTION / AVAILABILITY STATEMENT**

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**13. SUPPLEMENTARY NOTES**

**14. ABSTRACT**

Purpose of the first phase (12 to max. 18 months) of this project is to complete all administrative activities preparatory to research. During this report period four performance sites were confirmed including completion of site visits and identification of most of the Site PIs. We are in correspondence with three additional sites that have voiced strong interest in the study and are continuing site recruitment efforts despite challenges specifically with recruiting Navy sites. We obtained approval from Stanford IRB (IRB of Record), NDRI (our subcontractor SSIC's IRB), VAPAHCS RDIS and the IRB package was submitted to one of our military IRBs (David Grant Medical Center for Travis Air Force Base) with approval anticipated in Fall 2018. We keep finalizing study procedures and processes and submitted drafts of the Needs Assessment Interview Guide and TACTICS Implementation Manual as well as quarterly project reports according to our SOW deadlines. We continue to obtain IRB approvals for all entities involved in human subject research and to define the process of accessing identifiable AHLTA Progress notes for PTSD patients at participating sites according to the approved DoD contract.

| 15. SUBJECT TERMS<br>Posttraumatic Stress Disorder, Military Treatment Facilities, Prolonged Exposure Implementation, Site Recruitment, Site Visits, Regulatory, Refinement of Study Procedures, Identification of Data Collection Procedures, Development of Draft TACTICS Implementation Manual and Interview Guides, Administrative Activities | | | | | |
|---|---|---|---|---|---|
| 16. SECURITY CLASSIFICATION OF:<br>U | | | 17. LIMITATION OF ABSTRACT | 18. NUMBER OF PAGES | 19a. NAME OF RESPONSIBLE PERSON<br>USAMRMC |
| a. REPORT<br>U | b. ABSTRACT<br>U | c. THIS PAGE<br>U | UU | | 19b. TELEPHONE NUMBER<br>*(include area code)* |

**Standard Form 298 (Rev. 8-98)**
**Prescribed by ANSI Std. Z39.18**

## TABLE OF CONTENTS

1. **INTRODUCTION:** *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

   The purpose of this DoD-funded study is to develop and implement a novel approach, Targeted Assessment and Context-Tailored Implementation of Change Strategies (TACTICS), to help Military Treatment Facilities (MTFs) increase their use of Prolonged Exposure (PE) therapy for Posttraumatic Stress Disorder (PTSD) and to test the impact of TACTICS on care of Service members with PTSD over and above provider training alone. The project includes two phases: 1) providing PE training to any providers who need it, and 2) implementing a 5-month process improvement effort, TACTICS, which involves identifying clinic-specific barriers and facilitators to PE use and then working with a Site PI and clinic leader to implement an agreed upon plan to address selected barriers. Nine MTFs will be cluster-randomized as to when, after the PE training, the TACTICS intervention begins. Up to 600 behavioral health providers will be enrolled study-wide across those nine sites with between 5 and 60 behavioral health providers per study site. The study will be conducted over a period of 4 years with each site participating for about 20 months. We hope to learn about barriers to implementing PE, including provider attitude and knowledge, as well as strategies that work to make PE more widely available to PTSD patients in the Military Health System.

2. **KEYWORDS:** *Provide a brief list of keywords (limit to 20 words).*

   Posttraumatic Stress Disorder, Evidence-Based Psychotherapy, Prolonged Exposure, Military Treatment Facilities, Implementation Strategies, Cluster Randomization, Process Improvement

3. **ACCOMPLISHMENTS:** *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*

   **What were the major goals of the project?**
   *List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.*

   **Major Task 1: Secure approval at performance sites,** Timeline: 1-6 months. Status: 55%
   **Major Task 2: Obtain and maintain regulatory approvals,** Timeline: 1-15 months. Status: 25%
   **Major Task 3: Meet all contractual reporting requirements during preparatory phase,** as required.
   **Major Task 4: Finalize study procedures,** Timeline: 1-12 months. Status: 75%
   **Major Task 5: Hire and train study staff,** Timeline: 1-12 months. Status: 70%
   **Major Task 6: Stakeholder input to refine procedures,** as needed.
   **Major Task 7: Draft deliverables,** Timeline: 5-7 months. Status: 100%
   **Major Task 8: Manage study staff,** Timeline: 8-36 months. Status: 15%
   **Major Task 9: Collect study data and implement intervention,** Timeline: 15-36 months. Status: 0%

