PROTOCOL: #4735-B Pilot Test of a Self-Management Program for Completers of Trauma-Focused Therapy

VERSION DATE: 4/9/2019

Principal Investigator: Shannon Kehle-Forbes, PhD, LP

NCT03225859

2. Specific Aims. Annually, the Veterans Health Administration (VHA) provides care for over 610,000 Veterans with PTSD.[1] Left untreated, PTSD is often chronic and is associated with depression and other comorbidities, functional impairments, poor quality of life, and suicidality.[2-5] Fortunately, the two evidence-based trauma-focused therapies (TFTs), prolonged exposure and cognitive processing therapy, significantly reduce the suffering associated with PTSD for a majority of Veterans.[6-9] In addition to improvements in PTSD symptomology, Veterans who participate in a TFT report improvements in quality of life as well as social and role functioning.[6;10] Given their positive impact on the lives of Veterans, TFTs have been widely disseminated throughout VHA and an estimated 16,000 Veterans completed a TFT in the past year.[11]

Despite their effectiveness, our pilot data suggest that over 90% of Veterans who complete TFTs continue to perceive a need for mental health treatment; Veterans attended only slightly fewer mental health appointments in the six months following TFT completion than in the six months prior to initiation. The VA / Department of Defense (DoD) PTSD Clinical Practice Guidelines recommend that Veterans who demonstrate a full remission of symptoms and improvement in functioning following TFT should discontinue psychotherapy, and those who experience a partial response should decrease the frequency and intensity of care.[12] However, the guidelines do not provide recommendations for how to effectively reduce care such that treatment gains are maintained, and no evidence-based strategies for reducing the intensity of psychotherapy exist. Further, the goals of post-TFT mental health care have not been elucidated and, prior to our pilot data collection, Veterans' perceived needs for this care had not been assessed. In order to better understand Veterans' post-TFT treatment needs, we conducted qualitative interviews with recent TFT completers. Full and partial TFT responders reported that they wanted to continue to engage in mental health services in order to practice and apply skills learned during therapy with the goal of maintaining or building upon treatment gains. Veterans expressed low self-efficacy for being able to meet these goals without the support of their therapists and feared relapse without ongoing mental health services.

These expressed treatment needs are particularly well-suited to a therapist-assisted self-management approach. Self-management protocols emphasize patients' (rather than the providers') roles in managing symptoms and have been shown to increase perceptions of self-efficacy.[13] A secondary benefit of self-management is a reduced dependence on the mental health system and, in turn, increased community engagement.[14] This is consistent with recovery-oriented mental health care which encourages patients to "live beyond their illness" through engaging in meaningful activities and exemplifies RR&D's focus on functional outcomes and societal engagement.[14] The existing literature on self-management interventions for PTSD has demonstrated that such approaches are acceptable, safe, and effective; however, they have exclusively been used as stand-alone treatments or as the first step up in a stepped-care model.[15;16] We propose the first examination of a self-management intervention designed to be used to step down from an intensive course of psychotherapy for PTSD.

The overall objective of this study is to complete stages 1A and 1B of the Stage Model of Treatment Development for a therapist-assisted self-management program for Veterans who have recently completed a course of TFT for PTSD.[17] Specifically, we will achieve the following aims:

1. Refine a self-management treatment protocol through eliciting feedback from experienced TFT providers on a draft of the self-management program.
2. Conduct a pilot open trial to assess the (a) acceptability of the self-management program components, structure, and materials and (b) feasibility of the self-management program (retention and intervention fidelity) and the study approach (screening, recruitment, assessment process).
3. Explore the effects of the program on select outcomes including Veterans' confidence in managing their PTSD (self-efficacy) and the downstream effects of improved self-management on functioning, quality of life, community engagement, and mental health symptoms.

To achieve Aim 1, we will conduct semi-structured individual interviews with a sample of TFT providers (n = 10-12), during which participants will be asked to provide feedback on the planned components and structure of the self-management program. To achieve Aims 2 and 3, we will enroll twelve Veterans in a non-randomized, open-trial pilot test of the intervention at the Minneapolis VA Healthcare Systems (VAHCS).

Enrolled Veterans will complete survey batteries immediately post-TFT, and survey batteries and qualitative interviews two weeks after the final self-management program therapist contact. Findings from this project will strongly position us to apply for Merit funding to conduct a randomized clinical trial (Stage 2 of the Stage Model of Treatment Development) of this innovative self-management program designed to enable Veterans to take primary ownership of their PTSD-related symptoms and functioning following a successful course of TFT.

***2A. Background*.**

2A1. Background & Rationale for the Proposed Study. Posttraumatic stress disorder (PTSD) is a prevalent and debilitating condition. Estimates of the lifetime prevalence of PTSD among Veterans who served in a combat zone range between 13% and 17%.[18;19] Left untreated, PTSD fails to remit in one-third of cases and chronic PTSD is associated with diminished functioning, lower levels of social support, poor quality of life, poor physical health, and increased suicidality.[2;4;5;20;21] Fortunately, efficacious treatments for PTSD exist. Trauma-focused therapies (TFTs; prolonged exposure [PE] and cognitive processing therapy [CPT]) have larger evidence bases than any other treatments for PTSD and have been found to be effective across a wide range of Veteran populations.[6;8;22-24] Further, gains achieved in TFTs have been shown to persist for up to ten years post-treatment.[25] In addition to symptom reduction, completion of TFTs have been shown to have a positive impact on physical health, social and work functioning, quality of life, and life outlook.[6;10;26] Given these benefits, VHA has mandated that TFTs be made available to all Veterans with PTSD.[27] In order to achieve this goal, VHA launched the Mental Health Dissemination Initiative which was designed to create a nationwide workforce trained to deliver TFTs.[11] This implementation has led to an ever-increasing number of Veterans with PTSD completing TFTs and experiencing reductions in symptoms and improvements in functioning.[7;28]

