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Utilization of the Clinician-Administered PTSD Scale for DSM-5 to Assess PTSD Symptom Severity in an Intensive Outpatient Program

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Abstract

The Department of Veteran Affairs and Department of Defense Clinical Practice Guideline for the Management of Posttraumatic Stress Disorder (PTSD) and Acute Stress Disorder (ASD) recommend the use of a structured interview for confirming the diagnosis of PTSD. The Clinician-Administered Scale for the DSM-5 (CAPS-5) is an evidence-based structured interview which is supported by empirical evidence. The CAPS-5 is underutilized at Madigan Army Medical Center (MAMC) for the diagnosis of PTSD. Thus, the present project sought to improve the utilization of the CAPS-5 assessment. Active duty service members (n = 17) referred to the Psychological Health Intensive Outpatient Program (PHIOP) were assessed for PTSD utilizing the CAPS-5. All participants completed self-report questionnaires before and after treatment, providing baseline and post- intervention psychometric scores. Differences in pre- and post- psychometric scores were not clinically significant, collectively. Additionally, mean changes in scores were not clinically significant between severity groups: mild, moderate, and severe. However, patients with mild severity had the most significant decrease in scores. The authors' synthesis of evidence provides reliable support for increasing CAPS-5 utilization at MAMC to provide better care, better outcomes, lower cost, and improved military readiness.

Keywords: CAPS-5, PTSD, diagnosis, assessment, validity, reliability, and accuracy

Utilization of the Clinician-Administered PTSD Scale for DSM-5 to Assess Symptom Severity in an Intensive Outpatient Program

The United States has actively engaged in combat operations for the past 18 years. The Global War on Terror and subsequent operations are now the most protracted continuous conflict in the history of the nation (Tawoos, 2017). This protracted operation tempo has come at a cost to our military service members, as they currently exhibit posttraumatic stress disorder (PTSD) rates four times greater than the general population (Gradus, 2007). Increasing PTSD rates among veterans in the post 9/11 era are primarily attributable to frequent deployments and prolonged combat exposure (Reisman, 2016). PTSD is a complex cluster of symptoms that have significant overlap with other mental illnesses. Accordingly, a PTSD diagnosis can be difficult to confirm and differentiate from other conditions such as a mood or anxiety disorder (Greene, Neria, & Gross, 2016).

The Department of Veteran Affairs and Department of Defense Clinical Practice Guideline (VA/DoD CPG) for the Management of PTSD and acute stress disorder (ASD) recommends the use of a structured interview for confirming the diagnosis of PTSD (2017). The Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) is an evidence-based structured interview which is supported by empirical evidence (Weathers et al., 2018). The CAPS-5 scales the diagnosis based on symptom severity. This rating corresponds with each criterion listed within the Diagnostic and Statistical Manual of Mental Disorders: Fifth Edition (DSM-5) and produces a global PTSD severity rating. Severity scale grades are either absent, mild, moderate, severe, or extreme.

Madigan Army Medical Center (MAMC) policy does not mandate or recommend CAPS-5 utilization for the policy diagnosis of PTSD. The chief of the Department of Behavioral Health

at MAMC stated his belief that the CAPS-5 is currently underutilized in clinical practice (K. Goke, personal communications, September 12, 2018). Increased utilization will assist in validating PTSD diagnosis, provide clinicians a symptom severity rating, and the impact of PTSD on overall patient functioning (Weathers, Keane, & Davidson, 2001). This level of diagnostic clarity may allow providers to determine the most appropriate level of treatment and provides reliable benchmarks to track patient progress.

Significance of the Problem

Posttraumatic stress disorder is a mental health condition that causes significant distress or impairment in social, occupational or other important areas of functioning (American Psychiatric Association [APA], 2013). For the military population, impaired functioning translates to stressed families, ineffective team members, and reduced unit readiness (Walter, Levine, Highfill-McRoy, Navarro & Thomsen, 2018). To meet criteria for PTSD, an individual must have exposure to a traumatic event and present symptoms from four different symptom clusters for at least one month. The first criterion for PTSD establishes which situations are considered adequate for the diagnosis, and which are not. It also stipulates the traumatic event must be through an individual's direct experience with or witnessing of: death, serious bodily injury, or sexual violence. The DSM-5 does contain allowances for merely learning about such events, but in this scenario, the event must involve a close friend or family member and be violent, sudden, or shocking. This criterion can also be met by serial exposure to various forms of human misery, like those seen on a battlefield. The DSM-5 excludes exposure to traumatic experiences through news media, films, or videos as traumatic events.

After establishing guidance for determining a qualifying event, the DSM-5 lists twenty symptoms from four clusters of symptoms associated with PTSD: five intrusive symptoms, two

avoidance symptoms, six negative alterations in cognitions and mood symptoms, and seven change in arousal symptoms (APA, 2013). To meet criteria for PTSD patients must report six total symptoms from these symptom clusters: at least one intrusive symptom, one avoidance symptom, two cognition and mood symptoms, and two arousal symptoms. The persistence of all these symptoms must last more than thirty days and cause significant distress (APA, 2013). A PTSD diagnosis can be formed from over half a million different symptom combinations (Brewin et al., 2017). The complexity of PTSD symptomology and presentation makes diagnosing this disorder extremely challenging (Guina, Welton, Broderick, Correll, & Peirson, 2016).

The lifetime incidence of PTSD is estimated to be 9 to 15% with a lifetime prevalence of about 8% of the general population (Sadock, Kaplan & Sadock, 2015). Furthermore, 83% of patients diagnosed with PTSD share one or more mental health diagnoses such as depression, adjustment disorder, generalized anxiety disorder, and alcohol use disorder (Walter et al., 2018). In a study of service members that entered into service in the Navy and Marine Corps between 2006 and 2013, 1.8% of these service members were diagnosed with PTSD (Walter et al., 2018). Of those diagnosed with PTSD, 83.3% were diagnosed with none or more comorbid mental health disorder or physical condition (Walter et al., 2018). Prevalence of mental health disorders were significantly higher in the PTSD sample versus the non-PTSD sample: depressive disorder - 49% compared to 4.5%; adjustment disorder - 37% compared to 6.8%; and alcohol use disorder - 27% compared to 4.8% (Walter et al., 2018). PTSD and correlated comorbidities are associated with increased healthcare utilization, loss of productivity, and increased strain on primary care providers (VA/DoD, 2017; Walter et al., 2018).

Major depressive disorder, generalized anxiety disorder, traumatic brain injury, and adjustment disorder share symptoms with PTSD (APA, 2013). Sleep disturbance, concentration problems, and irritability are symptoms characteristic of PTSD, depression, and generalized anxiety disorder (Brewin et al., 2017). Negative beliefs about oneself and the world, self-blame, anhedonia, social isolation, and emotional numbing are symptoms of depression and PTSD (Brewin et al., 2017). Diagnostic criteria for PTSD, comorbid diagnoses, and shared symptomology with other mental health disorders, create the potential for misdiagnosis of PTSD (Guina et al., 2016). The potential for misdiagnosis is decreased with structured clinical interview techniques (Guina et al., 2016). The VA/DoD CPG for the management of posttraumatic stress disorder and acute stress disorder recommend the use of a structured clinical interview for diagnostic clarity (VA/DoD, 2017). The Clinician-Administered PTSD Scale for the DSM-5 (CAPS-5) is a structured clinical interview with empirical evidence that supports its use for the diagnosis of PTSD.