Subtask 1: Collect quantitative data from participating providers, Timeline: 15-36 months. Status: 0%
Subtask 2: Complete provider training and targeted implementation intervention, Timeline: 16-36 months. Status: 0%
Subtask 3: Collect qualitative data from participating providers, Timeline: 21-36 months. Status: 0%
**Major Task 10: Complete data analysis,** Timeline: 45-48 months. Status: 0%
**Major Task 11: Finalize deliverables and dissemination plan,** Timeline: 44-48 months. Status: 0%
Subtask 1: Finalize knowledge product deliverables, Timeline: 48 months. Status: 0%
Subtask 2: Develop a dissemination plan, Timeline: 44-48 months. Status: 0%
**Major Task 12: Meet all contractual reporting requirements during research phase,** Timeline: 50-51 months. Status: 0%
Subtask 1: Complete all contractual reporting requirements. Timeline: 50-51 months. Status: 0%

**What was accomplished under these goals?**
*For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.*

**Project start-up activities:** The majority of activities during this preparatory phase of the project focused primarily on networking with Behavioral Health Clinical Community (BHCC) and Defense Health Agency (DHA) Department leads for participating sites selection, sites recruitment, data collection procedures definition and regulatory activities.

- The award kick-off meeting was held Oct 19, 2017. Participants were Craig Rosen (PI), Carmen McLean (PI), Holly Campbell-Rosen (Contracting Officer's Representative at that time), Jennifer Tait (Contract Specialist), Elaine Staats (Director of Sponsored Research).
- PAVIR research staff (Study Coordinator, Research Assistant) were hired and trained in Dec 2017.
- The PIs met in person with BHCC liaisons CAPT Pauli, Col Pflanz, LTC Sarmiento and LTC Engerran on Feb 9, 2018 to obtain assistance with sites selection and information about service-specific organization and policy issues pertinent to the project.
- Throughout the first two quarters of year 1 we reviewed multiple small business contractors to replace the New England Research Institute (NERI), acquired by a larger company and did not meet the contract's small business requirement. We identified a contractor, Social Sciences Innovations, Corp. (SSIC), who meets our requirements. On Mar 5, 2018 SSIC was approved as small business plan to replace NERI.
- By the end of this reporting period we have confirmed the participation of four MTFs as performance sites (two Army, two Air Force): Schofield Barracks, Fort Bliss/William Beaumont Army Medical Center (WBAMC), Travis Air Force Base (AFB)/David Grant

Medical Center (DGMC), and Holloman AFB, and have completed site visits to all of them between June and July 2018.

- Site PI / PE Champions and alternate POCs have been identified at three of the sites (Travis AFB, Holloman AFB, Ft. Bliss).
- Dates for the 2-day PE training workshop for providers have been scheduled with Travis AFB for Jan 23/24, 2019. Our collaborator who delivers the training workshops is in correspondence with the Site PI at Holloman AFB to schedule training dates for either Jan or Feb 2019. Schofield Barracks has been notified that their training workshop date (previously scheduled for Dec 10/11, 2018) will likely has to be re-scheduled to either Jan 15/16 or Jan 29/30, 2019 due to the IRB approval process taking additional time.
- We continued site recruitment activities: Two Army sites, Joint Base San Antonio - Fort Sam Houston/Brooke Army Medical Center (BAMC) and Fort Stewart/Winn Army Community Hospital have expressed interest in participating and site visits by the research team are being scheduled. A site visit at BAMC has been tentatively scheduled for Oct 3, 2018. The site visit at Fort Stewart is expected for later in Fall 2018. An additional site, Keesler AFB, voiced interest in the project and we are in correspondence with the Mental Health Flight Commander to determine the site's eligibility for the study.
- Numerous attempts have been made to recruit Navy/Marine Corps sites, without success to date. We have approached the Naval Hospital (NH) Camp Pendleton, Naval Medical Center (NMC) Portsmouth, NMC Camp Lejeune, NH Clinic Hawaii, NH Jacksonville, NH Twentynine Palms and Beaufort Marine Hospital. Most of the sites declined due to staff shortage/no research resources available to support our project or because of ongoing competing research or their providers considered to being sufficiently trained in EBPs. Sites that did not reply with a firm "No" (NMC Camp Lejeune) have been approached again. We also reached out to the Navy Medicine East lead re. contacting NHCs New England and Cherry Point and the Navy Medicine West lead re. contacting NH Bremerton and NHC Oak Harbor.
- In an effort to secure additional Army sites, we have reached out to POCs at Forts Campbell and Gordon). We also reached out to Army DHA Behavioral Health leads (LTC Engerran and LTC Sarmiento) to request contact information for Mental Health leads at Forts Wainwright, Carson, Drum and Riley. However, they stated that given other demands, Army would not be able to include more than 4 sites in the study.
- We continue to correspond with our Program Officer (former COR Dr. Holly Campbell-Rosen and current COR Dr. Christie Vu) and USAMRMC POC/BHCC liaison Dr. Ronald Hoover about challenges with sites recruitment. Dr. Hoover confirmed that, in awarding the grant, it was part of the BHCC's responsibility to support our research team with recruiting sites. Hence, without a strong recruitment support from BHCC it would be understandable that we would not secure participation from nine sites by the end of the first contract year (Sep 20, 2018). In a phone conversation on Aug 17, 2018, Dr. Campbell-Rosen agreed and confirmed that we as the contractor should not be penalized for a slower than expected recruitment process. She also offered the possibility of an extension to the contract. However, we anticipate that we can still start the research activities as scheduled in the contract and that an extension to the contract will not be needed. Furthermore, Dr. Campbell-Rosen also noted that if no Navy sites could be recruited, the contract, which states that sites from all three military branches will be included, will be modified accordingly to allow us to recruit additional Army and Air Force sites instead.

