AWARD NUMBER: W81XWH-14-1-0264

TITLE: Do You Really Expect Me to Get MST Care in a VA Where Everyone is Male? Innovative Delivery of Evidence-Based Psychotherapy to Women with Military Sexual Trauma

PRINCIPAL INVESTIGATOR: Ronald Acierno, PhD

CONTRACTING ORGANIZATION: Medical University of South Carolina
179 Ashley Avenue
Charleston, SC 29425

REPORT DATE: OCTOBER 2019

TYPE OF REPORT: FINAL

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

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
October 2019	Final	01-AUG-2014 – 31-JUL-2019

4. TITLE AND SUBTITLE
"Do You Really Expect Me to Get MST Care in a VA Where Everyone is Male? Innovative Delivery of Evidence-Based Psychotherapy to Women with Military Sexual Trauma"

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-14-1-0264

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

Ron Acierno, PhD, Wendy Muzzy, MS, Anouk Grubaugh, PhD

E-Mail: Ronald.Acierno@uth.tmc.edu

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Medical University of South Carolina
171 Ashley Avenue
Charleston, SC 29425

8. PERFORMING ORGANIZATION REPORT NUMBER

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

US Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5014

10. SPONSOR/MONITOR'S ACRONYM(S)

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

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

Veterans who experience military sexual trauma (MST) are at heightened risk of developing psychiatric difficulties such as post-traumatic stress disorder (PTSD). However, this group of Veterans may under-utilize evidence-based interventions for PTSD such as Prolonged Exposure (PE). Likely reasons for this under-utilization include unique barriers to care faced by MST survivors such as avoidance of VA medical facilities due to their potential to cue distressing memories and symptoms. The current study includes a randomized controlled study design comparing clinical outcomes between two groups: Veterans receiving PE for PTSD-related MST via home-based telehealth (PE-HBT) and Veterans receiving PE for PTSD-related MST via standard service delivery (PE-SD). Women assigned to receive PE via home-based telehealth will have the particular advantage of being able to receive services from their home, thereby circumventing some of the traditional access to care barriers faced by this clinical population. It is anticipated that this advantage will result in increased session attendance and compliance, which in turn will result in better clinical and quality of life outcomes due to increased 'dosing' of the intervention. The proposed project stands to fill significant gaps in the literature with regard to how to optimally engage and retain MST positive Veterans in VA mental healthcare. There is only one PTSD treatment outcome study focused exclusively on female Veterans and no extant studies testing home-based telehealth for sexual assault victims. Thus, the proposed project also stands to make a significant contribution to mental health service delivery models for female Veterans and sexual assault victims more broadly.

15. SUBJECT TERMS
Military Sexual Trauma, MST, PTSD, Telemedicine, Prolonged Exposure, DOD/VHA research collaborations

16. SECURITY CLASSIFICATION OF: u			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			19b. TELEPHONE NUMBER *(include area code)*
Unclassified	Unclassified	Unclassified	Unclassified	24	USAMRMC

TABLE OF CONTENTS

INTRODUCTION:

Prevalence and clinical significance of MST. The Department of Veterans Affairs (VA) and the Department of Defense (DoD) define Military Sexual Trauma (MST) as receiving unwanted and uninvited sexual attention, such as touching, cornering, pressuring for favors, or verbal remarks (sexual harassment), or being threatened or forced to have unwanted sexual contact (sexual assault) during active duty military service (e.g., Department of Veterans Affairs, 2010). Extant data suggest that the prevalence of MST among women who use VA services ranges between 15 and 55% depending on the assessment methods used, the population sampled, and whether the definition of MST is limited to a completed versus attempted sexual assault (e.g., Frayne et al., 1999; Kimerling et al., 2008; Kimerling et al., 2010; Skinner et al., 2000). MST is associated with heightened risk of a variety of mental health problems including substance use, depression, and most notably Post-Traumatic Stress Disorder (PTSD). Epidemiologic investigations show that sexual trauma accounts for a higher percentage of PTSD cases than other traumatic events (Kang et al., 2005; Resnick et al., 1993), and *Military Sexual Trauma is even more likely to result in PTSD than either exposure to civilian sexual trauma (e.g., Suris et al., 2007) or combat (*e.g., Kang et al., 2005; Yaeger et al., 2006). When untreated, PTSD may become chronic (Foa et al., 1995; Kornor et al., 2000) and contributes to significant mental and physical health disability and morbidity which diminishes force strength among active duty personnel, and quality of life among Veterans (Frayne et al., 1999; Kimerling et al., 2000; Lang et al., 2003; Suris et al., 2008). Thus, to prevent threats to force readiness, emotional and financial costs associated with these negative health sequelae, researchers must identify strategies to optimize the use of effective treatments for PTSD. Currently, service use is intermittent, and evidence based treatments for MST related PTSD are underutilized. Thus, the VA spends approximately $10,880 on healthcare costs per military sexual assault survivor. Adjusting for inflation, this means that in 2009 alone, the VA spent almost $820 million dollars on sexual assault-related healthcare expenditures (Suris et al., 2004).

Mandatory screening improves the identification of Veterans with MST-related PTSD. The VA has implemented an exemplary policy initiative to ensure that Veterans with MST-related PTSD are identified and offered appropriate services (Department of Veterans Affairs, 2010a). These policies include: a) mandatory screening for MST during a Veteran's initial visit to primary care, b) provision of treatment for any MST-related condition free of charge, regardless of disability status, and c) designation of an MST coordinator within each VISN to oversee MST screening and referral procedures. To date, research suggests that the screen is consistently implemented with over 130 of 139 VA facilities meeting or exceeding the 90% target screening rate (Office of Mental Health Services, 2009). Furthermore, the MST screen appears to provide clinically valuable predictive information. According to Kimerling and colleagues (2008), for every 5.5 women who screen positive for MST, one woman accesses psychiatric

services. Although encouraging, these rates likewise suggest that 4 out of 5 women who screen positive for MST will not move on to receive psychiatric services at their respective VA. Clearly, these numbers could simply reflect the Veterans who do not believe they need or do not want MST-related services offered in VA settings. *On the other hand, these figures could reflect reluctance on the part of some female Veterans to initiate mental health services within the perceived male-oriented settings of the VA and DoD clinics, and our pilot data (discussed below) support just this conclusion.*

Prolonged Exposure (PE) is a best practice intervention for PTSD related to combat and sexual trauma exposure. A longstanding and formidable body of research supports Prolonged Exposure (PE) therapy as a frontline treatment for PTSD following both sexual assault and combat (e.g., Bradley et al., 2005; Beidel, Frueh, et al., 2011; Cloitre, 2009; Foa et al., 2007; Foa et al., 1991; Frueh et al., 1995; Powers, 2010). Recently, the VA/Department of Defense (DoD) identified PE as one of four evidence-based psychotherapies for Veterans with PTSD (DVA, 2010a) and launched a national initiative to disseminate PE into clinical practice (Ruzek & Rosen, 2009). Further, the Institute of Medicine (IOM, 2007) and NICE guidelines (2005) identified exposure therapy as the only PTSD treatment with sufficient evidence to support its use with Veterans with PTSD.

In a study published in the Journal of the American Medical Association (JAMA), Schnurr and colleagues (2007) found that female Veterans who received PE reported fewer PTSD symptoms than women who received present-centered therapy at post- and three-month follow-up. Although Veterans endorsed a variety of traumatic events (e.g., physical assault, war zone exposure) in this study, the majority identified "sexual trauma experienced during military service" as their index trauma, suggesting that PE is a viable and effective treatment for women with MST-related PTSD. However, nearly 40% of Veterans with PTSD dropped out of PE prior to completion, and 59% of participants in the PE condition maintained their PTSD diagnosis at follow-up. *These investigators urged researchers to identify strategies to "enhance" retention of female Veterans in evidence-based therapy (p.829).*

Barriers to care may compromise effective utilization of PE. Female active duty personnel and Veterans with MST-related PTSD experience subtle barriers to care that may compromise access to evidence-based interventions such as PE (Sayer et al., 2009; Seal et al., 2010; Spoont et al., 2010). Of Veterans with a recent PTSD diagnosis, approximately 39% receive "some counseling." Of these, only about 24% receive 8 sessions of treatment, the minimum number required for most exposure programs to be considered effective (Spoont et al., 2010). Additionally, female Veterans and MST positive Veterans with emotional health problems are more likely to receive mental health treatment in primary care in the form of medication than the relatively more effective evidence based psychological treatments for PTSD in specialty care clinics (Chatterjee et al., 2009; Maguen et al., 2010; Suris et al., 2004).

