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Full Length Article

STRONG STAR and the Consortium to Alleviate PTSD: Shaping the future of combat PTSD and related conditions in military and veteran populations

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Abbreviations: CAP, Consortium to Alleviate PTSD; CDE, common data element; CPT, Cognitive Processing Therapy; DoD, U.S. Department of Defense; DSMB, Data Safety and Monitoring Board; GSC, Government Steering Committee; IOM, Institute of Medicine; IRB, Institutional Review Board; NIH, National Institutes of Health; PE, Prolonged Exposure; PI, principal investigator; PTSD, posttraumatic stress disorder; RCT, randomized clinical trial; STRONG STAR, South Texas Research Organizational Network Guiding Studies on Trauma and Resilience; TBI, traumatic brain injury; VA, U.S. Department of Veterans Affairs..

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ABSTRACT

The STRONG STAR Consortium (South Texas Research Organizational Network Guiding Studies on Trauma and Resilience) and the Consortium to Alleviate PTSD are interdisciplinary and multi-institutional research consortia focused on the detection, diagnosis, prevention, and treatment of combat-related posttraumatic stress disorder (PTSD) and comorbid conditions in military personnel and veterans. This manuscript outlines the consortia's state-of-the-science collaborative research model and how this can be used as a roadmap for future trauma-related research. STRONG STAR was initially funded for 5 years in 2008 by the U.S. Department of Defense's (DoD) Psychological Health and Traumatic Brain Injury Research Program. Since the initial funding of STRONG STAR, almost 50 additional peer-reviewed STRONG STAR-affiliated projects have been funded through the DoD, the U.S. Department of Veterans Affairs (VA), the National Institutes of Health, and private organizations. In 2013, STRONG STAR investigators partnered with the VA's National Center for PTSD and were selected for joint DoD/VA funding to establish the Consortium to Alleviate PTSD. STRONG STAR and the Consortium to Alleviate PTSD have assembled a critical mass of investigators and institutions with the synergy required to make major scientific and public health advances in the prevention and treatment of combat PTSD and related conditions. This manuscript provides an overview of the establishment of these two research consortia, including their history, vision, mission, goals, and accomplishments. Comprehensive tables provide descriptions of over 70

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projects supported by the consortia. Examples are provided of collaborations among over 50 worldwide academic research institutions and over 150 investigators.

1. Introduction

The conflicts in Iraq and Afghanistan have been the longest military operations in U.S. history [1]. Many service members have deployed multiple times, and the high operational tempo over such an extended period is unprecedented for the U.S. military. Combat-related posttraumatic stress disorder (PTSD) is the psychological health problem most commonly associated with these deployments [2,3]. The potential military and public health consequences of combat-related PTSD in post-9/11 service members and veterans were brought to international attention through several seminal research reports [4–7]. These reports highlighted the need for effective treatments for PTSD in this new generation of combat veterans.

In 2008, a body of scientific literature existed on PTSD treatment in civilian and veteran populations [5,8–11]. Prolonged Exposure [12–14] and Cognitive Processing Therapy [15–18] were identified as the leading evidence-based, cognitive-behavioral treatments for these groups. However, the treatment-outcome literature in military populations was sparse, and no randomized clinical trials had been conducted to evaluate any treatment for PTSD in active duty military personnel [19,20]. In response to these research gaps, Department of Defense (DoD) funding was allocated to the Congressionally Directed Medical Research Programs to establish a Multidisciplinary PTSD Research Consortium. After a competitive, peer-reviewed process, the South Texas Research Organizational Network Guiding Studies on Trauma and Resilience, or the STRONG STAR Consortium, was funded in 2008 for 5 years. Headquartered at the University of Texas Health Science Center at San Antonio, STRONG STAR is a multidisciplinary, multi-institutional research consortium focused on the detection, diagnosis, prevention, and treatment of combat PTSD and related conditions (e.g., traumatic brain injury, sleep disorders, chronic pain, substance use disorders, tinnitus, suicide) in military personnel and veterans.

Initial DoD funding for STRONG STAR supported 14 projects and four research cores [21]. STRONG STAR investigators subsequently secured additional peer-reviewed funding through the DoD, Department of Veterans Affairs (VA), National Institutes of Health (NIH), and private organizations to support almost 50 STRONG STAR-affiliated projects. In 2013, STRONG STAR investigators partnered with the VA's National Center for PTSD and were selected for joint DoD/VA funding to establish the Consortium to Alleviate PTSD (CAP), which developed 11 additional research projects [21].

This manuscript includes an overview of the history, vision, mission, and goals of STRONG STAR and CAP. Supplemental materials describe over 70 projects, including almost 40 clinical trials previously or currently managed by the consortia. Also described are how research cores have supported the collaboration of over 50 academic institutions and more than 150 investigators. Additional details are provided on the (1) process for reviewing and approving new grant submissions, (2) use of common data elements, (3) consortia standard operating procedures, (4) adverse event safety monitoring program, (5) consortia data repository, (6) use of data sharing and use agreements, (7) review and approval process for presentations and publications, (8) integration of clinical and research trainees throughout the consortium, (9) STRONG STAR Organized Research Unit at the University of Texas Health Science Center at San Antonio, and (10) STRONG STAR-CAP website.

2. Addressing the psychological health needs of post-9/11 service members and veterans

In 2006, concerns about the emerging deployment-related mental health needs of the U.S. military led to the establishment of a DoD Task Force on Mental Health [22]. The task force published a report highlighting that the DoD and VA systems of care were insufficient to meet current and future psychological health needs of service members and veterans. The report specifically highlighted the significant risks for combat-related PTSD and traumatic brain injury (TBI) in service members who had deployed in support of post-9/11 combat operations. The report noted two major concerns, including significant staffing shortages of mental health personnel in the DoD and VA and limited empirical data available to guide treatment recommendations for combat-related PTSD, especially in active duty military populations. In response to these clinical and research needs of significant national importance, the U.S. Congress appropriated $300 million for DoD research programs targeting PTSD and TBI [23].

Given the dearth in 2007 of previous clinical trials treating combat-related PTSD in military personnel, the initial STRONG STAR research portfolio placed heavy emphasis on treatments with the strongest scientific evidence from previous clinical trials in civilian and veteran populations. Much of the scientific literature at the time had been reviewed and summarized in a report by the Institute of Medicine (IOM) titled *Treatment of Posttraumatic Stress Disorder: An Assessment of the Evidence*, which was publicly available as a prepublication copy in 2007 and subsequently published in 2008 [5]. That publication reported the results of the IOM committee review of 52 psychotherapy studies and 37 pharmacotherapy studies. In the overall summary, the IOM reported, "The committee finds that the evidence is sufficient to conclude the efficacy of exposure therapies in the treatment of PTSD" [5(p8)]. However, this conclusion was limited to work in civilian trauma. The committee found that the state of the research on the treatment of PTSD in U.S. veterans was inadequate to answer questions about (1) the efficacy of interventions with and (2) the settings and lengths of treatment that are applicable to military populations. Trauma-focused therapies were the only form of treatment to receive the IOM committee's highest level of endorsement.

The majority of the studies reviewed by the IOM included one or more cognitive-behavioral therapy approaches, and the largest proportion of these studies included an exposure- or trauma-focused therapy. The IOM committee recognized that exposure was frequently administered in combination with another cognitive-behavioral therapy technique. That led the committee to group together studies with exposure and exposure plus something else (e.g., Cognitive Processing Therapy). The committee concluded that there was inadequate evidence to determine the efficacy of Eye-Movement Desensitization and Reprocessing (EMDR) or any form of group therapy for PTSD. Similarly, the IOM concluded, data was insufficient to support efficacy of pharmacotherapy for PTSD.

The IOM report substantially guided STRONG STAR project selection. Prolonged Exposure (PE) [12,13], Cognitive Processing Therapy (CPT) [15–18], Cognitive-Behavioral Conjoint Therapy (CBCT) for PTSD [24], and various adaptations of these therapies were thought to have the most promise as interventions for combat-related PTSD in military personnel and recently discharged veterans. In addition, we envisioned that PTSD treatments provided soon after exposure to traumatic events could result in positive outcomes for this population that might rival the outcomes found in civilians. For example, in one civilian study, up to 80% of female sexual assault survivors who completed treatment with PE or CPT were found no longer to meet diagnostic criteria for PTSD or even to have been treated successfully into remission [16]. We therefore sought to develop clinical trials that evaluated these therapies' efficacy for the first time in military personnel and veterans of post-9/11 combat operations.

2.1. The STRONG STAR Multidisciplinary PTSD Research Consortium

In March 2008, STRONG STAR was selected for funding after a competitive peer review for the Multidisciplinary PTSD Research Consortium. Funding to support STRONG STAR was from the DoD's PTSD and TBI Research Program (W81XWH-07-PTSD-MRC) and was made through multiple independent research awards to the Partnering Principal Investigators (PIs). The original STRONG STAR Multidisciplinary PTSD Research Consortium included 14 research projects focused primarily on active military and recently discharged veterans in South and Central Texas, with one study even occurring in deployed settings. Supplemental Table 1 provides a summary of the projects including (1) the PI, (2) the project title, (3) a brief project description, (4) the research participants, recruitment sites, and participant sample sizes, and (5) the scientific manuscripts produced to date as a result of each project. Supplemental Fig. 1 illustrates how the consortium was administratively organized. It should be noted that, although the consortium was headquartered through an Administrative Core (see supplemental text) at the University of Texas Health Science Center at San Antonio, STRONG STAR was, from its inception, a nationwide consortium of individual PIs located at leading research institutions around the country. Project PIs worked through the Administrative Core to conduct multiple projects at one of four military or VA performance sites. The Administrative Core provided all infrastructure and support functions to conduct studies in full regulatory compliance according to International Conference on Harmonisation Good Clinical Practice (GCP) guidelines. The consortium was advised by a DoD-appointed External Advisory Board and a STRONG STAR Administrative Core-selected Executive Steering Committee.

2.2. STRONG STAR-affiliated projects

During the 5-year funding cycle of the STRONG STAR Multidisciplinary PTSD Research Consortium, its DoD External Advisory Board encouraged investigators to seek additional peer-reviewed grant awards so the consortium could be sustained with additional research funding beyond the initial award period. In response to this recommendation, STRONG STAR investigators collaborated to submit many grant applications to DoD, VA, NIH, and private funding sources. These projects are now referred to as *STRONG STAR-affiliated projects* to distinguish them from the projects supported by the original funding of the Multidisciplinary PTSD Research Consortium.

