

Of Implementation of Written Exposure Therapy for PTSD in VA Telehealth Clinical Resource Hubs

Summary of Changes from Previous Versions:		
Affected Section(s)	Summary of Revisions Made to Version 2	Rationale
Implementation Outcomes	For the reach and effectiveness outcomes, the primary endpoint was changed from 4-months to 6-months.	To allow more time for the patient to initiate and complete WET
	For the adoption outcome, the timeframe was changed from the six months of external facilitation to the six months after the patient's intake visit.	To ensure that each patient had the same amount of time (six months) to contribute to the therapist's adoption outcome.
	These changes were made prior to data analysis.	

Background

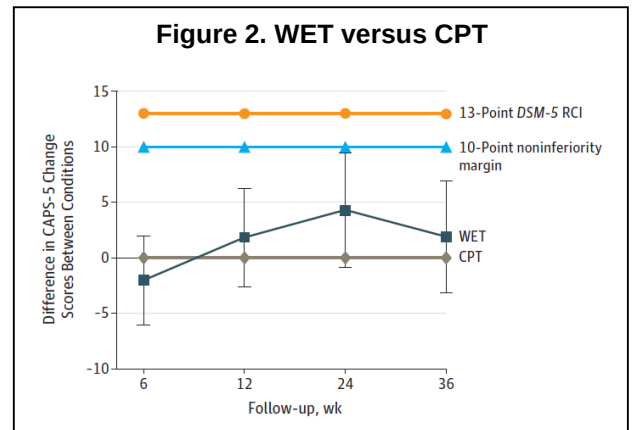
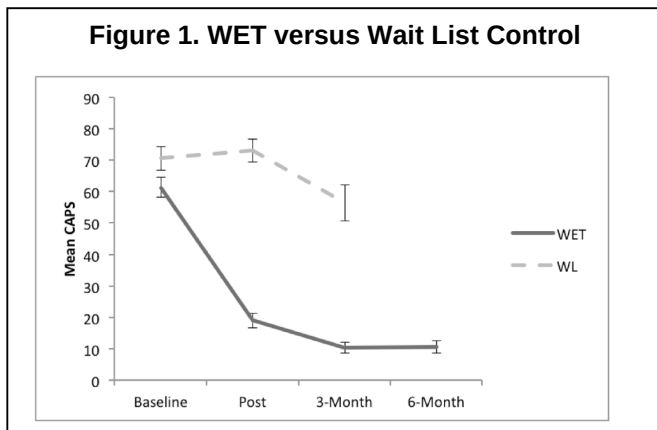
PTSD Burden – PTSD is extremely prevalent in VA (24.5%).¹ Over **1,000,000** Veterans receive service-connected compensation for PTSD.² Since 2001, almost **400,000** Operation Enduring Freedom (OEF), Operation Iraqi Freedom (OIF), and Operation New Dawn (OND) Veterans have been diagnosed with PTSD.³ PTSD is a major risk factor for engaging in unhealthy behaviors such as tobacco use, drug use, alcohol misuse, and is associated with high rates of morbidity, disability and mortality (including suicide).⁴⁻¹⁰ PTSD negatively impacts marriages,¹¹ educational attainment,¹² and occupational functioning.^{6,13-15} In primary care, 79%-88% of patients with PTSD go on to develop clinical depression,^{16,17} further contributing to disability.

Treatment of PTSD – Based on numerous RCTs and meta-analyses, trauma-focused psychotherapy is considered to be the first-line treatment for PTSD.¹⁸ VA has trained thousands of its providers to deliver first-line trauma-focused psychotherapies for PTSD (Prolonged Exposure [PE] and Cognitive Processing Therapy [CPT]) in specialty mental health and telemental health clinics.¹⁹ However, only a minority of patients with PTSD treated in VA specialty mental health settings receive trauma-focused psychotherapy.^{20,21} For example, only 6% of the Veterans seen in PTSD Outpatient Clinics in VISN 1 had any trauma-focused psychotherapy.^{22,23} Moreover, treatment drop-out from trauma-focused psychotherapies delivered in specialty mental health care settings is high both in RCTs (13%-39%²⁴) and routine care (36%-65%²⁵⁻²⁷). Further compounding the problem, is the fact that only 45%-62% of Veterans diagnosed with PTSD in primary care are successfully referred to specialty mental health in the first place.²⁸⁻³⁰