Exposure to MST elicits lower in-theater and post-deployment social support than exposure to combat, and this is predictive of lower service acquisition and benefit (Haskell et al., 2010). Low social support and withdrawal are risk factors for developing trauma-related mental health problems in military populations (e.g., King et al., 2003). Specifically, combat events are often experienced by multiple service members simultaneously and tend to involve "outside perpetrators" who are universally classified as "combatants". As such, to the extent that combat exposure is consistent with mission objectives, these events likely elicit a sense of camaraderie and a sense of unit cohesion. In contrast, MST events are inconsistent with the military mission. Victims of MST are often assaulted in isolation by individuals who are supposed to be comrades in arms; that is, they are victimized by perpetrators who in other contexts contribute to the safety and survival of the unit (e.g., fellow soldiers, superior officers). Thus, the experience of MST is necessarily divisive and sexually traumatized personnel bear the burden of disclosure alone, knowing that disclosure may compromise their own career and the well-being and morale of others. For MST survivors, this social isolation may continue post-deployment. Indeed, compared with male Veterans, female Veterans with PTSD have lower levels of social support, diminishing benefits of treatment and reducing likelihood treatment will be obtained (Haskell et al., 2010; Tarrier et al., 2000).

Regarding characteristics of conventional psychotherapeutic service delivery models, findings cited in a recent report on health service delivery to female Veterans suggest that characteristics of VA medical facilities may deter some women from accessing care [United States Government Accountability Office (GAO), 2009]. VA users are predominantly male. Thus, for MST-exposed female Veterans, seemingly mundane activities that typically accompany weekly attendance to psychotherapy appointments at VA facilities (i.e., maneuvering crowded hospital corridors, visual media that depicts male combat Veterans, standing/sitting in line at the pharmacy, sitting in a crowded waiting room) may provoke anxiety to the extent that these activities cue memories of the traumatic event. Furthermore, space constraints prevent many VA facilities from complying with requirements related to privacy for female Veterans (i.e., female-only waiting areas, provision of MST-services in clinics physically outside of general mental health). As such, these Veterans may be reluctant to initiate, adhere, and complete a treatment program that requires in-person attendance to VA facilities over an extended duration. Unfortunately, research examining the relationship between satisfaction with VA services and use of care supports these contentions. Female Veterans and Veterans with MST histories are likely to cite negative appraisals of VA treatments, facilities, and providers, and lack of transportation and childcare, as primary reasons for discontinuing VA services or for choosing private-sector care (Kelly et al., 2008; Washington et al., 2006). Other research suggests that concerns about the safety of VA facilities and the experience of "secondary victimization" (i.e., victim-blaming behaviors) by VA staff may deter MST-positive Veterans from seeking further care (Campbell & Raja, 2005; Fontana & Rosenheck, 2006).

We conducted an anonymous telephone survey to determine the service delivery preferences of MST positive Veterans who declined services at the Charleston VA PTSD clinic. This survey revealed that female survivors of MST reported that they would be more likely to receive evidence-based psychotherapy services for MST-related emotional problems if these services were available via home-based telehealth at a more than 2:1 ratio. Altogether, coupled with other research findings, the study team's data suggest that characteristics of traditional, DoD and VA office-based therapy may deter MST survivors with PTSD from initiating and/or completing exposure-based protocols. *Fortunately, telemental health, and home-based telemental health in particular, may circumvent these barriers to care and promote participation in evidence-based psychotherapeutic interventions such as PE.*

Researchers must adapt current models to meet the service delivery needs of Veterans with MST-related PTSD. Although Community Based Outpatient Clinics (CBOC) telemental health, wherein centrally located experts offer services to rural or distant locations via telehealth, circumvents some of the barriers to receiving evidence-based treatment such as PE (i.e., living in geographically remote areas without appropriate mental healthcare), it is unclear whether this approach, as currently implemented, addresses obstacles that are most salient to female active duty service members and Veterans with MST-related PTSD (i.e., avoidance of DoD/VA facilities that are perceived as threatening or unappealing or male-service oriented). Under the current model, these women must still access PE via VA clinics (i.e., CBOCs). In contrast, ***home-based telehealth care*** (i.e., service delivery to patients *in their homes* using consumer-friendly, video-conferencing technology) will likely enhance retention in PE by directly circumventing these and other barriers. Although HBT delivery of PE obviates the need for transportation and longer childcare times as well as reluctance to utilize facility-based services, there are no extant studies evaluating this modality for Veterans with MST-related PTSD – a patient population vulnerable to "falling through the cracks" and remaining underserved by virtue of their reluctance to seek and/or complete treatment at DoD/VA facilities. Thus, to address the aforementioned gap in knowledge, this study compared PE via home-based telehealth to standard, in-person, clinic-based delivery of PE using a mixed-methods, randomized controlled trial (RCT) study design.

KEYWORDS:

Veteran, Military Sexual Trauma, Telemedicine, telepsychiatry, telepsychology, telemental health, televideo, ptsd, post-traumatic stress disorder, prolonged exposure, cognitive behavior therapy, psychotherapy, learning theory, extinction, conditioning, PCL, depression, randomized controlled trial

OVERALL PROJECT STRATEGY:

Veterans who experience military sexual trauma (MST) are at heightened risk of developing psychiatric difficulties such as post-traumatic stress disorder (PTSD). Although the Veterans Health Administration (VHA) has identified MST positive Veterans as a high priority population, this group of Veterans may under-utilize evidence-based interventions for PTSD such as Prolonged Exposure (PE). Likely reasons for this under-utilization include unique barriers to care faced by MST survivors such as avoidance of VA medical facilities due to their potential to cue distressing memories and symptoms. The current study used a randomized controlled study design comparing treatment engagement and clinical and quality of life outcomes between two groups: Veterans receiving PE for MST-related PTSD via home-based telehealth (PE-HBT) and Veterans receiving PE for MST-related PTSD via standard service delivery (PE-SD). The intervention component of the study is complemented by a qualitative component (i.e., patient interviews) designed to better understand Veterans' reactions, preferences, difficulties, and suggestions for the intervention, as well as to solicit feedback about this patient population's service needs and preferences more broadly. We predicted that women assigned to receive PE via home-based telehealth will have the particular advantage of being able to receive services from their home, thereby circumventing some of the traditional access to care barriers faced by this clinical population, and that this advantage would result in increased session attendance and compliance, which in turn would result in better clinical and quality of life outcomes due to increased 'dosing' of the intervention. Thus, it is predicted that Veterans in PE-HBT will evidence better treatment engagement and more significant symptom improvement relative to Veterans in PE-SD.

RESEARCH STRATEGY OVERVIEW AND SUMMARY:

We proposed to use a randomized, between groups, repeated measures design and recruit 100 female Veterans with MST-related PTSD from the Charleston VA medical center catchment area during the study time frame. As dropout was higher than expected, we modified the protocol to increase recruitment up to 140 female Veterans to assure power would be sustained, and ultimately recruited 136. Thus, we actually exceeded initial recruitment goals. Veterans were randomized 1:1 to one of two conditions: PE via home-based telehealth (PE-HBT) or PE via standard service delivery (PE-SD), with final enrollment rates of 69 PE-HBT and 67 PE-SD. Participants randomized to PE-HBT received up to 12 weekly sessions of PE via in-home video-conferencing technology, and participants randomized to PE-SD received up to 12 sessions of PE via standard in-person care delivery. All participants were invited to be assessed at baseline, post-treatment, and at 3- and 6-months follow-up. Veterans who dropped out of the study prematurely, as well as those who completed the intervention but did respond to treatment (i.e., who are PTSD positive on the CAPS at post or who report minimal treatment gains) from both arms of the study, were also invited to complete an individually-administered thematic interview as part of their

post-assessment to learn more about their reactions, preferences, and suggestions for MST services, as well as with the mode of service delivery they received.

Description of the Intervention. Veterans randomized to Prolonged Exposure home based telehealth (PE-HBT) received 12, 90-minute sessions of PE delivered via standard desk or laptop computer running either VA/DoD approved Movi/Jabber or AKT4002 software (the precise televideo encryption chat program was updated regularly, and always met FIPS standards in place at the VA at the time). PE is based on emotional processing theory which suggests that traumatic events are incompletely and inaccurately encoded in memory as "fear networks." Gradual exposure to corrective information via the confrontation of traumatic stimuli within a safe and therapeutic environment results in a competing and antithetical memory structure that inhibits the conditioned fear response. PE relies on two primary therapeutic tools: (1) in vivo exposure; and (2) imaginal exposure. During in vivo exposure, the patient confronts feared, but safe, stimuli that cue trauma-related distress. During imaginal exposure, patients "revisit" the traumatic event, providing a detailed verbal account that includes sensory information, thoughts, feelings, and reactions experienced during the traumatic event.