In order to address this problem, this project aims to evaluate the utility of performing the CAPS-5 interview for patients entering into the trauma-focused intensive outpatient program (TFIOP) as an additional screening method to the current clinical interview. The authors performed the CAPS-5 interview for willing participants entering into the TFIOP from 3 six-week cohorts that started in October 2018, December 2018, and January 2019. The CAPS-5 assessment confirmed or ruled out PTSD diagnosis and provided more insight into the severity of symptoms. The goal is to assess if the results of the structured interview provide insight into which individuals are most likely to benefit from this intervention. If the CAPS-5 is found to be predictive of treatment outcomes, then it could help to approve appropriate patients and used to prevent patients who are not suitable from attending and taking a seat from a better candidate.

This project further aimed to facilitate evidence-based practice by implementing a tool that is already identified by the VA/DoD CPG as a preferred diagnostic instrument but infrequently used at MAMC. Also, increased availability and appreciation of the CAPS-5 may support its usage by providers across MAMC to confirm a PTSD diagnosis for any new cases of PTSD. Any product that can help identify patients who meet criteria for PTSD and assist with selecting the appropriate plan of care could have a significant impact across the MHS.

Review of Literature

PubMed, CINAHL, PsycINFO, and PILOTS databases were searched to access articles related to the Clinician-Administered PTSD Scale (CAPS) and CAPS-5. The search strategies varied for each database to yield results more specific to the clinical questions.

In the CINAHL database keywords used in the search were clinician-administered PTSD scale OR clinician-administered PTSD scale for DSM-5 OR CAPS OR CAPS-5 AND validity and reliability in assessment. The search was limited to full text, published dates from 2000-2018, peer-reviewed, adult patients. This search yielded 31 results.

In the PubMed database the following search strategy was used: ("Clinician-administered PTSD Scale" OR "CAPS" or "Clinician-administered PTSD scale for DSM-5" OR CAPS-5) AND ("post-traumatic stress disorders" OR "posttraumatic stress disorder" OR "PTSD") AND (diagnosis OR assessment) AND (validity OR reliability OR accuracy). The search was limited to clinical trials, controlled clinical trials, meta-analysis, randomized controlled trial, review, systematic review, full text, age 18 and over, and humans. This search yielded 143 results.

The PsycINFO database was searched for the terms test reliability OR test validity or psychometrics AND clinician-administered PTSD scale. The search was limited to full text, adult

patients, human, clinical trials, empirical study, experimental study, follow-up study, longitudinal study, prospective study, retrospective study, literature review, systematic review, meta-analysis, meta-synthesis, qualitative study, quantitative study, treatment outcome, and years 2000-2018. This search yielded 55 results.

The PILOTS database was searched for the keyword "clinician-administered PTSD scale for DSM-5". The search was limited to adults, PTSD (DSM-5), veterans, and peer-reviewed articles from 2013 to present. This search yielded 112 articles.

Of the 341 articles, seven duplicates were identified, leaving a total of 334 articles for abstract review. Of the abstracts reviewed, 300 were not relevant to the clinical question and were discarded. Thirty-four articles were kept for additional review. Of the 34 remaining articles, nine were substantive to the clinical question.

Literature Synthesis

Since the inception of the CAPS in 1990, there have been various versions which correspond with modifications of the *Diagnostic and Statistical Manual for Mental Disorders (DSM).* Throughout the modifications and versions, the CAPS, CAPS-IV, and CAPS-5 have continued to demonstrate high validity, reliability, consistency, specificity, and sensitivity in numerous studies across different age groups and patient populations. In addition to being valid for clinical utility in the diagnosis of PTSD, research studies use the CAPS as the gold standard for comparison of other screening and assessment tools (VA/DoD, 2017).

From the articles reviewed, the CAPS-5 was utilized as the standard to validate inter-rater reliability, consistency, specificity, sensitivity, and convergent validity of other PTSD screening and assessment tools such as the PCL-5, PTSD Symptom Scale-Interview (PSS-I), Posttraumatic

Diagnostic Scale (PDS-5) (Foa & Tolin, 2000; Weathers et al., 2018; Muller-Engelmann et al,. 2018). Three studies demonstrated the validity of different versions of the CAPS assessment: the original CAPS, CAPS-IV, and CAPS-5 (Paunovic & Ost, 2015; Pupo et al., 2011; Schnyder & Moergeli, 2002). Additionally, a literature review covering a ten-year period further supports the convergent and discriminant validity, diagnostic utility, and sensitivity or the CAPS assessment (Weathers et al., 2001).

Clinical Question

In adult patients referred to a trauma-focused intensive outpatient program, does a Clinician-Administered PTSD Scale for DSM-5 diagnosis and severity rating affect changes in psychometric scores over six weeks?

Focus Areas

This project has three primary focus areas. First, the authors conducted a four-hour online CAPS-5 training. Second, the authors utilized the CAPS-5 interview to conduct intake assessments of patients referred to the TFIOP and collect psychometric data at the beginning and end of TFIOP treatment. Third, the CAPS-5 severity rating and psychometric data will be analyzed to see if the CAPS-5 severity rating has any bearing on psychometric score changes.

Relevance to Military Nursing

Implementing the most effective evidence-based tools and methods, like the CAPS-5, supports value-based care and is a key element for establishing a high-reliability organization (Chassin & Loeb, 2013). The Department of Defense (DoD) recognizes that in order to maintain an effective fighting force, the Military Health System (MHS) requires more integration, standardization, and reliability (Department of Defense Inspector General, 2018). The Defense Health Agency (DHA) is tasked with accomplishing this task and created the MHS' Quadruple

Aim framework to guide its efforts. The first three Quadruple Aim components focus on: improving the health of the military community, creating a system that provides superior quality, and maximizing efficiency to lower per capita costs (Defense Health Agency [DHA], 2013). The last component, promoting readiness, means ensuring the military is medically ready to rapidly deploy and that medical personnel are trained and prepared to provide care regardless of the mission. The ability to identify PTSD upholds the first aspect of readiness by providing an accurate diagnosis of PTSD. Once diagnosed, service members can receive proper treatment and be medically ready for deployment. Having professionals trained to conduct the CAPS-5 supports the second aspect of readiness by enhancing the skill set of medical personnel with and evidence-based assessment tool to identify patients with PTSD.

In addition to diagnosing or ruling out PTSD, the CAPS-5 provides ratings of symptom severity. Rating symptom severity produces insight into which symptoms clinicians should prioritize in the formulation of their treatment plan. Also, personalized nursing care plans will address the symptoms individuals identify as causing the most dysfunction. For example, patients may present with PTSD symptoms across the symptom clusters but may have severe mood and cognitive symptoms with mild to moderate avoidance symptoms. This level of symptom distinction would allow nurses and members of the care team to tailor treatment plans to focus on symptoms that cause the most distress or impairment. With an accurate understanding of a patient's status, nurses will better anticipate patient needs. These added benefits have the potential to positively impacts patients' perception of care, improve patient outcomes, lower cost, preserve military readiness.

