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

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]**

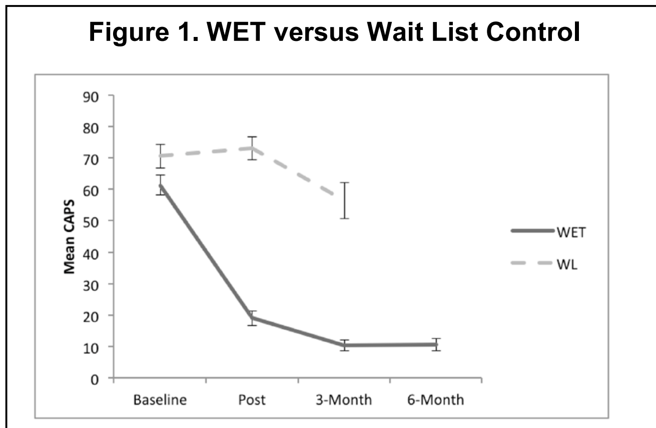

Figure 1. WET versus Wait List Control

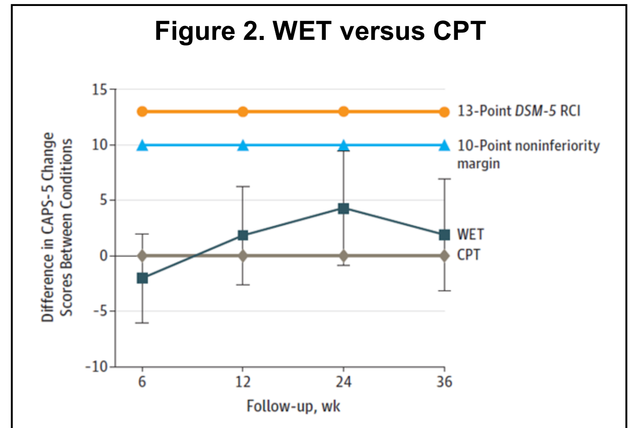

Figure 2. WET versus CPT

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 be 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 use 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 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 4 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 PCMHI 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 of external facilitation. 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 four-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 develop 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).

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