PE is a manualized treatment (Foa et al., 2007) that includes the following components: a) psycho-education about the common reactions to traumatic events and presentation of the treatment rationale (sessions 1 and 2); b) repeated in vivo exposure to traumatic stimuli (in vivo exercises are assigned as homework during sessions 3 through 11); c) repeated, prolonged, imaginal exposure to traumatic memories (imaginal exposure is implemented during sessions 3 through 11; patients listen to session audiotapes for homework between sessions); and d) relapse prevention strategies and further treatment planning (session 12).

Standard care delivery (PE-SD). The only difference in treatment conditions was the delivery modality. The comparison condition will consist of 12 sessions of PE delivered in person at the Charleston VA and surrounding CBOCs.

Primary Dependent Measures

1. Diagnostic/Screening Measures: 1) Demographic Form (pre-treatment only): age, race, gender, education, and employment information were collected via a study specific demographic form; 2) The Trauma Assessment for Adults (TAA; Resnick et al., 1996) is a 17-item instrument to assess lifetime history of a range of traumatic events. This instrument demonstrates strong psychometric properties and has been widely used in research on trauma exposure in adults. The TAA verified whether patients report an MST incident (all assessment measures so that episodes of new traumatic events are detected); 3) The Clinician Administered PTSD Scale-5 (CAPS-5; Weathers et al., 2013) is considered

the gold standard in PTSD assessment. The CAPS is a 30-item, structured interview that corresponds to the DSM-5 criteria for PTSD. For each diagnostic item, standardized questions and probes are provided. Questions focus on symptom presence, the onset and duration of symptoms, subjective distress, impact of symptoms on social and occupational functioning and improvement in symptoms. **Entry into the study required a diagnosis of PTSD with MST as the Criterion A event, based on the CAPS;** 4) The Mini International Neuropsychiatric Interview 7.0 (MINI 7.0) is a standardized structured interview used to assess psychiatric diagnoses according to the DSM-5. The MINI is similar in sensitivity, specificity, and inter-rater reliability to more lengthy diagnostic interviews, such as the SCID (Sheehan et al., 1998). The MINI was used to assess for a diagnosis of current depression and to screen for substance abuse/dependence.

2. Clinical Outcomes (all assessment points): 1) The CAPS (described above) total severity score will be used as the primary clinical outcome measure in analyses; 2) The PTSD Checklist-5 (PCL-5; Blevins, Weathers et al., 2015) is a new version of the PCL, among the most commonly used self-report measures of PTSD symptoms and intensity. The PCL-5 is structured to correspond to the DSM-5 PTSD criteria. The 20-items are scored on a 0-4 Likert scale for each symptom corresponding to "Not at all" to "Extremely". Total scores range from 0 to 80. Initial psychometric data are encouraging. With college student samples, Blevin et al found PCL-5 scores exhibited strong internal consistency (α = .94), test-retest reliability (r = .82), and convergent (rs = .74 to .85) and discriminant (rs = .31 to .60) validity. With Veteran samples, Bovin et al (2015) found that the PCL-5 had good internal consistency (α =.96) and test-retest reliability (r = .84). Moreover, signal detection analyses using CAPS-5 indicated a cutoff score of 31-33 on the PCL-5 optimally categorized PTSD diagnosis. The PCL was used as both a clinical outcome in analyses, as well as a tool to monitor patients' progress throughout the course of treatment; 3) The Beck Depression inventory-II (BDI-II; Beck et al., 1996) is a 21 item measure of depressive severity with higher total scores indicative of more severe depression. It demonstrates good convergent validity with the Hamilton Depression Rating Scale (r = .71), high one-week test–retest reliability (r =.93), and high internal consistency (α=.91). The BDI-II was used both as a clinical outcome in analyses, as well as a tool to monitor patient's progress during the course of treatment.

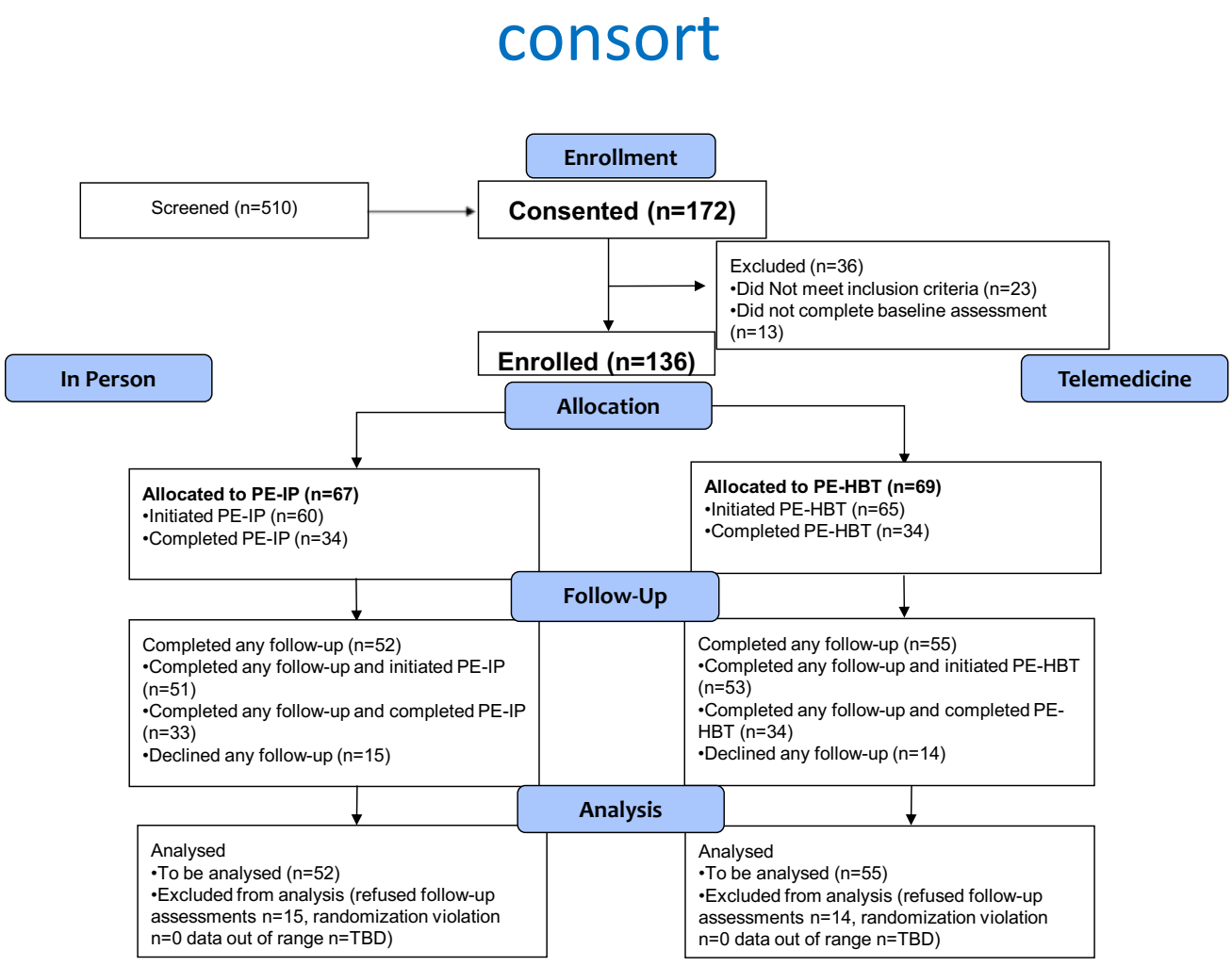
3. Post-treatment or Post-Dropout Qualitative Interviews: Dr. Grubaugh, who has extensive experience in qualitative methods and analyses, conducted the thematic interviews for the study of participants who finish treatment but retain their PTSD diagnosis at post-treatment, or who dropout early from treatment as specified earlier.

Sample Description:

Table 1 provides detail description of the sample; 510 potential participants were screened, 172 consented to treatment, and 136 were enrolled for this project with 67 assigned to standard in person PE and 69 assigned to Home Based Telehealth delivered PE. Of those consented but not enrolled, 15 did

not meet PTSD eligibility, 1 evinced severe substance use disorder, 1 evinced suicidal ideation, 13 did not complete assessment interviews, 3 did not complete self-reports, 2 evinced psychotic symptoms and 1 decided not to proceed. As is characteristic of this population, treatment dropout was high, with 33 of 67 dropping out of the in person treatment condition and 35 of 67 dropping out of the home based telehealth treatment condition, during the treatment phase of the study. However, 7 of these dropouts did complete at least 6 sessions. Ninety-eight participants provided post treatment data, 92 provided 3-month post treatment data, and 93 provided 6-month post treatment data, with 81 participants completing all assessments. (See Figure 1 below.)