From an operational standpoint, the CAPS-5 will identify service members with active PTSD and can be helpful to determine which individuals have stable symptoms and which

individuals are not currently able to deploy. This directly affects readiness because commanders will have a more accurate understanding of their assigned personnel's deployability. Simply possessing a PTSD diagnosis or experiencing some symptoms should not result in a non-deployable status. However, service members experiencing more severe symptoms and social distress pre-deployment are at much higher risk of having their PTSD exasperated during a deployment (Interian, Kline, Janal, Glynn, & Losonczy, 2014). Also, PTSD increases the likelihood for psychiatric evacuation from theatre on a second or third deployment (Wilmoth et al., 2015). The unexpected loss of service members with essential skills mid-tour could have a negative impact on mission success. Alternatively, identifying PTSD with the CAPS-5 and reducing delays in starting treatment does improve patient outcomes and return to duty rates (Boulos & Zamorski, 2015).

The CAPS-5 may not provide any direct benefit for diagnosing PTSD in a deployed setting. In fact, bestowing a PTSD diagnosis in theatre is controversial since all service members are adapting to a constant stressor. The continuing nature of the experience may make adjustment disorder a more appropriate diagnosis (National Collaborating Centre for Mental Health, 2005). Regardless of the label, patients who have a behavioral health issue in theatre are at higher risk of having a mental illness post-deployment (Conway et al., 2016). Therefore, even without an official diagnosis, the CAPS-5 evaluation and scoring of symptoms can be useful for identifying patients who would benefit from early intervention such as cognitive-behavioral therapies. Studies demonstrate that patients with PTSD that receive cognitive-behavioral based therapies, such as anxiety management training and cognitive restructuring, have fewer reexperiencing and depressive symptoms and demonstrate improvements in global severity ratings of PTSD (Kearns, Ressler, Zatzik, & Rothbaum, 2012).

Organizational Framework

The organizing framework for this project was Pettigrew and Whipp's Model of Strategic Management of Change. The model was developed in 1991 as a method to manage strategic change in the motor, financial, insurance, and publishing industries (Armstrong, 2007). Pettigrew and Whipp note that strategic change deals with broad, long-term, and organization-wide issues, while operational change looks at issues within a part of an organization (Armstrong, 2007). Pettigrew and Whipp's model involve three dimensions of change: context, content, and process (White & Dudley-Brown, 2012).

The context is the *why* of change; content is the *what* of change; and the process is the *how* of change. The context dimension involved an assessment of the internal and external driving forces for the change, organizational culture and character, leadership, and the clinical setting (White & Dudley-Brown, 2012). This assessment provided the Joint Base Lewis-McChord (JBLM) team with direction to best implement and utilize CAPS-5 within MAMC and the MHS. The content dimension, in this case, is the implementation and data collection of the CAPS-5 and psychometric scores. The JBLM team collected data on the predictive value of the CAPS-5 severity rating score on psychometric outcomes. This data was utilized to support further utilization of the CAPS-5 at MAMC and the MHS. The process dimension involves the strategies and methods that will be used to implement organizational change (White & Dudley-Brown, 2012). Data obtained from the content dimension and assessment during the context dimension directed the approach to the process dimension.

Pettigrew and Whipp's model is not linear but stresses the dynamic and uncertain nature of change (White & Dudley-Brown, 2012). It involves consistent assessment along the way to adapt to internal and external forces that may impact the change process. Research studies

related to change, suggest strategies that are essential for change as recognition of the importance of change, support from key stakeholders, a credible change agent, and staff ownership and empowerment to change (White & Dudley-Brown, 2012). Pettigrew and Whipp's model incorporate these strategies while remaining flexible to adapt to the dynamics of the MHS. The authors engaged with TFIOP leadership and clinicians during the three cohorts of the project via weekly clinic visits and correspondence to assess internal and external barriers.

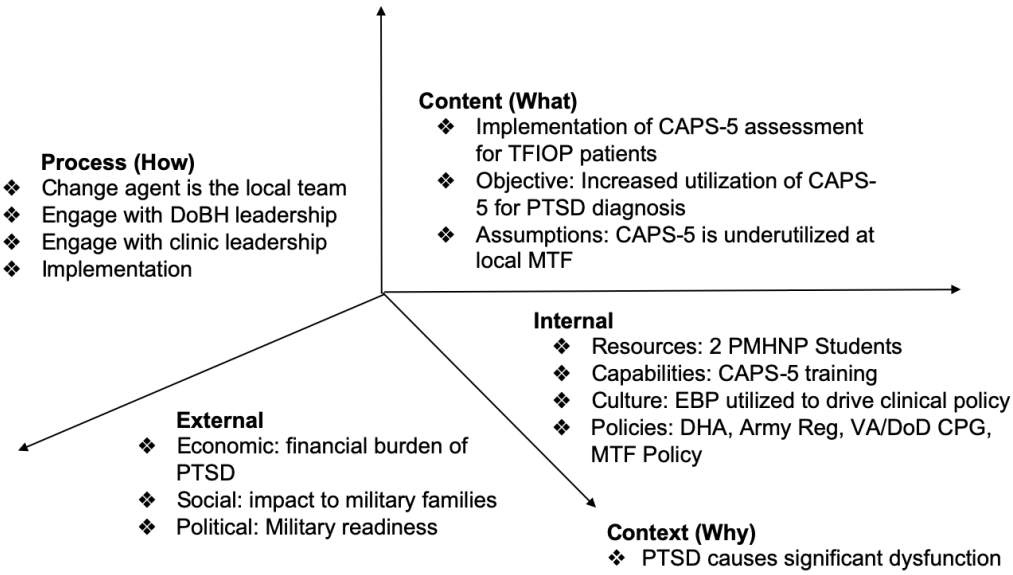

Figure 1. Pettigrew and Whipp Strategic Model of Change as used by local team. Adapted from https://www.researchgate.net/figure/The-Dimensions-of-Strategic-Change-Source-Andrew-Pettigrew-Richard-Whipp-1993_fig1_50938695.

Project design

General Approach

This project is designed to evaluate the use of a structured clinical interview and the effect the diagnostic rating has on psychometric outcomes following an intensive outpatient

program. By understanding the effect of current interventions, the JBLM team aims to identify opportunities to increase CAPS-5 utilization at MAMC.

Setting

The Psychological Health Intensive Outpatient Program (PHIOP) at MAMC provides intensive outpatient behavioral health treatment for active duty service members (ADSM). The PHIOP provides individual and group therapy, and medication treatment. The TFIOP is a group therapy that offers a general trauma track and a women's trauma track. Patients participate in group therapy for approximately four hours a day, five days a week, for six continuous weeks. Each group can accommodate up to 10 patients, and most cohorts meet or exceed capacity. A clinical psychologist, licensed mental health counselor, and two clinical social workers facilitate the group therapies. Between the women's trauma track and general trauma track, the PHIOP runs approximately 16 TFIOP groups annually. Upon completion of TFIOP treatment, patients are referred back to their primary behavioral health provider, with some patients continuing to engage in aftercare at PHIOP if needed.