Written Exposure Therapy (WET) - WET is a relatively *new* brief trauma-focused therapy developed at the VA *National Center for PTSD*. Patients write about their traumatic experience following scripted instruction from a therapist. The protocol for WET involves one 60 minute session, followed by four 40 minute sessions. The first session includes psychoeducation, provides a treatment rationale for approaching the trauma memory, and discusses the use of writing as a means of doing so. During sessions, patients write about the memory of their worst traumatic event for 30 minutes, with a focus on details of the event and thoughts and feelings that occurred during the event. Patients are directed to write about the same trauma memory during each session. The therapist keeps track of the time, and once the 30 minutes has elapsed stops the patient from writing. The therapist then inquires whether the patient experienced any emotional difficulties, and addresses these with the patient. The therapist reads the patient narrative between sessions to make sure instructions were followed. Feedback about the narrative is provided to the patient at the beginning of sessions 2-5. This feedback is used to prompt the patient for writing in the current session. The session ends with the

therapist instructing the patient to allow themselves to experience any trauma-related memories, images, thoughts, and feelings in the interval between sessions. While retaining the core exposure element of other trauma-focused psychotherapies, WET does not require patient homework between sessions and requires considerably less therapist time, training and supervision. It is feasible to deliver in both specialty mental health and A Primary Care Mental Health Integration (PCMHI) settings.

Clinical Effectiveness of WET - In contrast to the high drop-out rates for PE and CPT, drop-out rates for WET have ranged from 6.4%-14%.³³⁻³⁵ In a superiority trial conducted in a civilian population, WET was significantly ($p<0.001$) more effective than waitlist control, with between group effect sizes of 3.5 and 2.2 at the 6 week and 18 week assessment, respectively (Figure 1).³³ In a non-inferiority trial comparing 5 sessions of WET to 12 sessions of CPT, WET was found to be non-inferior to CPT (Figure 2).³⁵ Drop-out rates were significantly ($p<0.001$) lower for WET (6.3%) than for CPT (39.7%).³⁵ **WET is recommended as a first line treatment in the VA/DOD PTSD Clinical Practice Guidelines.**¹⁸



Implementation Context - The proposed implementation trial will focus on delivering WET for tele-therapists in Clinical Resource Hubs which provide both specialty mental health and PCMHI. CRHs are VISN-level telehealth hubs designed to support underperforming CBOCs with inadequate staffing. Mental health services are delivered to Veterans in CBOCs via interactive video and to Veterans in their homes using VA Video Connect (VVC). Proof of concept for delivering WET via interactive video and VVC has been demonstrated by the VA National Center for PTSD.

Specific Aims

The aims of the Written Exposure Tele-Therapy (WETT) implementation trial are:

Aim 1 – Compare adoption of WET by CRH tele-therapists randomized to standard WET training or WET training plus external facilitation.

Hypothesis 1 (Adoption). *CRH tele-therapists randomized to WET training plus external facilitation will be more likely to adopt WET than tele-therapists randomized to WET training only.*

Aim 2 – Compare reach and effectiveness outcomes among patients diagnosed with PTSD treated by CRH tele-therapists randomized to standard WET training or WET training plus external facilitation.

Hypothesis 2 (Reach). Patients diagnosed with PTSD will be more likely to initiate WET if their tele-therapist was randomized to WET training plus external facilitation than if their tele-therapist was randomized to WET training only.

Hypothesis 3 (Effectiveness). Patients diagnosed with PTSD will have greater improvements in PTSD severity if their tele-therapist was randomized to WET training plus external facilitation than if their tele-therapist was randomized to WET training only.