Figure 1. Consort



The ethnic and racial breakdown of study participants who were enrolled is as follows:

Racial Categories	Ethnic Categories: Not Hispanic/Latino — Female	Hispanic or Latino — Female	Unknown Ethnicity — Female	Total
American Indian/Alaskan Native	0	0	0	0
Asian	2	0	0	2
Native Hawaiian/Pacific Islander	1	0	0	1
Black/African American	80	3	4	87
White	36	4	0	40
More than one race	4	2	0	6
Unknown or Not Reported	0	0	0	0
Total	123	9	4	136

Table 1. Descriptive Information About the Sample

Variable	HBT (n=69)	In Person (n=67)	Total (n=136)
Demographics			
Age	41.55 (12.10)	45.31 (10.63)	43.40 (11.51)
Perpetrator in military	97.10% (67)	94.00% (63)	96.30% (130)
Sexual assault reported to military officials	27.50% (19)	28.30% (19)	28.60% (38)
Theatre			
OEF/OIF	50.70% (35)	43.30% (29)	47.10% (64)
Persian Gulf	23.20% (16)	22.40% (15)	22.80% (31)
Vietnam	4.30% (3)	7.50% (5)	5.90% (8)
Other/More than one	21.70% (15)	26.90% (18)	24.20% (33)
Combat exposure	34.30% (23)	32.80% (22)	33.60% (45)
Childhood sexual abuse	41.20% (28)	47.80% (32)	44.40% (60)
Forced sexual assault pre-military	39.10% (25)	44.30% (27)	41.60% (52)

Forced sexual assault post-military	17.50% (11)	16.40% (10)	16.90% (21)
Treatment			
Treatment satisfaction	3.96 (.96)	4.08 (.93)	4.02 (.94)
Number of sessions completed	6.80 (4.14)	6.28 (4.33)	6.54 (4.23)
Weeks to completion of treatment	15.29 (4.43)	13.56 (4.26)	14.43 (4.40)
Treatment credibility at week 4	7.09 (2.19)	6.89 (2.21)	6.98 (2.19)
CAPS Score			
Baseline	36.50 (8.19)	35.10 (9.63)	35.81 (8.92)
Post-Treatment	23.93 (13.08)	20.91 (12.69)	22.41 (12.90)
3-month follow-up	25.09 (12.63)	21.49 (13.32)	23.31 (13.03)
6-month follow-up	21.53 (14.44)	18.25 (14.60)	19.87 (14.53)
CAPS Positive			
Baseline	92.20% (59)	91.90% (57)	92.10% (116)
Post-Treatment	56.50% (26)	44.70% (21)	50.50% (47)
3-month follow-up	47.70% (21)	48.80% (21)	48.30% (42)
6-month follow-up	41.90% (18)	29.50% (13)	35.60% (31)
PCL-M Score			
Baseline	52.90 (12.91)	52.30 (12.42)	52.60 (12.63)
Post-Treatment	34.02 (22.14)	28.80 (22.01)	31.33 (21.11)
3-month follow-up	37.58 (20.03)	30.44 (20.66)	34.09 (20.54)
6-month follow-up	31.95 (20.47)	31.07 (22.34)	31.49 (21.34)
BDI-II Score			
Baseline	33.03 (12.52)	30.37 (10.76)	31.72 (11.72)

Post-Treatment	24.28 (16.49)	19.02 (14.55)	21.59 (15.67)
3-month follow-up	25.62 (15.75)	18.91 (13.06)	22.34 (14.81)
6-month follow-up	22.21 (16.14)	20.40 (14.28)	21.28 (15.15)

Data Analytic Strategy

Intent-to-treat analyses were conducted using growth curve modeling in MPlus 8.0. This approach was selected to accommodate the different distributional assumptions underlying variables of interest (count vs. continuous variables) as well as the different slopes that naturally occur both within treatment and post-treatment. Within treatment slopes included baseline, week 2, week 4, week 8, and week 10 time-points. Post-treatment slopes included post-treatment, 3 months after treatment, and 6 months after treatment. Slopes and intercepts of treatment time points and post-treatment times points were examined separately within the same model. Treatment condition and number of sessions completed were regressed on the treatment slopes and post-treatment slopes for PTSD symptoms and depressive symptoms.

Results

Treatment Fidelity

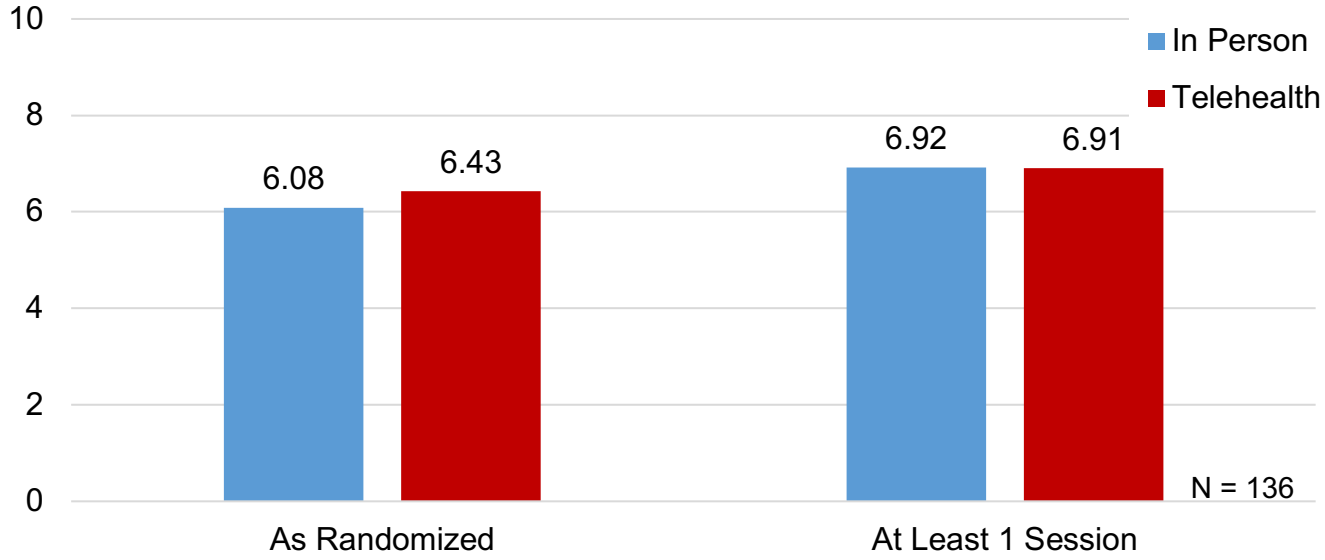
Ten percent of treatment sessions were randomly sampled to determine adherence to treatment using standardized rating forms covering key and treatment components. Overall treatment fidelity was 93%. Specific elements of treatment fidelity were as follows: adherence to each element of therapy listed in the session manual corresponding to that number session; average = 78% (i.e., 78% of sessions included every therapy strategy element that corresponded to the PE manual for that session within each element of therapy) and adherence to factors comprising that element; average = 100% (i.e., when conducting therapy elements, all essential aspects of that element were covered 100% of the time).

Posttraumatic Stress Disorder Symptoms

Results of the growth curve model indicated that number of sessions completed (B = -.152, p = .003) was negatively associated with posttraumatic stress symptom change (i.e., slope) during treatment (i.e., baseline to post treatment). In other words, as predicted, more sessions completed was associated with less posttraumatic stress symptoms over time during treatment. However, counter to predictions, there was no difference in PTSD symptom slope during the treatment phase among those in the HBT condition compared to participants in the in-person condition (B = .007, p = .903). In other words, during the baseline to the end of treatment phase, treatment was not more effective if delivered via HBT or in person. This was because results of the growth curve indicated, counter to predictions, that there was no