Supplemental Table 2 provides an overview of 48 STRONG STAR-affiliated projects that have been added over the past 13 years, including (1) the PI, (2) the funding source and award number, (3) the project title, (4) a brief description of the project and current status, (5) the research participants, recruitment sites, and participant sample sizes, if applicable, and (6) the scientific manuscripts produced to date as a result of each project. The focus of STRONG STAR-affiliated projects expanded to include common comorbid conditions such as sleep disorders (8 projects), chronic pain (5 projects), suicide (4 projects), tinnitus (2 projects), and traumatic brain injury (1 project). Supplemental Fig. 2 shows how the consortium was administratively organized to support affiliated projects. Multiple-PI arrangements or subawards allowed both the PIs and the consortium to receive funding from the funding agency. Investigators had options to work directly with their community sites or VAs or indirectly through the STRONG STAR Administrative Core and its affiliated military sites. Options also allowed investigators to use central data management and statistical analyses and to contribute to the data repository (see Section 2.3 and supplemental text).

2.3. The Consortium to Alleviate PTSD

On August 31, 2012, a National Research Action Plan was approved as part of an Executive Order from President Obama to improve access to mental health services for veterans, service members, and military families [25]. The National Research Action Plan outlined a framework for improved coordination across governmental organizations (e.g., DoD, VA, NIH, etc.) with the goal that scientists from the academic and industrial sectors share information, inspire innovations, and accelerate science. It also outlined key themes related to PTSD, TBI, and suicide-prevention research and allocated funding to support nationwide research consortia in each of these areas. The research consortia included the Consortium to Alleviate PTSD, the Chronic Effects of Neurotrauma Consortium, and the Military Suicide Research Consortium. The primary research priorities for PTSD were related to biomarkers, mechanisms, and treatment research.

In the initial award of the original STRONG STAR Multidisciplinary PTSD Research Consortium, all 14 research projects were funded with the original award. In contrast, the CAP Government Steering Committee (GSC) approved only one of the seven CAP projects proposed by PIs in the original application (i.e., the Treatment of Comorbid Posttraumatic Stress and Posttraumatic Headaches; PI: Donald McGeary, PhD). Because project approvals and funding were determined by the GSC, the Coordinating Center, which for the CAP functioned similarly to the STRONG STAR Administrative Core, published two Requests for Applications that were disseminated to over 84,000 potential applicants over the first 3 years of the CAP award. A scientific review process was developed that screened over 200 research preproposals. Approximately 10% were selected to submit full proposal applications that were evaluated through an independent, peer-reviewed process. Of those, 11 projects were finally selected and approved by the GSC to be part of the CAP research portfolio. The primary focus of CAP projects was to expand on the results of previous STRONG STAR studies and to integrate biomarkers to assess treatment prognosis, mechanisms of change, and treatment outcomes. An outline of the CAP projects is provided in Supplemental Table 3, including (1) the PI, (2) the project title, (3) a brief project description, (4) the research participants, recruitment sites, and participant sample sizes, and (5) the scientific manuscripts produced to date as a result of each project. Supplemental Fig. 3 shows how the CAP was administratively organized. All DoD funds were dispersed only through the Coordinating Center in San Antonio, while VA funds were granted through the central VA grants office. Because of increased funding through VA sources, the CAP included more local VA sites for investigators compared to STRONG STAR studies. The Coordinating Center fulfilled all administrative and sponsor roles for regulatory compliance and facilitated study activity and data management at multiple performance sites. It also provided overall project management and reporting to the GSC.

Another aspect of the National Research Action Plan was the overarching goal of standardizing, integrating, and sharing research data at a national level, which required a standard set of unique data identifiers and assessment measures known as common data elements, or CDEs [26,27]. A specific emphasis was placed on the assessment of war- or combat-related trauma [28–33]. The use of CDEs was initially established with the original STRONG STAR Consortium and then incorporated into the STRONG STAR-affiliated studies and the CAP studies. Revised versions of CDE measures were incorporated as necessary. Because of the consistent use of established and accepted CDEs across all research projects, we were able to transfer and store all CAP data in the STRONG STAR-CAP Repository (described in the supplemental text). This data repository was established in compliance with research regulations to promote and facilitate the sharing of data across projects and for other investigations beyond the original consortia and individual projects themselves.

2.4. Lessons learned in the management of a nationwide research consortium

There have been three different consortium funding and administrative management models used within STRONG STAR and CAP, and there are advantages and disadvantages of each (see Supplemental Figs.

1–3). First, the original STRONG STAR Consortium included the funding of 14 PTSD research projects as part of the initial award. A Government Officer Representative (e.g., science officer or program manager) managed it with consultation provided by an External Advisory Board. An advantage of this model was the streamlined decision-making process with regards to research administration, which allowed projects to be initiated immediately. A disadvantage of the model was the need to obtain regulatory approvals, establish participant recruitment methods, and initiate recruitment for 14 projects simultaneously. This led to delays in starting projects and a backlog of proposals submitted for review and approval by the single military Institutional Review Board (IRB) overseeing all of the projects. Overall, we believe that this is the most efficient and effective administrative model to support a multidisciplinary research consortium.

The second consortium funding and administrative management model is the one initiated with the funding of the first STRONG STAR-affiliated project in March 2009 and is the current model being used by the consortium. This involves the management of multiple investigator-initiated projects, with each project providing a small amount of funding to support STRONG STAR Consortium infrastructure in return for assistance with use of common data elements, access to military and veteran populations, and support for analysis, publication, and dissemination of results. The primary advantages of this model are the streamlined research administration and approval processes, consisting of an individual science officer for each project. Currently, these STRONG STAR-affiliated projects are also supported by additional infrastructure provided thus far by year-to-year funding from the University of Texas Health Science Center at San Antonio and the VA's National Center for PTSD. A disadvantage of this model is that it is difficult to maintain the necessary infrastructure without primary infrastructure funding from the DoD and/or VA to support multiple ongoing research projects.

The final consortium funding and administrative management model is the one that was used by CAP, which included funding from both the DoD and VA to support the research cores and projects. An advantage of this model was that both the DoD and VA contributed to and had a stake in the consortium and essentially doubled the funding to support research cores and projects. This model also provided investigators with the opportunity to recruit both active duty military and veteran participants into studies. CAP clearly demonstrated that joint DoD/VA research funding could be effectively leveraged to support the research goals of the DoD and VA. A drawback of the CAP model was the ungainly three-tiered administrative management model. The CAP Coordinating Center leadership reported to the Government Officer Representative, who reported to a Government Steering Committee led by two co-chairs (one from the DoD and one from VA), who reported to a panel of three senior leaders from the DoD, VA, and the Department of Health Affairs. This multi-layered consortium administrative management model was very inefficient, resulting in long delays for most research administrative activities. In addition, the CAP model required the CAP Coordinating Center to manage nationwide requests for applications, including the review of hundreds of pre-proposal applications along with the management of an external scientific review process. The time-consuming development and administration of the review process by the CAP Coordinating Center coupled with the three-tiered approval process resulted in the final two CAP research projects not being approved by the panel of senior leaders until the CAP was 3 years into its initial 5-year consortium award. With the primary focus of CAP being PTSD randomized clinical trials (RCTs)—often requiring a 3- to 5-year period of performance to complete—a 2-year extension without funds at the end of the third year of the consortium was necessary to complete the projects. The delays in obtaining administrative research approvals resulted in the Government Steering Committee members and panel of senior leaders being generally frustrated by and disappointed with the perceived lack of research progress. This led some Government Steering Committee members to repeatedly recommend the termination of ongoing clinical trials due to failure to meet the original recruitment goals. Nonetheless, despite delays in starting up the trials, by the end of the 2-year extension, 10 of the 11 projects successfully accomplished their research objectives, and many produced high-impact research results. Overall, we observed that the CAP model was the least efficient administrative model to support a multidisciplinary research consortium. However, a jointly funded DoD/VA research consortium similar to CAP would have excellent potential for success with (1) a streamlined governmental oversight model similar to the original STRONG STAR Consortium, (2) advance planning for distribution of nationwide requests for applications utilizing external scientific reviewers, and (3) an overall 7-year period of performance to allow for review of proposals and the conduct of clinical trials.

3. Discussion

The synergistic work of STRONG STAR and the CAP has contributed to major advances in the state-of-the-science on and the direct care and treatment of service members and veterans impacted by combat-PTSD and common comorbidities. In a team-science approach, over 150 nationwide investigators have secured approximately $200 million in peer-reviewed funding to support approximately 70 ongoing or completed projects, including over 40 clinical trials, involving 50 different civilian, military, VA, academic research and health care institutions. In their pioneer efforts to bring RCTs on combat-related PTSD and other psychological health conditions to active duty military and post-9/11 veteran populations, consortia leadership and investigators have developed specific and significant expertise in this area. To date, over 4000 patients have participated in STRONG STAR-CAP clinical trials, and almost 25,000 have participated in clinical observations studies.

This effort has led to significant military-relevant research and dissemination advances resulting from a unified research approach. For example, the consortia have established an unprecedented infrastructure to support psychological health research at military sites around the country. They also have implemented streamlined research regulatory approval processes to help investigators navigate a complex landscape of DoD, VA, and civilian IRBs as well as the DoD's Human Research Protection Office. The incorporation of common data elements across studies and the collection of study data into a repository enables large-scale analyses that could not be done with data from an individual study alone and creates the potential to address future questions not even foreseen today. The consortia's numerous clinical trials with service members and veterans also have allowed for the development of some of the most experienced and culturally competent research therapists in the country, who now train civilian providers nationwide in the delivery of evidence-based treatments for combat-PTSD and related conditions. In addition, the San Antonio Combat PTSD Conference was an outgrowth of our own investigator meetings. Now this international gathering provides a unique opportunity to share the latest advances on the state-of-the-science in combat-PTSD care and treatment with researchers, clinicians, policy makers, and the public. For more information on these items and other details about consortium operation, see the supplementary materials.

The ultimate benefits of the consortia's research are in our increased understanding of how best to prevent, assess, diagnose, and treat combat-PTSD and related conditions. Here, the collective efforts of our investigators have yielded over 200 published scientific manuscripts and more than 500 presentations at national and international conferences. Overall, the results of STRONG STAR-CAP clinical trials indicate that PTSD, sleep disorders (insomnia, nightmares, sleep apnea), chronic pain, substance use disorders, tinnitus, and suicidal ideation can be treated effectively in post-9/11 military and veteran populations using cognitive-behavioral therapies alone and/or with medications or medical devices (e.g., transcranial magnetic stimulation in combination with inpatient therapy). In general, the outcomes of these clinical trials with

service members and veterans have been less robust than those involving civilians treated for similar conditions. Possible explanations include the unique occupational demands of military personnel, the unique nature of traumas experienced in the military, and the potential for service-connected disability. Several reports have indicated that the length of deployments, number of deployments, cumulative overall duration of deployments, and limited dwell time between deployments (i.e., time at the service member's home station) may all increase the cumulative detrimental health risk for polymorbid physical and psychological health conditions [34–37]. The more modest outcomes for military personnel may also potentially be due to higher levels of perceived stigma in seeking out mental health treatment because of the possibility of negative career impacts (e.g., loss of weapons-bearing status or security clearances) [38]. Deployed military personnel may also be at increased risk for experiencing more traumatic losses [28]. Finally, military training that emphasizes maintaining high levels of vigilance and the precise adherence to policies, procedures, and a military ethos that may have life-saving consequences can be difficult to extinguish after returning from the combat theater.