Procedural Steps

Patients are referred to PHIOP by their primary behavioral health provider. Once referred to the PHIOP, a screening interview is performed to assess current patient safety, previous treatments, and coping skills. Based on this assessment, the PHIOP team decides on the appropriate track for the patient. In addition to the TFIOP, the PHIOP offers preparatory classes such as psychoeducation (PsyEd), launch group (LG), and skills resiliency training (SRT). These classes provide education and skill development to patients before starting TFIOP. Not all patients referred to the PHIOP possess a previous PTSD diagnosis. Additionally, a PTSD assessment is not a part of the initial screening process.

Patients referred to TFIOP volunteered to receive a CAPS-5 structured interview before or during the program. The CAPS-5 not only produces the number of PTSD symptoms the patient has experienced within the previous 30 days, but it will also score the severity rating of each symptom. Members of the JBLM team conducted the CAPS-5 assessment on patients that agreed to participate. This assessment resulted in no diagnosis or severity rating. Lastly, before and after the six-week treatment, patients completed computerized self-reports for the PTSD Checklist for DSM-5 (PCL-5), Generalized Anxiety disorder 7-item scale (GAD-7), Patient Health Questionnaire 9-item (PHQ-9), Insomnia Severity Index (ISI), and the Columbia-Suicide Severity Rating Scale (C-SSRS). These self-reports scales were selected for evaluation due to their correlation to PTSD symptoms, shared symptoms with PTSD, or ability to screening for distress or impairment.

Empirical evidence supports these screening tools (Bovin et al., 2016; Matarazzo et al., 2018; Moriarty, Gilbody, Mcmillan, & Manea, 2015; Spitzer, Kroenke, Williams, & Löwe, 2006). First, the PCL-5 was developed to specifically screen for symptoms related to PTSD using the updated criteria of the DSM-5 (Bovin et al., 2016). The PCL-5 has strong interrater reliability and consistently demonstrates sensitivity and specificity to a PTSD diagnosis (Bovin et al., 2017; Wortmann et al., 2016). Scores above 33 points are considered diagnostically significant for veteran populations (Bovin et al., 2017; Wortmann et al., 2016).

The GAD-7, though created to screed for GAD, does independently screen for anxiety symptoms. In a study of over 2700 participants, the GAD-7 was effective at identifying anxiety symptoms separately from depressive symptoms (Spitzer et al., 2006). Differentiation of anxiety

from depression is essential as these disorders frequently have overlapping symptoms, and are two separate domains (Spitzer et al., 2006).

Correspondingly, the authors recognized the need for a tool to delineate depressive symptoms. The PHQ-9 may not have as high sensitivity for major depressive disorder, as previous studies have demonstrated. However, measures of symptoms specific to depression remain validated (Moriarty et al., 2015). For this project, the PHQ-9 was useful to evaluate trends and severity of depressive symptoms over time.

The ISI is a self-report screening tool for insomnia consisting of seven items that are scored on a five-point Likert scale to assess insomnia over the previous two weeks (Wong et al., 2017). Scores for the ISI range from zero to 28, with higher scores indicating greater symptom severity. Comparison of the ISI self-report tool to a structured clinical interview for insomnia disorder demonstrated very good internal consistency and was validated with good psychometric properties (Wong et al., 2017). Two symptoms of from two separate clusters, intrusive symptoms and arousal symptoms, are related to sleep disturbances. For this project, the ISI was useful to assess changes in sleep disturbances over time.

Since the start of conflicts in Iraq and Afghanistan the rate of suicides among veterans has increased 32.2% (Gradus, 2018). Diagnosis of PTSD has been identified as a risk factor for suicide (Gradus, 2018). The authors included the C-SSRS to assess for suicide risk among participants in the project. A study by Matarazzo et al. (2018) demonstrated the reliability of the C-SSRS to screen for suicidal behavior in veterans. After the data is collected, an analysis was conducted to compare the CAPS-5 severity ratings to the aggregated psychometric data.

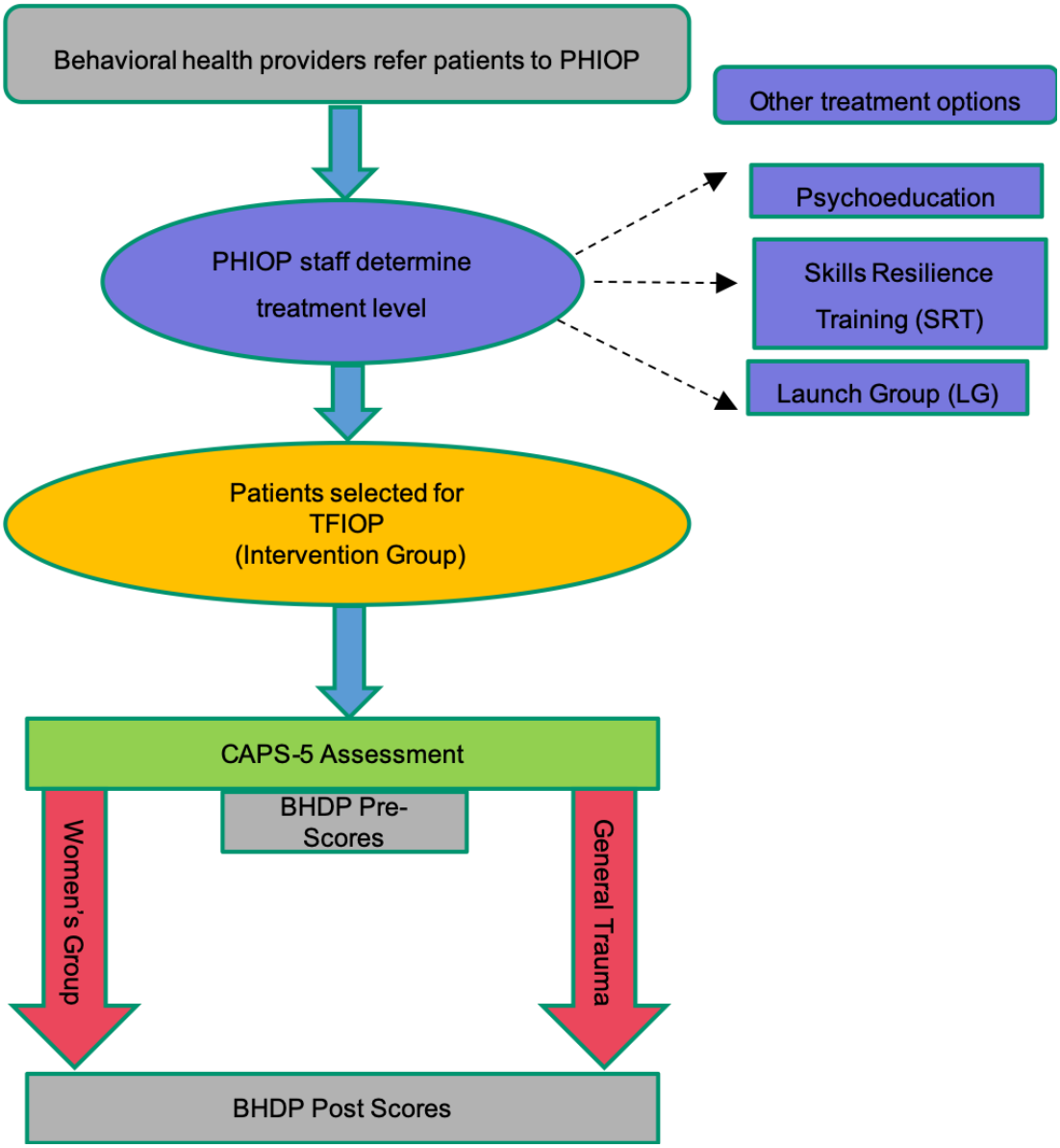

Figure 2. Patient referral, assessment, and treatment process from primary behavioral health providers through TFIOP treatment completion.

