

Written exposure therapy delivered to Veterans by tele-therapists for post-traumatic stress disorder

Submission date 07/09/2022	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 12/10/2022	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 12/10/2022	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Posttraumatic stress disorder (PTSD) is extremely prevalent (24.5%) in the US Department of Veterans Affairs (VA). PTSD is a major risk factor for engaging in unhealthy behaviors such as tobacco use, drug use, and alcohol misuse, and is associated with high rates of morbidity, disability and mortality (including suicide).

Based on various research, trauma-focused psychotherapy is considered the first treatment for PTSD. The US Department of VA has trained thousands of its providers to deliver trauma-focused psychotherapies for PTSD in specialty mental health and telemental health clinics. These therapies have included prolonged exposure (PE), during which trauma-related memories, feelings, and situations that have been avoided since the initial trauma can be approached in a safe environment, and cognitive processing therapy (CPT), a type of cognitive behavioural therapy which helps an individual evaluate and change upsetting thoughts that have occurred since the trauma. However, only a minority of patients with PTSD treated in VA specialty mental health settings receive trauma-focused psychotherapy. Moreover, treatment drop-out from trauma-focused psychotherapies delivered in specialty mental health care settings is high both in clinical studies (13%-39%) and routine care (36%-65%).

Written exposure therapy (WET) is a relatively new brief trauma-focused therapy developed at the VA National Center for PTSD. Patients write about their traumatic experiences following a script structured by 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 hand 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. Feedback about the narrative is provided to the patient at the beginning of sessions 2-5. In contrast to the high drop-out rates for PE and CPT, drop-out rates for WET have ranged from 6.4%-14%. In a superiority trial conducted in a civilian population, WET was

significantly more effective than not having the therapy. In a comparison of 5 sessions of WET to 12 sessions of CPT, WET was more effective than CPT. WET is considered a first treatment in the US VA/Department of Defense PTSD Clinical Practice Guidelines.

However, WET has not been delivered by tele-therapists at VA Clinical Resource Hubs (CRHs), regional telehealth hubs designed to support underperforming satellite outpatient clinics with inadequate staffing. Mental health services are delivered to Veterans via interactive video and to Veterans in their homes.

Who can participate?

Veterans enrolled in the United States Department of Veterans Affairs with a primary diagnosis of PTSD

What does the study involve?

Tele-therapists volunteer to participate in the project and their patients are sampled for six months for the evaluation. Multiple cohorts of tele-therapists will participate and the project is expected to last for two and half years. Therapists are randomized to one of two implementation strategies (WET training alone or WET training plus external facilitation) and complete a very brief survey monthly to assess their beliefs about delivering WET. Patients are sent opt-out emails and those not opting out are asked to complete two brief telephone surveys and permission to review their medical records.

What are the possible benefits and risks of participating?

Patients whose therapist was randomized to WET training plus external facilitation may be more likely to receive trauma-focused psychotherapy, which is recommended as the first line of treatment by the VA/DOD PTSD Clinical Practice Guidelines. However, there are no guarantees that patients participating in the evaluation will experience a clinical benefit. The risk to both therapists and patients is the potential loss of privacy of sensitive information.

Where is the study run from?

The VA Virtual Care QUERI Program (United States of America)

When is the study starting and how long is it expected to run for?

October 2020 to September 2025

Who is funding the study?

The VA Quality Enhancement Research Initiative (QUERI) (United States of America)

Who is the main contact?

John Fortney, PhD (United States of America)

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Contact information

Type(s)

Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

QUE 20-007

Study information

Scientific Title

Implementation of written exposure therapy for PTSD in Veterans Affairs telehealth clinical resource hubs

Acronym

WETT

Study objectives

Aim 1 – Compare adoption of Written Exposure Therapy (WET) by Department of Veterans Affairs Clinical Resource Hub (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.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The study activities described are not being conducted as part of a research project but as part of a non-research evaluation conducted under the authority of The Department of Veteran Affairs Office of Rural Health (confirmed 28/12/2020), which does not require ethics approval as per VHA Handbook 1200.21 (Veterans Health Administration 2019) under the United States of America's law.

Study design

Multi-site hybrid type III effectiveness-implementation cluster randomized trial with provider level randomization (1:1) unmasked study

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Other

Study type(s)

Other

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Posttraumatic Stress Disorder

Interventions

The interventions are not clinical interventions, they are implementation strategies designed to promote the adoption of evidence-based practice into routine care.

Implementation Strategy 1 - Therapist training in Written exposure therapy (WET) with clinical supervision of two patients.

Implementation Strategy 2 - Therapist training in WET with clinical supervision of two patients, plus a WET shared decision-making aid, a manual for remote sharing of written trauma narratives, and a virtual community of practice for six months.

Arms – The Standard WET training arm involves 6 hours of didactics and weekly clinical supervision until two patients have completed WET. The Standard WET training plus external facilitation involves 6 hours of didactics and weekly clinical supervision until two patients have completed WET and 6 months of 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.

Randomization – The randomization of therapists will be conducted using an online list randomization app (<https://www.random.org/lists/>) after completion of Standard WET training.

Intervention Type

Other

Primary outcome measure

Reach at the patient level, defined as whether the patient received the WET intervention, measured using chart reviews during the time period between the intake visit and 4 months later

Secondary outcome measures

1. Clinical effectiveness at the patient level measured using the PTSD Check List for DSM-V (PCL-5) survey to assess PTSD symptom severity and the Brief Inventory of Psychosocial Functioning (B-IPF) to assess relationship functioning at baseline and 4 months
2. Adoption at the therapist level measured using chart reviews to measure what proportion of each therapist's patients with PTSD received WET versus some other type of counseling during the six months of external facilitation
3. Mechanisms of action measured using provider surveys at 1, 2, 3, 4, 5, and 6 months after external facilitation began, including:
 - 3.1. Self-efficacy for PTSD treatment planning
 - 3.2. Attitude about WET
 - 3.3. Self-efficacy for delivering WET
 - 3.4. Usability for sharing trauma narratives
 - 3.5. Clinical Resource Hub (CRH) therapist support for delivering WET

Overall study start date

01/10/2020

Completion date

30/09/2025

Eligibility

Key inclusion criteria

1. Enrollee in the United States Department of Veterans Affairs
2. Primary diagnosis of post-traumatic stress disorder at an intake encounter

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

640 patients

Key exclusion criteria

Does not meet the inclusion criteria

Date of first enrolment

15/10/2022

Date of final enrolment

15/04/2025

Locations**Countries of recruitment**

United States of America

Study participating centre

United States Department of Veterans Affairs

810 Vermont Avenue, NW

Washington, D.C.

United States of America

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Sponsor information**Organisation**

United States Department of Veterans Affairs Quality Enhancement Research Initiative (QUERI)

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Sponsor type

Government

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Funder(s)

Funder type

Government

Funder Name

US Department of Veterans Affairs Quality Enhancement Research Initiative (QUERI)

Alternative Name(s)

Department of Veterans Affairs, United States Department of Veterans Affairs, US Department of Veterans Affairs, U.S. Dept. of Veterans Affairs, Veterans Affairs, Veterans Affairs Department, VA, USDVA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United States of America

Results and Publications

Publication and dissemination plan

1. Planned publication in a high-impact peer-reviewed journal
2. On the VA QUERI website

Intention to publish date

30/09/2026

Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the current project are not expected to be made available because they are derived from a quality improvement project, not a research study.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
version v1.0					

[Protocol file](#)

21/09/2022

22/09/2022

No

No