- During a BHCC meeting Aug 30, 2018, Dr. Hoover has brought up the BHCC's role and responsibilities in supporting the research team with sites recruitment for this project. During the meeting the need for more flexibility to meet recruitment expectations (Army and Air Force sites only instead of sites from all three service branches) and required timeframes were emphasized.
- To minimize history effects due to e.g. policy changes in the Military Health System we are aiming to have all sites start the study within a six-month timeframe and will follow our COR's guidance on when to no longer pursue the recruitment of Navy/Marines sites.
- Regulatory activities: Initial Stanford IRB approval for an expedited protocol was obtained Apr 5, 2018. Following recommendations from the Human Research Protection Office (HRPO) and our sponsor, we updated the Stanford IRB protocol and resubmitted on May 31, 2018. This resubmission clarified that Stanford protocol will serve as the Core protocol. The modified protocol also included additional details on the research and process improvement procedures, so that it can serve as a reference document used to inform study sites about our procedures. We obtained approval for these modifications on June 21, 2018.
- We submitted a modified protocol to Stanford IRB July 18, 2018 by changing the measure we will use to address our primary aim and including only the staff surveys and analysis of de-identified data from the Behavioral Health Data Portal (BHDP). This modification was approved Jul 23, 2018. We will submit an IRB amendment accordingly to add the coding of progress notes after we have clarity on the required permissions and logistical details of that process. Fortunately, analyses of these notes can be done retrospectively, so other parts of the project can proceed while we seek such approval.
- The National Development and Research Institutes (NDRI), IRB of our collaborator Social Sciences Innovations, Corp. (SSIC) has been provided with the Stanford IRB approval letter and is in the process of reviewing the protocol for approval.
- We submitted the study protocol for pre-review to the Human Research Protection Office (HRPO) on May 23, 2018 and on Sep 17, 2018 also provided HRPO with our IRB package submitted to DGMC for review.
- We submitted the study protocol to VAPAHCS Research and Development (RDIS) on Aug 3, 2018 and got approval Sep 19, 2018.
- On Sep 12, 2018 we submitted the IRB document package to David Grant Medical Center (DGMC) IRB for Travis AFB and expect to obtain approval in Fall 2018.
- We are preparing the IRB document package to the William Beaumont Army Medical Center (WBAMC) Human Protections Administrator (HPA) for review by the Regional Health Command – Central IRB for Fort Bliss and plan to submit in Oct 2018.
- We are also preparing the IRB document package for Holloman AFB and are collecting all required documents from the site. The plan is to request that Holloman AFB rely upon the DGMC IRB. The DGMC is willing to do this.
- Each time a site is approved to conduct this study, an amendment will be submitted to the Stanford Core protocol and then to HRPO for their review and approval.
- We finalized provider eligibility criteria and screening procedures of behavioral health providers and leadership to determine eligibility in participating in the project's research procedure (completion of online measures) prior to being guided to consenting and completion of online measures.
- We finalized all six online measures.

- The Provider Training Protocol for the 2-day PE Training workshops delivered by our collaborator CDP has been refined with outside PE consultant support, including the development of training materials, slides and handouts.
- As for products delivered, we submitted the draft of the TACTICS Needs Assessment Interview Guide and Pre-Interview Survey to our COR/CS for review as per required timeline on Feb 28, 2018.
- On Apr 30, 2018, we submitted the working draft of the TACTICS rubric for linking identified barriers with implementation strategies and TACTICS toolkits for addressing specific implementation domains materials to our COR/CS for review as per required timeline.
- Throughout Q2 of this reporting period we developed the "crosswalk" of the Consolidated Framework for Implementation Research (CFIR), Expert Recommendations for Implementing Change (ERIC) and CDP's Lessons Learned Manual (LLM), which provides the ground work for our TACTICS manual and implementation tools, including an algorithm for matching implementation strategies with identified barriers and needs.
- The Study Kick-off Meeting is scheduled for Nov 1-2, 2018 at the National Center for PTSD in Menlo Park, CA.
- We submitted all Year 1 Quarterly Progress Reports and Quad Charts for FY 2018, Qrts1-3 as per required timeline.
- Subcontracts with all but one of our five collaborators have been fully executed. The subcontract with our collaborator at the University of Washington (UW) is in preparation after updates to their Statement of Work have been approved. Until full execution of the contract, the UW team is working under an Authority to Proceed (ATP) letter. We are in the process of issuing ATP letters to our collaborators for Year 2 until fully executed contracts for Year 2 are in place.
- We continue to develop the data extraction requirements (identification of variables for data collection to address all project aims) and Data Sharing Agreement (DSA) with DHA to receive de-identified PTSD patient data from participating sites through DHA data pulls.
- We continue to consult with the DHA Privacy Office and the DHA Solution Delivery Division (SDD) about the best way to collect Psychotherapy Progress Notes to analyze for our primary study aim (PE use). We are working with the SDD to determine whether natural language processing could be used by SDD staff to code the progress notes so that coded, de-identified data could be sent to our collaborator SSIC (Data Coordination Core).