Despite the significant improvements that result from TFTs, Veterans who complete the treatments continue to seek mental health care. Although completion yields a modest reduction in mental health service use in the year following completion as compared to the year prior to initiation, our pilot data demonstrate that Veterans attend an average of one mental health appointment every other week in the six months after TFT completion (see 2A.3.1 for description of prior work).[29;30] Further, among a small sample (N = 23) of Veterans who completed TFTs, the vast majority of whom perceived improvements resulting from therapy, 88% reported additional mental health needs.[26] Prior to our pilot data collection, Veterans' reasons for continuing to engage in mental health care following completion of TFTs that yielded improvements in symptoms and functioning were unknown. Despite the documented stability of gains achieved during TFTs, our data demonstrate that the primary post-TFT mental health treatment need among completers who experienced at least a partial improvement in PTSD symptoms is support for additional practice and reinforcement of skills learned in TFT. Veterans expressed low self-efficacy for maintaining or building upon their existing gains and believed continued contact with their TFT therapist would increase their likelihood of success (see section 2A. 3.2).

These treatment needs are particularly well-suited to a therapist-assisted self-management approach. Self-management (SM) protocols teach patients to be responsible for the day-to-day management of their symptoms, thereby emphasizing patients' (rather than providers') roles in wellness.[13] This occurs through promoting the daily application of illness management skills, encouraging the maintenance and/or development of meaningful activities, and managing emotions that arise during the SM process.[13;31] Participation in SM programs has been shown to increase patients' self-efficacy in managing their illnesses in a variety of settings and contexts and studies have demonstrated the mediating role of increased self-efficacy on positive outcomes.[13;32;33] Further, SM is consistent with a recovery-oriented mental health orientation, which also emphasizes the role of patients in managing their own health and encourages patients to "live beyond their illness" through engaging in meaningful activities.[14] Thus, a second potential benefit of a SM approach is increased community engagement, which could result either directly from SM activities that encourage participation in meaningful activities or indirectly through reduced dependence on mental health services.[14] Finally, a SM approach is highly consistent with TFT protocols; continued and increasingly generalized application of TFT skills following treatment completion is an explicit goal of both PE and CPT.[34;35] While SM programs for PTSD with the goals of increasing knowledge, teaching general coping skills, and facilitating treatment seeking have been designed and evaluated, they were developed as stand-alone treatments or as the first step up in a stepped-care model.[15;16;36;36-38] In contrast, a post-TFT SM program would be a direct extension of what was learned in therapy; with the support and guidance of their TFT providers, Veterans would continue to manage trauma-related symptoms through the application of TFT skills and extend this new knowledge base to cope with additional stressors.

2A.2. Significance of the Proposed Work. Using data from the Mental Health Evidence-Based Psychology Dashboard, we estimate that more than 17,000 Veterans completed TFTs during the past year. A significant majority of these Veterans continue to seek mental health treatment; however, therapists are providing these services without the benefit of evidence regarding effective post-TFT care. The VA / Department of Defense (DoD) PTSD Clinical Practice Guidelines recommend that Veterans who demonstrate a full remission of symptoms and improvement in functioning following TFT should discontinue psychotherapy, and those who experience a partial response should decrease the frequency and intensity of care.[12] However, the guidelines do not provide recommendations for how to effectively reduce care (e.g. step-down) in a manner that is acceptable to Veterans and maintains treatment gains, as no evidence-based strategies for reducing the intensity of psychotherapy for PTSD exist. This project has the potential to improve the health and well-being of Veterans with PTSD and move the field forward by refining and evaluating the first intervention designed to help Veterans step-down from active to maintenance mental health services following a successful course of psychotherapy. Finally, the project will advance RR&Ds missions of evaluating interventions designed to maximize psychological recovery and prioritize functional outcomes and societal engagement.

2A.3. Prior Work.

2A.3.1. Post-TFT Mental Health Service Use among Completers in a National VHA Sample. Participation in TFTs is monitored via templated progress notes which are available as health factor data within the Corporate Data Warehouse (CDW). Using these template data, we sought to quantify engagement in mental health services following TFT completion. We identified Veterans who completed TFTs between November 2014 and March 2015 (n = 2,183). For those Veterans, we extracted the number and type of mental health encounters in the six months following TFT completion and six months prior to the estimated TFT initiation date from VHA administrative data sources. While there was a modest reduction in pre- to post-TFT mental health service use, the data clearly demonstrate that Veterans continue to engage in mental health treatment following TFT completion (Table 1). Since these data don't elucidate the target of these services (e.g., why Veterans continue to engage in care), we conducted interviews with TFT completers in order to understand Veterans' perceived post-TFT mental health treatment needs.

Table 1. Encounters for a National Sample of Completers 6-Months Pre- and Post-TFT

Service Category	Pre-PE/CPT *M(SD)*	Post-PE/CPT *M(SD)*	*d*
All Mental Health	22.13 (33.62)	16.03 (26.27)	0.20
Mental Health Group	4.96 (11.64)	3.85 (10.50)	0.10
Mental Health Individual	6.38 (5.58)	4.43 (4.96)	0.36
Medication Management	1.02 (1.66)	0.84 (1.73)	0.11
Mental Health Other	10.16 (23.94)	7.25 (17.93)	0.14

2A.3.1. Veterans' Post-TFT Mental Health Needs. As part of a funded project examining dropout from TFTs (PI: Kehle-Forbes; IIR14-030), we conducted interviews with 58 (including 20 women and 25 Operation Enduring Freedom [OEF] / Operation Iraqi Freedom [OIF]) Veterans who had recently completed TFT. We asked: "What (if anything) did you feel like you needed from treatment after PE/CPT?" A large majority reported additional mental health needs. Preliminary thematic analyses revealed that most Veterans with low to moderate post-TFT PTSD Checklist (PCL) scores expressed (a) concerns about maintaining gains or (b) hope for further improvement with sustained practice.[39] Veterans reported needing the following from post-TFT treatment: (a) additional practice and reinforcement of TFT skills, (b) support from their TFT therapist in continuing to implement the newly learned skills, and (c) additional coping skills. *Preliminary analyses suggest that these themes did not differ by gender or service era; further, completers of PE and CPT did not differ in their post-TFT treatment needs.* In summary, Veterans' report of low-self efficacy and perceived treatment needs led us to hypothesize that a therapist-assisted SM program would be an effective post-TFT intervention.

