Research Protocol Narrative
Improving Psychosocial Functioning in Older Veterans with PTSD

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Improving Psychosocial Functioning in Older Veterans with PTSD

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(1) Rationale

(a) Statement of the Problem. Evidence suggests that stressors associated with aging (e.g., retirement, increased medical problems, bereavement) can exacerbate PTSD symptoms. Older Veterans with partial and full PTSD are likely to have comorbid physical and medical problems, take multiple medications, and be more socially isolated than younger Veterans. All of these factors likely contribute to greater functional impairment and decreased quality of life. Given the prevalence of PTSD and comorbid mental and physical problems among older Veterans, it is important to develop interventions that assist older Veterans in regaining fuller, more satisfying functioning and quality of life.

(b) Hypotheses or Key Question. This study involves the development of an intervention for older male Veterans with PTSD. This study will be conducted in several phases. 1) Intervention development, 2) Conducting focus groups to help us better understand impairments in older Veterans with PTSD and to help us modify the proposed intervention modules, 3) Conduct pilot groups with the developed intervention, and 4) Conduct intervention groups and support group controls to evaluate the utility of the developed intervention. Primary outcomes are psychosocial functioning and quality of life, with PTSD and depressive symptoms as secondary outcomes. A complementary objective is to improve attitudes toward mental health treatment and to increase readiness for change and engagement in evidence-based psychotherapies, as appropriate. Results from this study will provide feasibility data for future development and testing of the intervention protocol.

Focus group research questions:

- To what extent do Veterans indicate that the proposed intervention modules address important areas of impairment?
- Within each intervention module, what areas do Veterans view as most and least important?
- In what ways do Veterans think the material from each module should be presented?
- Are there any additional areas that are important to address in the intervention protocol?

Pilot Phase research questions:

- Is the intervention feasible as conducted with older Veterans with PTSD?
- Are Veterans satisfied with the intervention?
- Do Veterans comply with assignments (e.g., monitoring forms)?

Comparison Phase research questions:

- Compared to support group participants, do intervention group participants experience greater increases in psychosocial functioning and quality of life and reductions in PTSD and depressive symptoms?
- Are pre-post changes maintained at 1 and 6 month follow-up?

(c) Specific Objectives.

Aim 1: Develop a group-based intervention for older Veterans with PTSD that targets areas of psychosocial functional impairment.
Aim 2: Conduct focus groups with older Veterans with PTSD and revise the intervention.
Aim 3: Implement pilot groups and revise protocol as indicated. Examine feasibility, acceptability, retention, and satisfaction.
Aim 4: Implement and evaluate the intervention protocol. Compare intervention against support group control. Consult expert panel and finalize intervention protocol.

(2) **Background and Significance**

(a) Background.

The demographic profile of Veterans in the United States is changing, with increasing numbers of Veterans advancing into older age. As of 2010, there were nine million U.S. Veterans who were at least 65 years of age.[1] This population represents Veterans of World War II, the Korean Conflict, and Vietnam. Additionally, current military and newer Veterans are older than those of earlier conflicts, given the increasing numbers of Reservists and National Guard troops being activated and deployed. An important mental health issue for aging Veterans is posttraumatic stress disorder (PTSD). As defined by the *Diagnostic and Statistical Manual of Mental Disorders* – Fifth Edition (DSM-5)[2], PTSD is a disorder that can develop after a person experiences an extremely stressful or traumatic event. Symptoms include intrusions (e.g., distressing memories, dreams, flashbacks), avoidance of reminders of the trauma (e.g., avoiding thoughts, people, situations), negative alterations in cognition or mood (e.g., negative beliefs or emotional state, feeling detached, inability to experience positive emotions), and hyperarousal (e.g., irritable behavior, hypervigilance, exaggerated startle). Symptoms must onset or increase following the trauma and last for at least one month, and also cause clinically significant distress or impairment in functioning. Older Veterans are seeking treatment for PTSD from the VA in increasing numbers[3], and for some, it is for the first time. Given the aging of the approximately 7.6 million Veterans who served during the Vietnam era, and the many more Veterans who will be reaching their older years in coming decades, it is important to develop and provide treatments that will meet the needs of older Veterans with PTSD.

Estimates of the prevalence of current PTSD in adults age 60 and older range from 0.6 to 4.5%.[4] Among older Veterans seeking mental health treatment, estimates of current PTSD are higher, 37-80%.[5] Some older Veterans may experience symptoms of PTSD but not meet the full diagnostic criteria. The percentage of older adults with sub-syndromal levels of PTSD symptoms range from 7-15%[6-8], and those with partial or sub-syndromal PTSD also experience related difficulties. Although many definitions of partial PTSD exist, for the purposes of the current project, it will be defined to include endorsement of a criterion A event, at least one intrusion symptom (cluster B), one avoidance symptom (cluster C), one symptom related to negative alterations in cognition or mood (cluster D), one symptom related to alterations in arousal or reactivity (cluster E), and the experience of distress or impairment in functioning (criterion G).[2] All further references to PTSD will include both partial and full PTSD.

There is some evidence to suggest that stressors associated with aging (e.g., retirement, increased medical problems, bereavement) can exacerbate PTSD symptoms.[9-10] Additionally, older Veterans with PTSD tend to report more somatic problems and are at greater risk for cognitive impairment.[11-12] Older Veterans with PTSD are also likely to have comorbid physical and medical problems, take multiple medications, and be more socially isolated than younger Veterans.[13] All of these factors likely contribute to greater functional impairment problems and decreased quality of life in this population. Given the prevalence of PTSD symptoms and common comorbid problems (such as difficulties in psychosocial functioning) among older Veterans, it is important for VA to develop and disseminate interventions that assist these Veterans in regaining fuller, more satisfying psychosocial functioning and enhancing their quality of life.

There are several evidence-based trauma-focused psychotherapies (EBPs) for PTSD that target a reduction in PTSD symptoms, such as Prolonged Exposure (PE)[14] and Cognitive Processing Therapy (CPT).[15] Evidence also suggests that more generalized cognitive-behavioral therapy (CBT) is effective; a meta-analysis conducted by Bradley and colleagues showed that 56% of those enrolled in PTSD treatment and 67% of those who completed it no longer met criteria for PTSD.[16] However, few of these treatments have been tested in RCTs with older Veterans. There is accruing evidence that PE can be delivered effectively with older Veterans.[17] However, not all

Veterans agree to engage in these types of interventions, and even if they do, some drop out or do not experience a significant decrease in their symptomatology.[18]

There are many possible explanations why some Veterans decline to participate in or drop out of PE or CPT or why VA providers do not offer such treatments to the Veterans on their caseloads.[19] For example, Veterans with complicated psychiatric comorbidities or active suicidal ideation might have more difficulty participating in such treatment. Avoidance or motivational issues could play a role. It is also possible that literacy issues or difficulties in complying with extensive between-session assignments influence these decisions. Additionally, some Veterans may not have the emotional or cognitive resources or coping skills they feel they need to engage in cognitive-affective processing of trauma.[20] Furthermore, Veterans may refuse trauma-focused treatments because they believe they are not "ready" to engage in this type of treatment. Providers have stated that they do not have enough clinical time to administer these treatments. In such instances, Veterans are often referred to skills-based treatment programs as a precursor, as an adjunct to CPT or PE, or instead of these other interventions.[21]

A recent study examined presenting problems that Veterans with PTSD identified as most important for them to improve when they engaged in treatment within a VA setting. The most prevalent concern reported was anger, followed by sleep problems, nightmares, and feeling isolated. About 20% of the sample identified a goal of improving relationships (trust, communication) and improving coping or functioning.[22] In summary, we need to expand the array of evidence-based treatments for individuals with PTSD that address some of the limitations of current treatments. In particular, we need to develop treatments that are suitable for older adults, target quality of life more broadly (versus symptom reduction in particular), and are amenable to those for whom more intense trauma-focused treatments are not suitable. In addition, it may be that participation in a pre-treatment intervention that provides an introduction to mental health treatment more generally, teaches symptom management skills, and provides information about available interventions, would increase some Veterans' willingness to engage in further treatment for PTSD.

Recovery-Oriented Conceptual Framework for Development of Psychosocial Intervention

The theoretical model used to frame the proposed study is recovery-oriented[23] and is based on the hypothesis that psychoeducation and skill building can significantly reduce functional impairment associated with PTSD. Although the recovery model is often applied to addictions or severe mental illness, it is also a useful framework for viewing change within other mental health disorders such as PTSD. Recovery is "a process of change through which individuals improve their health and wellness, live a self-directed life, and strive to reach their full potential (SAMHSA)."[24] Further, recovery is typically viewed as a process rather than an outcome or a cure. This model acknowledges that many people experience mental health conditions chronically and report symptoms that wax and wane over time. Recovery is based on continual growth and improved functioning.

At SAMHSA's 2005 summit on recovery, it was determined that recovery-oriented systems of care are as complex and dynamic as the process of recovery itself. These systems are designed to support individuals seeking to overcome disorders across their lifespan. Some of the important elements of a recovery-oriented intervention include being person-centered, research-based, and inclusive of family members or support people. As such, the recovery-oriented model supports interventions that focus on decreasing impairment and distress and improving functioning in a meaningful way.

This model presents a broad picture of the variety of domains of functioning that are affected by mental health problems. Areas of functional impairment associated with PTSD include social, interpersonal, occupational, educational, and physical health. Specifically, DSM-5 documents that PTSD is often associated with problems in social and familial functioning, problems at work, and lower educational and occupational achievement.[2] Common comorbid psychological problems include depressive disorders, anxiety, sleep problems, and substance abuse and dependence. Thus, there are a number of psychosocial functioning domain deficits associated with PTSD to

serve as potential targets for intervention. Improving psychosocial functioning in individuals with chronic disease has been linked to decreased depression[25], less loneliness[26], more support, and less use of health care resources.[27] Domains of psychosocial functioning (e.g., interpersonal relationships, social activity, communication skills, regulation of anger, behavioral activation, stress management) are the focus of the intervention to be developed in the current study. The importance of community and peer support delineated in the recovery model will also be incorporated into the group-based intervention for older Veterans with PTSD

In summary, by using a recovery-oriented conceptual model, the intervention developed in this project will fill the gap regarding improvement of psychosocial functioning for older Veterans with PTSD symptoms. This model will guide the focus of the intervention toward restoring psychosocial functioning and helping to improve quality of life across several domains.