HIPAA Concerns

Data collected for this project include CAPS-5 severity ratings, and psychometric data obtained from the Behavioral Health Data Portal (BHDP) for the PCL-5, PHQ-9, GAD-7, ISI, and C-SSRS. Demographic data for patients includes name, DoD identification number, date of birth, age, sexual orientation, time in service and number of deployments. Each participant

received a unique patient identification number for analysis and data tracking purposes. All original materials containing personally identifiable information (PII) and the patient identification number key were kept in a locked cabinet in a locked office, in a restricted area of TFIOP clinic. The authors redacted all personally identifiable information and protected health information from any published materials for this project. Lastly, the authors maintained current Health Insurance Portability and Accountability Act of 1996 (HIPAA) certifications.

Project Results

All of the eighteen participants were assessed using the CAPS-5 interview, and 17 completed the TFIOP intervention. The population was 57% male and 43% female. The mean age was 30 years (S.D = 8.20); the mean length of military service was 8.88 years (S.D. = 6.585), and 65% of patients had deployed at least once. The CAPS-5 severity rating scale has five severity ratings: absent, mild, moderate, severe or extreme. Three patients (18%) did not meet the DSM-5 criteria for PTSD and had a mild severity. Six patients (35%) presented with moderate severity and eight (47%) with severe severity.

Table 1

Gender

	Frequency	**Percentage**
Male	9	53
Female	8	47

Table 2

Severity Rating

	Frequency	**Percent**
Absent	0	0
Mild	3	17.6
Moderate	6	35.3
Severe	8	47.1
Extreme	0	0

A comparative analysis was performed using the paired sample t-test for pre- and post-sample scores for each of the scales: PHQ-9, GAD-7, PCL-5, ISI, and C-SSRS. There was no clinical significance between the pre- and post- psychometric scores for any of the scales. Additionally, there was no statistically significant pre- and post- scores for these psychometrics when analyzed according to severity rating: mild, moderate, or severe. There was an average decrease in score for PHQ-9 (-0.89) and GAD-7 (-0.27). There was an average increase in score for PCL-5 (1.06), ISI (0.01), and C-SSRS (0.46). However, an analysis of the variance could not be calculated between severity ratings and mean changes in psychometric scores due to the lack of clinical significance between scores. In comparison, the mean delta for pre-and post- PHQ-9 are as follows: mild severity (-4.33), moderate severity (0.33), and severe severity (-1.63). Mean delta for GAD-7 is mild severity (-2.33), moderate severity (1.50) and severe severity (-1.50).

Mean delta for PCL-5 are: mild (-6.00), moderate (4.00), and severe (1.5). Mean delta for ISI are: mild (-7.00), moderate (0.83) and severe (-0.63). Mean delta for C-SSRS are: mild (0.00), moderate (0.5), and severe (0.375).

Table 3

Mean Change in Scores

	PHQ-9 Delta	**GAD-7 Delta**	**PCL-5 Delta**	**ISI Delta**	**C-SSRS Delta**
Mild	-4.33	-2.33	-6.00	-7.00	0.00
Moderate	0.33	1.50	4.00	0.83	0.50
Severe	-1.63	-1.50	1.50	-0.63	0.38

Analysis of the Results

This quantitative approach to CAPS-5 diagnosis and severity rating did affect changes in psychometric scores. Patients that did not meet DSM-5 criteria for PTSD but had a mild severity rating had the most significant decrease in psychometric scores. Patients with a moderate severity rating have a mean increase in all psychometric scores, indicating a worsening of symptoms immediately following treatment. The mean PCL scores for patients with moderate and severe severity ratings increased from their pre-intervention measures; 4.00 points and 1.50 points respectively. These scores indicate an increase in self-report psychometric scores specific for PTSD. Patients with severe severity had clinically insignificant decreased scores for PHQ-9, GAD-7, and ISI with increased scores for C-SSRS. Mild improvement or worsening of psychometric scores suggests minimal benefit of TFIOP for patients with a PTSD diagnosis and a moderate to severe rating. Additionally, the results suggest that patients without a PTSD

diagnosis benefited from a TFIOP intervention while those with a PTSD diagnosis had mild benefit or worsening of symptom severity immediately following treatment. During a discussion, MAMC leadership acknowledgement their belief that PTSD symptoms increased for patients both during TFIOP and immediately afterwards. However, this was the first time the effect was analyzed based on a previous CAPS-5 rating (K. Goke, personal communications, May 3, 2019). This supports the need to further evaluate these psychometric score changes to determine the long-term trends regarding symptom increases or improvements. Also, A number of variables may be contributory to these findings: sample size; sample demographics; time frame for post-intervention data collection; amount of therapy received prior to TFIOP intervention; and physical or mental health comorbidities.

Limitations

Some limitations exist within the project. The sample size was small, with only seventeen participants completing the intervention. A greater *n* may increase confidence in statistical analysis. The study was limited to ADSM who predominantly came from the general trauma group with five participants from the women's trauma group. The women's trauma group includes women who have suffered from sexual assault, domestic abuse, or child loss (Madigan Army Medical Center, n.d.). A sample size expanded beyond ADSM, with more participants from both trauma groups would increase the generalizability of the results. SRT is a 4-week intervention offered at PHIOP for patients with varying diagnoses that utilizes group modalities including Cognitive Behavioral Therapy (CBT), Acceptance and Commitment Therapy (ACT), Dialectical Behavioral Therapy (DBT), and problem-solving therapy (PST).

Additionally, the sample population was limited to patients that received CPT group psychotherapy. Limited data exist on the efficacy of manualized group therapy for the treatment of PTSD, though group therapy is better than no therapy at all (VA/DoD, 2017). The timeframe

for data collection was an additional limitation. This project assessed psychometric data from immediately before and immediately after the intervention. Psychometric scores collected at intervals of one month to several months post-intervention may elucidate different findings with regards to symptom changes. Also, the amount of individual or group therapy received before starting TFIOP was not assessed and may have contributed to changes in psychometric scores. Lastly, the authors did not assess for comorbid mental or physical conditions that may impact clinical presentation. In this project, patients who did not meet PTSD criteria had better treatment outcomes based on GAD-7, PHQ-9, PCL-5, and ISI scores.