2A.4. Research Design & Method. We will complete stages 1A (therapy manual refinement and creation of training materials; Aim 1) and 1B (pilot testing of the intervention; Aims 2 & 3) of the Stage Model of Treatment Development.[17] To achieve Aim 1, we will conduct semi-structured individual interviews with a sample of TFT providers during which participants will be asked to provide feedback on a draft of the SM intervention (*data*

regarding Veterans' perceptions of post-TFT care needs were gathered as part of our prior work, see Section 2A.3.1). For Aim 2, we will enroll twelve Veterans in a non-randomized, open-trial pilot test of the intervention at the Minneapolis VAHCS and the Northwest Metro VA Clinic (Ramsey, MN). *We will assess the programs' acceptability, the dimensions of feasibility delineated by Leon and colleagues, Veterans' self-efficacy in managing PTSD symptoms (the primary mechanism through which the SM program is expected to improve outcomes), and a range of Veteran-centered outcomes expected to be impacted by the program*.[40] Following this work, we will be well positioned to apply for Merit funding for Stage 2 of the treatment development process (randomized trial testing the program's efficacy).[17]

2A.4.1. Aim 1 Methodology (Refine a self-management treatment protocol).

Sample Identification & Recruitment. Participants will be *ten to twelve* TFT providers at the Minneapolis VAHCS. To be eligible, providers must be staff providers who have delivered TFT to a minimum of four Veterans during the prior twelve months. Eligible providers will be identified via administrative data. To do so, we will first identify patients who received at least one session of TFT during the past year. Specifically, we will identify all Veterans at the Minneapolis VAHCS with Current Procedure Terminology codes indicative of an individual psychotherapy session (90832, 90834, 90837, 90845, 90847) for full or subthreshold PTSD (ICD-10: F43.10 - 43.12; F43.8, F43.9) during the prior 12 months. We will then search those records for the presence of health factor data generated from TFT templated notes (participation in TFT is indicated via templated progress notes available as health factor data in the CDW). For each identified TFT session, we will identify the primary provider. Providers who delivered at least one session of TFT to at least four unique Veterans and who are verified as being staff providers (via a crosscheck with a list of current staff provided by the Minneapolis VAHCS's PTSD Clinical Team program manager) will be invited to participate via an e-mail from the principal investigator. *Data maintained by the Evidence-Based Psychotherapy Coordinator indicates that there are currently 50 unique TFT providers at the Minneapolis VAHCS;* given our success enrolling TFT providers into qualitative studies (59% enrollment rate in IIR14-030) we are confident we will be able to reach our recruitment target of *five to six providers per month over a two-month period*.

Sampling Strategy. In qualitative methodology, there is no equivalent to a power calculation to determine the sample size needed to address the research question. Instead, qualitative methodologists agree that the objective is to conduct enough interviews to reach "saturation."[41] It has been demonstrated that a sample size of six results in the identification of over 90% of high-frequency themes and a sample size of twelve results in the identification of 90% of all themes *in a homogeneous population*.[42] *Our goal for this aim is to identify high-frequency themes. Since our sample of providers will be heterogeneous (e.g. will contain both PE and CPT providers), we will initially conduct ten provider interviews, using purposeful sampling to guarantee the sample contains at least four providers who deliver each TFT. If after the completion of ten interviews, analysis suggests that the major themes differ by treatment (which is not expected based on our prior work with Veterans), we will conduct two additional interviews (for a total of 6 PE and 6 CPT providers).*

Data Collection. Prior to the interview, participants will be e-mailed the draft SM program to review so that they have familiarity with the program at the time of the interview. Interviews will be conducted in person by Dr. Kehle-Forbes and will be audio-recorded and transcribed verbatim. A semi-structured interview guide will be used; interview guides systematize the interview (e.g., ensure that the same topics are explored within each interview), while also allowing for the emergence of new themes and the development of rapport.[43] *Interview domains of inquiry will be conceptually informed by the "appropriateness" domain of Levesque et al.'s Patient-Centered Access to Health Care framework*, *which posits that fit between services and patient needs, the timeliness of the intervention, the technical (e.g., intervention components and materials) and interpersonal (e.g., therapeutic contact) aspects of a treatment, and its effectiveness all impact a patients' likelihood of engaging in and adequately benefiting from a service.*[44] As such, providers will be asked if the proposed goals and format (frequency and type of therapist involvement) of the program fit Veterans' post-TFT needs, what existing components may be unnecessary, what content is missing, what they like and what they think could be improved for each existing program component, what strategies and materials they currently use to help patients meet similar goals, and perceived training needs (see draft interview guide in the Appendix).