Applying a Recovery-Oriented Framework to PTSD

The nature and course of PTSD can be variable, and several trajectories are commonly discussed in the literature. In the aftermath of a traumatic experience, individuals can experience an initial increase in symptoms, followed by gradual recovery from those symptoms. Others experience relatively mild symptoms and maintain a healthy (or resilient) trajectory. Still others can have no symptoms, or their symptoms remain at low levels until months or years following the traumatic event when symptoms increase, often in response to a specific trigger or change in functioning. A chronic trajectory, in which a person develops symptoms that are maintained over a long period of time, can also occur (See Figure 1).[28] Approximately a third of those who develop PTSD continue to experience symptoms at a chronic level.[29] These individuals are likely to have increased difficulties with work, social functioning, and physical health problems, as well as lower quality of life. Among a sample of older adults and Veterans, Chopra and colleagues (2014) documented both chronic and fluctuating courses of PTSD over the course of one year and found that those who met criteria for PTSD had worse mental health-related quality of life.[30] VA Cooperative Study 420 compared two group treatments for Vietnam Veterans: trauma-focused group therapy and present centered group therapy.

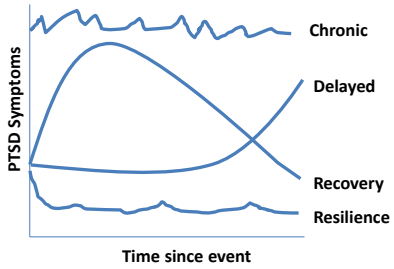


Figure 1. Trajectories of PTSD Symptomatology over time

In the three cohorts examined, the effect of trauma-focused therapy was stronger in one, the effect of present centered therapy was stronger in another, and there were no significant differences by treatment type in the third. However, 40% of the sample showed a clinically significant decline in PTSD severity on the Clinician-Administered PTSD Scale (CAPS) at 7 and 12 month follow-ups.[31] These results suggest that chronic symptoms can improve with treatment but may not completely disappear. These findings indicate that a recovery perspective, with a focus on symptom management and rehabilitation of quality of life and functioning, is an appropriate treatment goal.[32] Given that PTSD develops into a chronic disorder for numerous Veterans and is often maintained over many years, a recovery-oriented framework provides a solid foundation on which to conceptualize and investigate effective interventions.

PTSD and Difficulties in Psychosocial Functioning

Social isolation has been associated with a range of negative health factors such as cardiovascular disease, suicide risk, and all-cause mortality.[33] Research consistently links social support to better health outcomes, despite the vast array of definitions and measures used to

assess both constructs. In fact, public health experts suggest that evidence linking social ties to health is as strong as the epidemiological evidence linking smoking and negative health outcomes. Social isolation is associated with higher levels of psychological distress and loneliness as well as with poor overall health and well-being.[34] From a recovery standpoint, social support has been shown to mediate the relationship between recovery initiation and long-term maintenance; research also demonstrates that poor social support detrimentally impacts recovery and places individuals at risk for relapse.[35]A specific difficulty linked to decreased quality of life among those with PTSD symptoms, and perhaps particularly relevant for older Veterans, is having problems with psychosocial functioning.[36] PTSD symptoms are associated with decreased quantity and quality of social relationships. A negative consequence of this association is that Veterans who have problematic social relationships have worse treatment outcomes.[37] In addition, PTSD negatively affects family cohesion and marital relationships.[37-38] Specifically, emotional numbing, withdrawal, and the expression of anger by Veterans can push family members away. This withdrawal of support can serve to increase symptoms and create a vicious cycle that serves to maintain relationship dysfunction and symptoms. Unfortunately, chronic PTSD symptoms often lead Veterans to erode their support networks over time.

In addition to decreased social support and problems in social functioning in general, another psychosocial problem associated with PTSD is difficulty regulating anger. Cognitive, arousal, and behavioral deficits are several aspects of anger associated with combat-related PTSD.[39] Anger has been identified as a risk factor for the development and maintenance of PTSD and related problems.[40] Further, anger has been correlated with a variety of negative consequences, such as impulsive aggression[41] and poorer treatment outcomes.[42] Of note, the association between PTSD and anger is significant across trauma types, but Orth and Wieland[43] found it to be strongest among combat Veterans. Kulkarni and others[44] examined the relationship between PTSD and anger among 214 male Veterans who presented for treatment at a VA PTSD clinic. After accounting for demographic covariates, anger predicted PTSD symptom severity. These authors suggested that anger is an active avoidance strategy that provides a false sense of control and is associated with over-controlling behaviors such as hypervigilence and acting out. Despite these findings, it has been noted that anger and irritability are symptoms of PTSD, so it is important to question whether or not associations between PTSD and anger are inflated due to this overlap. This question was addressed in a sample of Vietnam combat Veterans by removing anger-related items from the PTSD measure and examining whether correlations were substantially reduced relative to the relationship between anger and the full PTSD measure. Findings indicated that the association between PTSD and anger was virtually unchanged.[45]

Another problem commonly reported by older adults and Veterans with PTSD that likely has an incremental impact on each of the psychosocial domains discussed above, is stress. Stress management strategies often include discussion of sleep, relaxation, exercise, and diet. Psychoeducation around the nature of sleep and common sleep problems, as well as introduction to and implementation of sleep hygiene strategies can be quite beneficial.[46] Finally, getting anyone (including older adults and Veterans) to make and maintain behavioral changes that promote healthier living and decrease stress is difficult. Depression is often comorbid with PTSD and especially relevant for older Veterans who tend to isolate from others. Older adults and Veterans face multiple challenges (e.g., retirement, physical ailments) that require important life changes. As such, it is particularly important, psychosocially and medically, for older adults and Veterans to make certain lifestyle changes to reduce stress and depression (often targeted using behavioral activation.)[47]

In summary, psychosocial domains such as poor social functioning (e.g., isolation, lack of social support), interpersonal dysfunction (e.g., poor communication strategies), anger, problems associated with stress and depression, are associated with PTSD symptom severity and contribute to impairment and decreased quality of life among Veterans. Thus, it is important to develop strategies to help Veterans improve in these areas. This is especially important for older Veterans

who are more likely to be socially isolated, have difficulty making behavioral changes on their own, and may have long histories of dysfunctional interpersonal relationships.

Interventions that Improve Quality of Life for Persons with PTSD

Perlman and colleagues[48] developed a 15-week group intervention to improve quality of life through physical and behavioral activation exercises emphasizing self-care, social interactions, physical activity, and relaxation exercises. The intervention was implemented with 83 Veterans who attended a mental health intake (regardless of psychiatric diagnosis). Veterans improved on 6 out of 8 subscales of the SF-36; the largest effect sizes were found for domains of social and emotional functioning (Cohen's *d* = .34 -.38). Subjective ratings of overall wellness also improved.

Other interventions have been developed to target some PTSD symptoms that do not always improve with exposure therapy, such as social skills difficulties, relationship problems, and anger management issues.[49] For example, Beidel and colleagues[50] presented the results of a randomized controlled trial that examined the efficacy of a multi-component cognitive-behavioral intervention, called Trauma Management Therapy (TMT), to reduce symptoms of PTSD and improve quality of life among male combat Veterans. There were two groups in this study, one received exposure therapy (14 sessions of exposure and 14 sessions of psychoeducation and supportive therapy), and the other received exposure therapy plus social and emotional rehabilitation training (TMT; 14 sessions of exposure and 14 sessions of social and emotional skills training). Both groups demonstrated improvement in PTSD symptoms and social functioning at post-treatment, but only the TMT group had significant increases in frequency and duration of social activities, and only after the social and emotional rehabilitation sessions. Neither group showed improvement on global ratings of anger or quality of life.

Interventions that Improve Psychosocial Functioning

Anger management interventions have successfully reduced anger and aggression in several populations[51], including combat Veterans with PTSD.[39,52] Many of these interventions include cognitive-behavioral techniques such as challenging unhelpful thinking, relaxation strategies, effective communication skills, and coping skills.[53] Some argue that the link between anger and PTSD can be partially explained by information processing deficits.[54] Specifically, men who experience anger and engage in aggression report more irrational beliefs and cognitive distortions than men who are nonviolent.[55] Thus, it would follow that teaching people with anger management difficulties to identify cognitive biases and use cognitive challenging skills would be beneficial. Further, when working to decrease anger, healthcare providers suggest conducting group interventions so that individuals understand that they are not alone in their difficulties and to create a forum for discussion of successful strategies as well as a place to share difficult feelings and situations. Additionally, a group is an ideal environment in which to model appropriate interpersonal behaviors and provide feedback on adaptive ways of handling difficult issues.[53]

In summary, with regards to psychosocial functioning, there is some support to be gained from the scientific literature to inform interventions. Given the reciprocal relationship between PTSD symptoms (such as emotional numbing, anger, and withdrawal) and lower social support, researchers have recommended that mental health practitioners include interpersonal skills training in treatment for Veterans. Additional recommendations include working with Veterans to maintain existing social supports as well as forming new ones.[38]

Interventions that Improve Psychosocial Functioning and Quality of Life for Older Adults and Veterans

Catten and colleagues[26] conducted a systematic literature review to determine the effectiveness of interventions targeting social isolation in older adults. They reviewed 30 intervention studies, about a half of which were randomized control trials and 17 were group interventions. Overall, effective interventions were group-based and targeted specific groups of people. Strategies used in the group interventions included education, discussion, self-help, exercise, and skills training. Five out of nine group interventions that utilized education demonstrated a significant decrease in social isolation. Several groups that focused on increasing social support were successful in decreasing social isolation among group members. Components

of these interventions included encouraging participants to organize social activities, increasing intra-personal resources, and improving communication skills.

Silverstein and Parker[56] conducted interviews with a nationally representative sample of older adults [from Sweden (N = 324) in 1981 and 1992] to determine factors that influenced change in their quality of life. Participants were questioned about 15 domains of activities. Results indicated that those participants who increased their involvement in activities across domains over time perceived improvement in their quality of life. This effect was strong for those who had lost spouses, had low contact with family, and for those who had developed functional impairment. Thus, for those older adults who had some impairments or interpersonal difficulties, engagement in enjoyable activities appeared to buffer some of the potential negative consequences of these problems.

(b) Significance.