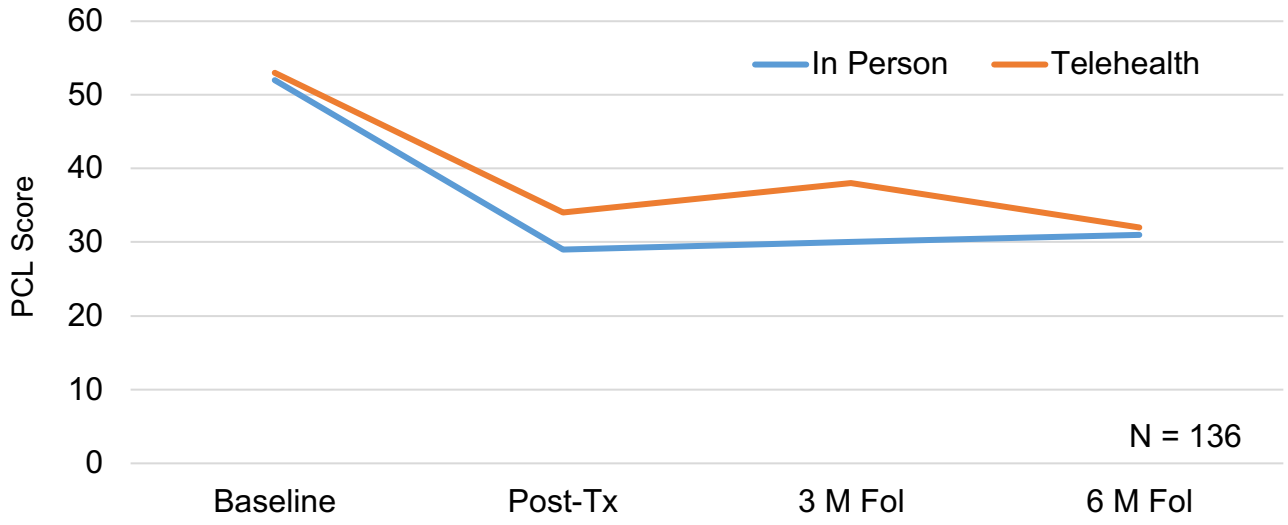
difference in dose (number of sessions completed) in post-treatment slope (*B* = -.026, *p* = .846) or treatment condition (*B* = -.048, *p* = .750). (See Figure 2.)

Figure 2: Dose Received



Importantly, the slope of PTSD symptom change from the post-treatment through follow-up period was significantly associated with baseline to post- treatment slope (*B* = -.456, *p* = .001) indicating that a higher decline in symptoms within treatment was associated with less symptom return post-treatment. Overall, therefore, delivering PE via HBT did not increase the dose, or number of sessions received, and thus this treatment modality was not associated with more dramatic reduction in PTSD symptoms. Participants in both PE delivery modalities completed about the same number of sessions and evinced about the same level of improvement. (See Figure 3 below.)

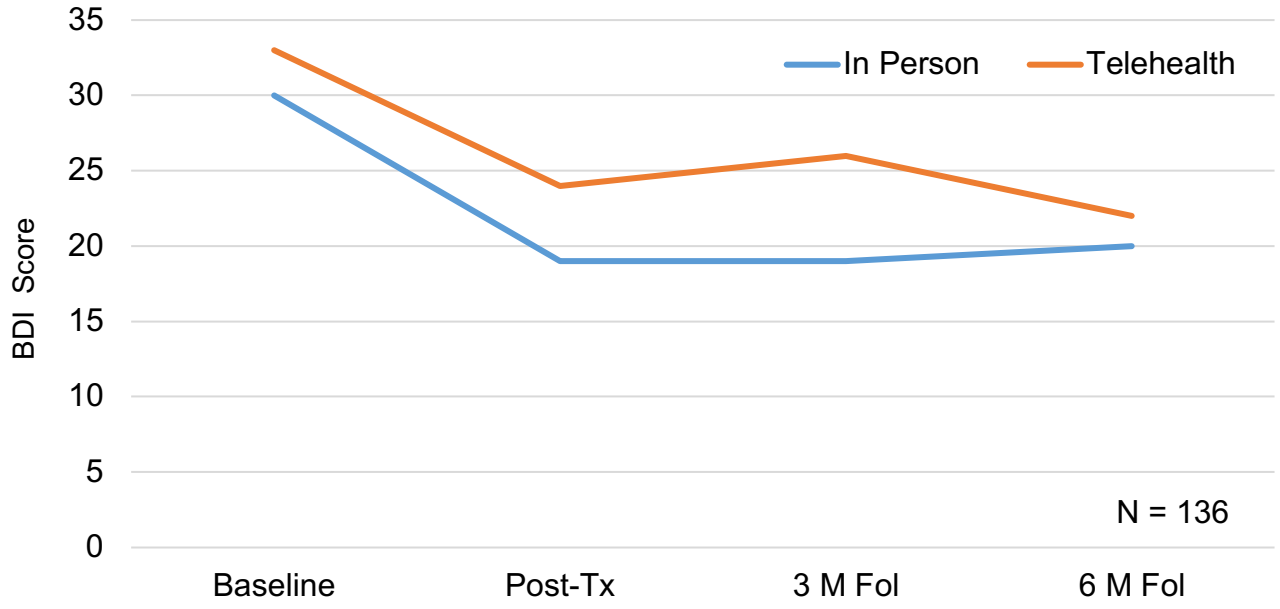
Figure 3: Post-Traumatic Stress Disorder Symptoms Baseline to Post Treatment



Depressive Symptoms

Results of the growth curve model indicated that neither number of sessions completed (B = -0.021, p = .174) or treatment delivery modality (B = -0.115, p = .397) were associated with slope of depressive symptoms from baseline to post treatment, or from post-treatment to follow-up (number of sessions B = -0.009, p = .406; treatment delivery modality B = -0.032, p = .664). Further, the slope of depression symptoms during treatment were not associated with the slope of depressive symptoms post-treatment (B = -0.052, p = .276). (See Figure 4 below.)

Figure 4: Depression Symptoms



Dropout Prediction

In *post hoc* analyses we identified a significant predictor of dropout that very likely accounted for the above null findings: difficulties with emotion regulation. As PE therapy for PTSD requires significant emotion regulation skills to engage in both in vivo and imaginal exposures and to even attend sessions, it makes sense that this factor emerged as relevant. To investigate this issue, data were analyzed by logistic regression with treatment dropout as the outcome. Predictors of dropout also included treatment condition (home-based telehealth vs. in person) alongside difficulties with emotion regulation. Other predictors of dropout, as identified in the literature, were included in the model as covariates: age, race/ethnicity (white vs. ethnic/racial minority), marital status (currently married vs. not currently married), employment (employed vs. not), and theatre (OEF/OIF vs. other theatres). **The only significant predictor of treatment dropout was difficulties with emotion regulation** (see Table 2), and this effect was observed over and above the effects of treatment modality, age, theatre, employment status, marital status, race, and PTSD symptom level. More specifically, individuals with more difficulties with emotion

regulation were significantly more likely to dropout than those with less difficulties with emotion regulation.

Table 2. Logistic Regression Predicting Treatment Dropout

	Estimate	*S.E.*	*Est./S.E.*	*p*
Age	0.056	0.155	0.361	0.718
Home-based Telehealth (vs. in person)	0.089	0.156	0.573	0.566
Theatre (OEF/OIF vs. others)	0.093	0.153	0.606	0.545
Employed (vs. unemployed)	-0.070	0.123	-0.572	0.567
Currently Married (vs. not)	0.056	0.121	0.462	0.644
White (vs. racial/ethnic minority)	-0.094	0.125	-0.755	0.450
Difficulties with Emotion Regulation	**0.394**	**0.148**	**2.661**	**0.008**
PTSD Symptoms	-0.158	0.165	-0.962	0.336

Preliminary Findings from Qualitative Interviews

Thematic interviews (N=35) suggest that the majority of women interviewed did not initiate treatment prior to this study due to: 1) fears regarding how it would be perceived by those close to them and/or to their employers (particularly if active duty); 2) feelings of shame; and 3) concerns about the potential negative impact of having to relive the event. Conversely, a motivating factor for seeking treatment was the realization that their symptoms/behaviors were not normal and/or were getting out of control and/or were due to pressure from a family member/romantic partner/close friend who was concerned frustrated by the Veteran's symptoms. Once the decision was made to seek care, women uniformly did not report any obstacles in enrolling in VA healthcare and found the process to be fairly straightforward/not too complex.

Considering Treatment Engagement. Those who completed treatment and did not have a PTSD diagnosis post-treatment (**treatment completers/responders; n=10**) described being "excited and somewhat nervous" and "eager" to get started. They generally reported that the rationale provided for PE was credible and "made sense" and that the treatment seemed relevant to them and for their symptoms. They also tended to note that the treatment got easier with time with almost all reported noticeable gains and/or decreased distress during imaginal and in vivo exercises early in treatment (i.e., after a few sessions). For the majority, distress experienced during the imaginal and in vivo exercises was perceived as manageable ("re PE: it was nothing couldn't handle"), and/or a "normal" reaction. If and when aspects of treatment were perceived as tough or challenging, these women reported persisting with care because they believed in the treatment or their therapist, didn't want to disappoint themselves or their therapist, and/or focused on the end result (I've come this far and done all this work, so why quit now?"; "I focused on the end goal"; "Didn't want to go back after 1st appointment but I stuck it out"). This group of women

also tended to employ a number of alternate strategies to help themselves felt better outside of sessions (i.e., prayer/church, breathing exercises, talking to friends/family).