**What opportunities for training and professional development has the project provided?**
*If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."*

*Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars,*

*study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.*

- A poster presentation "Targeted Strategies to Accelerate Evidence-Based Psychotherapy (EBP) Implementation in Military Settings" was presented at the 8th annual Traumatic Brain Injury (TBI) Research Forum held Mar 23, 2018 at the Palo Alto VA, CA. The poster was selected as winner of the poster contest.
- A presentation about "Crosswalking Implementation Theory and Practice: Applying the CFIR and ERIC Frameworks to EBPs in the DoD" was presented at the 5th annual Health Science Research (HSR) Conference held May 15, 2018 in Menlo Park, CA.
- A poster presentation "Targeted Strategies to Accelerate Evidence-Based Psychotherapy (EBP) Implementation in Military Settings" was presented at the 10th annual meeting of the Military Health System Research Symposium (MHSRS) held Aug 20-23, 2018 in Kissimmee, FL.

**How were the results disseminated to communities of interest?**
*If there is nothing significant to report during this reporting period, state "Nothing to Report."*

*Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.*

- Nothing to Report.

**What do you plan to do during the next reporting period to accomplish the goals?**
*If this is the final report, state "Nothing to Report."*

*Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.*

- Complete enrollment of all nine study sites: Confirm interest at additional 3 sites that voiced strong interest and complete all site visits; identify remaining 2 performance sites, conduct site visits and confirm study participation with command and Site PI.
- Obtain and maintain regulatory determinations from each of the military IRBs for enrolled performance sites, Stanford IRB/VA Palo Alto Health Care System (for PAVIR), NDRI/SSIC IRB, the Uniformed Services University of the Health Sciences (USUHS) (for the Henry Jackson Foundation), the University of Washington, the University of Texas Austin, the University of Texas Health Science Center at San Antonio.
- Submit individual site approved documents to HRPO for review and approval as they become available.
- Determine procedure for collecting Psychotherapy Progress Notes to analyze for primary study aim (PE use).

- Submit protocol for DHA privacy review in anticipation of submitting Data Sharing Agreement (DSA) application to DHA as soon as we have obtained the first military IRB approval and obtain DSA approval. The DSA will allow us to receive de-identified patient data from the Behavioral Health Data Platform (BHDP) coded by DHA as per our approved study protocol. Submit amendments to the DSA to add the additional sites as they have regulatory approvals.
- If needed, secure Data Use Agreements (DUAs) to access the military databases to access psychotherapy progress notes of PTSD patients receiving care at participating sites.
- Recruit Data Core staff for EMR data collection as needed.
- Begin chart review data collection as per defined and approved procedures, including interrater reliability checks of chart review data collection.
- Complete database development.
- Conduct the Study Kick-off Meeting on Nov 1-2, 2018.
- Begin inviting and consenting providers at performance sites to complete online surveys and begin survey data collection.
- Coordinating with all performance sites for in-person 2-day PE training workshop dates and space allocation.
- Deliver PE training workshops to participating providers at all performance sites (between Jan and May 2019) and start providing weekly 1-hour PE consultation calls to providers as requested.
- Train implementation coaches in TACTICS procedures.
- Cluster-randomize all performance sites as to when they begin with the TACTICS intervention according to the stepped wedge study design.
- Begin with the context-tailored TACTICS intervention including Needs Assessment interviews and TACTICS intervention plan development as well as its implementation at three performance sites, including weekly 1-hour TACTICS coaching calls with the Site PIs and introducing them to the web-based TACTICS rubric.

**4. IMPACT:** D*escribe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*

**What was the impact on the development of the principal discipline(s) of the project?**
*If there is nothing significant to report during this reporting period, state "Nothing to Report."*

*Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).*

- If the TACTICS Intervention approach is found to be effective in providing service members diagnosed with PTSD with an improved access to PE therapy, TACTICS may represent a scalable approach to accelerating the use of other behavioral health best practices in military settings.

**What was the impact on other disciplines?**
*If there is nothing significant to report during this reporting period, state "Nothing to Report."*

*Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.*

- Nothing to Report.