This project will provide valuable information about an intervention designed to enhance psychosocial functioning and quality of life, and reduce distress, among older male Veterans with PTSD. Specifically, the completion of this project will result in: 1) the development of a brief group intervention to improve psychosocial functioning among Veterans, 2) a greater understanding of psychosocial impairment within this population (through focus groups with Veterans), 3) the provision of aid to several groups of Veterans with PTSD and the collection of feasibility data, and 4) testing the effectiveness of the group intervention protocol against support group controls.

(c) Relevance to Veterans Health.

Older Veterans are seeking treatment for PTSD from the VA in increasing numbers[3], and for some, it is for the first time. Given the aging of the approximately 7.6 million Veterans who served during the Vietnam era, and the many more Veterans who will be reaching their older years in coming decades, it is important to develop and provide treatments that will meet the needs of older Veterans with PTSD. Given the prevalence of PTSD symptoms and common comorbid problems (such as difficulties in psychosocial functioning) among older Veterans, it is important for VA to develop and disseminate interventions that assist these Veterans in regaining fuller, more satisfying psychosocial functioning and enhancing their quality of life. This intervention will contribute to the work being done to fill this gap, as it involves the development of an intervention geared toward improving functioning and quality of life among older Veterans with PTSD.

(3) Work Accomplished

(a) The PI was previously involved with an examination of late-onset stress among older combat Veterans (at VA Boston). Late-onset stress symptomatology is a phenomenon that occurs among older combat Veterans without histories of stress-related disorders who start to reminisce, with or without associated distress, about their past experiences as they age. As part of studying this process, focus groups with older combat Veterans were conducted to gain an understanding of their perceptions and experiences of aging and the effects of military service in their lives. The PI was involved in the recruitment, planning, and facilitation of these focus groups. The PI also has experience with empirical research on aging and trauma and has worked with large longitudinal datasets comprised of older Veterans to answer questions related to understanding the effects of trauma over the lifespan. The PI is currently involved in a large scale validation study that involved recruitment, telephone screening, and collection of mail surveys to examine correlates of late-onset stress among older combat Veterans (*now in the data analysis phase*). The PI has also developed several brief group interventions for Veterans, mainly within a substance abuse clinic setting. In addition, the PI of this study is also currently PI on another study that focuses on development and validation of a psychoeducational discussion group for older Veterans with late-onset stress. Along with a Co-Investigator, Dr. Jennifer Moye, and several colleagues, the PI developed the group protocol for this study, and we recently completed data collection from the first group of older combat Veterans.Veterans reported benefiting from this group, and we had an 100% retention rate

for the 8 Veterans across the 10-week group and initial post-group assessment. Group sessions for the second cohort are currently underway.

Experience/competence of key collaborators

Trauma, PTSD and Health among Older Veterans, Lifespan Developmental Perspective, Research Design and Analysis – Dr. Avron Spiro

Dr. Avron Spiro has conducted research in the areas of aging, trauma, PTSD, personality, mental health and well-being, and the longitudinal effects of health and disease on cognitive aging for over 35 years. He brings expertise in research design and methodology to his work, and has written prolifically about the importance of incorporating a lifespan developmental perspective into longitudinal trauma and health research. Dr. Spiro and colleagues wrote one of the often-cited papers on PTSD in older men in which they address the long-term effects of combat and refer to military service as a "hidden variable" in the study of aging men.[57] In this study, among the 1,210 Veterans of World War II and the Korean War who participated, PTSD prevalence ranged from 0% to 12.4%. World War II Veterans who experienced moderate to heavy combat were 13.3 times more likely to have PTSD symptoms 45 years after the war than noncombat Veterans. Dr. Spiro is the co-director of the Stress, Health, and Aging Research Program (SHARP), a multidisciplinary group of researchers who investigate the effects of combat and other stressful or traumatic events on physical and mental health over the lifespan. In this role, Dr. Spiro has been involved in recent projects that make use of large longitudinal datasets to examine the effects of military service, stress, and trauma on long-term health.

Dr. Spiro has also examined the relationship between PTSD and health status among a large sample of male Veteran VA ambulatory care patients. Of those exposed to traumatic events, 24% screened positive for PTSD. Those with PTSD reported having more medical problems than those without. Veterans with PTSD had lower health status on all domains assessing quality of life than participants with depression and those with neither disorder. Veterans seeking mental health treatment reported worse health status than Veterans not in treatment. However, those who had received mental health treatment in the past were similar in health status to those who did not seek mental health treatment, suggesting that receiving mental health treatment may alleviate some of the negative effects of PTSD on health.[13]

Dr. Spiro continues to focus his research on the effects of trauma over the lifecourse. His is currently funded by the National Institute on Aging to examine the lifespan outcomes of military service. This project has formed a national multidisciplinary panel of experts to advise project progress and has created a website to provide researchers with information about military service variables in publically available longitudinal datasets that can be used to address relevant research questions. A book that portrays the long-term effects of military service on aging using data derived from these datasets is under development.

Effective Mental Health Treatments for Older Veterans with PTSD, Adaptation of Interventions, and Family Functioning among Older Veterans with PTSD – Dr. Joan Cook

Dr. Joan Cook is an Associate Professor in the Department of Psychiatry at Yale School of Medicine and a Research Affiliate of the VA's National Center for PTSD. She has written extensively about the state of the literature and the need for additional research that examines assessment and treatment of older adult trauma survivors and Veterans with PTSD. She has described the limited research on treatment for PTSD in older adults, and has noted that supportive and cognitive-behavioral group interventions have been successfully applied in this population. She has also outlined several issues for consideration when working with older adults, such as the appropriateness of exposure therapy, issues regarding conducting traditional psychotherapy in traumatized Veterans with moderate to severe cognitive impairment, the effects of aging-related physical health and role changes, and adjustments to the pace and modality of treatment.[58]

Dr. Cook has conducted research examining differences between older Veterans with PTSD and those without PTSD. Among a sample of older World War II former Prisoners of War (POWs), Cook and colleagues found that those with PTSD reported more relationship problems, issues with adjustment, and communication difficulties than did former POWs without PTSD.[59] Further, Dr. Cook

has detailed the need to focus interventions on improving functioning and quality of life and decreasing disability among older Veterans with PTSD in contrast to only examining symptom improvement.[32] In a study she conducted involving a supportive/cognitive behavioral group intervention for older combat Veterans with PTSD, pre-post Posttraumatic Stress Disorder Checklist symptom changes were not significant. However, participants and their family members reported significant improvement in the Veterans' interpersonal functioning, coping skills, and social interactions. Thus, suggestions for future research on interventions with older Veterans emphasized the importance of focusing on some of these types of outcomes: symptom management, stabilization, initiation and maintenance of new activities, improvement in interpersonal relationships, perceptions of improvement, and reduction of maladaptive coping strategies such as social isolation. Additionally, reports of family members and clinicians (in addition to Veteran self report) were acknowledged as essential.

Dr. Cook has also conducted research identifying barriers to mental health providers' adoption of evidence-based psychological treatments. Cook and colleagues surveyed over 1,600 North American psychotherapists via an internet survey to determine perceived barriers to implementing a new clinical intervention. Themes that emerged included: clinician attitudes, client characteristics, contextual or institutional factors, training issues, and other issues. The barrier most often cited was insufficient time for training, learning, and practicing new treatments.[60] Knowledge of such barriers and potential solutions to these barriers will help to guide the development and future implementation of the intervention protocols designed in the current study.

Implementation of Interventions with Older Veterans within the Geriatric Mental Health Clinic of VA Boston Healthcare system – Dr. Jennifer Moye

Dr. Jennifer Moye has expertise in geropsychology, implementation of interventions with older Veterans, and research methodology. Dr. Moye founded the Geriatric Mental Health Clinic at VA Boston and has subsequently recruited geropsychologists to direct clinical services and training programs. VA Boston is one of the leading programs in geropsychology training. Dr. Moye has taught psychotherapy with older Veterans to interns and fellows for more than 20 years, and received the APA Society for Clinical Geropsychology distinguished mentorship award for her work in teaching others. Dr. Moye has participated in a number of projects focused on mental health treatment in complex geriatric populations including a 9-site randomized trial of mental health outreach and treatment for under-treated Veterans and a 5-site randomized trial of care management for older Veterans with dementia. She has received VA RR&D funding to study interacting emotional and physical concerns in older cancer survivors including an observational cohort study and a randomized clinical trial. This work focuses in particular on the interaction of combat-related PTSD and late life stressors including cancer. Dr. Moye's recent published work in this area has integrated qualitative and quantitative methods to describe quality of life issues in these older veterans including PTSD/anxiety, posttraumatic growth, values/goals, and coping or meaning making.[61,62] Dr. Moye has also written about the diagnosis, prevalence, course, risk and protective factors, assessment, and treatment of Veterans with PTSD in the setting of medical illness.[63] In this paper, the authors described how various aspects of cognitive behavioral therapy, such as cognitive restructuring, relaxation training, psychoeducation, and pharmacological management are all helpful components of treatment.

Intervention Outcome Research within the National Center for PTSD – Dr. Denise Sloan

Dr. Denise Sloan has expertise in clinical trial research and methodology, treatment for PTSD, and protocol development. In a randomized clinical trial, Dr. Sloan and colleagues evaluated a brief (5 session) written exposure therapy intervention for PTSD.[64] Participants were 46 adult survivors of motor vehicle accidents who met diagnostic criteria for PTSD and were randomized to a written exposure or a wait list condition. Assessments were conducted at baseline, 6 weeks and 3 months post-intervention. Between group differences were large (g = 3.5 and 2.2) at 6 week and 3 month follow-up assessments, respectively, indicating that the written exposure group displayed larger reductions in PTSD symptoms than the no treatment group.

Dr. Sloan recently conducted a meta-analysis examining the efficacy of group treatments for PTSD.[65] Sixteen studies were included in the meta-analysis; among studies comparing group treatment for PTSD against a comparison condition (e.g., supportive therapy), there was a small significant effect size (*d* = .24). Within-group effect sizes ranged from small to very large. Effects for groups of men were smaller than for women or mixed-gender groups, and studies with combat Veterans displayed smaller effect sizes than did studies with other trauma populations (e.g., MVA). Dr. Sloan and colleagues emphasize the importance of measuring other aspects of change, such as social functioning, in addition to PTSD symptomatology. Dr. Sloan is currently the PI on two randomized controlled trials. One study is examining the efficacy of a cognitive behavioral group treatment for PTSD compared to a support group control. The other study explores whether a brief treatment for PTSD is equally efficacious in comparison to a more intensive, evidence-based treatment for PTSD.