It is noteworthy that STRONG STAR and CAP investigators have conducted relatively few psychopharmacology clinical trials. This limited research was guided initially by the 2008 IOM report on the treatment of PTSD [5(p85)], which stated, "Based on its assessment of the medications for which randomized controlled trials were available… the committee found the evidence for all classes of drugs reviewed inadequate to determine efficacy for patients with PTSD." Over the past 13 years, the consortium reviewed dozens of research proposals to evaluate various medications and compounds for PTSD treatment. The majority were not selected for funding after scientific and programmatic review. The consortium has conducted three RCTs evaluating sertraline (Supplemental Table 1; PI: Roache), doxazosin (Supplemental Table 3; PI: Back), and ketamine (Supplemental Table 3; PI: Krystal). Unfortunately, none of these RCTs found the medications to be efficacious in treating PTSD. These results are consistent with those of other pharmacological studies conducted with civilian, veteran, and military populations, and they highlight what has been described as a crisis in the pharmacotherapy of PTSD, as well as the need for additional research [39].

At the time of STRONG STAR's initial funding in 2008, no RCTs had been conducted to evaluate any form of treatment for combat-related PTSD in active duty military personnel. STRONG STAR and CAP investigators have now conducted 26 clinical trials focused specifically on combat-related PTSD in military and post-9/11 veteran populations [21]. Working collaboratively as a research consortium, we have used each PTSD clinical trial in our portfolio systematically and incrementally to improve our understanding of combat-related PTSD and its treatment and to examine the functional outcomes with service members, veterans, and their families. In many cases, a series of clinical trials evaluating treatments such as Prolonged Exposure, Cognitive Processing Therapy, Cognitive-Behavioral Conjoint Therapy, and Written Exposure Therapy have been conducted, with each subsequent clinical trial building on the results of previous trials to further improve outcomes and functioning. No PTSD treatment has been established that helps all patients. However, STRONG STAR and CAP investigators have developed, evaluated, and disseminated a number of evidence-based treatments for combat-related PTSD to help fill the clinical toolbox for behavioral health providers. Additionally, consortium investigators have pushed out effective treatments to specialty mental health to improve access through interventions set in primary care, provided through telehealth, and offered through web-based applications.

Despite the tremendous contributions made by STRONG STAR and CAP investigators to advance research and clinical practice related to the treatment of combat-related PTSD, much work remains to be done. With recovery rates limited to slightly more than 50% of those treated with current evidence-based interventions, and as the incidence of PTSD continues to persist in military and veteran populations, there is a critical need for continued funding of a nationwide PTSD research consortium.

Additional research is needed to further improve the assessment, diagnosis, treatment, and prevention of PTSD and comorbid conditions in service members and veterans. More trials are needed on how best to tailor treatments and treatment protocols to yield the best outcomes for these complex cases. Clinical trials are also needed to evaluate the combination of cognitive-behavioral therapies with medications and medical devices. In addition, brief interventions that can be administered soon after trauma exposure in far-forward combat locations need to be evaluated as methods to prevent the onset of chronic PTSD. As was done at various points throughout the history of the consortium, the use of community-based participatory research and the inclusion of key stakeholders such as service members, veterans, family members, and military leaders should be incorporated into the planning, review, approval, and management of clinical studies.

Continued federal funding is needed to advance and expand upon the many important scientific and public health contributions made by STRONG STAR and CAP investigators since 2008. For a list of identified research gaps that remain to be targeted, see the supplementary materials. Despite the expiration of joint DoD/VA funding of a nationwide PTSD research consortium in 2020, the STRONG STAR Consortium has continued with ongoing support from about 20 current peer-reviewed, individual, investigator-initiated projects funded by the DoD, VA, NIH, and private funding organizations (see Supplemental Table 2). However, the long-term sustainment of the infrastructure needed for a nationwide research consortium is extremely difficult to achieve with individual investigator-initiated research projects. Federal infrastructure funding is urgently needed to continue to leverage the synergistic power of team science that has been made possible through the federal funding of PTSD research consortia [40].

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There are no competing interests from any co-authors related to the preparation of this manuscript.

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Supplemental Table 1. Overview of STRONG STAR Multidisciplinary PTSD Research Consortium Projects[a]

Principal Investigator, Primary Affiliation, & Period of Performance	Project Title	Project Description	Research Participants/ Recruitment Sites	Manuscripts
Jeffrey Cigrang, Wilford Hall Medical Center, 2008-2017	Brief Cognitive-Behavioral Treatment of Deployment-Related PTSD in Primary Care Settings: A Randomized Controlled Trial	Study 1: Nonrandomized pilot clinical trial of brief cognitive-behavioral therapy (CBT) for PTSD in primary care	*N* = 24 *n* = 24 active duty *n* = 0 veterans San Antonio Military Health System, San Antonio, Texas	[1-3]
		Study 2: Two-armed RCT of brief cognitive-behavioral therapy for PTSD in primary care	*N* = 67 *n* = 67 active duty *n* = 0 veterans San Antonio Military Health System, San Antonio, Texas	
Edna Foa, University of Pennsylvania, 2008-2017	Prolonged Exposure for PTSD in OIF/OEF Personnel: Massed Versus Spaced Trials	Four-armed RCT of spaced (weekly) PE, massed (daily) PE, Present-Centered Therapy (PCT), or a minimal-contact control condition	*N* = 366 *n* = 366 Active duty *n* = 0 veterans Carl R. Darnall Army Medical Center (CRDAMC), Fort Hood, Texas	[4-31]
Peter Fox, UT Health San Antonio, 2008-2016	Neuroimaging Studies of PTSD and PTSD Treatment Among Combat Veterans	Neuroimaging study of pre-post CPT and PCT patients from the Resick STRONG STAR Study 1 and combat controls	*N* = 59 *n* = 19 active duty – CPT group *n* = 21 active duty – PCT group *n* = 19 active duty – combat control group *n* = 0 Veterans CRDAMC, Fort Hood, Texas	[32-36]
Robert Gatchel, University of Texas at Arlington, 2008-2016	Treatment of Chronic Stress Reaction and Chronic Pain After Traumatic Orthopedic Injury	Four-arm RCT of CBT for comorbid PTSD and chronic pain	*N* = 47 *n* = 47 active duty *n* = 0 veterans San Antonio Military Health System, San Antonio, Texas	[37-40]
Jay Higgs, Brooke Army Medical Center, 2008-2016	Fibromyalgia Syndrome (FMS) in Military Personnel With and Without PTSD and Their Family Members	Study 1: FMS in military patients with PTSD	*N* = 761 participants from STRONG STAR RCTs CRDAMC, Fort Hood, Texas	[41]

		Study 2: Assessment of fibromyalgia across a military deployment	Assessment of Williamson STRONG STAR study participants predeployment (n = 3,915) and postdeployment (n = 1,761) Fort Hood, Texas	
Brett Litz, VA Boston Health Care System, 2008-2016	Causal Modeling, Meta-Analysis, and Predictors of Trajectory for the Omnibus Dataset	Analyses of omnibus clinical assessment data from STRONG STAR RCT participants	San Antonio Military Health System and Fort Hood, Texas	[5, 16, 18, 23, 28, 31, 42]
Candice Monson, Ryerson University, and David Riggs, Uniformed Services University, 2008-2016	Individual Prolonged Exposure Versus Couples' Cognitive-Behavioral Therapy for Combat-Related PTSD	Two-armed RCT of Cognitive-Behavioral Conjoint Therapy versus PE	N = 64 (32 couples) San Antonio Military Health System and Fort Hood, Texas	[43]
Alan Peterson, UT Health San Antonio, 2008-2015	Outcomes of PE and CPT for Combat Operational Stress Reactions in Deployed Settings	Nonrandomized clinical trial of PE and CPT delivered during a military deployment	N = 12 n = 12 Active duty n = 0 Veterans Iraq and Afghanistan	[44-50]
Patricia Resick, Duke University, 2008-2016	Project 1: Group Cognitive Processing Therapy versus Group Present-Centered Therapy for Combat-Related PTSD	Two-armed RCT of group CPT versus group PCT	N = 108 n = 108 active duty n = 0 veterans CRDAMC, Fort Hood, Texas	[5, 16-18, 23, 28-31, 33-36, 51-69]
	Project 2: Individual versus Group Cognitive Processing Therapy for Combat-Related PTSD	Two-armed RCT of individual CPT versus group CPT	N = 268 n = 268 active duty n = 0 veterans CRDAMC, Fort Hood, Texas	
John Roache, UT Health San Antonio, 2008-2016	Alcohol Use Disorder in PTSD Patients Treated with SSRIs: An Alcoholic Subtype Hypothesis of Vulnerability	Two-armed RCT of sertraline versus placebo for comorbid PTSD and alcohol dependence (Type A & Type B)	N = 54 n = 0 active duty n = 54 veterans South Texas Veterans Health Care System, San Antonio, Texas	[70-72]
Randy Strong and David Morilak, UT Health San Antonio, 2008-2017	Mechanisms of Vulnerability to PTSD: The Role of Early Life Stressors	Preclinical study of four animal models of early life stress as triggers for PTSD	Not applicable	[73-75]
Douglas Williamson, UT Health San	Genetic and Environmental Predictors of Combat-Related PTSD	Longitudinal cohort study of genetic and environmental factors related to PTSD	N = 4,119 predeployment n = 4,119 active duty n = 0 veterans	[29, 41-42, 76-79]

Antonio, 2008-2016			Fort Hood, Texas	
Stacey Young-McCaughan, UT Health San Antonio, 2008-2016	The Impact of the Treatment of PTSD on Comorbid Insomnia and Pain	Analyses of changes in insomnia and pain in STRONG STAR RCT patients	San Antonio Military Health System and Fort Hood, Texas	[80]
TOTAL STRONG STAR STUDY PARTICIPANTS			*N* = 5,248 total human participants *n* = 1,129 clinical trial participants *n* = 4,119 observational study participants	

CBT, cognitive-behavioral therapy; CPT, Cognitive Processing Therapy; CRDAMC, Carl R. Darnall Army Medical Center; FMS, fibromyalgia syndrome; OEF, Operation Enduring Freedom; OIF, Operation Iraqi Freedom; PCT, Present-Centered Therapy; PE, Prolonged Exposure; PTSD, posttraumatic stress disorder; RCT, randomized clinical trial; SSRI, selective serotonin reuptake inhibitor; UT Health San Antonio, University of Texas Health Science Center at San Antonio.