Organizational Impact / Implications to Practice and Policy

The VA/DoD PTSD CPG recommends a diagnostic evaluation for PTSD that includes all DSM-5 criteria and suggests consideration for a structured clinical interview (VA/DoD, 2017). The authors recognize that there remain opportunities to increase CAPS-5 utilization at MAMC and recommend optimizing its application in clinical practice. The CAPS-5 dissects and scores each of the 20 PTSD symptoms individually. Dissection of individual symptoms allows a provider to identify which symptoms are the most prescient to the patient for targeted treatment. Also, a baseline symptom measurement provides a means to evaluate if individuals are benefitting from treatment. Further, confirming a PTSD diagnosis with the CAPS-5 ensures that patients receive appropriate evidence-based treatment. Therapeutic modalities with empirical support for PTSD treatment include individual manualized; Cognitive Processing Therapy (CPT), Eye Movement Desensitization and Reprocessing (EMDR), or Prolonged Exposure (PE) (VA/DoD, 2017). These therapies have demonstrated benefits over other modalities, like CBT, which would be better suited to treat generalized anxiety disorder, major depressive disorder, or adjustment disorder (VA/DoD, 2017). Additionally, a ruled-out PTSD diagnosis by a provider

may prevent unnecessary referrals PHIOP. Of the 17 patients who received a CAPS-5, three did not even meet criteria for PTSD.

Further recommendations, to support CAPS-5 utilization, including changes to organizational policy and placement of a designated interviewer (DI) within each behavioral health clinic (BHC) at MAMC. The DIs could administer the CAPS-5 and be a resource to other members of the BHC that want to conduct CAPS-5 interviews. The DI can be a licensed independent practitioner (LIP): psychiatric-mental health nurse practitioner, psychiatrist, licensed clinical social worker, or psychologist, but this is not required. Alternatively, Army psychiatric/behavioral health nurses (66C), Army behavioral health specialists (68X), and their civilian equivalents can conduct the CAPS-5 assessment (VA, 2018). Having a 66C or 68X as a DI will expand their capabilities while staying within their scope of practice. Utilizing these behavioral health team members to conduct the assessment allows LIPs to spend more time on essential duties. The LIP would gain reliable data to inform their case formulation and diagnosis and not have to sacrifice a treatment appointment. The VA offers a four-hour online training module for CAPS-5 certification at no cost.

Incorporating the CAPS-5 into practice supports the MHS' Quadruple Aim framework goals of better care, better outcomes, and lower cost to increase military readiness (DHA, 2013). The CAPS-5 provides an accurate PTSD diagnosis to members of the treatment team so patients can receive appropriate evidence-based treatments. When patients get the right treatment, this results in better care. Also, analysis of baseline and subsequent CAPS-5 scores will indicate which interventions are beneficial and which are underperforming. This data provides valuable information when reviewing current practices, leading to better outcomes. Being treated sooner and avoiding unnecessary referrals promotes efficient use of resources and lowers costs. When

combined, these changes reduce the return to duty times, improve patient satisfaction, and increase military readiness. Madigan Army Medical Center can continue to distinguish itself as a high-reliability organization by maximizing an asset like the CAPS-5.

Future Directions for Research and Practice

Future research or evidence-based projects should consider assessing treatment outcomes utilizing the Behavior and Symptoms Identification Scale - 24 (BASIS-24). The BASIS-24 is a self-report screening tool with measures across six domains: depression/functioning, interpersonal problems, psychotic symptoms, alcohol/drug use, emotional lability, and self-harm (Tarescavage & Ben-Porath, 2014). Utilizing the BASIS-24 would assess overall functioning or impairment as well as screen for alcohol or drug use and risk of self-harm. Patients with PTSD will reliably report their distress across all six domains, and an elevated BASIS-24 score is predictive for outpatient service needs (Minsky et al., 2015). This psychometric was not identified for collection from patients at the beginning of the TFIOP and therefore was not integrated in the results analysis. However, the BASIS-24 is included in the BHDP making it readily available for future teams.

Another consideration is conducting serial CAPS-5 interviews on a longer timeline. The results of this project indicated that patients with moderate severity ratings experienced increases in symptoms following treatment. Follow-up scores completed at one month, three months, and six months will offer a better understanding of the long-term trends in symptom severity. These scores may demonstrate if gains for the moderate group take longer to realize, or conversely sustained improvements by the mild severity group.

Lastly, a project to evaluate the accuracy of PTSD diagnosing at MAMC would explore variances between providers. Looking at groups of patients currently in treatment and identifying

the rate of misdiagnosis for PTSD may support standardizing policy to include a CAPS-5 before conferring a formal PTSD diagnosis. Such a policy change would likely have a significant impact on daily practice. However, MAMC would establish a framework for implementing CAPS-5 across the entire MHS if it is supported by the evidence.

Conclusions

The diagnosis of PTSD is challenging due to comorbidities, patient avoidance of treatment, and the heterogeneity of symptoms. More importantly, the negative impacts of PTSD can be devastating to the lives of patients by destroying relationships, ruining careers, and too often leading to suicide (Ramsawh et al., 2014). Despite the VA/DoD's recommendation for the utilization of a structured clinical interview for the diagnosis of PTSD, MAMC does not have an established policy that supports incorporating the CAPS-5 into practice. This project demonstrated the impact a CAPS-5 rating has on the psychometric scores of patients going through a TFIOP. However, the goal of this project was supporting quality care, efficient practices, measurable outcomes, and enhancing readiness. The authors' synthesis of evidence provides reliable support for increasing CAPS-5 utilization at MAMC to accomplish this goal. The JBLM team identifies the CAPS-5 as a valid, reliable, and available evidence-based tool that MAMC leadership can implement now to the great benefit of patients and staff who battle against PTSD every day.

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Appendix A

Timeline

Project Year 3 (2018)												
Activity/Month	**JAN**	**FEB**	**MAR**	**APR**	**MAY**	**JUN**	**JUL**	**AUG**	**SEP**	**OCT**	**NOV**	**DEC**
USU VPR Submission and Approval									**X**	**X**		
Site IRB Waiver Submission									**X**	**X**		
Development of PICO, literature search and synthesis									**X**	**X**		
Meeting with DBH OIC for presentation									**X**			
Meeting with IOP leadership and staff for presentation of project and guidance on engagement									**X**			
Start Intake assessment and CAP-5 survey (Target 2 six-week cohorts with start dates 23 OCT and @ 9 DEC)										**X**	**X**	**X**
Data collection of CAPS-5 and BHDP data (continuous at intake, midterm and discharge for each cohort)										**X**	**X**	**X**
Data Analysis											**X**	**X**
Dissemination												

Project Year 3 (2019)												
Activity/Month	**JAN**	**FEB**	**MAR**	**APR**	**MAY**	**JUN**	**JUL**	**AUG**	**SEP**	**OCT**	**NOV**	**DEC**
USU VPR Submission and Approval												
Site IRB Waiver Submission												
Project Planning												
Development of PICO, literature search and synthesis												
Meeting with DBH OIC for presentation												
Meeting with IOP leadership and staff for presentation of project and guidance on engagement												
Start Intake assessment and CAP-5 survey (Target 3 six-week cohorts with start dates 23 OCT, 9 DEC, and 29 JAN)												
Data collection of CAPS-5 and BHDP data (continuous at intake, midterm and discharge for each cohort)	**X**	**X**	**X**									
Data Analysis	**X**	**X**	**X**									
Dissemination			**X**	**X**	**X**							

Appendix B

CITI Certificates

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- Name: Roderick Bowser (ID: 5744606)
- Email: roderick.bowser@osd.mil
- Institution Affiliation: Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 603)
- Phone: 703-731-8809

- Curriculum Group: OUSD P&R Human Research
- Course Learner Group: Biomedical Investigators and Research Study Team
- Stage: Stage 1 - Biomedical Investigators