Focus Group Development, Facilitation, and Analysis – Dr. Dawne Vogt

Dr. Dawne Vogt has multiple areas of research expertise; of particular importance to this project, she focuses on risk and resilience factors for PTSD as well as issues related to interpersonal functioning and resilience in Veterans. Dr. Vogt has nearly 20 years of experience designing, implementing, and analyzing data from focus groups with Veteran participants, and is well-suited to provide consultation on this aspect of the current project.

(4) **Work Proposed**

Although some studies have demonstrated efficacy for improving psychosocial functioning among Veterans with PTSD[50] and well-being among Veterans[48], there have not been any rigorous studies to our knowledge that demonstrate improvement in these areas for older Veterans with partial or full PTSD and reduced quality of life. In addition to functional domains described above, there are several areas of psychosocial functioning (e.g., problems related to stress, activity limitations, and depression), that may be beneficial to include in a therapeutic intervention for older Veterans. The purpose of this project is to develop an intervention to improve psychosocial functioning and quality of life for older Veterans with partial and full PTSD. This project will develop a group protocol geared toward restoring older Veterans to better, fuller functioning. Focus groups will be conducted with older Veterans with PTSD to gain additional understanding of functional impairments and preferences for the proposed intervention modules.

Proposed Intervention

The intervention protocol will be developed following consultation with an expert panel. The intervention will be modified following focus groups with older Veterans with PTSD, and this revision will be approved by the expert panel. Each module in the intervention protocol will present didactic information, provide skills training, and will utilize role plays to facilitate rehearsal and skill application and generalization. Between-session work will be assigned, and participants will be provided with feedback. Based on the research reviewed above, we will incorporate several topic areas into the intervention. For example, the intervention protocol will contain modules that provide anger management strategies, communication skills, and education about interpersonal relationships and social support. In addition, psychoeducation about behavioral activation and stress management (discussion of common sleep problems and sleep hygiene techniques, relaxation strategies, as well as the benefits of exercise and healthy diet changes) will be included. All modules will be based on manuals used within the PTSD Clinic at VA Boston Healthcare System, with additional modifications included based on supporting literature, such as applicable components of TMT. These modules will be enhanced with information and examples relevant for older Veterans. Veterans will be taught about the ways in which disability and decreased autonomy can influence thoughts and perceptions as well as mood – which in turn affects the experience of stress, depression, and verbal and nonverbal communication. The connection between such aging-related changes and interpersonal functioning will be reviewed. Another modification will involve a discussion about coping with common aging-related stressors, such as bereavement, caretaking an

ill family member, and increased medical problems. The ramifications that experiencing these stressors have on each intervention domain will be reviewed and discussed as applicable.

Support Group Control Condition

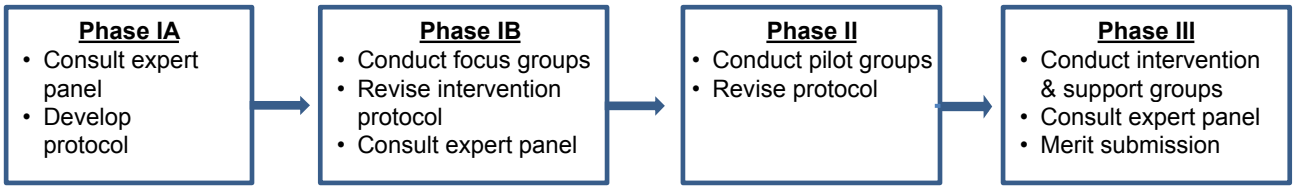
The support groups will be process-oriented in nature with core elements manualized to facilitate consistency of the intervention. In particular, group leaders will facilitate a check-in with the group, and the agenda will be open to topics brought in by group members. The group therapists will intervene by inviting group feedback, noting similarities among group members, and summarizing key points. Group sessions will be the same length as the intervention sessions, and group members will be given between-session assignments. In this way, the dose will be kept as consistent as possible between the two conditions.

Completion of the proposed project will provide data to support the potential efficacy of the intervention protocol (compared to support group controls) and serve as pilot data for a VA Merit application that involves a more rigorous randomized clinical trial (RCT) of the intervention.

Research Design and Methods:

Design Overview*:* The purpose of this project is to develop an intervention to improve psychosocial functioning and quality of life for older Veterans with PTSD. This project will develop, implement, and evaluate a group protocol geared toward restoring older Veterans to better, fuller functioning. This project adds to the existing knowledge by testing a program of resources (the group protocol) with a unique population: older Veterans with PTSD. The developed group protocol will be compared against a support group intervention for Veterans (see Table 1 for a timeline of proposed research activities).

This project will be completed over several phases (see Figure below).



Phase IA (Develop Protocol):

Consult with the expert panel to review the initial intervention plan and to further assess areas of dysfunction and impairment for older Veterans with PTSD. Areas identified using this process will further inform protocol development. In this phase, the intervention protocol and finalization of assessment measures will take place, guided by expert panel suggestions. The protocol will be a brief (~10 session) group-based intervention designed to improve psychosocial functioning and quality of life. Components of the group intervention for Veterans with PTSD include likely domains of psychosocial functioning such as anger management, communication skills, social activity, interpersonal relationships, stress management and behavioral activation. Typical cognitive-behavioral interventions for improving anger management skills include psychoeducation about anger and the anger response, differences between aggressive, assertive, and passive behaviors, presenting the rationale for and demonstration of how to monitor anger levels, and relaxation skills training. Communication skills training often involves education about verbal and non-verbal communication, active listening, and use of "I" statements. Regarding interpersonal relationships, techniques for improving communication strategies, with loved ones in particular, may be included, as well as didactic information about the importance of social support and increasing engagement in social activities. Some interventions have successfully included sessions in which facilitators encourage and assist group members in problem-solving barriers to engaging in social activities.[26] In the stress management module, areas such as sleep hygiene, relaxation, exercise, and dietary changes will be included. The behavioral activation module will include information about increasing

motivation for behavior change, goal-setting, and strategies for engaging in activities and decreasing depression. The VA Office of Patient Centered Care and Cultural Transformation has developed "Components of Proactive Health and Well-being" to illustrate how each area of self-care is connected. Materials from these approaches will be modified for use in the current study. The use of psychosocial self-report assessment measures will be supplemented with ratings indicative of psychosocial functioning, such as use of anger management strategies, monitoring of communication and relaxation techniques used, weekly social activity ratings, and time spent with friends and relatives.

Procedure: Using the areas identified by the expert panel, the initial group intervention modules will be modified. Educational materials to be included in the intervention will be developed (using existing manualized components as a starting point). A facilitator manual will likely be developed, as well as handouts for participants to be given at each session and between-session assignments.

Phase IB (Development and Facilitation of Focus Groups):
The research team will finalize the focus group guide (see attached), review recruitment strategies, and design the focus group sessions. Focus groups allow the researcher to understand the focal concept(s) from the perspective of the population being studied.[66] The PI will conduct two focus groups with older Veterans with PTSD to obtain feedback on the group intervention developed. Specifically, Veterans will provide feedback on each proposed module, for their thoughts about the content of the modules, and for their opinion about the most effective mode of delivering the material. Information learned from focus groups will be used, along with feedback from the expert panel, to inform revision of the intervention protocol.

Procedure: Two focus groups will be held at VA Boston Healthcare System and facilitated by the PI and a trained research technician. Six to 10 Veterans will be recruited for each focus group. Veterans recruited by flyer or word of mouth will call and express interest in the study and receive a return call. All potential focus group participants will be administered the Primary Care PTSD Screen for DSM-5 (PC-PTSD-5)[67] over the telephone. **Note: this is a change from the original protocol, which indicated that potential participants would be administered the PTSD module of the Structured Clinical Interview for DSM Disorders (SCID)[68]. This change was made because it was determined that a PTSD screen would be sufficient for focus group participants, and to reduce participant burden. In addition, the PC-PTSD-5 has demonstrated excellent diagnostic accuracy and compares with a structured diagnostic interview[67].** Veterans who meet eligibility criteria will be invited to participate in a focus group. Focus group participants will receive a $75 compensation for time and travel (i.e., up to two hours in a focus group and completing assessment measures plus travel to and from the VA Boston facility). Focus groups are expected to last approximately 1.5 to 2 hours, including informed consent. Veterans will be consented as a group, with the option of being consented on an individual basis if requested (we will have another room an RA could take the individual Veteran for consent). Veterans will be given the opportunity to ask questions before signing the consent form. During the focus group visit, participants will complete self-report measures of demographics, PTSD symptomatology (the Posttraumatic Stress Disorder Checklist-5)[69], and psychosocial functioning (the Inventory of Psychosocial Functioning)[70] (see attached measures).The facilitators will begin by assuring Veterans that their participation is confidential and that their names will not be used in any subsequent scientific presentations or publications. Participants will be asked not to use their names to protect the anonymity of their responses. Focus groups will be audio-recorded to facilitate data analysis and interpretation. Potential participants will be informed of the intent to audio-record the focus groups when they are contacted for the telephone screening. Potential participants who do not agree to be audio-recorded will be excluded from the study. Once the focus groups have been conducted, each participant will be contacted by telephone to ask if they have any additional comments that they did not feel comfortable sharing with the group.

Data Analysis Plan: Several different approaches can be taken to analyze focus group data, and the choice depends on the goals of the analysis.[71] While some researchers develop a transcript of focus groups and use a popular qualitative data analysis package, such as QSR International's NVivo 10 program[72], simple coding of transcripts is an economical alternative for a smaller study such as this one.[73] Therefore, we will apply a general inductive approach[74] that involves developing a transcript of each focus group and coding themes identified in this transcript. For the purposes of this study, the themes are content areas covered within the proposed intervention modules. Two individuals, one of whom was physically present during the focus groups and another research assistant, will listen to the recordings and review the transcripts of each focus group and identify themes. Separate coders (research assistants) trained by the PI will be provided with these themes and their definitions and will be told that they may or may not have been discussed during the focus group. Coders will listen to the recordings once and review the transcripts twice. First, they will simply listen to the recording and read the transcript to become familiar with the flow of the conversation and the topics that were raised. On the second review of the transcript, coders will mark up the transcript each time they see an identified theme, thus documenting where it was discussed. Coders will also be instructed to mark up the transcript if they identify additional themes not included among the previously identified list. Next, the coders will meet to discuss their review of the recordings and transcripts. To the extent that coders are in agreement on examples of identified themes, quotes relevant to each of the key constructs will be compiled. Disagreements regarding which themes quotes fit into will be resolved through discussion between the coders. In the event that an agreement cannot be reached, the PI will meet with the coders to assist in resolution. As recommended by focus group experts[68], newly nominated themes and ongoing refinements of conceptualizations of key themes will be incorporated in the subsequent focus group. The information in the final compilations will be used to inform the revision of the intervention protocol. Once coding of focus group transcripts has been completed, we will be able to address our research questions. After the transcripts are marked up by the coders, each sentence identified will be sorted by the theme it represents. Information gleaned from review of these materials will be used to a) assist us in determining what existing content will be most important to include and emphasize in intervention modules; b) identify additional content to address in intervention modules; and c) provide examples within the modules to increase face validity of the intervention. Finally, we will identify any areas of difference between themes identified by the Veterans compared to those identified by the expert panel that were included in the proposed intervention protocol.