[a]Funding for the STRONG STAR Multidisciplinary PTSD Research Consortium was by the U.S. Department of Defense through the U.S. Army Medical Research and Materiel Command, Congressionally Directed Medical Research Programs, Psychological Health and Traumatic Brain Injury Research Program awards : W81XWH-08-02-0109 (Alan Peterson), W81XWH-08-02-0110 (Douglas Williamson), W81XWH-08-02-0111 (Edna Foa), W81XWH-08-02-0112 (Peter Fox), W81XWH-08-02-0113 (Robert Gatchel), W81XWH-08-02-0114 (Brett Litz), W81XWH-08-02-0115 (Candice Monson), W81XWH-08-02-0116 (Patricia Resick), W81XWH-08-02-0117 (John Roache), and W81XWH-08-02-0118 (Randy Strong).

Supplemental Table 2. Overview of STRONG STAR-Affiliated Projects

Principal Investigators	Source of Funding/ Award #	Project Title	Project Description and Status	Research Participants/ Recruitment Sites	Manuscripts
Monty Baker, Wilford Hall Medical Center & Alan Peterson, UT Health San Antonio, 2006-2015	DoD FA86-50-11-2-6162	Project BLAST (Balad Longitudinal Assessment of the Symptoms of TBI & PTSD)	Cross-sectional assessment of PTSD and TBI after acute blast. Recruitment is completed.	*N* = 894 deployed U.S. military personnel Joint Base Balad, Iraq	[81-84]
Monty Baker, Wilford Hall Medical Center & Alan Peterson, UT Health San Antonio, 2007-2017	DoD FA8650-13-2-6408	OIF/OEF Psychiatric Aeromedical Evacuations	Assessment of psychiatric patients before aeromedical evacuation from Joint Base Balad, Iraq. Recruitment is completed.	Study 1 *N* = 690 deployed U.S. military personnel Joint Base Balad, Iraq	[85-90]
			Cross-sectional assessment of OEF/OIF psychiatric aeromedical evacuation patients. Recruitment is completed.	Study 2 *N* = 10,320 deployed U.S. military personnel Iraq and Afghanistan	
Craig Bryan, Ohio State University & Lily Brown, University of Pennsylvania, 2018-present	NIH R01 MH117600	Identifying Suicidal Subtypes and Dynamic Indicators of Increasing and Decreasing Suicide Risk	Secondary analyses of STRONG STAR Repository data. Data analyses are ongoing.	*N* = 4,961	[29, 30]
Matthew Burg, Yale University, 2017-2021	NIH HL125587	PTSD, Sleep, and Risk for Incident Hypertension	Prospective observational study to determine the relationship of PTSD to sleep and ambulatory blood pressure in veterans. Recruitment is completed.	*N* = 28 Brooke Army Medical Center, San Antonio, Texas; Carl R. Darnall Army Medical Center, Fort Hood, Texas; and South Texas Veterans Health Care System, San Antonio, Texas	
Ellen DeVoe, Boston University, 2014-2019	DoD W81XWH-14-2-0123	Strong Families Strong Forces	Two-armed RCT comparing Strong Families to Parental Self-Care Protocol across the deployment cycle. Recruitment is completed.	*N* = 152 military families Fort Hood, Texas	[91-94]
Katherine Dondanville, UT Health San Antonio, 2017-2018	Texas Veterans & Family Alliance 529-17-0058-00012	STRONG STAR Texas Training Initiative	Dissemination project of evidence-based treatments for PTSD to veteran-serving Texas mental health providers. Training is completed.	Trained over 200 providers throughout Texas	[95]

Katherine Dondanville, UT Health San Antonio, 2017-2020	Bob Woodruff Foundation Award	STRONG STAR National Training Initiative	Dissemination project of evidence-based treatments for PTSD to veteran-serving mental health providers nationally. Training is ongoing.	Trained over 200 mental health providers nationwide	[96]
Katherine Dondanville, UT Health San Antonio, 2020-present	Boeing Award	STRONG STAR Nationwide Training Initiative	Dissemination project of evidence-based treatments for PTSD to veteran-serving mental health providers nationally. Training is ongoing.	Trained 125 mental health providers nationwide	
Katherine Dondanville, UT Health San Antonio, 2019-2021	Bob Woodruff Foundation Qatar Harvey Fund	STRONG STAR Texas Gulf Coast Training Initiative	Dissemination project of evidence-based treatments for PTSD to veteran-serving mental health providers in the Texas Gulf Coast. Training is ongoing.	Trained over 90 mental health providers from the Texas Gulf Coast region	[97]
Katherine Dondanville, UT Health San Antonio, 2021-present	USAA Foundation	STRONG STAR Training Initiative	Dissemination project of evidence-based treatments for PTSD to veteran-serving mental health providers nationally. Training is ongoing.	Will train over 100 mental health providers nationwide	
Brooke Fina, UT Health San Antonio, 2018-2019	Texas Veterans + Family Alliance Award HHS000125400018	STRONG STAR Texas Training Initiative: Crisis Response Training for Suicide Prevention	Dissemination project of Crisis Response Plan for Suicide Prevention for veteran-serving mental health providers in Texas. Training is completed.	Trained over 200 mental health providers from Texas	
Edna Foa, University of Pennsylvania, 2015-2020	DoD W81XWH-15-10555	Efficacy of 90-Minute vs. 60-Minute Sessions of Prolonged Exposure for PTSD: A Randomized Controlled Trial in Active Duty Military Personnel	Two-armed RCT noninferiority trial. Recruitment is completed.	*N* = 140 Active duty military at Joint Base Charleston, South Carolina	[98]
Edna Foa, University of Pennsylvania, 2013-2019	DoD W81XWH-12-2-0116	Evaluation of Standard Versus Extended PE Training for Army Mental Health Providers	Two-armed hybrid type III randomized implementation trial. Recruitment is completed.	*N* = 103 military behavioral health providers *N* = 242 PTSD patients Fort Bliss, Texas; Fort Campbell, Kentucky; and Fort Carson, Colorado	[99, 100]
Cubby Gardner & Antoinette Shinn, Wilford Hall Ambulatory Surgical Center & Alan Peterson, UT	DoD 711th Human Performance Wing, FA8650-19-2-69498	Service-Connected Life Trajectory Comparison of Psychiatric Aeromedical Evacuation and Non-Psychiatric Aeromedical	Cross sectional analysis of military electronic health records. Data analyses are ongoing.	Proposed N ~ 10,000 each from 4 groups: 1: Psychiatric evacuation 2: Medical evacuation 3: Deployed, non-evacuation	

Health San Antonio, 2019-present		Evacuation Patients from 2001 to 2013		4: Active duty, non-deployed	
Vanessa Jacoby, UT Health San Antonio, 2018-present	Texas DHHS HHS0001172001 (2018-2020) Texas DHHS HHS0007115000 01 (2020-2015)	Military Families and Veterans Prevention Program Service Member, Veterans, and Families Program	Provides Strong Families prevention and evidence-based PTSD treatment (CPT, PE) to active duty service members, veterans, and their families. Services are ongoing.	*N* = 156 families Fort Hood, Texas	
Vanessa Jacoby, UT Health San Antonio, 2018-2019	APA Division 19 Military Psychology Award	Supporting Active Duty Military Families Following a Deployment: An Open Trial Pilot Study of Strong Families Strong Forces-Condensed Format	Pilot project testing 2-day format of Strong Families Reintegration Program. Recruitment is completed.	Consented = 29 Fort Hood, Texas	
Abby Blankenship, UT Health San Antonio, 2019-2020	APA Division 29 2019 Charles Gelso Psychotherapy Research Grant	Strong Families Strong Forces: Improving Programing for Military Families	Qualitative study designed to improve understanding of barriers to prevention services for military families. Recruitment is ongoing.	Fort Hood, Texas	
M. Danet Lapiz-Bluhm, UT Health San Antonio, 2013-2018	Robert Wood Johnson Foundation Nurse Faculty Scholar Program	Cognitive and Neuronal Markers in PTSD	Biomarkers assessment of participants in Resick Variable-Length CPT study. Recruitment is completed.	*N* = 127 Fort Hood, Texas	[101, 102]
Brian Marx, VA Boston Healthcare System, 2019-present	DoD Military Suicide Research Consortium W81XWH-16-2-003	Decreasing Suicide Risk Among Service Members With Posttraumatic Stress Using Written Exposure Therapy	Two-armed RCT of Written Exposure Therapy. Recruitment is ongoing.	Proposed *N* = 124 *n* = 62 enrolled to date Fort Hood, Texas	[103, 104]
Cindy McGeary & Tabatha Blount, UT Health San Antonio, 2016-2017	University of Texas Health Science Center at San Antonio Award	Conjoint Therapy for Pain Management: A Pilot Study	Pilot clinical trial of conjoint pain management for couples. Recruitment is completed.	*N* = 10 San Antonio, TX	[105]
Donald McGeary, UT Health San Antonio, 2014-2019	NIH R01 AT008422	Establishing Efficacy of a Functional-Restoration CAM Pain Management Program in a Combat Injured Veterans Population	RCT of a functional restoration program or usual care for veterans with chronic musculoskeletal pain, depression, PTSD, and persistent opioid use. Recruitment is completed.	*N* = 103 South Texas Veteran Health Care System, San Antonio, Texas	[106, 107]