Aim 3 – Compare implementation mechanisms of action among CRH tele-therapists randomized to standard WET training or WET training plus external facilitation, and test for mediation.

Hypothesis 4 (Mechanisms). Tele-therapists randomized to WET training plus external facilitation will be more likely to report greater increases in attitudes, self-efficacy, usability and social norms over time than tele-therapists randomized to WET training only.

Hypothesis 5 (Reach Mediation). The greater likelihood of initiating WET among patients treated by tele-therapists randomized to WET training plus external facilitation will be partially mediated by better attitudes, greater self-efficacy, usability and social norms.

Methods

Study Design – This is a Hybrid Type III effectiveness-implementation trial, with provider level randomization. It has been designated by the VA Office of Rural Health as a quality improvement project, not research. Multiple sequential cohorts of CRH tele-therapists will be recruited to receive training in WET by the VA National Center for PTSD until approximately 70 tele-therapists have completed the WET training. After all the tele-therapists in each training cohort have completed the training, they will be randomized 1:1 to receive additional external facilitation or not.

Recruitment - During the six months after randomization of the tele-therapists in each training cohort, we will identify patients for the evaluation of that training cohort. **Inclusion criteria:** 1) a new encounter (i.e., intake) with a randomized tele-therapist, and 2) a primary diagnosis of PTSD assigned during that encounter.

Exclusion criteria: none. Weekly data extractions from the VA Corporate Data Warehouse will be used to identify patients meeting inclusion criteria and a random sample will be sent an opt-out email. Those not opting out will be contacted and asked to agree to complete two surveys and permit a review of their medical records. We will recruit until we have obtained approximately 9-10 patients per tele-therapist, for a target sample size of 650 patients.

Implementation - Participating therapists (n=70) at the CRHs will be randomized to either: 1) a one-time training followed by clinical supervision for two patients (standard WET deployment) or 2) training and supervision plus external facilitation. External facilitation will have three main components: 1) WET shared decision-making aid, 2) manual for remote sharing of written trauma narratives, and 3) virtual community of practice. The community of practice calls will last for six months, and will be hosted by trained facilitator and a veteran with lived experience. The content of the community of practice calls will be based on the needs of the therapists. The external facilitation team will include an experienced QUERI facilitator and a veteran with lived experience with PTSD including engaging in trauma-focused psychotherapy.

Implementation Outcomes – *Reach* will be the primary outcome and 46 months the primary endpoint. Reach represents whether the patient received WET. Reach will be measured at the patient level (n=650) by conducting chart reviews of the sampled patients to determine what proportion received WET within 4 months of their CRH intake visit. Chart review will be also used to determine whether patients initiating WET completed all 5 sessions (6 sessions for PCMH therapists). The other outcomes are considered secondary. *Adoption* will be measured at the therapist level (n=70) by conducting chart reviews of the sampled episodes to measure what proportion of each therapist's patients with PTSD received WET versus some other type of intervention (e.g., non-trauma focused psychotherapy) during the six months after their intake visit. Repeated measures of adoption will be assessed every month for six months (70X6=420 observations). *Clinical effectiveness* will be measured at the patient level (n=650) from survey. At baseline, we will administer the PTSD Check List for DSM-V (PCL-5) to assess PTSD symptom severity and the Brief Inventory of Psychosocial Functioning (B-IPF) to assess relationship functioning. At the six-month follow-up, we will re-administer the PCL-5 and the B-IPF and compare change scores across implementation arms. The survey will ask closed-ended questions about reasons for non-initiation or drop-out of WET. We expect at least an 80% follow-up rate (n=520).

Mechanisms of Action – To explore whether the external facilitation implementation strategy is successfully targeting hypothesized mechanisms of action, we will administer brief surveys to therapists once a month for six months ((70X6=420 observations). Hypothesized mechanisms of action include: 1) self-efficacy for PTSD treatment planning, 2) attitude about WET, 3) self-efficacy for delivering WET, 4) usability for sharing trauma

narratives, and 5) CRH therapist support for delivering WET. Each construct will be assessed using a single question developed for the study.