Those who completed treatment but retained a PTSD diagnosis post-treatment (**treatment completers/non-responders; n=10**) also generally found the treatment rationale for PE credible and relevant. Unlike the treatment completers/responders, however, this group reported more difficulties with the treatment. In particular, they seemed to have mixed responses about homework assignments with some particularly disliking listening to their audiotaped sessions. Although they retained a PTSD diagnosis post treatment, n=4 women experienced a 10-15 point decrease in their symptoms and the remaining women experienced a less than 5 point change in their PTSD severity score in either direction. The majority of women also reported other meaningful gains from treatment such as being able to calm down more quickly, being less avoidant, having better insight and/or having a better understanding of themselves and their experience.

Those who dropped out of treatment prematurely (**treatment non-completers; n=15**) generally reported that the rationale for PE did not make sense to them or they were skeptical of the rationale and were not convinced about the potential efficacy of PE for improving their symptoms. Those who received ≥ 2 sessions found the imaginal exposure to be overly distressing (i.e., called imaginal exercises "traumatic", "cruel", "like an interrogation") and they perceived that their symptoms got worse over time. Notably, pre to post treatment change scores for these individuals fluctuated by no more than 7 points and typically reflected a decrease, rather than an increase in severity, across the two assessment time points. They generally reported that they dropped out of treatment because the treatment was too stressful/distressful ("It was just too much") and was not making them better (or in fact was making them worse). Those who dropped out of treatment prior to session 3 reported a number of non-intervention specific reasons for their early termination such as physical health issues, work, and distance (if in-person).

Across the three groups, women reported trusting their providers, found telehealth to be a comfortable/satisfactory medium of care; liked having a female provider; and expressed an interest in participating in a support group or therapeutic group with other women with MST. Interviews corroborated quantitative findings that drop-out was not predicted by treatment condition (in person vs telehealth). Therapist fidelity to PE was corroborated through the interviews with all women confirming that the prescribed elements of PE (psychoeducation, breathing retraining, imaginal, and in vivo exposure) were adequately covered. Imaginal exposure was considered the most critical element to recovery.

KEY RESEARCH ACCOMPLISHMENTS:

- *Met Recruitment Criteria: Consented 172 and Enrolled 136 (n=69 home telehealth; n=67 in person) (original enrollment target 100).*

- *Significant reduction of PTSD symptoms in both groups.*
- *No effect of home-based delivery of PE on Dose Received of PE.*
- *No effect of home based delivery of PE on differential clinical outcomes of PE.*
- *Major finding: Difficulties with emotion regulation strongly predicted dropout, over and above treatment delivery modality, war theatre, employment status, marital status, race, ethnicity, and baseline PTSD symptom intensity*

CONCLUSION:

Despite strong legislative efforts that include MST education, MST services in active duty settings, mandatory screening for MST in VA settings, and free evidence-based care for MST-related problems in VA settings, only half of female Veterans with an MST history actually use VA healthcare (Calhoun et al., 2016; Resick et al., 2017); and among these, only one in five who screen positive for PTSD actually pursue VA mental health services (Kimerling et al., 2008). More recent studies on the topic have found that approximately 40 to 50% of Veterans and/or Active Duty personnel with MST had not used VA healthcare (Calhoun et al., 2018; Zinzow et al., 2015) and about one third of those who initiated treatment dropped out prematurely (Zinzow et al., 2015). Thus, although treatment engagement appears to be increasing, nearly half of those identified as having experienced MST have not sought or benefited from treatment.

When female Veterans with MST do pursue services, they are more likely to receive pharmacological treatment for mental health conditions through primary care, rather than more effective evidence-based psychosocial interventions for PTSD such as Prolonged Exposure (PE; Foa et al., 2008) offered through VA specialty care clinics relative to female Veterans without an MST history (Chatterjee et al., 2009; Maguen et al., 2010). This represents a missed opportunity because recent data indicate that PTSD treatment outcomes do not differ based on MST status ***if treatment is completed*** (Tiet et al., 2015). Thus, given adequate access to VA care, Veterans with MST histories are likely to benefit from PTSD specialty treatment.

This DoD funded study tested whether we could increase evidence-based psychotherapy (i.e., Prolonged Exposure Therapy) “dose received” in female Veterans who experienced PTSD related to Military Sexual Trauma by using home-based telehealth to overcome barriers to care (e.g., stigma, avoidance of male Veterans, logistical barriers). As such, we compared rates of session attendance and treatment outcome to traditional ‘in person’ delivered PE, with the assumption that barriers to care associated with receiving services from within the VA clinic were instrumental in producing high rates of dropout, and overcoming these barriers via home-based telehealth would reduce dropout (i.e., increase ‘dose received’). In support of this rationale, and prior to this study we conducted an anonymous telephone survey to determine the service delivery preferences of MST positive Veterans who declined

services at the Charleston VA PTSD clinic. This survey revealed that female survivors of MST reported that they would be more likely to receive evidence-based psychotherapy for MST-related emotional problems if these services were available via home-based telehealth at a more than 2:1 ratio. This finding, coupled with other research findings on telehealth, pilot study data suggested that characteristics of traditional, DoD and VA office-based therapy may deter MST survivors with PTSD from initiating and/or completing exposure-based protocols. *We predicted that home-based telehealth would circumvent barriers to care and promote completion of evidence-based psychotherapeutic interventions such as PE, thereby increasing 'dose received' and subsequent treatment benefit.* Neither of these predictions were supported by the data. *However, our data did indicate that, for about half the Veterans seeking MST-related PTSD care, deficits in emotional regulation skills were present.*

Dropout from PTSD specialty care is common, with rates ranging from 24-40% for PE across all Veterans (Gros et al., 2011; Gutner et al., 2016; Hembree et al., 2003; Hernandez-Tejada et al., 2014; Jeffreys et al., 2014; Mott et al., 2014; Rauch et al., 2012; Van Minnen et al., 2002). Unfortunately, and despite our novel study focus addressing barriers to care (i.e., using home-based telehealth to deliver treatment), our dropout rate in the current trial was 50%, a rate only slightly better than that observed in our VA MST clinic. Our data indicate that this may be because core components of PE treatment include emotional processing / graphic review of the traumatic event which requires patients to tolerate and regulate their emotions within and between sessions during exposure to traumatic memories and when confronted with external reminders of the event. *Indeed (a) MST is associated with difficulties in emotion regulation* (Luterek et al., 2011)*, and (b) given our findings on the association between treatment drop-out and poor emotion regulation,* ***it appears that emotion regulation plays a key role in treatment dropout*** *among Veterans with MST-related PTSD.*

PUBLICATIONS, ABSTRACTS, AND PRESENTATIONS:

Publications

- Gilmore, A. K., Davis, M. T., Grubaugh, A., Resnick, H., Birks, A., Denier, C., ... & Acierno, R. (2016). "Do you expect me to receive PTSD care in a setting where most of the other patients remind me of the perpetrator?": Home-based telemedicine to address barriers to care unique to military sexual trauma and Veterans affairs hospitals. *Contemporary clinical trials*, *48*, 59-64.
- Gilmore, A., Lopez, C., Muzzy, W., Grubaugh, A., Oesterle, D., & Acierno, R. (under review). Emotion dysregulation predicts dropout of Prolonged Exposure among female veterans with military sexual trauma-related post-traumatic stress disorder. *Clinical Psychology & Psychotherapy*.
- Hernandez-Tejada, M. A., Acierno, R., & Sanchez-Carracedo, D. (2017). Addressing dropout from prolonged exposure: Feasibility of involving peers during exposure trials. *Military Psychology*, *29*(2), 157.

Presentations

- Lopez, C., Muzzy, W., Grubaugh, A., Resnick, H., Radic, M., Rosenlieb, T., Zeigler, S., & Acierno, R. (2016, February). Characteristics and preferences of female veterans most likely to engage in mental health services. Poster presented at Women's Health Research Day in Charleston, SC.
- Muzzy, W., Hamski, S., & Acierno, R. (2017, December). Women participating in clinical research studies VA example: Recruiting women where everyone is male. Presented at the MUSC Special Populations meeting in Charleston, SC.
- Hahn, C., Gilmore, A., Ruggiero, K., Muzzy, W., & Acierno, R. (2018, November). Telemedicine versus in-person delivery of Prolonged Exposure for military sexual trauma-related PTSD. Poster presented at the 34th Annual Meeting for International Society for Traumatic Stress Studies (ISTSS) in Washington, DC.

INVENTIONS, PATENTS AND LICENSES:

None

REPORTABLE OUTCOMES:

Home based delivery of evidence-based treatment for PTSD to MST patients does not increase the number of sessions received and is not related to dropout. However, MST patients with low emotion regulation are far more likely to drop out. Therefore, emotion regulation strategies may need to be integrated into MST PTSD treatments.