**What was the impact on technology transfer?**
*If there is nothing significant to report during this reporting period, state "Nothing to Report."*

*Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:*
- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

- Nothing to Report.

**What was the impact on society beyond science and technology?**
*If there is nothing significant to report during this reporting period, state "Nothing to Report."*

*Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:*
- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

- Nothing to Report.

**5. CHANGES/PROBLEMS:** *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:*

- We are behind schedule in recruiting participating sites, and have not secured interest from any Navy/Marines sites. These issues have been discussed at length with the COR and USAMRMC POC. It has been agreed that we will follow COR guidance as of when we will stop pursuing the recruitment of Navy sites if all attempts to recruit those sites are unfruitful and whether at that point we will enroll more Army and Air Force sites or whether we will conduct the project with fewer sites in total. Following such decision, the DoD-approved

contract would need to be modified accordingly. We will continue to seek additional BHCC support with sites recruitment.

- We have not yet finalized a process for accessing the psychotherapy progress notes from AHLTA to answer our primary study aim (PE use). We are keeping our COR and USAMRMC POC up to date about these challenges and are adjusting our study protocol and regulatory process accordingly.

**Changes in approach and reasons for change**

*Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.*

- We needed to replace the New England Research Institute (NERI) after they got acquired. On Mar 5, 2018, our small business plan to replace NERI with Social Sciences Innovations, Corp. (SSIC) was approved.

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

*Describe problems or delays encountered during the reporting period and actions or plans to resolve them.*

The following describes anticipated problems that we might encounter:

- Lack of recruitment of Navy/Marine sites: Details and possible action plan discussed above.
- Data extraction: Due to the DHA integration expected in the following years, DHA might have limited staff capacities to obtain BHDP data from all three services to help us address our study aims. We will continue to discuss issues and solutions with our DHA POC and explore alternate approaches to collect our data with the SDD.

**Changes that had a significant impact on expenditures**

*Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.*

- Thus far the delays in sites recruitment have not lead to any significant impact on expenditures. We will follow the guidance of our COR and USAMRMC POC on site recruitment as described above (5. Changes/Problems, 1st bullet point).

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

*Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.*

**Significant changes in use or care of human subjects**

- Nothing to Report

**Significant changes in use or care of vertebrate animals:**

- N/A

**Significant changes in use of biohazards and/or select agents:**

- N/A

**6. PRODUCTS:** *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."*

- **Publications, conference papers, and presentations**
  *Report only the major publication(s) resulting from the work under this award.*

  See section "Opportunities for training and professional development", page 10.

  **Journal publications.** *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

  - Nothing to Report.

  **Books or other non-periodical, one-time publications.** *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

  - Nothing to Report.

  **Other publications, conference papers and presentations**. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

  See section "Opportunities for training and professional development", page 10.

**Website(s) or other Internet site(s)**
*List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.*

- Nothing to Report.

**Technologies or techniques**
*Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.*

- Nothing to Report.

**Inventions, patent applications, and/or licenses**
*Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.*

- Nothing to Report.

**Other Products**
*Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:*
- *data or databases;*
- *physical collections;*
- *audio or video products;*
- *software;*
- *models;*
- *educational aids or curricula;*
- *instruments or equipment;*
- *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
- *clinical interventions;*
- *new business creation; and*
- *other.*

- Feb 28, 2018: We submitted a draft of the TACTICS Needs Assessment Interview Protocol and Pre-Interview Survey to the COR/CS for review as per required timeline.

- Apr 30, 2018: We submitted a working draft of the TACTICS rubric for linking identified barriers with implementation strategies and the TACTICS toolkits for addressing specific implementation domains materials to the COR/CS for review as per required timeline.

- In Q2/Year 1 (between Dec 2017 and Mar 2018) we developed a "crosswalk" of the Consolidated Framework for Implementation Research (CFIR) / Expert Recommendations for Implementing Change (ERIC) / CDP's Lessons Learned Manual (LLM). The product provides the groundwork for our TACTICS manual and implementation tools, including an algorithm for matching implementation strategies with identified barriers and needs.

## 7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

**What individuals have worked on the project?**
*Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change".*

Name: Craig Rosen, PhD
Project Role: PI (PAVIR/NCPTSD)
Research Identifier:
Nearest person month worked: 3
Contribution to Project: Dr. Rosen has overseen all aspects and activities of the study and took part in all four site visits conducted so far.

Name: Carmen McLean, PhD
Project Role: PI (PAVIR/NCPTSD)
Research Identifier:
Nearest person month worked: 3
Contribution to Project: Dr. McLean has overseen all aspects and activities of the study. She was on maternity leave between May 28 and Aug 23, 2018.

Name: Shannon Wiltsey-Stirman, PhD
Project Role: Co-PI (PAVIR/NCPTSD)
Research Identifier:
Nearest person month worked: 1
Contribution to Project: Dr. Wiltsey-Stirman has collaborated on the development of the provider surveys, qualitative interviews and PE implementation barriers and facilitators "crosswalk".