Data Analysis – For *Reach* and *Clinical Effectiveness*, logistic and linear regression analysis will be used to determine if patients seeing a therapist in the external facilitation implementation arm are more likely to receive WET and experience greater decreases in PTSD symptom severity than patients seeing a provider in the standard implementation arm, controlling for casemix factors extracted from the electronic healthcare record. Patients will be the units of observation. For *Adoption*, we will use a two-level model with longitudinal observations (level-1) nested within therapists (level-2). Mixed models included a random intercept, random linear slope, and 1, 2, 3, 4, 5, and 6 month indicators to allow for non-linear change over time. The group-by-time interaction terms will be used to estimate the change in the differences in adoption across groups.

Power Analysis – For the primary outcome, we calculated a required sample size of 70 therapists and 650 patients (9.3 patients per therapist) to provide >80% power to test our superiority hypothesis assuming 10% of patients treated by standard implementation therapists and 25% of patients treated by external facilitation therapists would receive WET respectively. This estimate was calculated assuming a two-tailed test, $\alpha = .05$, 0% attrition rate, and clustering within therapists (intraclass correlation coefficient of 0.27 and a coefficient of variation of cluster sizes of 0.2).

1. Spottswood M, Davydow DS, Huang H. The Prevalence of Posttraumatic Stress Disorder in Primary Care: A Systematic Review. *Harvard review of psychiatry*. 2017;25(4):159-169.
2. Department-of-Veterans-Affairs. VA Statistics at a Glance Pocket Card. 2019.
3. Department_of_Veterans_Affairs. Analysis of VA Health Care Utilization among Operation Enduring Freedom (OEF), Operation Iraqi Freedom (OIF), and Operation New Dawn (OND) Veterans. 2017.
4. Schnurr PP, Green BL. Understanding relationships among trauma, post-traumatic stress disorder, and health outcomes. *Adv Mind Body Med*. 2004;20(1):18-29.
5. Ouimette P, Cronkite R, Henson BR, Prins A, Gima K, Moos RH. Posttraumatic stress disorder and health status among female and male medical patients. *Journal of traumatic stress*. 2004;17(1):1-9.
6. Kessler RC. Posttraumatic stress disorder: The burden to the individual and to society. *Journal of Clinical Psychiatry*. 2000;61(Suppl 5):4-12.
7. Boscarino JA. External-cause mortality after psychologic trauma: The effects of stress exposure and predisposition. *Comprehensive Psychiatry*. 2006;47:503-514.
8. Gillock KL, Zayfert C, Hegel MT, Ferguson RJ. Posttraumatic stress disorder in primary care: prevalence and relationships with physical symptoms and medical utilization. *General hospital psychiatry*. 2005;27(6):392-399.
9. Alonso J, Petukhova M, Vilagut G, et al. Days out of role due to common physical and mental conditions: results from the WHO World Mental Health surveys. *Mol Psychiatry*. 2011;16(12):1234-1246.
10. Nock MK, Hwang I, Sampson N, et al. Cross-national analysis of the associations among mental disorders and suicidal behavior: findings from the WHO World Mental Health Surveys. *PLoS Med*. 2009;6(8):e1000123.
11. Taft CT, Street AE, Marshall AD, Dowdall DJ, Riggs DS. Posttraumatic stress disorder, anger, and partner abuse among Vietnam combat veterans. *Journal of Family Psychology*. 2007;21:270-277.
12. Manguno-Mire G, Sautter F, Lyons J, et al. Psychological distress and burden among female partners of combat veterans with PTSD. *The Journal of nervous and mental disease*. 2007;195(2):144-151.
13. Smith MW, Schnurr PP, Rosenheck RA. Employment outcomes and PTSD symptom severity. *Mental Health Services Research*. 2005;7:89-101.
14. Magruder KM, Frueh BC, Knapp RG, et al. PTSD symptoms, demographic characteristics, and functional status among veterans treated in VA primary care clinics. *Journal of traumatic stress*. 2004;17:293-301.
15. Hoge CW, Terhakopian A, Castro CA, Messer SC, Engel CC. Association of posttraumatic stress disorder with somatic symptoms, health care visits, and absenteeism among Iraq war veterans. *American Journal of Psychiatry*. 2007;164:150-153.