REFERENCES:

Affonso, D., Mayberry, L., et al. (2010). Cultural context of school communities in rural Hawaii to inform youth violence prevention. *J School Health, 80, 146*-152.

Angen, M. (2000). Evaluating interpretive inquiry: Reviewing the validity debate & opening the dialogue. *Qualitative Health Res*, *3*, 378-395.

Andersen, R. (1995). Revisiting the behavioral model & access to medical care: Does it matter? *J of Health & Soc Beh, 36,* 1-10.

Andersen, R.M. & Newman, J.F. (1973). Societal & individual determinants of medical care utilization in the United States. *Milbank Qtrly, 51,* 95-124.

APA. (2000). *DSM-IV-TR*. Washington, DC: American Psychiatric Association.

Baron, R., & Kenney, D. (1986). The moderator-mediator variable distinction in social psych research: Conceptual, strategic, & statistical considerations. *J Person & Social Psych, 51,* 1173-1182.

Beck, A., Steer, R., et al. (1996). BDI-II. San Antonio, TX: 1996.

Beidel, D., Frueh, B., et al. (2011). Multicomponent beh treatment for chronic combat-related PTSD: A RCT. *J Anxiety Disorders, 25,* 224-31.

Blake, D., Weathers, F., et al. (2005). The development of a Clinician-Administered PTSD Scale. *J Traumatic Stress, 8,* 75-90.

Blanchard, E., Jones-Alexander, J., et al. (1996). Psychometric properties of the PTSD Checklist (PCL). *Beh Res Ther, 34,* 669-673.

Borkovec, T. & Nau, S. (1972). Credibility of analogue therapy rationales. *J Beh Ther Exper Psych,3,* 257-260.
Bouchard, S., Paquin, B., et al. (2004). Delivering CBT for panic disorder & agoraphobia in videoconference. *Telemed J E Health, 10,* 13-25.
Bradley, R., Greene, J., et al. (2005). A multidimensional meta-analysis of psychother for PTSD. *Am J Psych, 162*, 214–217.
Brady, K., Dansky, B., et al. (2001). ET in the treatment of PTSD among cocaine-dependent individuals: Preliminary findings. *J Subst Abuse Treatment, 21,* 47-54.
Cahill, S., Rauch, S., et al. (2003). Effect of cognitive behavioral treatments for PTSD on anger. *J Cog Psychother, 17,* 113–131.
Campbell, R. & Raja, S. (2005). The sexual assault & secondary victimization of female Veterans: Help-seeking experiences with mil & civilian social systems. *Psych of Women Quarterly, 29*, 97-106.
Chatterjee, S., Rath, M., et al. (2009). Gender differences in VHA mental health service use: Effects of age & psychiatric diagnosis. *Women's Health Issues, 19*, 352.
Charmaz, K. (2006). Constructing grounded theory: A practical guide through qualitative analysis. Sage, London.
Cloitre, M. (2009). Effective psychotherapies for PTSD: A review & critique*. CNS Spectrum, 13,* 32-43*.*
Cohen, D. & Crabtree, B. "Qualitative Research Guidelines Project." July 2006. Available on Robert Wood Johnson Foundation website, http://www.qualres.org/HomeTria-3692.html.
Creswell, J. (1998). *Qualitative inquiry & res design: Choosing among 5 traditions*. Thousand Oaks, CA: Sage.
DVA (2010a). *Programs for Veterans with PTSD* (VHA Handbook No. 1160.03).
DVA (2010b). *MST Programming* (VHA Directive 2010-033).
Foa, E., Dancu, C., et al. (1999). A comparison of ET, SIT, & their combination for reducing PTSD in female assault victims. *J Consulting & Clin Psych, 67*, 194-200.
Foa, E., Heart-Ikeda, D., et al. (1995). Evaluation of a brief cog-behav program for the prevention of chronic PTSD in recent assault victims. *J Clin & Consulting Psych, 63*, 948-955.
Foa, E., Hembree, E., et al. (2007). *PE for PTSD: Emotional processing of traumatic events, therapist guide.* Oxford University Press: New York.
Foa, E., Rothbaum B., et al. (1991). Treatment of PTSD in rape victims: A comparison between cog-behav procedures & counseling. *J Consulting & Clin Psych, 59,* 715-723.Fontana, A. & Rosenheck, R. (2006). Treatment of female Veterans with PTSD: The role of comfort in a perdominantly male environment. *Psychiatric Quarterly, 77*, 55-67.
Frayne, S., Skinner, K., et al. (1999). Medical profile of women Veterans Adminstration outpatients who report a history of sexual assault occuring while in the mil. *J Women's Health & Gender-Based Med, 8*, 835-845.
Frueh, B., Cusack, K., Grubaugh, A., et al. (2006). Clinicians' perspectives on cog-behav treatment for PTSD among persons with severe mental illness. *Psych Services, 57,* 1027-1031.
Frueh, B., Pellegrin, K., et al. (2002). Patient satisfaction among combat Veterans receiving specialty PTSD treatment. *J Psych Prac, 8,* 326-332.
Frueh, B., Sauvageot, J., & Grubaugh, A. (2006). Perceptions of elderly former POWs regarding care & benefits provided by the VA system: A qualitative study. *J Trauma Practice, 5,* 1-11.
Frueh, B., Turner, S., et al. (1995). ET for combat-related PTSD: A critical review. *Clin Psych Review, 15*, 799-817.
Greene, C., Morland, L., et al. (2008). Noninferiority & equivalence designs: Issues & implications for mental health Res. *J Traumatic Stress, 21*, 433-439.
Haskell, S., Gordon, K., et al. (2010). Gender differences in rates of depression, PTSD, pain, obesity, & MST among Connecticut war Veterans of Iraq & Afghanistan. *J Women's Health, 19*, 267-271.
Hedeker, D. & Gibbons, R. (2006). *Longitudinal data analysis.* John Wiley & Sons, Hoboken NJ.
Holmbeck, G. (1997). Toward terminological, conceptual, & statistical clarity in the study of mediators & moderators. *J Consulting & Clin Psych, 65,* 599-610.

Institute of Med & National Res Council. (2007). *Treatment of PTSD: An assessment of the evidence*. Washington, DC: National Academies Press.
Kang, H., Dalager, N., et al. (2005). The role of sexual assault on the risk of PTSD among Gulf War Veterans. *Annals of Epid, 15,* 191-195.
Kang, H., et al. (2003). PTSD & chronic fatigue syndrome-like illness among Gulf War Veterans: A population-based survey of 30,000 Veterans. *Am J Epid, 157,* 141-148.
Kazis, L. (2000). The SF-36 Health Status Questionnaire: Development and application in the Veterans Health Administration. *Medical Outcomes Trust Monitor, 5,* 1-14.
Kazis, L., Miller, D., et al. (2004). Improving response choices of the SF-36 role functioning scales: Results from the Health Study. *J Ambul Care Mgmt, 27,* 263-280.
Kelly, M., Vogt, D., et al. (2008). Effects of military trauma exposure on women Veterans' use & perceptions of VHA care. *J Gen Internal Med, 23*, 741-747.
Kimerling, R., Clum, G., et al. (2000). Relationships among trauma exposure, chronic PTSD symptoms, & self-reported health in women: Replication & extension. *J Traumatic Stress, 13*, 115-128.
Kimerling, R., Gima, K., et al. (2007). The VHA & MST. *Am J Public Health, 97*, 2160-2166.
Kimerling, R., Street, A., et al. (2008). Evaluation of universal screening for MST. *Psych Services, 59*, 635-640.
Kimerling, R., Street, A., et al. (2010). MST among VHA patients returning from Afghanistan & Iraq. *Am J Public Health, 100,* 1409-1412.
King, D., King, L., et al. (2003). Manual for the Deployment Risk & Resilience Inventory (DRRI): A collection of measures for studying deployment-related experiences in mil veterans. Boston, MA: NCPTSD.
Kornør, H., Winje, D., et al. (2008). Early trauma-focused CBT to prevent chronic PTSD & related symptoms: A systematic review & meta-analysis. *BMC Psych, 8,* 100-105.
Krippendorff, K. (2004). *Content analysis: An Introduction to its methodology*. Thousand Oaks, CA: Sage.
Little, T. & Rubin, D. (1987). *Statistical analysis with missing data*. NY: John Wiley & Sons, Inc.
Maguen, S., Ren, L., et al. (2010). Gender differences in mental health diagnoses among Iraq & Afghanistan Veterans enrolled in Veterans Affairs Health Care. *Am J Public Health, 100,* 2450-2460.
Monnier, J., Knapp, R., & Frueh, B. (2003). Recent advances in telepsych: An updated review. *Psych Services, 54,* 1604-1609.
Morland, L., Frueh, B., et al. (2009).Issues in the design of a randomized noninferiority clinical trial of telemental health psychotherapy for rural combat veterans w/PTSD. *Contemp Clin Trials, 30*, 513-522.
Morse, J., Barrett, M., et al. (2002). Verification strategies for establishing reliability and validity in qualitative research. *Inter J of Qual Methods, 2*, 13-22.
National Collaborating Centre for Mental Health. (2005). Clinical Guideline 26. PTSD: The management of PTSD in adults & children in primary & secondary care. National Institute for Clinical Excellence.
Noel, P., Frueh, B., et al. (2005). Needs & preferences of primary care patients with multimorbidity. *Health Expectations, 8*, 54-63.
Office of Mental Health Services. (2009). MST Screening Report: Fiscal Year 2009. Washington DC:DVA
Patton, M. (1987). *How to use qualitative methods in evaluation.* Newbury Park: Sage.
Pellegrin K, Stuart, G., Maree, B., Frueh, B., et al. (2001). Assessment of patient satisfaction in psychiatry clinics: Development of a reliable and valid instrument. *Psych Services,* 52, 816-819.
Powers, M. (2010). A metanalytic review of PE for PTSD. *Clin Psych Review, 30,* 635-641.
Resick P., Nishith, P., et al. (2002). A comparison of CPT with PE & a waiting condition for the treatment of chronic PTSD in female rape victims. *J Consulting & Clin Psych, 70,* 867-879.
Resnick, H. (1996). Psychometric review of Trauma Assessment for Adults (TAA). In Stamm, B.H. (Ed). *Measurement of stress, trauma & adaptation.* Lutherville, MD: Sidran Press.