Donald McGeary, UT Health San Antonio & Jeffrey Goodie, Uniformed Services University, 2018-present	DoD W81XWH-18-2-008	Targeting Chronic Pain in Primary Care Settings Using Internal Behavioral Health Consultants	Open clinical trial. Recruitment has not yet started.	*N* = 43 for pilot project CRDAMC, Fort Hood, Texas	[108-112]
			Two-armed RCT. Recruitment is completed.	Proposed *N* = 716 for RCT San Antonio Military Health System, San Antonio, Texas, and CRDAMC, Fort Hood, Texas	
Donald McGeary, UT Health San Antonio, 2021-present	DoD PR203511	Project MARCH: Multisite Advancement of Research on Chronic Posttraumatic Headache	A 7-Site noninferiority RCT of Cognitive-Behavioral Therapy for Posttraumatic Headache delivered in person or via telehealth. Recruitment has not yet started.	1. South Texas Veterans Health Care System, San Antonio, Texas 2. Palo Alto VA Healthcare System, Palo Alto, California 3. Minneapolis VA Health Care System, Minneapolis, Minnesota 4. Schofield Barracks, Honolulu, Hawaii 5. Carl R. Darnall Army Medical Center, Fort Hood, Texas 6. Brooke Army Medical Center, San Antonio, Texas 7. Walter Reed National Military Medical Center, Bethesda, Maryland	
Carmen McLean, VA Palo Alto Health Care System, 2015-2019	DoD W81XWH-14-1-0008	Web-PE: Internet-Delivered PE for PTSD	Study 1: Two-armed RCT of Web-PE versus PCT. Recruitment is completed.	*N* = 40 for RCT CRDAMC, Fort Hood, Texas	[113-115]
			Study 2: Open clinical trial of Web-PE. Recruitment is completed.	*N* = 34 for open trial Nationwide recruitment	
John Moring, UT Health San Antonio, 2018-2020	KL2 TR002646	Network Dysregulation Among Individuals with Comorbid Tinnitus and PTSD	Pilot clinical trial of CPT for the treatment of comorbid PTSD and tinnitus. Recruitment is completed.	*N* = 10 San Antonio, Texas	[116, 117]
John Moring, UT Health San Antonio, 2021-present	K23 11K23MH12 2579-01A	An Evaluation of Neurobiological Similarities of Tinnitus and PTSD	Prospective evaluation of overt emotional, behavioral, and cognitive symptoms related to tinnitus-related distress and PTSD, and the overlapping functional connectivity between tinnitus and PTSD	*N* = 120, including 30 each with tinnitus, PTSD, comorbid tinnitus & PTSD, and healthy controls San Antonio, Texas	

Vincent Mysliwiec, UT Health San Antonio & Matthew Brock. Wilford Hall Ambulatory Surgical Center, 2018-present	DoD DMRDP FA8650-18-2-6953	Sleep Disorders and Comorbidities in Military Women	Nonrandomized clinical trial of military women and men with insomnia, obstructive sleep apnea (OSA), or comorbid insomnia and OSA (COMISA). Recruitment is ongoing.	Proposed $N = 480$ including 240 males/240 females with OSA ($n = 80$), insomnia ($n = 80$), and COMISA ($n = 80$); $n = 304$ enrolled to date San Antonio Military Health System, San Antonio, Texas	[118-121]
Alan Peterson, UT Health San Antonio, 2004-2011	DoD USAF Surgeon General's Operational Medicine Research Program FA7014-07-C-0036	Risk and Resiliency in Deployed Military Medics	Longitudinal cohort study of USAF medical personnel across the deployment cycle. Recruitment is completed.	Baseline $N = 1,248$ Mid-deployment $N = 1,161$ 1-month postdeployment $N = 390$ 6-month postdeployment $N = 275$ 12-month postdeployment $N = 194$ Balad Air Base, Iraq	[122-129]
Alan Peterson, UT Health San Antonio, 2012-2019	DoD W81XWH-12-2-0073	Clinical Effectiveness Trial of In-Home CPT for Combat-Related PTSD	Three-armed RCT of In-Office, Telebehavioral Health, and In-Home CPT. Recruitment is completed.	$N = 120$ San Antonio, Texas	[130-132]
Alan Peterson, UT Health San Antonio, 2017-2018	Texas Veterans + Family Alliance 529-17-0058-00011	Maximizing Treatment Accessibility for Texas Veterans with Deployment-Related PTSD	Support for Texas veterans to attend 3-week PE intensive outpatient treatment program. Recruitment is completed.	$N = 24$ San Antonio, Texas	
Alan Peterson, UT Health San Antonio, 2019-present	DoD W81XWH-19-1-0628	Enhancing Resiliency and Optimizing Readiness in Military Personnel	Two-armed RCT to evaluate a resiliency-enhancement intervention for Security Force Assistance Brigade members. Recruitment has not yet started.	Proposed $N = 600$ Fort Hood, Texas	
Alan Peterson, UT Health San Antonio, 2019-present	Bob Woodruff Award #: PETERSON-BWF	Project Remission: Intensive Outpatient PTSD Treatment for Texas Gulf Coast Region Veterans	Open label clinical trial of 3-week PE IOP for PTSD. Recruitment is ongoing.	Proposed $N = 40$ $n = 22$ enrolled to date Texas Gulf Coast region	
Alan Peterson, UT Health San Antonio, 2020-2021	UTHSCSA Clinical Pilot Program	Combining Stellate Ganglion Block and Massed PE to Treat PTSD in Active Duty Service Members: A Pilot Study	Open label pilot. Recruitment is completed.	$N = 12$ San Antonio, Texas	
Alan Peterson, UT Health San Antonio, 2021-present	Texas Veterans + Family Alliance Grant Program	Couple's Retreats for PTSD: Healing the Impacts of Trauma in Texas Veteran Families	Evaluation of Abbreviated, Intensive Multicouple Cognitive Behavioral Conjoint Therapy for PTSD.	$N = 200$ (100 military and veteran couples) South-Central Texas	

			Recruitment has not yet started.		
Kristi Pruiksma, UT Health San Antonio, 2016-2018	Sleep Research Society Award 119-FP-15	A Pilot Randomized Controlled Trial of Treatment for Trauma Related Nightmares in Active Duty Military Personnel.	Pilot RCT. Recruitment is completed.	*N* = 40 Fort Hood, Texas	[133-136]
Kristi Pruiksma, UT Health San Antonio, 2021-present	DoD Peer Reviewed Medical Research Program	Web-based Provider Training for Cognitive Behavioral Therapy for Nightmares (CBT-N)	Development of a web-based training program for Cognitive-Behavioral Therapy for Nightmares	N/A	
Patricia Resick, Duke University, Alan Peterson, UT Health San Antonio, 2013-2019	DoD W81XWH-13-2-0013	Variable-Length CPT for Combat-Related PTSD	Nonrandomized clinical trial. Recruitment is completed.	*N* = 130 Fort Hood, Texas	[137, 138]
Craig Rosen & Carmen Mclean, VA Palo Alto Health Care System, 2017-present	DoD W81XWH-17-C-0236	Dissemination and Implementation Science to Optimize Select Evidence-Based Posttraumatic Stress Disorder Treatment Contract (TACTICS)	Cluster randomized stepped-wedge design at 8 U.S. military medical facilities. Recruitment is ongoing.	Recruitment is ongoing; Proposed *N* = 80-300 behavioral health providers. US Air Force sites: Keesler Medical Center, Biloxi, Mississippi; Holloman AFB, New Mexico; David Grant USAF Medical Center, Travis AFB, California US Army sites: Brooke Army Medical Center, San Antonio, Texas; Fort Bliss, Texas; Fort Campbell, Kentucky; Fort Wainwright, Alaska US Navy sites: Jacksonville Naval Air Station, Florida	[139]
David Rudd, University of Memphis, 2009-2012	DoD W81XWH-09-1-0569	Brief Cognitive-Behavioral Intervention for Suicide	Two-armed RCT comparing Brief cognitive-behavioral treatment for suicide versus treatment as usual in high-risk U.S. military service members. Recruitment is completed.	*N* = 152 active duty U.S. Army Fort Carson, Colorado	[140-159]

Denise Sloan, VA Boston Healthcare System, 2015-2020	DoD W81XWH-15-1-0391	Brief Treatment for PTSD: Enhancing Treatment Engagement and Retention	Two-armed RCT comparing Written Exposure Therapy to Cognitive Processing Therapy. Recruitment is completed.	*N* = 170 Fort Hood, Texas	[160]
Stephen Stern, UT Health San Antonio, 2013-2016	VA Award #: D-0809-P	The Impact of Companion Dog Adoption on PTSD and Related Symptoms in Veterans	Two-armed pilot RCT. Recruitment is completed.	*N* = 19 San Antonio, Texas	[161, 162]
Casey Straud, UT Health San Antonio, 2021-present	KL2 TR002646	Safety, Feasibility, and PTSD Symptom Reductions Associated with cannabidiol versus Placebo: A Pilot Training Investigation	Two-armed pilot RCT of massed PE plus cannabidiol or placebo for PTSD. Recruitment planning in progress.	*N* = 24 San Antonio, Texas	
Daniel Taylor, University of North Texas, 2010-2014	DoD W81XWH-10-1-0828	Comparing Internet and In-Person CBT for Insomnia	Study 1: Three-armed RCT of in-person CBTi, web CBTi, and a wait-list control. Recruitment is completed.	Study 1 *N* = 100 Fort Hood, Texas	[29, 133, 134, 163-171]
			Study 2: Two-armed RCT of in-person CBTi versus a wait-list control. Recruitment is completed.	Study 2 *N* = 151 Fort Hood, TX	
Daniel Taylor, University of North Texas, 2017-2020	DoD W81XWH-17-1-0165	Web-Based Provider Training for Cognitive Behavioral Therapy of Insomnia (CBTi)	Randomized trial of web-based or in-person training for CBTi. Recruitment is completed.	*N* = 44 *n* = 21 web-based *n* = 23 in-person	[172, 173]
Steven Vannoy, University of Massachusetts, 2011-2015	DoD W81XWH-11-1-0588	Development and Validation of a Theory Based Screening Process for Suicide Risk	Cross-sectional cohort of postdeployment U.S. Army soldiers. Recruitment is completed.	*N* = 1,382 Fort Hood, Texas	[174]
Shannon Wiltsey-Stirman, VA Palo Alto Health Care System & Katherine Dondanville, UT Health San Antonio, 2021-present	NIH R01 MH128785 PAR-20-243 R01	Telehealth 2.0: Evaluating effectiveness and engagement strategies for asynchronous texting based trauma focused therapy for PTSD			

Jeffrey Yarvis, Carl R. Darnall Army Medical Center & Katherine Dondanville, UT Health San Antonio, 2017-2019	DoD W81XWH-17-P-0168	Telehealth 2.0; Preserving Continuity of Behavioral Health Clinical Care to Patients Using Mobile Devices	Developing, testing and refining existing mobile health products for behavioral health providers and service member patients. Recruitment is completed.	Fort Hood, Texas	[175]
Stacey Young-McCaughan, UT Health San Antonio, 2009-2014	DoD Tri-Service Nursing Research Program Award #: HU0001-09-1-TS15, N09-C08	The Role of Exercise in the Treatment of PTSD Symptoms	Four-armed RCT of exercise, imaginal exposure, or both compared to nursing education control. Recruitment is completed.	*N* = 72 Fort Hood, Texas	
TOTAL STRONG STAR-AFFILIATED STUDY PARTICIPANTS				*N* = 21,831 total human participants *n* = 2,181 clinical trial participants *n* = 19,650 observational study participants	

APA, American Psychological Association; CAM, complementary and alternative medicine; CBTi, Cognitive-Behavioral Therapy for Insomnia; COMISA, comorbid insomnia and obstructive sleep apnea; CPT, Cognitive Processing Therapy; CRDAMC, Carl R. Darnall Army Medical Center; DHHS, Department of Health and Human Services; DoD, U.S. Department of Defense; IOP, intensive outpatient program; NIH, National Institutes of Health; OEF, Operation Enduring Freedom; OIF, Operation Iraqi Freedom; OSA, obstructive sleep apnea; PTSD, posttraumatic stress disorder; PCT, Present-Centered Therapy; PE, Prolonged Exposure; RCT, randomized clinical trial; STRONG STAR, South Texas Organizational Network Guiding Studies on Trauma and Resilience; TBI, traumatic brain injury; UT Health San Antonio, University of Texas Health Science Center at San Antonio; VA, U.S. Department of Veterans Affairs; Web-PE, Web-based Prolonged Exposure.