Phase II (Conduct Pilot Groups, Revise Protocol):

Activity 1: Conduct two pilot intervention groups for older Veterans with PTSD. These groups will be used to pilot all study procedures and measures, and to identify any changes needed. Additionally, the pilot groups will be used to collect feasibility and pilot data prior to Phase III. This phase will also provide information about how best to minimize drop out; strategies deemed to be useful will be implemented in Phase III.

Activity 2: Revise Veteran intervention protocol as indicated by pilot data, as well as by group member and facilitator feedback.

Recruitment and Participant Characteristics:

- Veteran participants will be recruited from: a) flyers posted at each VA Boston Healthcare System campus, b) flyers and information given to clinicians within the PTSD clinics and the Geriatric Mental Health Clinic, c) contacting Veterans in the PTSD clinic whom have stated an interest in research, and d) a volunteer roster of Veterans who have previously sought services through the National Center for PTSD and the PTSD clinic and agreed to participate in future studies.
- Approximately 10 participants will be recruited (target group membership is 8 participants) per group.

Inclusion/Exclusion Criteria: See human subjects document.

Procedure: Veterans recruited by flyer or word of mouth will call to express interest in the study and receive a return call. Veterans obtained via the PTSD clinic (who have indicated interest in research) will be called. Research staff will also mail recruitment letters to Veterans who have received care in the VA Boston Healthcare System or have an appointment scheduled in relevant clinics (e.g. Behavioral Medicine, Audiology, Pain, Physical Therapy) as indicated in the electronic medical records system, and have been identified as over age 60. Veterans recruited from the roster will receive a letter describing the study and a postcard that can be returned if participants do not wish to be contacted or if they are interested in learning more about the study. Those Veterans who indicate interest or who do not return the postcard may be called and screened to see if they are eligible to participate. A HIPAA waiver has been submitted to collect PHI (month/year of birth, name, and last 4 of SSN will be asked during the screening call) prior to completion of ICF and HIPAA. If potential Veteran participants are interested in the study and meet preliminary eligibility criteria during the screening call, they will be invited to attend an in-person appointment with the PI or a trained research staff member. Research staff will access CPRS to identify exclusionary criteria, such as current treatment for PTSD, diagnosis of a psychotic disorder or currently experiencing psychotic symptoms, being hospitalized for suicidal ideation or psychosis within the past year, or having a diagnosis of dementia or other severe cognitive disorder. At the baseline appointment, Veterans will be administered the PTSD questions from the SCID along with additional assessment measures. The PI will review all assessment materials and make a determination of eligibility. Veterans who are eligible to participate in the pilot intervention groups will be contacted by telephone to schedule appointments.

Two pilot intervention groups with Veterans will be conducted during this phase. Groups will be audio-recorded. The PI will train and work with a psychology trainee or research staff to facilitate groups in this study phase. The PI will train all group facilitators via mini-workshops prior to conducting groups in which all intervention materials will be reviewed and discussed. Several assessment measures will be completed at the start of each session (see Assessment section). At the end of each session, Veterans will complete satisfaction ratings and provide feedback. Group facilitators will also provide ratings and feedback at the end of each session.

The intervention developed as part of this project is conceptualized as being the first stage in a stepped care approach. As such, Veterans will be recruited from the PTSD and Geriatric Mental Health Clinics if they are: new patients, established patients who have declined or dropped out of more structured trauma-focused therapy, have partial PTSD, or if they are deemed inappropriate for trauma-focused therapy due to health impairments. Following post-group assessments, if any participants are still reporting significant symptoms and distress and indicate interest, they may be referred to other groups within one of the VA clinics or to trauma-focused EBPs such as Prolonged Exposure or Cognitive Processing Therapy or other EBPs (e.g., CBT for Insomnia). Veterans will be provided with descriptions of a variety of evidence-based treatment options, and will be given referrals as appropriate. Veterans' attitudes about mental health treatment and readiness to change will be examined before and after group participation.

Groups will be conducted during regular business hours. Dr. Pless Kaiser (the PI) is a licensed clinical psychologist, and will be available during screening calls, baseline and follow-up assessments, and during group sessions in case of a clinical emergency. If needed, the PI will be contacted to conduct a risk assessment with a patient, and if it is determined that immediate care is needed, will walk the participant down to urgent care. The PI will also have referral information and important resources (e.g., the Veteran's crisis line, suicide prevention coordinator numbers) available. In the event that the PI is not available to provide clinical coverage, another licensed provider will be asked to provide coverage.

For each group session attended we will provide compensation ($10) for travel expenses, as is consistent with attendance at clinical appointments for service-connected conditions through VA.

Starting with the second pilot group, a booster or follow-up session will be scheduled for 1 to 3 months following the end of the 9-session group. The purpose of this session is to check-in with

group members, discuss treatment gains and current symptoms, and to provide referrals and resources as appropriate. Veterans will also receive $10 for attending this session.
Research Questions:

- Is the intervention feasible as conducted with older Veterans with PTSD?
- Are Veterans satisfied with the intervention?
- Do Veterans comply with assignments (e.g., monitoring forms)?

Data Analysis Plan: Baseline demographics (e.g., age, race, service era) will be summarized. To evaluate feasibility, we will descriptively examine recruitment and retention characteristics, such as ease of recruitment, number of sessions attended by participants, and study attrition. Secondly, we will examine compliance and satisfaction measures, such as participant and clinician ratings and participant feedback to gain a better understanding of the effectiveness of the groups in facilitating change and teaching group members about included concepts. Participant commitment will be evaluated by monitoring session attendance, compliance with assignments, and level of participation in group sessions. Participants' open-ended comments provided at the end of each session will be coded and categorized into themes, which will then be used to inform changes to the protocol as appropriate.

Phase III (Conduct Groups to Compare Intervention against Support Group):

Activity 1: The PI will provide training to group facilitators, compare the revised intervention protocol for older Veterans with PTSD against a support group control, and conduct three groups with the revised intervention protocol and three support groups, both among older Veterans with PTSD. Outcomes will be compared between intervention and support groups.

Activity 2: After the groups are completed, the group intervention protocol will be revised according to group member and facilitator feedback. The expert panel and mentors will be consulted prior to final revision of the protocol.

Activity 3: Following data analysis, a manuscript detailing the results of the study will be prepared. In addition, final revisions will be made to the intervention protocol according to group member and facilitator feedback, expert panel suggestions, as well as lessons learned in this phase of the study. To evaluate the utility of the intervention in preparing Veterans for trauma-focused therapy, utilization of mental health treatment will be assessed at the six month follow-up.

Finally, data collected as part of this study will be used as pilot data (including effect size estimates for power calculations) in the development of a possible VA Merit award submission to conduct a RCT of the group intervention.

Recruitment and Participant Characteristics:

- For both the intervention and support groups, recruitment of Veteran participants will be conducted in the manner used in Phase II.
- For all groups, approximately 14 participants will be recruited (target group membership is 10 participants per group).

Inclusion/Exclusion Criteria: For both the intervention and support groups, inclusion/exclusion criteria for Veteran participants will be the same as used in Phase II of this study. In addition, participants of Phase II will be excluded from participation in Phase III.

Procedure: This procedure will be the same as followed in Phase II. Those Veterans who are eligible to participate will be randomized in groups of 3 (block randomization) to participate in either an intervention group or a support group. Three intervention groups and support groups will be conducted during this phase. All groups will be conducted by doctoral level psychologists or psychology trainees or research staff who the PI will have trained. Given that this is a small study, there is a limited number of available group facilitators, and therapeutic allegiance effects are not expected, group facilitators will conduct either intervention groups or support groups. All groups will be audio recorded. Several assessment measures will be completed at the start of each session. At the end of each session, Veterans will complete satisfaction ratings and provide feedback. Veterans in both conditions (intervention and control) will be given between-session assignments that will be collected. Fidelity to the intervention and support group protocols will be monitored by a doctoral

level psychologist who is not part of the study team and is familiar with cognitive-behavioral interventions for PTSD. Each group session will be digitally recorded, and the monitor will listen to a randomly selected sample (20% of the sessions) and complete a fidelity monitoring form. Group facilitators will also provide ratings and feedback at the end of each session. Following the last session, Veteran participants will be asked to complete post-group assessment measures. Veterans will be asked to complete follow-up assessments at one month and six months, either via postal mail or in person.

Consistent with the recruitment method followed in Phase II, Veteran participants for both the intervention and support groups will be recruited from the PTSD and Geriatric Mental Health Clinics if they are new patients, if they are established patients but have declined or dropped out of more structured trauma-focused EBPs, if they have partial PTSD, or if they are deemed inappropriate for trauma-focused therapy due to health impairments or other reasons. The same procedure will be followed as in Phase II after the six month follow-up. Specifically, Veterans will be presented with descriptions of a variety of evidence-based treatments, including trauma-focused EBPs, and provided with referrals should they request them. Attitudes toward treatment and readiness for change will also be assessed. In addition, the VA electronic medical records will be reviewed to document enrollment and completion of mental health treatment at the six month follow-up.

Groups will be conducted during regular business hours. Dr. Pless Kaiser (the PI) is a licensed clinical psychologist, and will be available during screening calls, baseline and follow-up assessments, and during group sessions in case of a clinical emergency. If needed, the PI will be contacted to conduct a risk assessment with a patient, and if it is determined that immediate care is needed, will walk the participant down to urgent care. The PI will also have referral information and important resources (e.g., the Veteran's crisis line, suicide prevention coordinator numbers) available. In the event that the PI is not available to provide clinical coverage, another licensed provider will be asked to provide coverage.