Name: Margaret Mackintosh, PhD
Project Role: Co-PI (PAVIR/NCPTSD)

Research Identifier:
Nearest person month worked: 1
Contribution to Project: Dr. Mackintosh has provided consultation on study data management.

Name: Andrea Neitzer, MS
Project Role: CRC II (PAVIR/NCPTSD)
Research Identifier:
Nearest person month worked: 9
Contribution to Project: Ms. Neitzer has managed and tracked day-to-day study activities in support of the Management Core, supported submission to and correspondence with Stanford IRB, coordinated the site visits, is organizing the study kick-off meeting, made sure all deadlines and requirements were met in a timely fashion and coordinated communication across all four project Cores.

Name: Adrian Davis, MA
Project Role: RA II (PAVIR/NCPTSD)
Research Identifier:
Nearest person month worked: 9
Contribution to Project: Ms. Davis assisted with the day-to-day project coordination, support of the Management Core, developed and refined the PE implementation barriers and facilitators "crosswalk" and is helping with the organization of the study kick-off meeting.

Name: David Riggs, PhD.
Project Role: Co-I (CDP/USUHS)
Research Identifier:
Nearest person month worked: 1
Contribution to Project: Dr. Riggs provided leadership in developing the Barriers-Strategies catalog and drafting the TACTICS manual and implementation tools. He also led the development of the training material for the provider PE training workshops. As one of the key collaborators he took part at the site visits to Ft. Bliss and Travis AFB in person and joined the Holloman AFB site visit by phone.

Name: Jeffrey Cook, PhD.
Project Role: Director of Military Programs, Co-I (CDP/HJF)
Research Identifier:
Nearest person month worked: 3

Contribution to Project: Dr. Cook provided support in developing the Barriers-Strategies catalog and drafting the TACTICS manual and implementation tools. He also joined the site visit at Schofield Barracks by phone.

Name: Melissa Mistretta, B.A.
Project Role: Project Manager (CDP/HJF)
Research Identifier:
Nearest person month worked: 1
Contribution to Project: Ms. Mistretta provided overall management and oversight of CDP/HJF's role on the project. She also worked with the program team to develop the Barriers-Strategies catalog. She was on maternity leave from June 18 to Sep 10, 2018.

Name: Rabia Mir, MPH
Project Role: Implementation SME, Temp. Project Manager (CDP/HJF)
Research Identifier:
Nearest person month worked: 1
Contribution to Project: Ms. Mir worked closely with the program team to help develop the Barriers-Strategies catalog and draft the TACTICS manual and implementation tools. She provided overall management and oversight of CDP/HJF's role on the project while Ms. Mistretta was on maternity leave including the scheduling of two of the 2-day PE training workshops at participating sites. She went on maternity leave August 27, 2018.

Name: Erin Frick, Psy.D.
Project Role: SME (CDP/HJF)
Research Identifier:
Nearest person month worked: 1
Contribution to Project: Dr. Frick assisted with drafting the TACTICS manual and creation of implementation tools.

Name: Alan Peterson, PhD.
Project Role: Site-PI (UTHSCSA, STRONG STAR)
Research Identifier:
Nearest person month worked: 2
Contribution to Project: Dr. Peterson has applied his experience in developing large research studies to the project and served as a consultant. As one of the key collaborators he took part at all four site visits conducted so far to help strengthen a trustful relationship with stakeholders and to leverage the start of the project at participating sites. He is also planning to join the site visit at

Brooke Army Medical Center (BAMC) tentatively scheduled for Oct 3, 2018.

Name: Katherine Dondanville, Psy.D.
Project Role: Co-I (UTHSCSA, STRONG STAR)
Research Identifier:
Nearest person month worked: 2
Contribution to Project: Dr. Dondanville has applied her extensive knowledge of implementing studies at military settings to this project.

Name: Erin Finley, PhD.
Project Role: Co-I (UTHSCSA, STRONG STAR)
Research Identifier:
Nearest person month worked: 1
Contribution to Project: Dr. Finley has collaborated on the development of the provider surveys and qualitative interviews.

Name: Stacey Young McCaughan, RN, PhD.
Project Role: Co-I (UTHSCSA, STRONG STAR)
Research Identifier:
Nearest person month worked: 2
Contribution to Project: Dr. Young McCaughan has overseen the development of study regulatory materials and provided consultation regarding IRB review processes. As one of the key collaborators she took part at the site visit conducted at Travis AFB and Schofield Barracks and is also planning to join the site visit at BAMC tentatively scheduled for Oct 3, 2018. Her goal is to help strengthen a trustful relationship with stakeholders at the sites and to address IRB specific issues with the sites' IRB representatives.

