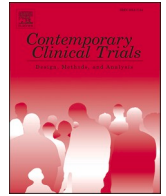


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Full Length Article



## 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 post-traumatic 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 Post-traumatic 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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## Disclaimer

The views expressed herein are solely those of the authors and do not reflect an endorsement by or the official policy or position of Brooke Army Medical Center, C.R. Darnall Army Medical Center, the U.S. Army Medical Department, the U.S. Army Office of the Surgeon General, the Department of the Army, the Department of the Air Force, the Department of Defense, the Department of Veterans Affairs, the National Institutes of Health, or the U.S. Government.

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The authors of this manuscript made the following contributions in accordance with the CRediT (Contributor Roles Taxonomy) guidelines.

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## Declaration of Competing Interest

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

## Appendix A. Supplementary data

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