Self-Management Intervention. The SM program is cognitive-behavioral (CB) in its theoretical orientation and is conceptually rooted in the Supportive Accountability model of self-management and Bandura's CB theory of self-efficacy[45;46]. It is also grounded in evidence regarding the characteristics of

effective SM programs. Effective SM interventions must 1) facilitate problem solving, 2) guide decision making (help patients identify normal fluctuations in symptoms and those that require provider involvement), 3) encourage the use of existing resources (e.g., other SM or community resources), 4) promote an ongoing relationship with providers, 5) support action (e.g. goal setting), and 6) be tailored to the patient.[13] *The program is designed to be used by completers of both PE and CPT. While the two TFTs are comprised of different components, both are rooted in CB theories of behavior change and teach CB strategies. Thus, this SM program which applies CB principles to increase self-efficacy for managing PTSD symptoms is consistent with both approaches, even though some of the specific skills or strategies for which self-efficacy is being developed will differ. Our confidence in the utility of developing one program for both TFTs is bolstered by our prior work examining post-TFT treatment needs (Section 2A.3.1)*. The overall objectives of the therapist-assisted self-management program are to increase Veterans' self-efficacy for managing their PTSD, enable the maintenance or building upon gains made in TFT (e.g. formalize the expectation for continued practice of TFT skills and provide structure for the ongoing use of skills), and encourage engagement in meaningful activities. The program's components, the element of effective SM programs addressed by each component, and the specific goals associated with the components are outlined in Table 2 (strategies that will be employed within each component are expanded upon in the detailed outline of the intervention included in the Appendix). TFT therapists will assist Veterans with tailoring their plan to reflect their goals,

Table 2. Draft Self-Management Intervention

Treatment Component	Goal	Element of Effective Self-Management Programs
Self-monitoring of symptoms	1. Identify normal fluctuations in symptoms vs. those that require therapist involvement 2. Evaluate effectiveness of problem solving strategies	Problem solving skills; Decision making
Continued practice of TFT skills	1. Finish exercises not completed during active treatment 2. Apply skills to new situations and contexts (e.g., generalization) 3. Increase self-efficacy & encourage greater engagement with environment	Problem solving skills
Acquisition / application of additional coping skills	1. Address psychosocial stressors & residual / comorbid symptoms 2. Increase self-efficacy & encourage greater engagement with environment	Problem solving skills; Identification and utilization of existing resources
Engagement in meaningful activities	1. Identify and pursue non-symptom management goals; "living beyond illness" 2. Encourage greater engagement with environment / community participation	Identification and utilization of existing resources
Therapist assistance	1. Tailor intervention to Veteran 2. Provide accountability & emotional support 3. Assist with problem solving & goal setting 4. Evaluate and address symptom exacerbation	Relationship with provider
Goal setting	1. Develop strategy for enacting self-management strategies with a focus on short-term (1-2 week) goals 2. Teach Veteran to effectively set short-term goals	Taking action

Table 3. Self-Management Intervention & Assessment Schedule

	Weeks Since Final TFT Session												
Self-Management Sessions	0	1	2	3	4	5	6	7	8	9	10	11	12
In-person session	X				X								
Phone check in			X										
Phone session											X		
Assessment Schedule													
Baseline survey	X												
Follow-up survey													X
Follow-up interview													X

strengths, and the TFT completed (*PE and CPT modules will be available for components that require TFT-specific content; e.g. continued practice of TFT skills)*. The draft program proposes four planned therapist contacts over the ten weeks following TFT completion (Table 3). Specifically, TFT therapists will meet with Veterans in person or through V-tel at the conclusion of TFT (SM intervention introduced during an expanded final TFT session), by phone for a brief check in two weeks after TFT completion, in person or through V-tel approximately four weeks after TFT completion, and by phone ten weeks after TFT completion. Therapists will also be available for additional contact as needed by Veterans; however, as *Veterans gradually develop greater self-efficacy in managing their PTSD symptoms, their need for therapist contact should decrease. Intervention development and refinement is ongoing and will continue until immediately prior to the Aim 2 therapist training*.

Data Analysis and Intervention Refinement. We will utilize an efficient, rapid turn-around analytic approach well-suited to short-term projects, interviews that use targeted guides, and projects that lend themselves to straightforward explanatory analyses.[47] This process improves on past rapid procedures through its systematic, rigorous approach, and is less time and resource intensive than traditional analytic techniques.[47] This approach uses data reduction, rather than coding, as the first step of analysis. Following transcription of the first three interviews, Dr. Kehle-Forbes (with feedback from co-investigators) will develop a draft template that will be used to summarize each transcript. The template will include sections for each main topic of inquiry, unexpected findings, and exemplary quotes. After fielding the template and making any necessary revisions, Dr. Kehle-Forbes and the project coordinator (trained by Dr. Kehle-Forbes) will carry out the data reduction process. After all transcripts have been summarized, the project coordinator will transfer the summary points to a data matrix that organizes the summary points for each main topic of inquiry. Finally, following a meeting during which each investigator will provide their impression of the matrix contents, Dr. Kehle-Forbes will create a memo summarizing the findings and noting key themes. The findings will be used to refine the draft intervention prior to the start of Aim 2. Some examples include *(a) a program component may be added to address a post-TFT treatment need frequently cited by providers as missing from draft program (if addressable within a self-management framework), (b) providers' existing strategies and materials used to address program components may be adapted for use with providers' permission, (c) the timing or amount of therapist contact may be modified, or (d) the number of components with TFT-specific modules may be expanded.*

2A.4.2. Aim 2 (Conduct a pilot open trial to assess the (a) acceptability of the SM program and (b) feasibility of SM program and the study approach) *and Aim 3 (Explore the effects of the SM program)* methodology.