Supplemental Table 3. Overview of Consortium to Alleviate PTSD Projects[a]

Principal Investigator	Project Title	Project Description	Research Participants/ Recruitment Sites	Manuscripts
Sudie Back & & Julianne Flanagan, Medical University of South Carolina, 2015-2020	Doxazosin in the Treatment of Co-Occurring PTSD and Alcohol Use	Two-armed RCT of doxazosin versus placebo for comorbid PTSD and alcohol use disorder in veterans	*N* = 144 *n* = 0 active duty *n* = 144 veterans Ralph A. Johnson VA Medical Center, Charleston, South Carolina; and VA Community Based Outpatient Clinic, Savannah, Georgia	[176]
Peter Fox, UT Health San Antonio, 2016-2019	Image-guided, Robotically Delivered Transcranial Magnetic Stimulation for Combat-Related PTSD	Two-armed RCT of image-guided, robotically delivered, transcranial magnetic stimulation for PTSD	*N* = 119 *n* = 114 active duty *n* = 5 veterans Laurel Ridge Treatment Center, San Antonio, Texas	
Steffany Fredman, Pennsylvania State University, 2015-2018	Multi-Couple Group Intervention for PTSD	Non-randomized clinical trial to evaluate an abbreviated, intensive, multi-couple group version of Cognitive-Behavioral Conjoint Therapy for PTSD delivered in a retreat format for active duty military and veteran couples	*N* = 24 couples *n* = 17 active duty *n* = 7 veterans Carl R. Darnall Army Medical Center, Fort Hood, Texas	[177-179]
John Krystal, Yale University, 2015-2020	Ketamine for Antidepressant-Resistant PTSD	Two-armed RCT of 4 weeks of twice-weekly ketamine infusions versus placebo for antidepressant-resistant PTSD	*N* = 158 *n* = 51 active duty *n* = 107 veterans West Haven VA Medical Center, West Haven, Connecticut; and Brooke Army Medical Center, San Antonio, Texas	[180]
Meghan McDevitt-Murphy, University of Memphis, 2015-2019	Behavioral Economic Analysis of PTSD Using Ecological Momentary Assessment	Observational study to investigate patterns of activity engagement among veterans with PTSD	*N* = 114 *n* = 4 active duty *n* = 12 Reserve n = 6 National Guard *n* = 92 veteran Memphis, Tennessee	
Donald McGeary, UT Health San Antonio, 2014-2020	RCT of Cognitive-Behavioral Therapy for Posttraumatic Stress and Headache	Three-armed RCT of Cognitive Behavioral Therapy for Headaches, CPT, or treatment as usual for comorbid posttraumatic headaches and PTSD symptoms	*N* = 193 *n* = 3 active duty *n* = 190 veterans South Texas Veterans Health Care System, San Antonio, Texas	[181-187]
Shannon Miles, James A. Haley	Emotion Regulation to Decrease Aggression in Veterans with PTSD	Non-randomized clinical trial of a 3-session treatment that	*N* = 20 *n* = 0 active duty	[188]

Veterans' Affairs Hospital, 2015-2018		teaches emotion regulation skills to decrease aggression for veterans with PTSD.	*n* = 20 veterans James A. Haley Veterans' Hospital, Tampa, Florida	
Alan Peterson, UT Health San Antonio, 2016-2020	Project Remission: Maximizing Outcomes with Intensive PTSD Treatment	Two-armed RCT to evaluate two versions of intensive outpatient PE for combat-related PTSD in service members and veterans	*N* = 234 *n* = 149 active duty *n* = 85 veterans Carl R. Darnall Army Medical Center, Fort Hood, Texas; Brooke Army Medical Center, San Antonio, Texas; South Texas Veterans Health Care System, San Antonio, Texas; and Central Texas Veterans Health Care System, Waco, Texas	[48, 189-191]
Sheila Rauch, Emory University, 2015-2019	Neurobiological Predictors/Mechanisms in Exposure Therapy for PTSD	Biomarkers study (cortisol, DHEA, and allopregnanolone) examined in two studies: an RCT comparing Web-PE to PCT and an effectiveness trial of intensive outpatient PE	Study 1: *N* = 40 (Web-PE) *n* = 37 active duty *n* = 3 veterans Carl R. Darnall Army Medical Center, Fort Hood, Texas Study 2: *N* = 212 veterans Emory Healthcare Veterans Program, Atlanta, Georgia	[113, 192, 193]
Daniel Taylor, University of Arizona, 2015-2019	Treatment of Comorbid Sleep Disorders and PTSD	Three-armed RCT of CPT before or after CBTi versus CPT alone for comorbid sleep disorders and PTSD	*N* = 94 *n* = 87 active duty *n* = 7 veterans	[133, 194, 195]
Douglas Williamson, Duke University, 2015-2019	Genetic and Epigenetic Alterations as Biomarkers for PTSD Diagnosis and Prognosis	Evaluation of blood-based biomarkers for PTSD diagnosis, prognostic risk to develop PTSD, and prognosis of treatment response in human and postmortem samples	*N* = 200 pre/postdeployment *N* = 200 pre/posttreatment *N* = 96 postmortem Carl R. Darnall Army Medical Center, Fort Hood, Texas	
TOTAL CAP STUDY PARTICIPANTS			*N* = 1,752 total human participants *n* = 986 clinical trial participants *n* = 766 observational study participants	

CBTi, Cognitive-Behavioral Therapy for Insomnia; CPT, Cognitive Processing Therapy; DHEA, dehydroepiandrosterone; PTSD, posttraumatic stress disorder; PCT, Present-Centered Therapy; PE, prolonged exposure; RCT, randomized clinical trial; UT Health San Antonio, University of Texas Health Science Center at San Antonio; Web-PE, Web-based Prolonged Exposure.

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Supplemental Text

S1. Incorporation of new research projects and sustainment of consortium infrastructure

S1.1. Review and approval of STRONG STAR-affiliated project grant submissions

Proposed STRONG STAR-affiliated projects are first brought to the STRONG STAR Administrative Core (see Section S2.1) for an initial review. This initial review considers (1) the research credentials of the proposed principal investigator (PI), (2) the general scientific and public health merit of the proposed project, (3) the feasibility of the proposed project, (4) the proposed participant recruitment and performance sites, (5) whether the proposed project aligns with the overall consortium research portfolio, (6) whether the proposed project will complement or compete with ongoing STRONG STAR studies, (7) which STRONG STAR Research Cores will be used to support the project, and (8) the proposed source of research funding.

If the proposed STRONG STAR-affiliated project is determined to have potential merit according to the criteria outlined above, it is reviewed by the STRONG STAR PI Committee during one of the regularly scheduled investigator teleconferences. The STRONG STAR PI Committee is comprised of all STRONG STAR PIs who have received peer-reviewed funding. If the consensus of the PI Committee is that the proposed project has merit according to our review criteria, STRONG STAR collaborates with the proposed PI for the grant submission. Over the past 13 years, approximately 200 STRONG STAR-affiliated grant applications have been submitted, and about 50 have been selected for funding.

S1.2. Additional research infrastructure support

Additional infrastructure support for the sustainment of the consortium has been provided by the University of Texas Health Science Center at San Antonio and with Department of Veterans Affairs (VA) funding through the National Center for PTSD. As a result of that funding, and to continue the nationwide collaborative efforts to support the long-term funding for a nationwide PTSD research consortium, STRONG STAR and Consortium to Alleviate PTSD investigators submitted 45 peer-reviewed research proposals in 2020.

S2. STRONG STAR and Consortium to Alleviate PTSD (CAP) research operations

S2.1 STRONG STAR and CAP research cores

Both STRONG STAR and CAP were established with four research cores to support investigators: (1) the Administrative Core (for STRONG STAR) and the Coordinating Center (for CAP), (2) the Assessment Core, (3) the Data Management and Biostatistics Core, and (4) the Biomarkers and Genomics Core. Independent research projects were encouraged, but not required, to include collaboration with each research core. Perhaps the greatest emphasis was placed on individual project use of common data elements (CDEs) so long as these did not overburden or override the individual project needs. The specific level of support needed by these research cores has been determined on a study-by-study basis. For example, not every project includes the collection of biomarkers. Note that although the performance periods for the original STRONG STAR Multidisciplinary PTSD Research Consortium and for the CAP have

come to an end, many of the cores and support staff remain in operation, particularly in support of ongoing STRONG STAR-affiliated projects but also as the group continues to seek funding for and incorporate new research efforts into the STRONG STAR portfolio. Additional details about our research cores are available at the STRONG STAR website (www.STRONGSTAR.org).

S2.2. Use of common data elements (CDEs)

The establishment of CDEs for posttraumatic stress disorder (PTSD) [196] started with the original STRONG STAR Multidisciplinary PTSD Research Consortium to help ensure that similar measures would be used across all of the research projects. The STRONG STAR CDEs were revised with the funding of the CAP with two main goals: (1) to encourage military-related PTSD researchers to use these measures in future studies, and (2) to facilitate comparison, replication, and data aggregation. The process for selecting CDEs and the list of currently recommended CDEs were published in 2019 [197] to encourage the above goals across the field of combat-related PTSD research. The selection of CDEs for the CAP was contingent upon the following: (1) construct and content applicability to military-related PTSD; (2) precedence in previous, related research; (3) published psychometric evidence; (4) no cost (available in the public domain); and (5) brevity [198].

S2.3. Standard operating procedures

The establishment of detailed standard operating procedures (SOPs) facilitates the collection and management of high-quality data across multiple projects. As part of the STRONG STAR and CAP intent to implement all clinical research projects in full compliance with the International Conference on Harmonisation – Good Clinical Practice (GCP) guidelines ICH-E6R2 (https://www.ich.org/page/efficacy-guidelines), we established and documented required training for investigators, coordinators, and study staff in GCP generally, and pertinent to their roles, specifically. STRONG STAR and CAP have a library of 60 SOPs to help guide various processes and procedures for the supervision and management of research projects individually and collectively from initial preparation/approval through study conduct and reporting, study close-out, and document archiving.