Name: Allison Hancock, PhD.
Project Role: Co-I (UTHSCSA, STRONG STAR)
Research Identifier:
Nearest person month worked: 1
Contribution to Project: Dr. Hancock has worked with Dr. Young-McCaughan on overseeing the regulatory review and approval processes. She took part at the site visits conducted at Ft. Bliss and Holloman AFB to help strengthen a trustful relationship with stakeholders at the sites and to address IRB specific issues with the sites' IRB representatives. She resigned from UTHSCSA on July 13, 2018.

Name: Elisa Borah, PhD.
Project Role: Site PI (UT Austin)
Research Identifier:
Nearest person month worked: 2
Contribution to Project: Dr. Borah has supported the development of study methods and study procedures for the project.

Name: Katherine Anne Comtois, PhD.
Project Role: Site PI (UW)
Research Identifier:
Nearest person month worked: 1
Contribution to Project: Dr. Comtois has worked on procedures for tracking implementation processes/fidelity and supported the development of the TACTICS manual and implementation tools.

Name: Karin Hendricks, MA
Project Role: Research Coordinator (UW)
Research Identifier:
Nearest person month worked: 4
Contribution to Project: Ms. Hendricks has assisted Dr. Comtois in the development of the TACTICS manual and implementation tools and procedures for tracking implementation processes/fidelity.

**Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**
*If there is nothing significant to report during this reporting period, state "Nothing to Report."*

*If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.*

**CDP/HJF – related:**
Dr. Riggs had several awards close during the reporting period of 9/21/17-9/20/18. Those now closed awards include:

- $210,345 contract from the PsychArmor Institute to deliver online workshops to promote the use of evidence-based psychotherapy treatments. The award ended 10/28/17.

- $58,593 from Emory University to deliver the STAR Behavioral Health Program in Georgia. This program provides specialized training in understanding and treating military service members and their families. The award ended 1/31/18.

- $98,425 contract from Rediscover Mental Health to deliver training and consultation to ReDiscover Mental Health behavioral health providers. This program provides specialized training in understanding and treating military service members and their families. The award ended 11/14/17.

**UTHSCSA/STRONG STAR – related:**
Dr. Allison Hancock, Deputy Director of Research, UT Health San Antonio STRONG STAR Research Consortium and one of the study Co-Is has resigned from her position at UTHSCSA on Jul 13, 2018. She supported Dr. Young-McCaughan in overseeing the regulatory review and approval processes. Dr. Young-McCaughan is now managing this part of the project with additional support from Ms. Hargita.

**SSIC – related:**
There have been no changes in SSIC Key Personnel. Due to a delay in receipt of getting the subcontract from PAVIR to SSIC, as well as preexisting SSIC obligations to other ongoing projects during this time period, SSIC staff effort for this period are lower than anticipated. However, as of May 2018, upon execution of the fully executed contract, the official SSIC effort levels as originally proposed are active.

**What other organizations were involved as partners?**
*If there is nothing significant to report during this reporting period, state "Nothing to Report."*

*Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.*

Organization Name: Center for Deployment Psychology / Henry Jackson Foundation (CDP/HJF)
Location of Organization: 6720A Rockledge Drive, Suite 100, Bethesda, Maryland 20817
Partner's contribution to the project: Collaboration – CDP/HJF leads the Implementation Core of the project and is developing and delivering PE training workshops and consulting. They also lead the implementation intervention that is the core of the project.

Organization Name: University of Texas Health Science Center at San Antonio / South Texas Research Organizational Network Guiding Studies on Trauma and Resilience (UTHSCSA/STRONG STAR Consortium)
Location of Organization: 7550 Interstate 10 West, Suite 1325 San Antonio, TX 78229
Partner's contribution to the project: Collaboration – UTHSCSA/STRONG STAR leads the Regulatory Core and develops and submits all Institutional Review Board materials needed to obtain and maintain regulatory approvals to conduct the project.

Organization Name: Social Sciences Innovations, Corp. (SSIC)
Location of Organization: 4th Floor, 71W 23rd St, New York, NY 10010
Partner's contribution to the project: In-kind support, collaboration – SSIC leads the Data Coordination Core, develops the Data Management System, UI of the provider online consenting and online surveys. SSIC also develops and administers all study assessments and oversees all data management and analyses.

Organization Name: University of Washington (UW)
Location of Organization: University of Washington, Seattle, WA 98195
Partner's contribution to the project: Collaboration – The team from UW is collaborating with other members of the Implementation Core on developing the TACTICS rubric. They are leading the PE implementation fidelity monitoring and supporting the development of the TACTICS tools and materials.

Organization Name: University of Texas, Austin
Location of Organization: University of Texas at Austin, Main Building (MAI) 110 Inner Campus Drive, Austin, TX 78705
Partner's contribution to the project: Collaboration – Our collaborator at UT Austin supports the development of study methods, interventions and overall study progress.