Sample Identification and Recruitment. Participants will be *twelve* Veterans at the Minneapolis VAHCS or Northwest Metro VA Clinic who experienced a clinically-significant improvement in PTSD symptomology (e.g., a decrease of at least 10 points on the PCL) following a course of individually-delivered TFT with a provider trained to deliver the SM intervention (study therapist). *While the Stage Model of Treatment Development does not recommend a sample size for stage 1B activities, published accounts of psychotherapy treatment development frequently report on samples of ten to twelve participants.*[48-51] Potential participants will be identified via referrals from study therapists; study therapists will refer their own patients to whom they will then deliver the intervention. To facilitate this process, we will identify potential participants via administrative data and notify study therapists that they are treating a Veteran who may be eligible for the study. We will first identify potential participants using the method described in Aim 1 Sample Identification (identification of Veterans who received an individual psychotherapy session for full or subthreshold PTSD and who have health factor data indicative of TFT delivery by one of the study therapists). Veterans who have attended at least six PE or eight CPT sessions (e.g., those nearing treatment completion as Veterans will be enrolled in the study immediately prior to treatment completion) will be selected for manual chart review, which will be used to confirm TFT delivery and verify additional inclusion criteria. Study therapists will introduce potential participants to the study; with the Veterans' permission, study staff will then contact him/her to describe the project in greater detail and ensure eligibility. Participants will complete informed consent with study staff one to three weeks before their final TFT session. If unable to complete during that timeframe, then informed consent will be completed immediately prior to their final TFT session. In some instances, Veterans may be mailed consent form and HIPAA to be returned to staff prior to first self-management

intervention session. Study staff will set a time to review the consent and HIPAA over the phone before the Veteran is asked to sign, date, and return the forms. Using data drawn from the Mental Health Evidence-Based Psychology Dashboard and published rates of treatment completion and response, we conservatively estimate that 64 Veterans will be eligible to participate during the seven-month recruitment period.[7;52] We are confident in our ability to meet our recruitment target of 1-2 Veterans per month for seven months. To ensure the representativeness of our sample, we will seek to enroll at least two women and four OEF/OIF Veterans.

Therapist Training, Consultation, & Fidelity Assessment. The intervention will be delivered by existing trauma-focused therapists at the Minneapolis VAHCS (see Dr. Meyers's letter of support). Study therapists will complete a two-hour in-person training with Drs. Polusny and Galovski and will be provided with the finalized SM program manual. In order to ensure fidelity and skillful delivery of the protocol, Drs. Polusny and Galovski will lead a monthly group consultation for study therapists and be available as needed for additional consultation. All SM sessions will be audio-recorded. Drs. Kehle-Forbes and Possemato will develop a fidelity checklist for the program and apply that checklist to one randomly-selected SM session for each participant.

Data Collection. Data will be collected via a survey assessment, semi-structured qualitative interview, and administrative data. *The outcomes of interest for Aims 2 & 3, the source from which the data will be drawn, and the specific survey measure (as applicable) are presented in Table 4.* Participants will complete a survey assessment immediately before their final TFT session (baseline) and two weeks after their final SM program contact (follow-up; three months after final TFT session, see Table 3). The baseline survey will be administered in person; the follow-up survey will be administered via mail using a modified Dillman protocol frequently used by Drs. Kehle-Forbes and Polusny.[53] Participants who complete and return a survey will receive $20 as compensation. *Veterans will also complete a 45-60 minute semi-structured interview two weeks after the final SM therapist contact (follow-up).* The interviews will follow the methodology described in Aim 1, with the exception that interviews will be conducted via telephone. As with Aim 1, the interviews will be *conceptually informed by the "appropriateness" domain of Levesque et al.'s Patient-Centered Access to Health Care*

Table 4. Aims 2 & 3 Outcomes & Data Sources

Domain	Source	Survey Measure
Acceptability		
Program Components & Structure	Survey; Interview	Credibility-Expectancy Scale*[54]; Client Satisfaction Scale**[55]
Materials	Interview	N/A
Feasibility		
Program Retention	*Administrative; Interview*	*N/A*
Intervention Fidelity	*Administrative*	*N/A*
Screening Approach	*Administrative*	*N/A*
Recruitment Approach	*Administrative*	*N/A*
Assessment Process	*Survey; Interview*	*All Survey Measures*
Self-Efficacy Related to PTSD Self-Management	Survey; Interview	Personal Control Subscale of the Illness Perception Questionnaire - Revised[56]
Outcomes Associated with Improved Self-Management		
Symptomology (PTSD and Depression)	Survey; Interview	PTSD Checklist[57]; Patient Health Questionnaire-9[58]
Perceived Mental Health Functioning	Survey; Interview	Current Mental Health subscale of the Recovery Orientation Scale[59]
Physical and Mental Health Functioning	Survey; Interview	Short Form Survey[60]
Quality of Life	Survey; Interview	World Health Organization Quality of life - BREF[61]
Community Engagement	Survey; Interview	Military to Civilian Questionnaire[62]
Psychosocial Functioning	Survey; Interview	Brief Inventory of Psychosocial Functioning

* Baseline survey only; ** Follow-up survey only

framework.[44] The interviews will assess Veterans' (1) *attitudes regarding the components (e.g. intervention targets), structure (e.g. level of therapist contact), and materials (e.g. handouts) of the intervention, (2) suggestions for improving the acceptability and efficacy of the SM program,(3) engagement with the SM program and materials (including retention), and perceived barriers/facilitators to engaging with the program, (4) perceptions of the impact of the program on the intervention targets (e.g. self-efficacy, outcomes associated with improved self-management) and exploration of unexpected domains impacted by the program, and (5) the completeness and time burden of the survey battery.* Veterans will be paid $25 for completing the interview. We will also extract the following administrative data: (*1) the number of SM sessions attended by each Veteran (from electronic medical record; retention), (2) SM program fidelity ratings (see Fidelity Assessment above), (3)* the number of "as-needed" contacts between Veterans and study therapists (from the electronic medical record; *intervention fidelity*), (4) *the number of participants screened each month (screening), and (5)* the number of eligible Veterans who declined participation (*recruitment*).