16. Craske MG, Stein MB, Sullivan G, et al. Disorder-specific impact of coordinated anxiety learning and management treatment for anxiety disorders in primary care. *Archives of general psychiatry*. 2011;68(4):378-388.
17. Fortney JC, Pyne JM, Mouden SB, et al. Practice-based versus telemedicine-based collaborative care for depression in rural federally qualified health centers: a pragmatic randomized comparative effectiveness trial. *American Journal of Psychiatry*. 2013;170(4):414-425.
18. VA/DOD. VA/DOD Clinical Practice Guideline for the Management of Posttraumatic Stress Disorder and Acute Stress Disorder. Washington D.C.2017.
19. Karlin BE, Ruzek JI, Chard KM, et al. Dissemination of evidence-based psychological treatments for posttraumatic stress disorder in the Veterans Health Administration. *Journal of traumatic stress*. 2010;23(6):663-673.
20. Hessinger JD, London MJ, Baer SM. Evaluation of a shared decision-making intervention on the utilization of evidence-based psychotherapy in a VA outpatient PTSD clinic. *Psychological services*. 2018;15(4):437-441.
21. Maguen S, Li Y, Madden E, et al. Factors associated with completing evidence-based psychotherapy for PTSD among veterans in a national healthcare system. *Psychiatry research*. 2019;274:112-128.
22. Watts BV, Shiner B, Zubkoff L, Carpenter-Song E, Ronconi JM, Coldwell CM. Implementation of evidence-based psychotherapies for posttraumatic stress disorder in VA specialty clinics. *Psychiatric services (Washington, DC)*. 2014;65(5):648-653.
23. Shiner B, D'Avolio LW, Nguyen TM, et al. Measuring use of evidence based psychotherapy for posttraumatic stress disorder. *Administration and policy in mental health*. 2013;40(4):311-318.
24. Steenkamp MM, Litz BT, Hoge CW, Marmar CR. Psychotherapy for Military-Related PTSD: A Review of Randomized Clinical Trials. *Jama*. 2015;314(5):489-500.
25. Kaysen D, Schumm J, Pedersen ER, Seim RW, Bedard-Gilligan M, Chard K. Cognitive processing therapy for veterans with comorbid PTSD and alcohol use disorders. *Addictive behaviors*. 2014;39(2):420-427.
26. Kehle-Forbes SM, Meis LA, Spont MR, Polusny MA. Treatment initiation and dropout from prolonged exposure and cognitive processing therapy in a VA outpatient clinic. 2016;8(1):107-114.
27. Niles BL, Polizzi CP, Voelkel E, Weinstein ES, Smidt K, Fisher LM. Initiation, dropout, and outcome from evidence-based psychotherapies in a VA PTSD outpatient clinic. *Psychological services*. 2018;15(4):496-502.
28. Spont MR, Murdoch M, Hodges J, Nugent S. Treatment receipt by veterans after a PTSD diagnosis in PTSD, mental health, or general medical clinics. *Psychiatric services (Washington, DC)*. 2010;61(1):58-63.
29. Magruder KM, Frueh BC, Knapp RG, et al. Prevalence of posttraumatic stress disorder in Veterans Affairs primary care clinics. *General hospital psychiatry*. 2005;27(3):169-179.
30. DeViva JC. Treatment utilization among OEF/OIF veterans referred for psychotherapy for PTSD. *Psychological services*. 2014;11(2):179-184.
31. Possemato K, Johnson EM, Wray LO, Webster B, Stecker T. The implementation and testing of a referral management system to address barriers to treatment seeking among primary care veterans with PTSD. *Psychological services*. 2018;15(4):457-469.
32. Schnurr PP, Friedman MJ, Oxman TE, et al. RESPECT-PTSD: re-engineering systems for the primary care treatment of PTSD, a randomized controlled trial. *Journal of general internal medicine*. 2013;28(1):32-40.
33. Sloan DM, Marx BP, Bovin MJ, Feinstein BA, Gallagher MW. Written exposure as an intervention for PTSD: a randomized clinical trial with motor vehicle accident survivors. *Behaviour research and therapy*. 2012;50(10):627-635.
34. Sloan DM, Lee DJ, Litwack SD, Sawyer AT, Marx BP. Written exposure therapy for veterans diagnosed with PTSD: a pilot study. *Journal of traumatic stress*. 2013;26(6):776-779.
35. Sloan DM, Marx BP, Lee DJ, Resick PA. A Brief Exposure-Based Treatment vs Cognitive Processing Therapy for Posttraumatic Stress Disorder: A Randomized Noninferiority Clinical Trial. *JAMA psychiatry*. 2018;75(3):233-239.
36. Department_of_Veterans_Affairs. Annual Report. In: Health OoR, ed. Washington DC2018.
37. Fortney JC, Pyne JM, Kimbrell TA, et al. Telemedicine-based collaborative care for posttraumatic stress disorder: a randomized clinical trial. *JAMA psychiatry*. 2015;72(1):58-67.
38. Boren T, Ramey J. Thinking aloud: Reconciling theory and practice. *Professional Communication, IEEE Transactions on*. 2000;43:261-278.