For each group session attended we will provide compensation ($10) for travel, a practice that is consistent with VA policy to reimburse for travel expenses for VA appointments for service-connected conditions.

After the final session, a booster or follow-up session will be scheduled for 1 to 3 months following the end of the 9-session group. The purpose of this session is to check-in with group members, discuss treatment gains and current symptoms, and to provide referrals and resources as appropriate. Veterans will also receive $10 for attending this session.

Procedures implemented during the Coronavirus Pandemic

In light of the current COVID-19 pandemic, we will be transitioning all study-related in-person procedures to a virtual telehealth format, as follows:

Procedure

Recruitment

Veteran recruitment will remain the same as described above in Phase III for in-person groups.

Obtaining Consent & Baseline Appointments

Veterans who indicate interest in the study will receive a screening call from a study staff member. A revised HIPAA waiver has been submitted to allow the collection of PHI (month/year of birth, name, email, and last 4 of SSN) during the screening call, prior to completion of the combined ICF/HIPAA. This is different from the previously approved HIPAA waiver, as we are collecting each Veteran's email address in order to send them the link to the video appointments, as well as replacement study materials as needed (please see page 18). If potential Veteran participants are interested in the study and meet preliminary eligibility criteria during the screening call, they will be sent an envelope

in the mail with a cover letter, the ICF/HIPAA document, and all baseline measures except the SCID. A pre-addressed, stamped envelope will be included to facilitate return of all documents to study staff. It will be emphasized over the phone during the screening call that participants should not begin the baseline measures until they have completed the informed consent documents with study staff.

A telehealth appointment (using a platform such as VVC or Webex or telephone) will be scheduled with the Veteran to review the consent forms and surveys. Veterans will be given the opportunity to ask questions about study participation during the informed consent process. Participants will be reminded to put the signed consent documents and surveys in the pre-addressed, stamped envelope to be mailed back to study staff. At the end of the informed consent review call, a second appointment will be scheduled with the participant to complete the PTSD interview questions from the SCID. Participants will be reminded that the next appointment cannot be completed until the consent forms and survey documents have been received. If a session has been scheduled but the documents have not been received, the session will be rescheduled. The PI or a trained study staff member will conduct the PTSD interview questions from the SCID via telehealth (video or telephone). Participants will be given the opportunity to ask any questions they have before and after the completion of the SCID questions.

Once the SCID is completed and all forms are reviewed by the study team, the participant will be informed if they are eligible to participate in the group sessions, and if so, will be added to the list for randomization to study condition. Veterans will be compensated $20 after completion of the SCID appointment.

Group Sessions

Groups will be conducted using a telehealth platform that has options for video and telephone-only participation (such as WebEx). Participants will be sent email invitations that contain links to join the sessions. Video sessions will start 10 minutes prior to the session start time, to provide participants enough time to work through any technological issues with study staff prior to the start of the sessions. Study participants will be asked to provide verbal consent to participating in the virtual telehealth sessions at the start of the first session, after being informed about the limits of confidentiality and important safety issues. The participants will be reminded of these issues at the beginning of the remaining sessions, but will not be verbally re-consented each week. Additionally, participants will be reminded that the session is being audio-recorded. The study PI, a licensed psychologist, or another licensed clinician will be available by phone following the sessions in case any of the participants indicate experiencing distress. Veterans will receive $10 per session that they attend. Payments will be mailed via check through the agent cashier at two timepoints: after session 4, and after session 9.

Prior to the start of group sessions, participants will be sent a package of all assessments to be completed in sessions, along with a pre-addressed, stamped envelope. Assessment measures will be clearly labeled with Veteran ID, session #, and whether the measure is to be completed at the start or at the end of the group session. During each session, group leaders will facilitate the completion of measures at the start and the end of each group session, and participants will be asked to indicate when they have finished measures and placed them in the included envelope to be returned at the end of the 9 weeks. Study staff will send replacement assessment measures as needed, through postal mail or e-mail.

Post-Assessment and Follow-Ups

Following the last session, Veteran participants will be asked to complete post-group assessment measures (which will be mailed to them). The follow-up booster session will also be conducted over a telehealth platform. Veterans will be asked to complete follow-up assessments at approximately

one month and six months via postal mail. Appropriate clinical referrals will be provided following the end of study participation.

Technical Assistance

Study staff may provide some technical assistance via telephone to participants at different points during their involvement in the study. Veterans who meet all telephone screening criteria other than "Has access to a home computer or device that will allow telehealth delivery of the intervention utilizing secure audio/video platforms (e.g. VVC, Webex) may receive assistance in connecting to secure platforms in order to determine if the home devices are sufficient to meet this criteria. Study staff may assist participants in connecting to complete the Informed Consent and baseline appointment process. Study staff may also assist participants prior to and following randomization to ensure that they are able to access the remote systems and utilize devices to participate in the group interventions. This assistance may include provision of telephone numbers and websites for VA technical support, methods to request VA-provided tablets, and trial sessions to work through potential issues (such as where to place cameras, how to maximize audio clarity, how to ensure privacy for the session, etc.).

Use of Email

Study staff may use e-mail to send remote access instructions or previously approved group handouts or measures to participants as needed (e.g. if postal mailing is delayed or participants ask for additional copies). Standard VA-approved language indicating that Veterans should not reply to these e-mails will be included in each e-mail.

Research Questions:

- Compared to support group participants, do intervention group participants experience greater increases in psychosocial functioning and quality of life and reductions in PTSD and depressive symptoms?
- Are pre-post changes maintained at 1 and 6 month follow-up?

Data Analysis Plan: Baseline demographics (e.g., age, race, service era) will be summarized for each condition (intervention and support groups). Descriptive statistics will be presented for all outcome variables. Prior to analyzing the data, the adequacy of randomization will be checked and any factors that are unbalanced between groups will be controlled for in group comparisons. Data will be analyzed using SPSS and Mplus. Change in primary outcomes (psychosocial functioning and quality of life) will be evaluated from pre- to post-intervention and at 1 and 6 month follow-ups. We will also evaluate change in secondary outcomes (e.g., PTSD and depressive symptoms). Hierarchical linear modeling (HLM)[72] may be used to evaluate changes in these measures over time. HLM is an optimal strategy for analyzing change over time, with strengths such as handling missing data efficiently, providing powerful and accurate estimation procedures, and modeling flexibility. We will account for missing data by using full information maximum likelihood estimation. Intent-to-treat analyses will be conducted, and completers will be compared against drop-outs to determine any group differences. For our primary and secondary outcomes, we will specify a random intercepts and random slopes model in which Time, Condition, and the Condition x Time interactions will be included as predictors. Time will be coded by assessment time point (baseline, post-group, follow-ups) and modelled as a random effect to allow for individual differences in trajectories of change. We will examine between group effect sizes (e.g., Hedges g[73]) for the intervention compared to the support group at post-group and follow-up assessments. Additionally, we will look at the portion of each group (intervention versus comparison) who experienced reliable change on primary outcomes. Given the developmental nature of this study, results may be used to provide preliminary data for a subsequent trial.

Assessments and Participant Compensation:

Focus group participants will be contacted by telephone after they have participated in order to collect individualized feedback and additional comments. Veterans who participate in the focus groups will be compensated $75 for their time and participation.

All Veterans who participate in Phase II and Phase III (intervention group pilot testing and comparison of group intervention with support group) will complete a structured diagnostic interview, baseline assessments, satisfaction ratings of each session, and post-group assessments. Phase III participants will complete one and six month follow-up assessments. Participants will be remunerated for their time and inconvenience. Baseline assessments (including the SCID questions) are estimated to take about 90 minutes and participants will be compensated $20 for completion. Post-group and follow-up assessments are estimated to take 1 hour and participants will be compensated $35 for each assessment they complete (Phase III participants will receive $40 for completion of the six month follow-up). Additionally, all participants in Phases II and III will be remunerated $10 to cover travel expenses for each group session they attend. Thus, Veterans who participate in Phase II could receive up to $155 total and Veterans who participate in Phase III could receive up to $230 total.

In case of a lapse between the time of baseline and the start date of the cohort, we may decide to reassess the participant and recomplete the baseline appointments. If the Veteran has a SCID lifetime rating, the SCID does not have to be recompleted; otherwise, both the SCID and the measures will be re-administered. In the event that this is the case, we will pay participants $20 for their recompletion of the baseline.

Measures *(see Table 2)*

Note: This proposal is being written after publication of DSM-5 but prior to the release of appropriately updated assessment measures. Revised versions of all assessment measures that are available at the time the study is conducted will be used.

Phase IA: This is the protocol development phase. No participants will be enrolled or assessment measures collected during this phase.

Phase IB: Prior to being invited to participate in the focus groups for Veterans, potential participants will be screened over the telephone with the PC-PTSD-5.

All focus group participants will be contacted by telephone after attending the focus groups and asked several open-ended questions to gather feedback and allow participants a chance to share comments they may not have felt comfortable disclosing during the focus groups themselves.

Phases II and III: Prior to being invited to participate in intervention and control groups, Veterans will attend an in-person appointment at VABHS. During this appointment, they will be administered the PTSD module from the SCID[67] and several additional measures.