Data Analysis. To assess the acceptability of the treatment program, we will calculate the percentage of participants who report neutral or better treatment credibility and expectancy on the Credibility-Expectancy scale and examine the distribution of scores on the Client Satisfaction Scale. *We will triangulate these quantitative data with qualitative themes related to acceptability* (qualitative data will be analyzed using the same methodology as described in Aim 1 *Data Analysis); specifically, we will create a matrix with themes that emerge from the interviews regarding the programs' acceptability stratified by Veterans' quantitative Credibility-Expectancy and Satisfaction scores. Qualitative themes regarding the feasibility domain of program retention will be triangulated with administrative data regarding session attendance; a matrix presenting themes associated with high, medium, and low attendance (tertiles) will be produced by Dr. Kehle-Forbes. Descriptive statistics and graphical representations depicting intervention fidelity, screening, and retention will be generated. To assess the feasibility of the assessment approach, we will calculate rates of survey non-response and item missingness. We will also create a matrix summarizing themes related to the assessment process. Finally,* we will calculate and graphically display the direction and magnitude of change from baseline

to follow-up for self-efficacy and outcomes associated with improved SM; we will also calculate the percentage of participants who improved, worsened, and experienced no change for each of these measures. *These quantitative data will be triangulated with qualitative themes regarding self-efficacy and other program-related outcomes; themes and exemplary quotations will be presented in a matrix stratified by self-reported change (improved, worsened, no change) on the survey measures. W*e will also calculate descriptive statistics and pre-to-post treatment effect sizes for the sample.

2A.4.3. Limitations. The primary limitation is the project's focus on individually-delivered TFT given that a significant minority of CPT is delivered in groups. Once the efficacy of the SM intervention is established for individually-delivered TFT, we plan to modify and evaluate the protocol for use with completers of group TFT. A second limitation is our reliance on the templated TFT progress notes for sample identification. The implementation of the templated notes has been variable; as such, our sample identification procedures will not identify all Veterans who completed a TFT. Because generalizability is not a goal of a pilot examination, we chose not to employ a more time and labor intensive method that would identify all TFT completers. Finally, provider and system factors not addressed by the SM intervention may impact Veterans' perceived need for post-TFT care. Assessing those contextual variables is beyond the scope of this project; we plan to qualitatively explore such factors as part of our Stage 2 evaluation.

2A.5. Project Management. Study activities are detailed in Table 5. Dr. Kehle-Forbes will be responsible for the overall conduct and integrity of the project, conduct Veteran and provider interviews, participate in data analysis, conduct fidelity ratings, and have primary responsibility for intervention refinement. Drs. Polusny and Galovski will develop the therapist training and provide supervision to study therapists. Dr. Possemato will

Table 5. Project Timeline

	Year 1 by Month												Year 2 by Month											
Task	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12
Finalize data extraction method to identify Aim 1 & Aim 2 samples	X	X																						
Recruit, & conduct Aim 1 interviews		X	X																					
Analyze Aim 1 data			X	X																				
Refine intervention & develop therapist training materials	X	X	X	X	X	X	X	X	X	X													X	X
Train therapists											X													
Recruit Aim 2 participants & collect baseline data												X	X	X	X	X	X	X						
Deliver intervention												X	X	X	X	X	X	X	X	X				
Collect Aim 2 post-intervention quantitative & qualitative data														X	X	X	X	X	X	X	X			
Analyze Aim 2 data															X	X	X	X	X	X	X	X	X	
Dissemination / Begin Stage 2 (efficacy RCT) grant submission																							X	X

participate in developing the therapist training and conduct fidelity ratings. All investigators will participate in data interpretation, intervention refinement, and dissemination activities.

HUMAN SUBJECTS

For Aims 1 and 2, we will obtain approval from the Minneapolis VA Health Care System's (VAHCS) Institutional Review Board (IRB) for all research activities involving human subjects. We will also seek union approval prior to recruiting providers for Aim 1 activities. With the exception of the providers being interviewed as part of Aim 1, the project will not involve any other non-Veteran participants.

1. Human Subjects Involvement and Characteristics

Aim 1. We aim to enroll 10-12 trauma-focused therapy (TFT) providers at the Minneapolis VAHCS. Providers will be asked to complete a 45-60-minute semi-structured interview during which they will provide their opinion on a draft version of a self-management intervention for Veterans who have completed TFTs. The interviews will be recorded and transcribed. We will use VHA administrative data to identify potential participants.

Providers will be eligible to participate in the interviews if (a) they provided a TFT to at least four Veterans during the past twelve months and (b) are staff providers (e.g. not trainees).

Aim 2. We will enroll 12 Veterans that seek care at either the Minneapolis VAHCS or Northwest Metro VA Clinic (Ramsey, MN), to participate in the post-TFT therapist-assisted self-management intervention. Veterans will be asked to participate in the self-management intervention, complete a brief survey at baseline (immediately prior to the first self-management session) and follow-up (12 weeks later), and participate in a 45-minute semi-structured interview at the follow-up time point. While follow-up procedures are planned to be completed 12 weeks after a participant's first self-management session, there can be unforeseen scheduling and logistical conflicts that may push this timeline back. Provider and veteran can handle these circumstances on an individual basis and adjust the timeline as seen fit. Follow-up procedures should be completed with the goal of 12 weeks after the first self-management session but can be completed up to 16 weeks after the first self-management session if unable to stick to the original outlined study schedule. Veterans will be eligible to participate if they (a) are about to complete a course of individually-delivered TFT (enrollment will occur one to three weeks prior the final session or immediately before the final session) with a provider trained to deliver the self-management intervention, (b) experienced a clinically meaningful reduction in PTSD symptomology (PCL decrease of at least 10 points) from pre-TFT to the time of the enrollment, (c) at the time of enrollment are not planning to initiate another active course of psychotherapy for PTSD in the following three months, (d) are willing to participate in a self-management intervention, and (e) can provide informed consent. Veterans will be excluded if they have suicidal or homicidal ideation that in the opinion of their TFT therapist needs to be the focus of treatment. We will use a combination of provider referrals and administrative data to identify potential participants. We will also access VHA administrative data for surveyed Veterans in order to collect contact information, demographic characteristics, and mental health service utilization information.