- Report ID: 20630190
- Completion Date: 28-Aug-2016
- Expiration Date: 28-Aug-2019
- Minimum Passing: 80
- Reported Score*: 95

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	28-Aug-2016	3/3 (100%)
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	28-Aug-2016	5/5 (100%)
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	28-Aug-2016	4/5 (80%)
Module for Non-DoD Personnel Conducting Research Involving Human Subjects Supported by the DoD (ID: 16759)	28-Aug-2016	No Quiz
History and Ethics of Human Subjects Research (ID: 498)	28-Aug-2016	6/7 (86%)
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	28-Aug-2016	5/5 (100%)
Informed Consent (ID: 3)	28-Aug-2016	5/5 (100%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	28-Aug-2016	4/4 (100%)
Records-Based Research (ID: 5)	28-Aug-2016	3/3 (100%)
Genetic Research in Human Populations (ID: 6)	28-Aug-2016	4/5 (80%)
Vulnerable Subjects - Research Involving Children (ID: 9)	28-Aug-2016	3/3 (100%)
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10)	28-Aug-2016	3/3 (100%)
FDA-Regulated Research (ID: 12)	28-Aug-2016	5/5 (100%)
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	28-Aug-2016	5/5 (100%)
Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 912)	28-Aug-2016	No Quiz
Vulnerable Subjects - Research Involving Prisoners (ID: 8)	28-Aug-2016	4/4 (100%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid independent Learner.

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COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the required scores at the time all requirements for the course were met.

- Name: Roderick Bowser (ID: 5744605)
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- Institution Affiliation: Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 603)
- Phone: 703-731-8809

- Curriculum Group: OUSD P&R Human Research
- Course Learner Group: Biomedical Investigators and Research Study Team
- Stage: Stage 1 - Biomedical Investigators

- Report ID: 20630190
- Report Date: 28-Aug-2016
- Current Score**: 95

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
History and Ethics of Human Subjects Research (ID: 490)	28-Aug-2016	6/7 (86%)
Informed Consent (ID: 3)	28-Aug-2016	5/5 (100%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	28-Aug-2016	4/4 (100%)
Records-Based Research (ID: 5)	28-Aug-2016	3/3 (100%)
Genetic Research in Human Populations (ID: 6)	28-Aug-2016	4/5 (80%)
Vulnerable Subjects - Research Involving Prisoners (ID: 8)	28-Aug-2016	4/4 (100%)
Vulnerable Subjects - Research Involving Children (ID: 9)	28-Aug-2016	3/3 (100%)
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10)	28-Aug-2016	3/3 (100%)
FDA-Regulated Research (ID: 12)	28-Aug-2016	5/5 (100%)
Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 912)	28-Aug-2016	No Quiz
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	28-Aug-2016	5/5 (100%)
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	28-Aug-2016	3/3 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	28-Aug-2016	5/5 (100%)
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	28-Aug-2016	5/5 (100%)
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	28-Aug-2016	4/5 (80%)
Module for Non-DoD Personnel Conducting Research Involving Human Subjects Supported by the DoD (ID: 16769)	28-Aug-2016	No Quiz

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

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COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- Name: JOHN MCINERNEY (ID: 5744310)
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- Phone: 9107231102

- Curriculum Group: OUSD P&R Human Research
- Course Learner Group: Biomedical Investigators and Research Study Team
- Stage: Stage 1 - Biomedical Investigators

- Report ID: 20629497
- Completion Date: 28-Aug-2016
- Expiration Date: 28-Aug-2019
- Minimum Passing: 80
- Reported Score*: 97

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	28-Aug-2016	3/3 (100%)
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	28-Aug-2016	5/5 (100%)
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	28-Aug-2016	5/5 (100%)
Module for Non-DoD Personnel Conducting Research Involving Human Subjects Supported by the DoD (ID: 16769)	28-Aug-2016	No Quiz
History and Ethics of Human Subjects Research (ID: 490)	28-Aug-2016	7/7 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	28-Aug-2016	5/5 (100%)
Informed Consent (ID: 3)	28-Aug-2016	5/5 (100%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	28-Aug-2016	4/4 (100%)
Records-Based Research (ID: 5)	28-Aug-2016	3/3 (100%)
Genetic Research in Human Populations (ID: 6)	28-Aug-2016	4/5 (80%)
Vulnerable Subjects - Research Involving Children (ID: 9)	28-Aug-2016	3/3 (100%)
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10)	28-Aug-2016	3/3 (100%)
FDA-Regulated Research (ID: 12)	28-Aug-2016	5/5 (100%)
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	28-Aug-2016	4/5 (80%)
Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 912)	28-Aug-2016	No Quiz
Avoiding Group Harms - International Research Perspectives (ID: 14081)	28-Aug-2016	3/3 (100%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid independent Learner.

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COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- Name: JOHN MCINERNEY (ID: 5744310)
- Email: johnmcinerney@utexas.edu
- Institution Affiliation: Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 603)
- Phone: 9107231102

- Curriculum Group: OUSD P&R Human Research
- Course Learner Group: Biomedical Investigators and Research Study Team
- Stage: Stage 1 - Biomedical Investigators

- Report ID: 20629497
- Report Date: 28-Aug-2016
- Current Score**: 97

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
History and Ethics of Human Subjects Research (ID: 498)	28-Aug-2016	7/7 (100%)
Informed Consent (ID: 3)	28-Aug-2016	5/5 (100%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	28-Aug-2016	4/4 (100%)
Records-Based Research (ID: 5)	28-Aug-2016	3/3 (100%)
Genetic Research in Human Populations (ID: 6)	28-Aug-2016	4/5 (80%)
Vulnerable Subjects - Research Involving Children (ID: 9)	28-Aug-2016	3/3 (100%)
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10)	28-Aug-2016	3/3 (100%)
FDA-Regulated Research (ID: 12)	28-Aug-2016	5/5 (100%)
Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 912)	28-Aug-2016	No Quiz
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	28-Aug-2016	4/5 (80%)
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	28-Aug-2016	3/3 (100%)
Avoiding Group Harms - International Research Perspectives (ID: 14081)	28-Aug-2016	3/3 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	28-Aug-2016	5/5 (100%)
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	28-Aug-2016	5/5 (100%)
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	28-Aug-2016	5/5 (100%)
Module for Non-DoD Personnel Conducting Research Involving Human Subjects Supported by the DoD (ID: 16769)	28-Aug-2016	No Quiz

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid independent Learner.

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Web: https://www.citiprogram.org

Appendix C

Notice of Project Approval Letter

USU
Uniformed Services University

OFFICE OF RESEARCH
4301 JONES BRIDGE ROAD
BETHESDA, MAYLAND 20814
PHONE: (301) 295-3303; FAX: (301) 295-6771

NOTICE OF PROJECT APPROVAL
Change Number: Original

VPR Site Number:	GSN-61-10454
Principal Investigator:	Bowser, Roderick
Department:	Graduate School of Nursing
Project Type:	Student
Project Title:	Utilization of the Clinician Administered PTSD Scale for DSM-5 to Assess PTSD Symptom Severity in an Intensive Outpatient Progam
Project Period:	3/25/2019 to 5/1/2019

Assurance and Progress Report Information:

Name	Sup	Approval Type	Status	Approved On	Forms Received
Progress Report	0		Final	To be Submitted	N/A

Remarks:
This Notice of Project Approval has been reviewed and approved. Please remember that you must submit a final Progress Report (Form 3210) upon completion of this project.