## 8. SPECIAL REPORTING REQUIREMENTS

**COLLABORATIVE AWARDS:** *For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to* ***https://ers.amedd.army.mil*** *for each unique award.*

- N/A

**QUAD CHARTS:** *If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.*

- Please find included with the submission of this report.

## 9. APPENDICES: *Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.*

- N/A

# Targeted Strategies to Accelerate Evidence-Based Psychotherapy (EBP) Implementation in Military Settings

PT169001; W81XWH-17-C-0236

**PIs:** Craig Rosen, PhD, Carmen McLean, PhD **Org:** Palo Alto Veterans Institute for Research **Award Amount:** $8,265,060

## Study/Project Aims

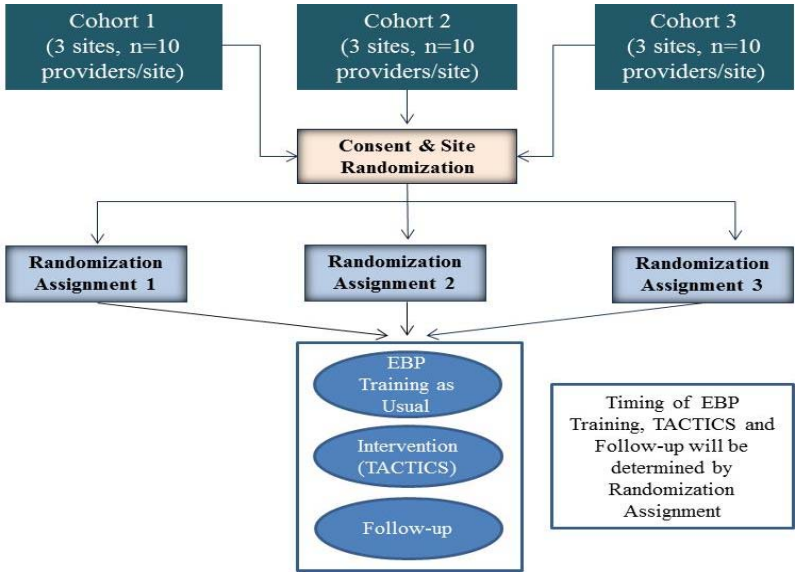
Primary Aim: *Reach* - To determine the impact of a multi-modal, tailored strategy (Targeted Assessment and Context-Tailored Implementation of Change Strategies; TACTICS) over and above conventional training in evidence-based practice on the proportion of posttraumatic stress disorder (PTSD) patients who receive Prolonged Exposure (PE) to treat the PTSD. The primary goal of this improvement effort will be demonstrated by an increase in PE therapy coded in electronic medical record data.

Secondary Aims: *Effectiveness* - To examine the impact of TACTICS over and above evidence-based practice training on patient outcomes to be measured through improvement in military treatment facility clinic patients' scores on the PTSD Checklist for DSM-5 (PCL-5), which is routinely collected at behavioral health appointments for all patients with PTSD.

*Satisfaction*: To evaluate the usability of and overall satisfaction with TACTICS among senior leaders, clinic leaders, and providers and to identify successful components to inform refinements of TACTICS for scale-up and spread.

## Approach

Cluster-randomized stepped wedge design, mixed methods approach at nine military behavioral health outpatient clinics with provider training in PE and clinic-based needs assessment, then implementation of TACTICS components.




## Timeline and Cost

| Activities FY | 18 | 19 | 20 | 21 |
|---|---|---|---|---|
| Secure approval at performance sites | | | | |
| Train providers at performance sites | | | | |
| Implement TACTICS intervention | | | | |
| Data cleaning & analysis | | | | |
| **Estimated Budget ($M)** | **$1.8** | **$2.3** | **$2.4** | **$1.7** |

**Updated:** 2018-10-18

**Accomplishments**: Obtained Stanford IRB for expedited review (expedited protocol review); Recruitment of 4 performance sites complete, incl. site visits, most Site PIs identified; package to one military IRB and to HRPO submitted for review; visit with additional site scheduled; 3 more sites voiced strong interest

**Goals/Milestones**

**FY18 Goals** – Secure all 9 performance sites

✓ Submit draft of needs assessment to COR/SC

✓ Submit draft of TACTICS rubric and draft of TACTICS toolkits to COR/SC

❑ Enroll all nine performance sites (anticipated completion by Q2 of FY19)

❑ Study procedures and processes finalized (anticipated completion by Q1 of FY19)

**FY19-FY20 Goals**

❑ PE provider training

❑ Collect study data and implement TACTICS intervention

**FY21 Goals**

❑ Data cleaning & analyses

❑ Finalize deliverables and dissemination plan

**Budget Expenditure to Date:** Projected Expenditure: $917,081; Actual Expenditure: $830,163 (all but one Year 1 subcontracts fully executed, ATP letters in place.)