2. Data Sources

The proposed project will use information that we gather through individual TFT provider interviews, Veteran surveys, individual Veteran interviews, audio recordings of the self-management sessions, and VHA administrative data. VHA administrative data will also be extracted to identify potential Veteran participants. The data will be gathered solely for research purposes.

3. Potential Risks

For both Aim 1 and Aim 2, the proposed research poses "minimal risk" to subjects as the risks are no greater than what are encountered in routine clinical care.

Aim 1 Risks: The primary risk to provider study participants is the potential loss of privacy and confidentiality; during the interviews, participants will be asked to provide their opinion on the self-management intervention, not their own personal experiences, so the consequences of a breach of privacy and/or confidentiality are believed to be negligible. There are no anticipated economic, physical, or social risks in this study.

Aim 2 Risks: The primary risk is the potential loss of privacy and confidentiality. The other potential risk associated is psychosocial stress resulting from either participation in the assessments or the intervention. The questionnaires and interviews will ask about current mental symptoms and functioning; the questions are consistent with those included in routine clinical care, and participants can refuse to answer any question(s). The self-management intervention may cause individuals to experience some psychological or social discomfort; however, we believe the intervention is likely to increase their well-being given that they are continuing to implement skills that they have already found to be helpful. The potential economic risks include potential loss of wages and transportation costs associated with traveling to and participating in the research intervention. There are no anticipated physical or social risks in this study.

Adequacy of Protection from Risks

1. Recruitment and Informed Consent

Provider Aim 1 Interview Recruitment & Consent: Eligible providers will be invited to participate in a 45 to 60-minute semi-structured interview via an e-mail from the principal investigator and will be able to either opt out of the study or to schedule an interview via e-mail. If providers do not respond to the initial e-mail, they will receive an additional e-mail and a follow-up phone call. If we fail to reach or receive a contact back from a provider after those contacts, we will assume they are not interested in participating in the study. We anticipate this activity will be IRB exempt and therefore will not include informed consent.

Veteran Aim 2 Recruitment & Consent: Veterans who meet eligibility criteria will be introduced to the study by their TFT provider. If participants agree to be contacted by the project, we will call participants to invite them to participate in the study. Veterans will receive three phone calls; if we fail to reach or receive a contact back from a Veteran after those contacts, we will assume they are not interested in participating in the study. Once we make contact with a Veteran, project staff will describe the purpose of the study and the risks and benefits associated with participating. Study staff will also administer a PTSD Checklist via the telephone to verify study eligibility. Veterans who are interested in participating in the study will meet in-person at the Minneapolis VA Medical Center or Northwest Metro VA Clinic with study staff one to three weeks before their final TFT session. If unable to complete during that timeframe, then informed consent will be completed immediately prior to their final TFT. If travel is burdensome or Veteran is unable to meet in person, then the Veteran can be mailed a consent form and HIPAA to be returned to staff prior to beginning the self-management intervention sessions.

2. Protection Against Risk

For both Aim 1 and Aim 2, the proposed research poses “minimal risk” to subjects as the risks are no greater than are encountered in routine clinical care. The potential risks to study participants include loss of privacy and confidentiality, psychosocial stress (any research project with direct contact with human subjects contains some risk of deleterious effects due to psychosocial stress), and loss of wages / transportation costs associated with study participation. There are no known physical or social risks of participating in the study. CCDOR has well-established methods to limit the risk of loss of confidentiality and protect the privacy of research participants.

The following procedures will be employed to ensure privacy and confidentiality:

Interviews & Session Audio-recordings:

1. Participants will be assigned a pseudonym identifier to be used instead of actual names in the audit trail, interview transcripts, and interview labels.
2. The only copy of the key linking actual names to pseudonyms will be kept in a password protected file, stored on a secure server.
3. Other individuals referred to by participants during the interviews will not be referenced by name in the study materials but only by salient but non-identifiable characteristics.
4. All electronic recordings, interview transcripts, and analytic notes will be stored in VA servers.
5. Handwritten notes will be stored in a locked cabinet in Dr. Kehle-Forbes’s VA office.
6. At the conclusion of the study, data will be destroyed in accordance with VA policy.

Survey Data:

1. Veteran contact information will be stored in a SQL server database. A study identification number (StID) will be pre-printed onto the survey so Veterans’’ identifying information remains private while maintaining the ability to link the survey back to an individual.
2. The data analyst will construct SAS datasets for analyses. All PHI will be removed from the SAS files, and a StID will serve as the only key to the initial data files. The programmer will have the only access to a crosswalk file linking StIDs with securely stored initial data files. Once the period for the required data maintenance has expired, all data will be destroyed under the supervision of the PI.
3. Our DART request will include permission to transfer necessary data to a local server to facilitate subject recruitment for Aim 1. We will create a separate workspace on a local server accessible only to the project programmers/data managers to process CDW abstracted data necessary for identification and recruitment of eligible subjects. The CCDOR Core Data Group works with OIT staff to maintain permission, data storage, and

server applications. All individuals with server access privileges have clearance to work with PHI. Backups are written to secured tapes and data stored in password protected project folders.