S2.4. Regulatory coordination

While the Department of Defense (DoD) and VA research regulations are very similar to the civilian federal regulations, there are unique differences that need to be considered [199]. The consortia have kept abreast of the new Common Rule and the associated and updated DoD Instructions and VA Directives. The consortia have helped the DoD and VA make maximum use of the new regulations by working between organizations to execute Institutional Agreements for Institutional Review Board (IRB) Review and to help DoD and VA organizations implement new pathways for IRB review. The consortia conceptualized and operationalized IRB-approved processes for online consent, research assessments by videoconference, and collection and shipping of biological specimens. The consortia's experience with engagement in research determinations, alterations and waivers of informed consent, intimate knowledge of DoD and VA research regulatory guidelines, and close working relationships with the U.S. Army Medical

Research and Development Command (USAMRDC) Human Research Protection Office (HRPO) and the VA Office of Research Protections, Policy, and Education (ORPP&E) have allowed the consortia to minimize the time it takes for regulatory approvals to maximize the time available to conduct the studies.

S2.5. Data safety and monitoring

As part of the STRONG STAR-CAP Data Safety and Monitoring Plan (DSMP), we standardized a plan addressing trial management, data management and analysis, quality assurance, regulatory compliance, trial safety, trial efficacy, and DSMP administration. A unique component of the STRONG STAR-CAP DSMP is the monitoring of trial safety, including the assessment and adjudication of possible adverse events (AEs), serious adverse events (SAEs), and unanticipated problems involving risk to subjects and others (UPIRSOs) in behavioral health trials using psychological interventions. Though many of the studies of the consortia have been primarily behavioral psychotherapy-based treatments, we have focused on thorough assessment and reporting of AEs that might occur either due to our study treatment or to their common occurrence within our participant study populations [200, 201]. As our guiding principle in the development of our AE monitoring and reporting policies and practices, we used procedures that had been developed within the context of drug and device trials monitored by the U.S. Food and Drug Administration. This has subsequently required standardized assessments and documentation of observed AEs and a PI and consortium review and adjudication of observed events.

As part of the STRONG STAR-CAP DSMP, we also established a Data Safety and Monitoring Board (DSMB). The STRONG STAR-CAP DSMB is an independent group of national civilian and military clinical and research experts who review and monitor our clinical trials and advise STRONG STAR and CAP investigators. The DSMB membership reflects the disciplines and specialties necessary to interpret the data from the clinical trials and to fully evaluate participant safety.

S2.6. Establishment of the STRONG STAR-CAP Repository

One of the most significant accomplishments of the consortia has been the establishment and development of the STRONG STAR-CAP Repository. To our knowledge, this is the largest repository of data from studies targeting combat PTSD and related conditions in active duty military personnel and veterans. The original purpose of the repository was to establish a central data repository for all research data, including clinical data, biological samples, and neuroimages, and to allow for the long-term storage, maintenance, and use of both identified and de-identified data collated together from multiple studies. The establishment of this repository was not required or even suggested by the funding agencies. However, over time it has become apparent that this well-characterized data set is invaluable for omnibus analyses of military-related PTSD and its treatment, and it will continue to be a national asset for future research to advance science and inform national policy.

As noted, development of the STRONG STAR Repository was initiated with the STRONG STAR Multidisciplinary PTSD Research Consortium. With the subsequent funding of additional STRONG STAR-affiliated clinical research studies, PIs were encouraged to participate in the optional incorporation of the repository protocol as part of their project. Then,

with the awarding of the CAP in 2013, additional electronic data and biological specimens were incorporated into the repository, and it was renamed the STRONG STAR-CAP Repository. The repository now includes research data from approximately 17,500 research participants from about 40 clinical research studies, including about 30 clinical trials.

S2.7. Review and approval of scientific presentations and publications

STRONG STAR and CAP have established policies and procedures to guide the review, approval, and tracking of scientific presentations and publications. The overall goal is to help ensure that all presentations and publications are technically correct, include the correct DoD, VA, or government disclaimers, contain proper acknowledgement of grant funding, and meet all the requirements and guidelines for presentations and publications. This is especially important related to the presentation and publication of data from active duty military populations to help ensure that the proper military reviews and approvals are obtained prior to the public release of research findings.

All authors are required to make contributions to a scientific manuscript in accordance with the requirements of specific journals as well as standard publication guidelines [202, 203]. The consortia policy is that military site PIs be included as co-authors on publications and presentations of data generated from projects for which they have assumed military institutional responsibility, assuming they also meet the authorship contribution guidelines. As a minimum, this should include the review, editing, and approval of the final version of all scientific presentations and publications prior to submission for review and approval through official military channels.

S2.8. Data Sharing Agreements, Data Use Agreements, and Recipient Investigator Agreements

Data Sharing Agreements, Data Use Agreements, and Recipient Investigator Agreements are used when research data are shared with or transferred to investigators and institutions. In compliance with an IRB-approved repository protocol, only de-identified data are released from the STRONG STAR-CAP Repository. The Data Use or Recipient Investigator Agreement outlines the specific purpose of the release of the data, and it is signed by (1) the recipient of the data, (2) the corresponding PI or PIs whose data is being requested, and (3) the STRONG STAR-CAP Repository PI. Recipients agree to limit their use of the data to that specified in the Recipient Investigator Agreement (i.e., for analysis and publication of particular manuscripts) and not to use it for other purposes (i.e., sharing with other investigators or storing data in another data repository).

S3. Education, training, and dissemination

S3.1. The integration of clinical and research trainees throughout the consortia

Over the past 13 years, STRONG STAR has trained over 100 postgraduate research assistants, doctoral students, psychology interns, psychiatry residents, psychology postdoctoral fellows, and social workers to support various research projects. Approximately 50 psychology postdoctoral fellows have served as research therapists for many STRONG STAR and CAP

clinical trials evaluating the efficacy of a variety of cognitive-behavioral treatments, including Prolonged Exposure [204], Cognitive Processing Therapy [205], Cognitive-Behavioral Conjoint Therapy for PTSD [206], Written Exposure Therapy [207], and Cognitive-Behavioral Therapy for Insomnia [208].

S3.2. The STRONG STAR Training Initiative

The STRONG STAR Training Initiative grew out of the experience of University of Texas Health Science Center at San Antonio faculty and clinicians who garnered unparalleled experience and expertise in adapting and delivering evidence-based PTSD treatments to military service members and veterans. With many civilian providers being called upon to serve the mental health needs of military personnel and veterans, we developed a program and obtained funding to train civilian providers in the leading evidence-based treatments for PTSD and provide them with the cultural competency needed to help them deliver those treatments most effectively to our nation's psychologically wounded war fighters. This led to what now is a national program called the STRONG STAR Training Initiative. The STRONG STAR Training Initiative uses a competency-based "Learning Community" training model to promote successful adoption of evidence-based treatments into practice [209-211]. To date, the STRONG STAR Training Initiative has trained over 1,000 community-based, veteran-serving, mental health professionals across 33 states, reaching thousands of patients with evidence-based treatments.

S3.3. The STRONG STAR-CAP website

The STRONG STAR website (URL: www.STRONGSTAR.org) includes both a public website and a limited-access secure website for consortia investigators. The public section of the website serves as the face of the consortia and introduces site visitors to the national research group and its activities and findings. Website visitors include members of the general public, military service members and their families, veterans and their families, military and VA leaders, clinicians, researchers, potential collaborators, journalists, representatives of funding agencies, and potential donors.

S3.4. The San Antonio Combat PTSD Conference

Beginning with the initial funding of the STRONG STAR Multidisciplinary PTSD Research Consortium in 2008, an annual investigators' meeting was held in San Antonio, Texas. When the Consortium to Alleviate PTSD was funded in 2013, a joint STRONG STAR and CAP investigators' meeting was held. In 2016, it was decided to expand the annual investigators' meeting and open the attendance to the public. The inaugural San Antonio Combat PTSD Conference attracted almost 400 attendees, and it continues to be held annually.

S4. Targeted research gaps to be addressed in future research

The following is a list of specific research gaps that remain to be targeted:

- Clinical trials to enhance current evidence-based psychotherapies
  - Matching patients to treatments based on clinical trial outcome data algorithms
  - Matching therapists to treatment-intervention approaches

  - Using biomarkers to guide treatment and monitor response
  - Shared decision-making including patient factors, treatment factors, facility or clinic factors, delivery modality
  - Targeting common comorbidities such as mild traumatic brain injury (TBI), sleep disorders, chronic pain, substance use disorders, health conditions (such as cardiovascular abnormalities or metabolic syndrome), relationship/family dysfunction, suicide
- Clinical trials to combine evidence-based, cognitive-behavioral treatments with the use of medications and devices to enhance efficacy
  - Ketamine, transcranial magnetic stimulation (TMS), stellate ganglion block (SGB), oxytocin, 3,4-methylenedioxymethamphetamine (MDMA), etc.
- Clinical trials of cognitive-behavioral therapies specifically tailored for military sexual trauma
- Clinical trials to evaluate transdiagnostic, complementary, integrative, and holistic treatment approaches
- The establishment of civilian models of PTSD similar to that seen in combat veterans (e.g., firefighters, police, first responders) to continue treatment development
- Early interventions with application to far-forward environments
- Interventions to reduce risk, enhance psychological resiliency, and increase military readiness
- The development of new and novel treatments for PTSD