Resnick, H., Kilpatrick, D., et al. (1993). Prev of civilian trauma & PTSD in a representative national sample of women. *J Consulting & Clin Psych*, *61*, 984-991.
Richardson, L., Frueh, B., Grubaugh, A., et al. (2009). Current directions in videoconferencing telemental health res. *Clin Psych: Science & Practice, 16,* 323-338.
Robins, C., Sauvageot, J., et al. (2005). Consumers' perceptions of negative experiences & "sanctuary harm" in psychiatric settings. *Psych Services, 56*, 1134-1138.
Rubin, H. & Rubin, I. (2005). *Qual interviewing: The art of hearing data (2nd ed.).* Thousand Oaks, CA: Sage.
Ruzek, J., & Rosen, R. (2009). Disseminating evidence-based treatments for PTSD in organizational settings: A high priority focus area. *Beh Res & Ther, 47*, 980-989.
Sayer, N., Friedmann-Sanchez, G., et al. (2009). A Qualitative study of determinants of PTSD treatment initiation in Veterans. *Psychiatry, 72,* 238-255.
Schnurr, P. Friedman, M., et al. (2007). CBT for PTSD in women: A RCT. *JAMA, 297,* 820-830.
Seal, K., Maguen, S., et al. (2010). VA mental health services utilization in Iraq & Afghanistan Veterans in the first year of receiving new mental health diagnoses. *J Traumatic Stress, 23,* 5-16.
Sheehan, D., Lecrubier, Y., et al. (1998). The Mini-International Neuropsychiatric Interview (MINI): The development & validation of a structured diagnostic psych. interview for DSM-IV & ICD-10. *J Clin & Consulting Psych, 59,* 22-33.
Skinner, K., Kressin, N., et al. (2000). The prev of mil sexual assault among female veterans' administration outpatients. *J of Interpersonal Violence, 1*5, 291-310.
Spoont, M., Murdock, M., et al. (2010).Treatment receipt by Veterans after a PTSD diagnosis in PTSD, mental health, or gen medical clinics. *Psych Services, 61,* 58-63.
Suffoletta-Maierle, S., Grubaugh, A., Magruder, K., Monnier, J., & Frueh, B. (2003). Trauma-related mental health needs & service utilization among female Veterans. *J Psychiatric Prac, 9,* 367-375.
Suris, A., & Lind, L. (2008). MST: A review of prev & associated health consequences in Veterans. *Trauma, Violence, & Abuse, 9*, 250-260.
Surís, A., Lind, L., et al. (2007). Mental health, quality of life, & health functioning in women Veterans: Differential outcomes associated with mil & civilian sexual assault. *J Interpersonal Violence, 22*, 179-97.
Surís, A., Lind, L., et al. (2004). Sexual assault in women Veterans: An examination of PTSD risk, health care utilization, & cost of care. *Psychosomatic Med, 66*, 749-756.
Tarrier, N., Sommerfield, C., et al. (2000). Factors associated with outcome of cog-beh treatment of chronic PTSD. *Beh Res & Ther, 38,* 191-202.
US Government Accountability Office (GAO). (2009). Preliminary findings on VA's provision of health care services to women Veterans. *Testimony, Committee on Veterans' Affairs, U.S. Senate.*
Washington, D., Yano, E., et al. (2006). To use or not to use: What influences why women Veterans choose VA Health Care? *J Gen Internal Med, 21*, S11-18.
Weathers, F., Litz, B., et al. (1993). The PTSD checklist (PCL): Reliability, validity, & diagnostic utility. Paper presented at the 9th Annual Meeting of ISTSS.
Weathers, F., Ruscio A., et al., (1999). Psychometric properties of the nine scoring rules for the clinician administered posttraumatic stress disorder scale. *Psych Assessment, 11,* 124-133.
Yano, E., Bastian, L., et al. (2006). Toward a VA women's health res agenda: Setting evidence-based priorities to improve the health & health care of women Veterans. *J Gen Internal Med, 21*, S93-101.
Yaeger, D., Himmelfarb, N., et al.(2006). DSM-IV diagnosed posttraumatic stress disorder in women veterans with and without military sexual trauma. J Gen Intern Med., 21, suppl 3:S65-9.
Zinzow, H., Grubaugh, A., Monnier, J., Suffoletta-Maierle, S., & Frueh, B. (2007). Trauma among female Veterans: A critical review. Trauma, Violence, & Abuse, 8, 384-401.

Do You Really Expect Me to get MST Care in a VA Where Everyone is Male? Innovative Delivery of Evidence Based Psychotherapy to Women with Military Sexual Trauma

W81XWH-14-1-0264 / PT130434

PI: Ronald Acierno, PhD **Org:** Medical University of South Carolina **Award Amount:** $2,064,315

Study/Product Aim(s)

•Objective 1: To compare, at post, 3 and 6-month follow-up, whether PE-HBT is superior to PE PE-SD across critical clinical and quality of life outcomes (i.e., PTSD, depression, quality of life) due to increased PE 'dosing' that results from improved session attendance and reduced attrition.
•Objective 2: To compare at post-intervention whether PE-HBT is superior to PE-SD across critical process outcomes (e.g., session attendance, satisfaction, and treatment adherence).

Approach

Using a randomized, between groups, repeated measures design, 175 female Veterans with MST-related PTSD will be recruited from the Charleston VA medical center catchment area during the study time frame. Veterans will be randomized 1:1 to one of two conditions: PE via home-based telehealth (PE-HBT) or PE via standard service delivery (PE-SD). The active intervention phase is 12 weeks. Participants randomized to PE-HBT will receive 12 weekly sessions of PE via in-home video-conferencing technology, and participants randomized to PE-SD will receive 12 sessions of PE via standard in-person care delivery. All participants will be assessed at baseline, post-treatment, and at three and 6 months follow-up.

Pilot Data indicate MST survivors prefer PTSD Treatment via Home Based Televideo at a rate of 2:1.

Accomplishments this quarter:
The final quarter consisted of finishing treatment with any remaining active study patients and gathering follow up data. All study activities are completed. Between 01-AUG-2014 and 31-JUL-2019, 510 participants were screened and 136 were enrolled. Additionally, 98 post assessments and 185 follow up assessments (92 three-month; 93 six-month) were completed throughout the course of the study.

Future activities:
Future activities will consist of analyzing data and publishing study findings.

Timeline and Cost

Activities / YEAR	1	2	3	4	5
Approvals: IRB / VA / DoD					
Recruit and Treat Participants					
Data Analysis and Reports					
Dissemination					
Budget (Direct and Indirect Costs)	$459,071	$537,799	$553,331	$514,114	NCE

Updated: 29-OCT-2019

Goals/Milestones

YR1 Goal – Institutional Human Subject Approvals Submitted
☑ IRB, VA Research, DoD HRPO approvals obtained

YR2 Goals – Recruitment, Reports
☑Establish recruitment protocols and procedures
☑Recruit and consent participants

YR3 & 4 Goal – Recruitment, Reports
☑ Continue to recruit and consent participants

YR5 Goal – Complete Recruitment, Analyze Data, Submit Publications
☑ Submit final report and presentations to DoD

Comments/Challenges/Issues/Concerns
- None at this time