The CCDOR Statistical and Data Management (SDM) team maintain several secure servers accessible only SDM team members who have been screened and obtained proper security clearance. One common-access server contains individual project data. Access to that data is granted only through authorization by the principal investigator. Other VA investigators have used these procedures in previous studies and they have proved both feasible to execute and acceptable to multiple IRBs.
The second possible risk is distress among participants. While this risk is unlikely, we will take several steps to minimize this risk. Participants will be informed that participation is voluntary, that they may choose not to answer any questions and that they may discontinue their participation at any time. Further, we will provide participants with the Principal Investigator's (PI's) phone number so that participants can contact Dr. Kehle-Forbes with any questions or concerns. The PI is a licensed clinical psychologist with extensive experience working with Veterans with PTSD. Finally, if any study activities cause psychological distress or a psychiatric emergency emerges among participants, Dr. Polusny will assess risk and provide appropriate referrals. All surveys will be screened upon receipt by study staff. If a psychiatric emergency is reported on surveys (i.e., expression of risk for suicide or homicide), Dr. Kehle-Forbes or Polusny will contact the disclosing participant by phone, assess risk and safety, and provide the participant with appropriate referrals. We will utilize access to local and national mental health resources available through the VA, including the suicide prevention hotline, risk assessments through Mental Health during regular business hours (Psychiatry Urgent Care), or the facility's Emergency Room during off hours.

The final risk is economic. Participants may choose to take time off work or may incur transportation costs as a result of participating in this study. Every effort will be taken to schedule assessments and therapy sessions at times convenient to participants.

All collaborators will have completed appropriate human subjects trainings in the areas of research ethics and protection of human subjects.

Potential Benefits of the Proposed Research to the Subject and Others
There are no direct benefits to participation, although Veterans will receive $20 for completing the Aim 2 baseline surveys; $20 for completing the Aim 2 follow-up surveys; and $25 for completing the Aim 2 semi-structured interviews. Thus, Aim 2 Veteran participants can receive up to $65 for participation. Some participants may find it interesting to share their opinions. The knowledge to be gained during the course of this study may positively impact Veterans with PTSD's health and well-being.

Importance of Knowledge to be Gained
Most Veterans who complete trauma-focused therapies (TFTs) for PTSD continue to seek mental health treatment; however, therapists are providing these services without the benefit of evidence regarding effective post-TFT care. The VA / Department of Defense (DoD) PTSD Clinical Practice Guidelines recommend that Veterans who demonstrate a full remission of symptoms and improvement in functioning following TFT should discontinue psychotherapy, and those who experience a partial response should decrease the frequency and intensity of care (e.g. step-down). However, the guidelines do not provide recommendations for how to effectively reduce care in a manner that is acceptable to Veterans and maintains treatment gains. This project has the potential to improve the health and well-being of Veterans with PTSD and move the field forward by refining and evaluating the first intervention designed to help Veterans step-down from active to maintenance mental health services following a successful course of psychotherapy. Further, the project will advance RR&Ds missions of evaluating interventions designed to maximize psychological recovery and prioritizing functional outcomes and societal engagement.

Data and Safety Monitoring Plan
Privacy protections: All study data will be stored on CCDOR's secure data servers. CCDOR protects data collected for the purpose of conducting research projects at a level higher than that provided for clinical

encounters. We use “stand-alone,” secure data servers that are accessible only to designated, security-cleared, and trained personnel and data are de-identified as quickly as is feasible. Details about CCDOR’s specific data privacy assurance procedures to be employed for this study are provided below.

Maintaining Secure Servers: CCDOR maintains three secure computer servers that are protected under the Minneapolis VAMC Windows 2000 network. All individuals with administrative access privileges to the Center’s servers, including IRM personnel and the CCDOR SDM Team, have been screened and assigned a security clearance putting them in trusted positions of the hospital with clearances to work with patient level data. These individuals and their access to the CCDOR servers is ultimately monitored and controlled by Sean Nugent, Senior Program Analyst for the CCDOR Statistical & Data Management Team. IRM’s access to the data is strictly limited to backing up server data, which prevents catastrophic loss of data. Backups are written to tapes that are stored in a secure location accessible only to IRM personnel. CCDOR’s Statistical & Data Management Team members maintain permissions, data storage, and all server applications.

Organization and Access to Research Data: With the exception of one server, named the “CCDOR Server,” only the CCDOR Statistical & Data Management Team has access to remaining Center servers. Data on the “CCDOR Server” are organized by projects within folders designated by each investigator. Only members of a given project have access to a specific project folder on the “CCDOR Server.” Even then, access to project data is obtained through Windows authentication (i.e., PIV card). It is virtually impossible for any person without a login name and password to the VAHCS hospital’s domain network to access data on the Center’s servers. Thus, all data housed on the “CCDOR Server” is extremely secure, and access by unauthorized persons highly unlikely.

Securing Confidential Research Data: Primary data (e.g. interviews transcripts and survey responses) are identified only by participant number. The original data sources (e.g. digital recordings and paper notes) will either be kept in locked cabinets within a locked room or stored in a secure folder stored on the CCDOR server. Only individuals with a need to access the data, as vetted by the project’s Principal Investigator are granted access. Even then, only the absolute minimum number of data elements is released. This protects the integrity of the data as well as its confidentiality.

Inclusion of Women and Minorities

Women and minorities will be represented in our study sample; all Veterans who complete TFT at the Minneapolis VAHCS who meet our inclusion criteria are eligible to participate. We will purposively sample women Veterans, with the goal of recruiting at least two women for Aim 2 activities. We will not purposively sample for race / ethnicity, but we anticipate that our sample will reflect the demographics of the population; given the demographic makeup of the Minneapolis VAHCS (82% White, 10% African American or Black; 3% Hispanic in the outpatient PTSD treatment program), we anticipate the majority of our sample will be White.

Inclusion of Children

All study subjects are expected to be 18 years of age or older.