Table 1. Timeline of Study Activities

	Year 1				Year 2				Year 3				Year 4				Year 5			
Activities by Quarters	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Phase IA (Develop Protocol)																				
1. Consult with expert panel	*x*																			
2. Develop intervention protocol	*x*	*x*																		
3. Consult with mentors and with expert panel	*x*	*x*																		
4. Finalize intervention protocol			x																	
Phase IB (Focus Groups)																				
5. Consult with expert panel				x																
6. Develop focus group guide				x																
7. Recruit and screen participants for focus groups					x															
8. Conduct focus groups						x	x													
9. Analyze focus group data							x	x												
Phase II (Pilot Intervention Protocol)																				
10. Recruit and screen participants for intervention groups								x	x											
11. Conduct intervention groups									x	x	x									
12. Consult with mentors and expert panel; revise protocol												x	x							
13. Analyze pilot data												x	x							
Phase III (Compare Intervention & Support Groups)																				
14. Recruit/screen participants for groups												x	x							
15. Conduct intervention and support groups												*x*	x	x	x					
16. Conduct follow-up assessments														x	x	x	x			
17. Consult with mentors and expert panel; revise protocols															x	x				
18. Data analysis															x	x	x			

Additional Measures to be Completed by Veterans at Baseline and Post-Group (Phases II and III), and at Follow-Up Assessments (Phase III):

The Veterans Rand 12-item Health Survey (VR-12).[76] The VR-12 is a 12-item scale that assesses the effects of physical and mental health on well-being, and is often used to assess quality of life. Item scores are used to compute two broad component scores: the physical component score (PCS) and the mental component score (MCS). The component scores are standardized T-Scores (M = 50, SD = 10) and the population standard for this measure was recently updated.[77]

The Quality of Life Inventory (QOLI).[78] The QOLI is a 32 item self-report measure that assesses life satisfaction across 16 life domains (e.g., health, work, recreation). For each domain, the respondent rates how important the domain is on a 0-2 scale and how satisfied he or she is in this area of life on a 7-point scale. Satisfaction scores on the measure are weighted based on the respondent's rating of the importance of the life domain in order to achieve a total score. The measure was validated across a number of samples, including psychiatric inpatient and outpatient VA samples. Test-retest reliability was excellent over a one-month interval (r = .91) as was the internal consistency of the measure (alphas ranged from .86-.89). The measure also demonstrated convergent and discriminant validity with other measures of life satisfaction.

The Inventory of Psychosocial Functioning (IPF).[79] The IPF is an 80-item self-report measure designed to assess multiple domains of functional impairment experienced by Veterans. Respondents rate how often they have acted a certain way over the past 30 days. Items are rated on a 7-point scale ranging from 0 ("never") to 6 ("always"). The IPF yields a total score and scores for seven subscales: romantic relationships, family, work, friendships and socializing, parenting, education, and self-care functioning. Respondents have the option to skip sections that do not apply to them. The IPF has excellent internal consistency reliability (overall alpha = .93) and the scale correlates with other self-report measures of quality of life and functional impairment, such as the QOLI (r = .59).

Measures to be Completed by Veterans at Each Group Session:

Phase II: Veteran participants will be asked to monitor or rate their use of various strategies at the beginning of each group session. For example, participants will be asked to report on social activities and time spent with friends and family and to rate their use of anger management strategies, coping skills, and relaxation strategies. Several additional behavioral ratings will also be administered. Participants will be asked about the number of nightmares, flashbacks, and hours slept the previous week. They will also be asked about frequency of anger outbursts and will provide a rating of their current distress. As a global process measure, participants will be asked to rate the extent to which they are doing better or worse than the previous session. Additionally, they will be asked to provide satisfaction ratings at the end of each group session. Satisfaction will be rated using several items (e.g., how relevant did today's group feel to you?) with Likert-type response scales (e.g., 1 = *not at all* to 4 = *very*). In addition, Veteran participants will be given the opportunity to provide open-ended comments at the end of each session. Participant treatment engagement will be evaluated by monitoring session attendance, compliance with assignments, and level of participation in group sessions.

Phase III: The measures used in this phase will be the same as used in Phase II, except that the scales used at baseline and post-group will also be administered at follow-up assessments (one and six months).

Limitations to be Addressed in Current Study

As with any study that evaluates a treatment outcome intervention, it is important to anticipate and attempt to minimize problems related to drop-out. For each of the group interventions (pilot, intervention, and support groups), several precautions will be taken to minimize drop-out. Group members will receive a schedule at the start of the group with the dates and times of each group session. Participants will also be given a binder in which to keep all group-related materials. The group schedule will be put in the front of this binder. At the end of each group session, all members will be given an appointment card with the details of the next group session date, time, and location (as well as contact information for group facilitators) on it. Additionally, participants will receive weekly reminder calls from one of the group

facilitators. Finally, all group members will be given the option of receiving a mid-week telephone check-in with one of the group facilitators. Despite these measures, there will inevitably be some drop-out that occurs during the study. When this occurs, group facilitators will contact the Veteran to explore reasons for discontinuing their participation in the study. This information will be used to inform future phases of the study and future work. Full information maximum likelihood estimation techniques will be utilized when analyzing data and intent-to-treat results will be examined to account for the missing data due to drop-out.

Limitations to be Addressed in Future Research

The overall sample size for the current study is fairly small. However, this study will address questions of feasibility and satisfaction with/acceptance of the developed intervention protocol. Additionally, it will provide preliminary comparisons between the intervention protocol and support groups and provide effect size estimates and information about the group size needed for larger studies. The data gathered from this study will serve as pilot data for a larger randomized clinical trial to be conducted in the future.

Another limitation of the current study is that it is focused on older male Veterans with PTSD. Future research may use the intervention protocol developed in the current study to test the effectiveness with other populations (such as with older women Veterans or with younger Veterans with PTSD).

Table 2. Assessment Measures

	Veteran Pilot Groups (Phase II)				Veteran Intervention/Support Groups (Phase III)					
Domain	Screening	Baseline	All Group Sessions	Post-Group	Screening	Baseline	All Group Sessions	Mid-Group	Post-Group	Follow Up Assessments
Screening										
Structured Clinical Interview for DSM Disorders (SCID) – PTSD Questions only	x				x					
Primary Outcome										
The Quality of Life Inventory (QOLI)		x		x		x			x	x
The Inventory of Psychosocial Functioning (IPF)		x		x		x			x	x
Veterans RAND 12-item Health Survey (VR-12)		x		x		x			x	x
Additional Outcome										
Depression, Anxiety, Stress Scales (DASS-21)		x		x		x			x	x
Sense of Mastery		x		x		x			x	x
Posttraumatic Stress Disorder Checklist (PCL)		x		x		x			x	x
Beck Depression Inventory (BDI-II)		x		x		x			x	X
Other										
Endorsed and Anticipated Stigma Inventory (EASI)		x		x		x			x	x
University of Rhode Island Change Assessment Scale (URICA)		x		x		x			x	x
Satisfaction ratings			x				x			
Activity/Skills use monitoring forms			x				x			
Behavioral PTSD ratings			x			x			x	x

k. **Human Studies Section**

(1) **Risk to subjects**

(a) Human subjects involvement and characteristics. All participants included in the current study will be male Veterans. *Focus groups with Veterans*: Veterans who already receive care through VA Boston Healthcare System will be recruited as participants for this part of the study. Veterans from the community may also be recruited for this study. Two focus groups with Veterans will be held, each with up to 10 Veterans. Approximately 20 Veterans will be recruited to participate in these focus groups. Veteran participants will be recruited from a) flyers posted at each VA Boston Healthcare System location, b) flyers and information given to clinicians within the PTSD clinics, the Geriatric Mental Health Clinic, and medical clinics, and c) word of mouth from other participating Veterans. Inclusion criteria: Veterans need to be male and at least 60 years old to be eligible to participate in the focus groups. Potential participants will be assessed with the PC-PTSD-5 prior to being invited to participate. Inclusion criteria include endorsement of a military-related criterion A event and a score of at least 3 on the PC-PTSD-5. Exclusion criteria: Veterans who are diagnosed with a psychotic disorder or have psychotic symptoms, have been hospitalization for suicidal ideation or psychosis within the past year, or have a diagnosis of dementia or other severe cognitive disorder. Women will be excluded from participation, since this study focuses on older male Veterans. Potential participants will also be excluded if they do not agree to be audio recorded.

Pilot intervention groups for Veterans: Veterans who already receive care through VA Boston Healthcare System, *as well as Veterans from the community may* be recruited as participants for this part of the study. *Two pilot intervention groups of up to 10 Veterans each will be conducted during this phase.* Approximately 28 participants will be recruited for these groups. Veteran participants will be recruited from a) flyers posted at each VA Boston Healthcare System location, b) flyers and information given to clinicians within the PTSD clinics, the Geriatric Mental Health Clinic, and medical clinics, c) contacting Veterans from the PTSD clinic who have expressed an interest in research, d) word of mouth from other participating Veterans, and e) a roster of Veterans who have sought services through the VA National Center for PTSD and have indicated consent to be contacted for other research studies. Inclusion criteria: Veterans need to be at least 60 years old to be eligible to participate in the study. Potential participants will be assessed with the PTSD questions from the SCID prior to being invited to participate. Inclusion criteria include endorsement of a military-related criterion A event, at least one intrusion symptom (cluster B), one symptom of avoidance (cluster C), one symptom related to negative alterations in cognition or mood (cluster D), one symptom related to alterations in arousal or reactivity (cluster E), and report of impairment in functioning (cluster G; DSM-5). Exclusion criteria: Veterans who are in current treatment for PTSD, are diagnosed with a psychotic disorder or have psychotic symptoms, have been hospitalized for suicidal ideation or psychosis within the past year, or have a diagnosis of dementia or other severe cognitive disorder. Veterans will be asked not to join therapy groups or other interventions for the duration of their participation in the study. Potential participants will also be excluded if they do not agree to be audio recorded.

Comparison condition - Intervention and support groups for Veterans: Veterans who already receive care through VA Boston Healthcare System*, as well as community-based Veterans who do not use the VA, may* be recruited as participants for this part of

the study. Three intervention groups of up to 14 Veterans each, as well as three comparison support groups will be conducted during this phase. Approximately 84 participants will be recruited for these groups. Veteran participants will be recruited from a) flyers posted at each VA Boston Healthcare System location, b) flyers and information given to clinicians within the PTSD clinics, the Geriatric Mental Health Clinic, and medical clinics, c) contacting Veterans seen in the PTSD clinic who indicated interest in research d) word of mouth from other participating Veterans, and e) a roster of Veterans who have sought services through the VA National Center for PTSD and have indicated consent to be contacted for other research studies. Inclusion criteria: Veterans need to be at least 60 years old to be eligible to participate in the study. For both intervention and support groups, participants (who will be assessed with the PTSD questions from the SCID prior to being invited to participate), must endorse a military-related criterion A event, at least one intrusion symptom (cluster B), one symptom of avoidance (cluster C), one symptom related to negative alterations in cognition or mood (cluster D), one symptom related to alterations in arousal or reactivity (cluster E), and report of impairment in functioning (cluster G; DSM-5). Exclusion criteria: Veterans who are in current treatment for PTSD, are diagnosed with a psychotic disorder or have psychotic symptoms, have been hospitalization for suicidal ideation or psychosis within the past year, or have a diagnosis of dementia or other severe cognitive disorder. Veterans will be asked not to join therapy groups or other interventions for the duration of their participation in the study. Potential participants will also be excluded if they do not agree to be audio recorded. In addition, Veterans who participated in the pilot phase of the study will be excluded from participating in the comparison condition phase.