39. Cooke L. Assessing Concurrent Think-Aloud Protocol as a Usability Test Method: A Technical Communication Approach. *Professional Communication, IEEE Transactions on*. 2010;53:202-215.
40. Lyon AR, Munson SA, Renn BN, et al. Human-Centered Design to Improve Implementation of Evidence-Based Psychotherapies in Low-Resource Communities: UW ALACRITY Center Methods Core Protocol. *Journal of medical Internet research*. 2019.
41. Weiner BJ, Lewis CC, Stanick C, et al. Psychometric assessment of three newly developed implementation outcome measures. *Implementation science : IS*. 2017;12(1):108.
42. Erwin K, Musick H. Institute for Healthcare Delivery Design - University of Illinois, Tailoring Interventions to Fit People: Using Human-Centered Design. Paper presented at: Workshop - HSR&D Center of Innovation for Veteran-Centered and Value-Driven Care June 26-27, 2019, 2019; Seattle, WA.
43. Truong KN, Hayes GR, Abowd GD. Storyboarding: an empirical determination of best practices and effective guidelines. Proceedings of the 6th conference on Designing Interactive systems; 2006; University Park, PA, USA.
44. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implementation science : IS*. 2009;4:50.
45. Glasgow RE, McKay HG, Piette JD, Reynolds KD. The RE-AIM framework for evaluating interventions: What can it tell us about approaches to chronic illness management? *Patient Education & Counseling*. 2001;44(2):119-127.
46. Pyne JM, Fortney JC, Tripathi S, Maciejewski ML, Edlund MJ, Williams DK. Cost-effectiveness analysis of a rural telemedicine collaborative care intervention for depression. *Archives of General Psychiatry*. 2010;67(8):812-821.
47. Pyne JM, Fortney JC, Moudén S, Lu L, Hudson TJ, Mittal D. Cost-Effectiveness of On-Site Versus Off-Site Collaborative Care for Depression in Rural FQHCs. *Psychiatric services (Washington, DC)*. 2015;66(5):491-499.
48. Liu CF, Hedrick SC, Chaney EF, et al. Cost-effectiveness of collaborative care for depression in a primary care veteran population. *Psychiatric Services*. 2003;54(5):698-704.
49. Liu CF, Rubenstein LV, Kirchner JE, et al. Organizational cost of quality improvement for depression care. *Health services research*. 2009;44(1):225-244.
50. Fortney JC, Pyne JM, Burgess JF, Jr. Population-Level Cost-Effectiveness of Implementing Evidence-Based Practices into Routine Care. *Health Serv Res*. 2014.