Authors: MAJ Roderick J. Bowser & MAJ John R. McInerney

Questions regarding this approval should be directed to the following person in the Office of Research:
Sharon McIver, (301) 295-9814.

[redacted]

Yvonne T. Maddox, Ph.D. -04'00' Date
Vice President for Research
Uniformed Services University of the Health Sciences

cc: Bowser, Roderick
File

Appendix D

MTF IRB/PI Letter of Determination

DEPARTMENT OF THE ARMY
MADIGAN ARMY MEDICAL CENTER
9040 JACKSON AVENUE
TACOMA, WASHINGTON 98431-1100

MCHJ-ISN DATE: 17 October 2018

TO: Roderick J. Bowser, MAJ, AN and John R. McInerney, MAJ, AN
FROM: Exempt Determination Official

SUBJECT: Not Research Determination
STUDY TITLE: Utilization of the Clinician Administered PTSD Scale for DSM-5 to Assess PTSD Symptom Severity in an Intensive Outpatient Program

REFERENCE #: 013
ACTION: Determination Letter
REVIEW TYPE: Not Research

1. This project has been reviewed and determined to be exempt from the regulatory requirements of 32 CFR 219.

2. This opinion is based on federal regulation 32 CFR 219 and associated OHRP (Office of Human Research Protection) guidance. The following is the basis for this opinion.

> Federal regulation at 32 CFR 219.102(d) defines research as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

3. This project does not constitute research because the activity is a systematic investigation but is not designed to develop or contribute to generalizable knowledge (draw inferences or a general conclusion from). The Evidence-Based Practice (EBP) Project description states that you will evaluate the utility of performing the Clinician Administered PTSD Scale for DSM 5 (CAPS-5) interview for patients entering into the Madigan Army Medical Center trauma-focused intensive outpatient program (TFIOP) as an additional screening method to the current clinical interview. You also plan to collect initial, mid-term, and discharge psychometric scores to include PHQ-9, GAD-7, and PCL-5 from the Behavioral Health Data Portal. Initial CAPS-5 severity ratings along with psychometric scores will be analyzed to discern if CAPS-5 scores are predictive of treatment outcomes. *The Data Key form containing PHI must be stored in a secure location during the project and shredded upon completion of the project.* As such, this project is determined Not Research, and no further action regarding regulatory guidance is necessary. **You may begin your project.**

4. You are not authorized to take project data away from the institution.

5. Please note that any future changes to the project, such as extension of data collection activities to include the use of additional instruments, or further exploration of the Behavioral

MCHJ-ISN
SUBJECT: Not Research Determination

Health Data Portal, may affect its exempt status. In the event that the project undergoes any change, you are required to resubmit the project to the undersigned for another review in order to determine its exempt status.

7. The Department of Clinical Investigation (DCI) reminds you that a publication clearance is required for all written materials (i.e. manuscript or abstract) being submitted for publication/presentation.

8. If you have any questions, or need further assistance, please contact the undersigned at 253-968-3695, or e-mail at mary.s.mccarthy1.civ@mail.mil.

[redacted]

MARY S. McCARTHY, PhD, RN, FAAN
Exempt Determination Official
Center for Nursing Science & Clinical Inquiry
Madigan Army Medical Center

Appendix E

PAO Clearance

CLEARANCE APPROVAL FORM v5.4

Requirements based on MAMC Reg 360-2 = http://go.usa.gov/xkMbx

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Submission Title:* Utilization of the CAPS-5 Assessment to Assess PTSD Symptom Severity in an Intensive Outpatient Program

Submission Type:* Outside Madigan lecture

Project Type:* ◯ Human Subjects Research ◯ Animal Subjects Research ◯ Quality improvement ◉ Other: DNP Project for graduation

Author List:

Bowser, Roderick; McInerney, John

Enter all authors in the form of firstname lastname, suffix, separated by a semicolon (;).

First Madigan Author:

Email: roderick.bowser2.mil@mail.mil

Dept/Serv: Behavioral Health

Other Dept/Serv: Medical Education

Chief Email: tommy.l.thompson58.mil@mail.mil

Item is intended for publication: ◯ NO ◉ YES

Destination of Item:

This grants dissemination approval of DNP project for Uniformed Services University graduation. May, 2019, Bethesda, MD: Abstract submitted for USU Research Days, Oral Presentation and Poster presented during USU Research Day events, and Final Report in USU Archive.

Journal name or Conference, Date, Location or Destination (whichever is applicable)

Protocol/Determination: # *Enter protocol/determination number*

Provide e-signature & your department chief e-signature on the next page before submitting.

Title: Utilization of the CAPS-5 Assessment to Assess PTSD Symptom Severity in an Intensive Outpatient Program

Signatures

Signature of author:

[redacted]

Signature of author's department chief:

[redacted]

Signature of Public Affairs Officer rep:

[redacted]

Signature of OPSEC rep:

[redacted]

Department of Clinical Investigation (DCI) Administrator:

[redacted]

Human Protections Administrator or Veterinarian (If required):

Chief, DCI:

[redacted]

Appendix F

Data Collection Forms

Patient	Name	DODID	DOB	Gender	Years of Service	Deployments	Age	Grade	ED Level	Participant ID
1	*Koopa, Mario*	*1.235E+09*	*1/1/72*	*Male*	*23*	*3*	*46*	*O-4*	*Graduate Degree*	*MK1234*
2										
3										
4										
5										

Figure 1. Example of data collection form used for demographic data.

Participant ID	CAPS-5 Score	Severity Rating	PHQ9; I	GAD-7; I	PCL-5; I	ISI; I	CSSRS; I		PHQ9-D	GAD-7; D	PCL-5; D	ISI; D	CSSRS;D
Ex: RJ1234	*27*	*1*	*13*	*10*	*67*	*18*	*0*		*6*	*7*	*65*	*8*	*0*

Figure 2. Example of data collection from used for CAPS-5 score and severity, and psychometric scores.

Appendix G

DNP Project Completion Verification Form

Appendix G: Daniel K. Inouye Graduate School of Nursing
DNP Project Completion Verification Form

DOCTOR OF NURSING PRACTICE PROJECT
Completion Verification Form

The DNP Project titled: Utilization of the Clinician-Administered PTSD Scale for DSM-5 to Assess PTSD Symptom Severity in an Intensive Outpatient Program
was completed at Joint Base Lewis-McChord by the following students:

___Roderick J. Bowser___ [redacted] _10 MAY 2019_
___John R. McInerney___ [redacted] _10 MAY 2019_

The DNP Practice Project Team verifies that the following components of the DNP project, accomplished by the above students, is of sufficient rigor and demonstrates doctoral level scholarship to meet the requirements for USUHS GSN graduation:

- Presentation of DNP project to the leadership/stakeholders at the Phase II Site,
- Abstract/Impact Statement (*Appendix F*), and
- DNP Project written report.

Verified by:

JoEllen Schimmels [redacted] _10 MAY 2019_ Senior Mentor

Tommy Thompson [redacted] _10 MAY 2019_ Team Mentor & Phase II Site Director

Form Version: 26 Aug 2017