(b) Sources of materials.
Focus group participants will provide data in the form of audio recordings that will be transcribed, demographic information, and responses to survey measures. Veterans participating in the pilot intervention groups and the comparison condition (intervention and support groups) will provide data in the form of self-report assessment measures collected during and after group participation. Veteran participants will be recruited using data from a roster of Veterans who have sought treatment through the VA National Center for PTSD or PTSD clinic. This roster is an electronic database maintained by the VA National Center for PTSD – Behavioral Science Division. Participant entry into the database is done on a voluntary basis and written consent for future contact has already been established.

(c) Potential risks. The potential psychological, physical, social or other risks to Veterans who participate in the proposed study are minimal. Veteran focus group participants will be discussing domains of psychosocial functioning that they view to be problematic for themselves or for other Veterans. Additionally, Veterans who participate in the intervention groups will be asked to complete psychological and psychosocial assessment measures and discuss areas of difficulty for them. There is a slight chance that Veterans discussing these issues may experience some psychological discomfort when reflecting on such experiences. Dr. Pless Kaiser (the PI), as a trained clinical psychologist, will be able to provide thorough assessment in the event of a participant's adverse reaction to focus group participation. In addition to Dr. Pless Kaiser, another licensed clinical psychologist will be available during each of the focus groups. If a Veteran becomes distressed and it is clinically appropriate, the Veteran will be allowed to leave the group and speak with the available psychologist. If clinically appropriate, the Veteran will participate for the remainder of the focus group and Dr. Pless Kaiser will speak with him individually as the group is over to assess distress and any other clinical

needs. Appropriate intervention and/or referral for treatment can be provided, if needed. No other known physical, social or legal risk associated with participation in the proposed research project is identified.

(2) **Adequacy of Protection from Risks**

(a) Recruitment and informed consent.
Issues related to recruitment and obtaining informed consent are relevant to the proposed study. For recruitment details, see the above section. For the focus groups, informed consent will be obtained by Dr. Pless Kaiser or a trained research technician prior to the start of the focus group. For Veterans who participate in an intervention or support group, informed consent will be obtained by Dr. Pless Kaiser, a psychology trainee, or trained research technician at the assessment session held prior to the start of the groups. Informed consent will be obtained from all study participants prior to participation, according to the guidelines established by the Institutional Review Board (IRB) at VA Boston Healthcare System. Following the completion of the informed consent form, the consent form will be given to the research technician for photocopying for the participant copy. All participants who decline the study or do not meet study criteria will be given appropriate feedback and referrals for other treatment as needed (e.g., to one of the psychology clinics at VA Boston Healthcare System).

(b) Protection against risk. The primary risk associated with the proposed study includes psychological distress resulting from increased focus on psychosocial problems during the assessment, focus group, and/or intervention sessions. To address this potential risk, Dr. Pless Kaiser, a trained clinical psychologist, is in a good position to provide further evaluation of a participant's distress. This evaluation may include contact with a participant's current healthcare providers, including mental health professionals, if needed. Dr. Pless Kaiser will also be in a good position to make referrals for further evaluation and/or treatment, and to ensure that such consults are placed on the participant's behalf. Study staff will immediately report any serious adverse events to Dr. Pless Kaiser, and she will, according to standardized procedures, report them to the IRB within the required timeframe. In addition, all participants will be provided with Dr. Pless Kaiser's contact information, and encouraged to establish contact at any time during the study as needed. All other incidents (e.g., theft of loss of data), will be reported in accordance with VA policy. Efforts will be made to protect confidentiality. Focus group members will be asked not to discuss information about other individuals in the group outside of the group setting. Participants will be asked not to state their names when speaking in order to protect confidentiality on the audio recordings of the focus group sessions. Study staff will immediately report any serious adverse events to the PI. The PI will, according to standardized procedures, report them to the IRB within the required timeframe. The confidentiality of the data that is gathered from participants (audio recorded group sessions, telephone screen data, survey measures) will be protected through secure storage of such media in a locked cabinet in Dr. Pless Kaiser's office that is kept locked when unattended. Data will be de-identified by removing all individually identifiable (all 18 HIPAA identifiers) prior to data analysis. The PI will provide members of the research team with de-identified datasets as needed. Once research staff are no longer working on the study, they will be removed from the protocol. All information kept electronically, including digital recordings of focus groups, will be kept behind the VA firewall on a secure server in a restricted access computer file. Records will be destroyed in accordance with the VA Record retention schedule (www1.va.gov/VHAPUBLICATIONS/RCS10/rcs10-1.pdf). Records will be destroyed,

when applicable, in a manner in which they cannot be retrieved. Additionally, all information will be de-identified for the purposes of analysis and dissemination of findings.

(3) **Potential benefits to subjects and others**

The proposed study is consistent with the overall mission of the VA, which assures that all persons cared for in the VA healthcare system can reliably count on prompt and appropriate treatment of psychological distress. The proposed study seeks to develop, implement, and evaluate a psychosocial intervention for older Veterans with PTSD. The efficacy of the intervention developed will be compared to support group controls. The intervention has the potential to reduce problems related to psychosocial functioning and PTSD, and to improve quality of life for older Veterans with PTSD symptoms. This intervention will address the missions of the VA and the VA National Center for PTSD and directly address the care of older participants with PTSD symptoms, a high priority problem within the VA.

In addition, this study will provide valuable research data on interventions that are effective with older Veterans with PTSD, an understudied population. Aging in the context of PTSD is a high priority research area within the VA National Center for PTSD. The data collected during the course of this study will help to inform the future development and refinement of the intervention protocol to help improve psychosocial functioning and quality of life among older Veterans with PTSD symptoms. Thus, there is substantial potential for the proposed study to benefit Veterans who participate in the current study as well as to indirectly help others who experience psychosocial problems related to PTSD.

(4) **Importance of knowledge to be gained**

Given the aging of our Nation's Veterans, it is important to develop and provide interventions that will help those with partial and full PTSD manage their symptoms and improve their lives. One area that is affected by PTSD symptoms and will be targeted by the intervention developed in the proposed study is psychosocial functioning. There are several evidence-based trauma-focused interventions for PTSD, such as Prolonged Exposure and Cognitive Processing Therapy. There is some evidence to suggest that these interventions are helpful for older Veterans. However, not all Veterans engage in or are offered these types of interventions (for various reasons), and among those who do, some do not improve and others drop out. Thus, additional types of interventions designed to reduce symptoms and enhance quality of life and functioning are needed for this population. The intervention to be developed may be able to serve as a pre-treatment intervention, increasing readiness for change and attitudes toward treatment among older Veterans. The focus groups conducted as part of this study, in concert with recommendations from the expert panel, will guide the revision of the development intervention. Thus, this study will produce an intervention informed by the perspectives of Veterans with PTSD, will be used in future phases of the study to test the effectiveness of the intervention.

(5) **Resources**

(a) **Research Space**:

(1) The VA National Center for PTSD (NCPTSD) is a VA Center of Excellence for research and education on the prevention, understanding, and treatment of PTSD. The proposed research will take place in the Behavioral Science Division (BSD) of the NCPTSD,

located at the Jamaica Plain campus of the VA Boston Healthcare System (VABHS). The Jamaica Plain campus is conveniently located, with several public transportation alternatives (subway and bus lines) within a few blocks of the medical center. Additionally, parking is free for visitors, and there are shuttles that run from the medical center to other VA medical centers and outpatient clinics. Thus, the site of the proposed study is easily accessible for potential participants. BSD is under the direction of Dr. Terence Keane, Associate Chief of Staff for Research, Executive Director, and is well-staffed by clinical psychologists, post-doctoral fellows, psychology interns, research technicians, and support staff. The Principal Investigator (PI), Dr. Pless Kaiser, has a dedicated office for her ongoing program of research on the 12th floor of the VABHS medical center in BSD. Space will be provided to the PI throughout the duration of the study. The PI's office includes locked file cabinets which will be used to store screening forms, interview data, digital recordings of focus groups, and assessment forms. The Division's office space includes networked computers and printers as well as duplication, fax, scanning, and mailing facilities. Additional space will be made available to house research staff (i.e., the Research Technician) hired for the project. The NCPTSD also has office space and conference rooms that can be reserved and used for conducting focus groups with Veterans.

(c)**Other Research Resources:**

(d) The backbone of the NCPTSD computer operations is a fiber optic local area network for the more than 50 computer workstations in use by staff and support personnel. The LAN operates from a set of primary and secondary servers, running Windows operating systems that provide security, deliver a wide array of applications, and support large-scale file storage and backup. The LAN is directly linked to the cluster of servers that service VABHS, and is linked to the wider network of servers across the VA system. This nationwide VA network connects to a gateway onto the Internet, as well as to a mirrored FTP server that allows secure transfer of large files to/from outside computers. The system also provides secure remote access capabilities through a Virtual Private Network (VPN), which is used by NCPTSD staff to increase productivity and manage responsibilities while away from the worksite. All of the NCTPSD workstations are recent-vintage Windows-based PCs. Each year, the NCPTSD obtains 8-10 new computers with the latest available features and specifications to maintain technological currency. Printing is predominately centralized through six high-speed laser and color printers. Windows-compatible software of various types is available to all staff via the network. Specific examples of the software include MS Office Suite (word processing, spreadsheets, database administration, graphics, and presentations), Adobe Illustrator and Photoshop for digital image manipulation, EndNote for reference and bibliography development, and Adobe Acrobat for PDF file manipulation. Examples of available statistical packages include SPSS, SAS, LISREL, MPlus, EQS, AMOS, and HLM. Staff have access to VA subscriptions to electronic databases for research, including PsycInfo service for literature searches and PsycArticles for full text electronic access to journals published by the American Psychological Association. Both of these resources can be accessed directly from the LAN and remotely via VPN. In addition, through the NCPTSD's affiliation with Boston University School of Medicine, there is electronic and physical access to journal articles, books, databases, and other references. The VA electronic library also provides full text on a wide array of journal articles and interlibrary loan is available.

(n) **Publications/Presentations from Last Funding Period (as applicable).** None.

(o) **Literature Citations (as applicable).**

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