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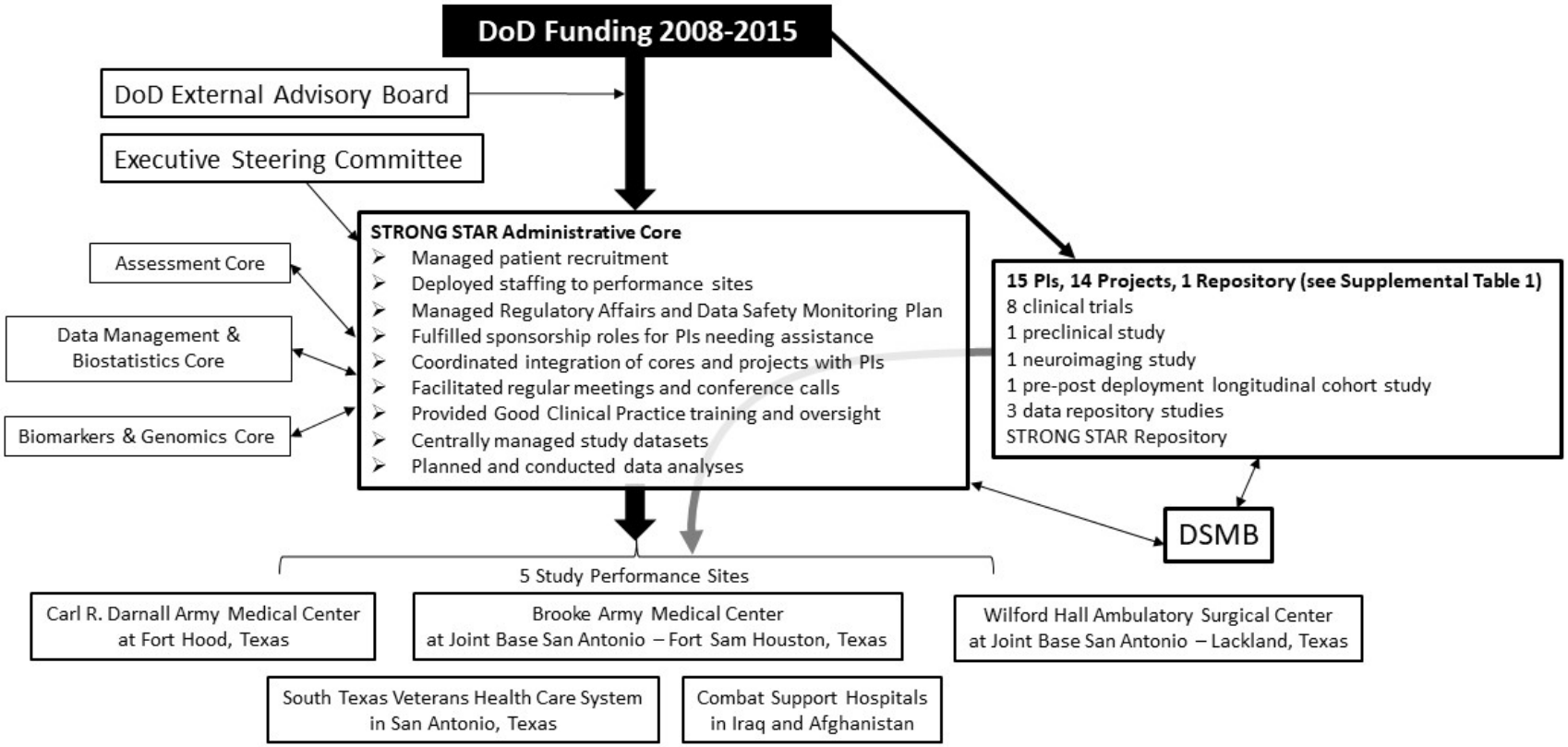
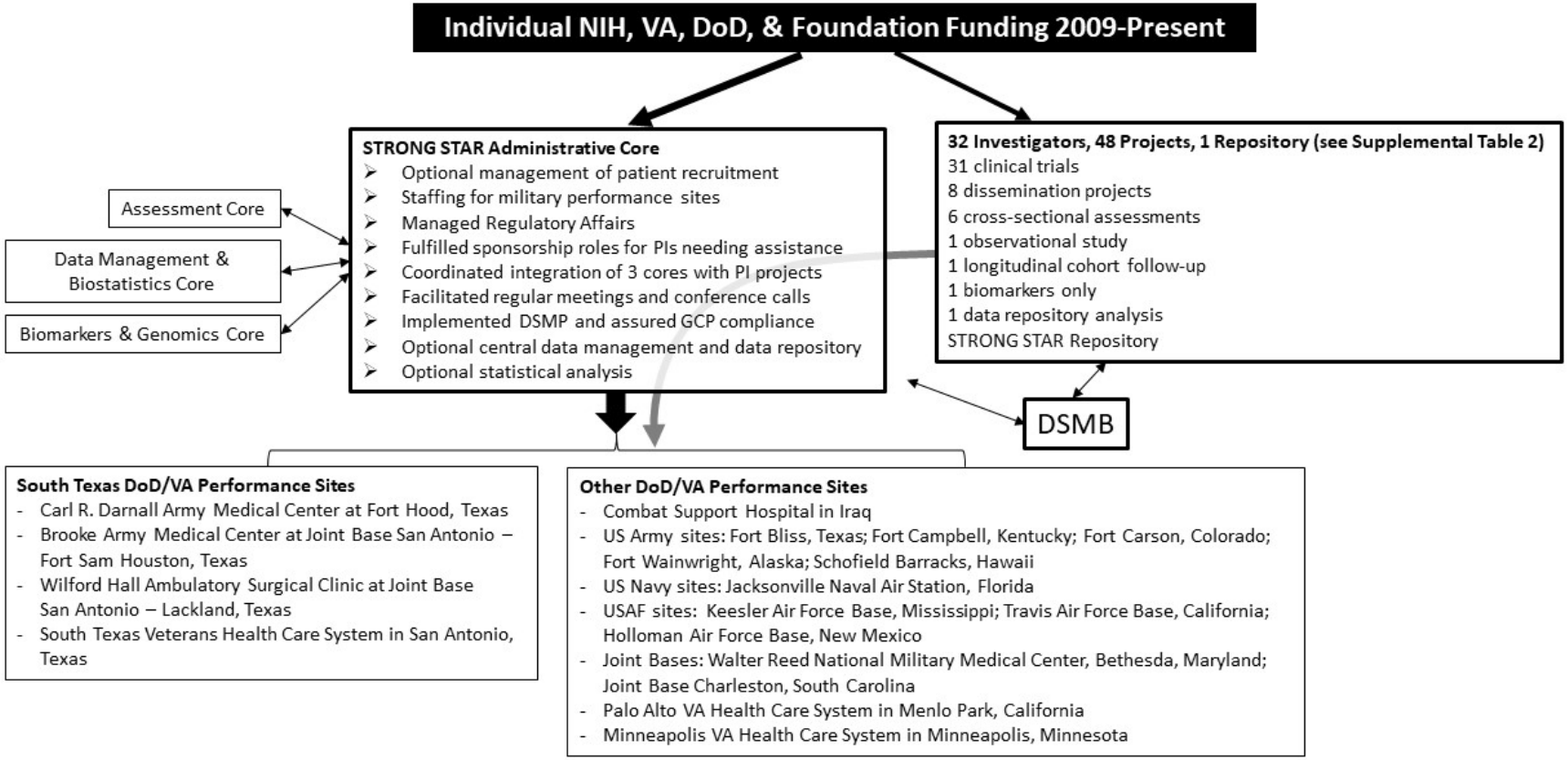
Supplemental Figure 1: The STRONG STAR Multidisciplinary PTSD Research Consortium



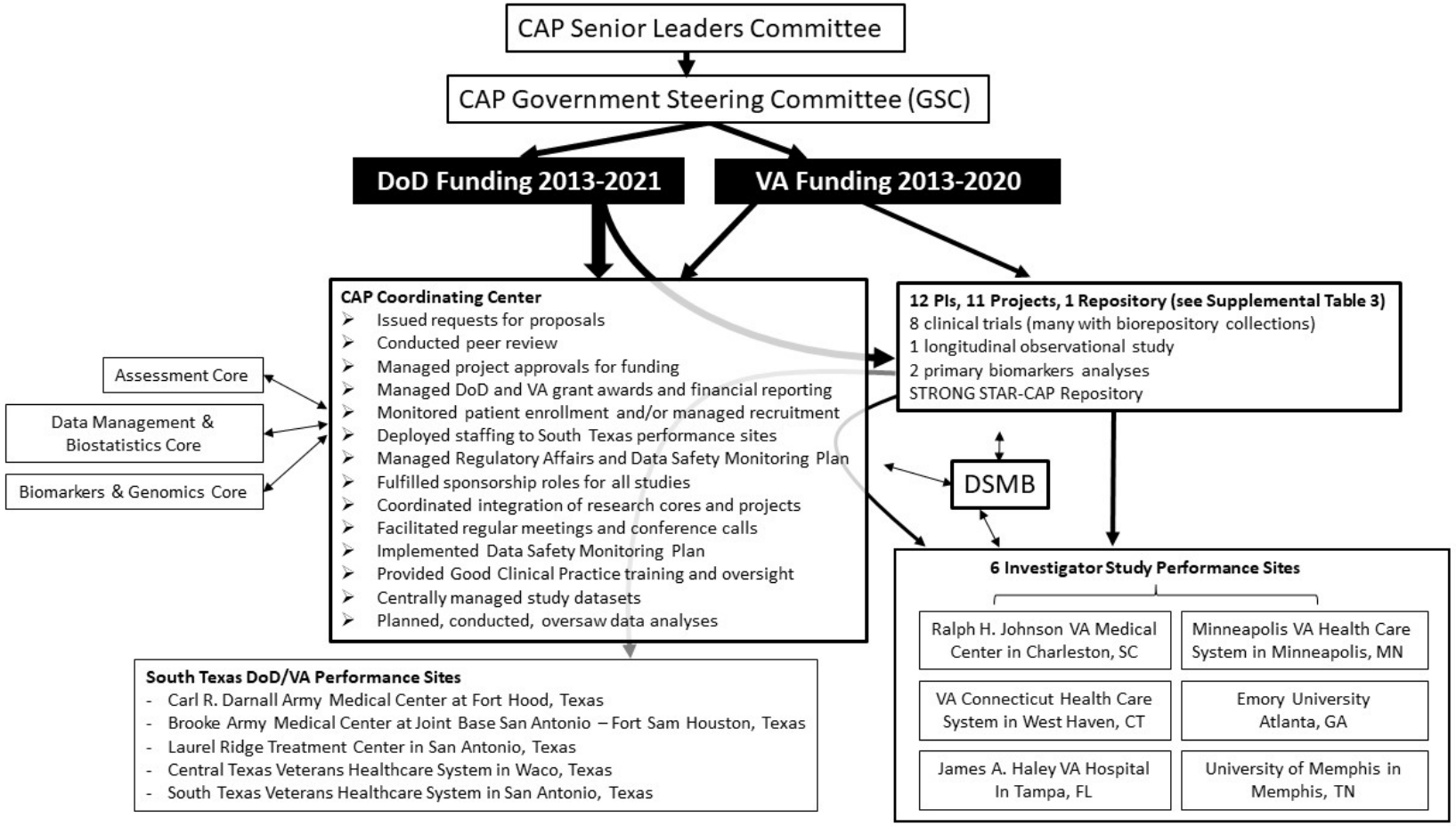
Note. DoD, U.S. Department of Defense; DSMB, Data Safety and Monitoring Board; PI, principal investigator.

Supplemental Figure 2: STRONG STAR Consortium Support for Affiliated Studies



Note. DoD, U.S. Department of Defense; DSMB, Data Safety and Monitoring Board; DSMP, Data Safety and Monitoring Plan; GCP, Good Clinical Practice; NIH, National Institutes of Health; PI, principal investigator; VA, U.S. Department of Veterans Affairs.

Supplemental Figure 3: The Consortium to Alleviate PTSD (CAP)



Note. DoD, U.S. Department of Defense; DSMB, Data Safety and Monitoring Board; PI, principal investigator; VA, U.S. Department of Veterans Affairs.