

# Testing an implementation strategy to help primary care providers provide mental health medications for veterans with PTSD (PROMPT trial)

<b>Submission date</b> 25/02/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 06/03/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 20/12/2021	<b>Condition category</b> 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

Some veterans with PTSD are reluctant to see mental health providers, and so do not receive mental health care. Others have reduced access to medication treatments for PTSD because of the distance they live from VA medical centers where more mental health prescribers are available. To provide more rural veterans and those reluctant to see mental health providers with an additional pathway to receive medications for PTSD, we developed an intervention to help primary care providers at VA community clinics become more competent in and comfortable with prescribing medications recommended by clinical practice guidelines for their patients with PTSD.

### Who can participate?

VA community clinics

### What does the study involve?

We developed a clinic-based intervention to increase primary care providers' prescribing rates for their patients with PTSD. The intervention included tools to help providers learn about medication treatments for PTSD in greater depth, an electronic medical record-based tool to provide prescribing information and help providers make decisions about medication treatments, and a one-time help with problem solving local changes to patient flow that might result from primary care providers taking on this added responsibility. Control sites did not receive these tools or assistance.

### What are the possible benefits and risks of participating?

Not applicable

### Where is the study run from?

Center for Care Delivery and Outcomes Research, Minneapolis VA Health Care System

When is the study starting and how long is it expected to run for?  
March 2012 to March 2017

Who is funding the study?  
This study was funded by VA Health Services Research & Development grant CRE-12-020.

Who is the main contact?  
Michele Spont, PhD  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
CRE 12-020

## Study information

**Scientific Title**  
Promoting Evidence-Based Pharmacotherapy for PTSD in Community Based Outpatient Clinics

**Acronym**  
PROMPT

**Study objectives**

Can the implementation intervention (i.e., training and decision support tools) encourage primary care providers to increase the proportion of veterans with PTSD in their panels to whom they prescribe an evidence based medication for PTSD?

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 04/02/2013, VA Central Institutional Review Board (vacentralirb@va.gov; 1-877-254-3130; no postal address available), ref: 12-36

### **Study design**

Clustered randomized pre-post pragmatic implementation trial

### **Primary study design**

Intentional

### **Secondary study design**

Cluster randomised trial

### **Study setting(s)**

GP practice

### **Study type(s)**

Other

### **Participant information sheet**

None available

### **Health condition(s) or problem(s) studied**

Prescribing medications for Posttraumatic Stress Disorder (PTSD)

### **Interventions**

We tested whether an implementation intervention (i.e., optional free CME training in guideline-recommended PTSD pharmacotherapy, point-of-care provider decision support tool availability, and external facilitation) would encourage primary care providers to expand their scope of practice to prescribe PTSD pharmacotherapy for the relevant patients in their panels. Clinic clusters were randomized to receive or not receive these tools. All primary outcomes from VA prescribing databases.

This study recruited paired clusters of VA community clinics and randomized one of the site clusters to an implementation intervention. Quantitative Outcomes were from VA administrative databases. Also conducted a formative evaluation of implementation strategy.

It was difficult to fit this study into the format of a traditional RCT despite the use of randomization because the "participants" were community clinics, not individuals. This was, effectively, an organizational intervention in which organizational leaders consented to have their community clinics participate in the study. That is, facility organizational leaders gave us permission to randomize their facility and attendant community clinics to either the project control arm or intervention arm. Community clinics in the intervention arm were provided with resources that primary care providers could choose (or not choose) to make use of – online

training module, provider decision support tool in the electronic medical record, and facilitated negotiation of roles between primary care providers and mental health providers in the clinic regarding the care of patients with PTSD. Although provider behavior (i.e., prescribing rates of specific medication classes) was the target of the intervention, providers were not enrolled. Instead, study resources were simply made available to primary care providers in the control arm, whereas providers in control arm clinics were not given access to these resources.

**Intervention Type**

Other

**Primary outcome measure**

Change in the proportion of patients in providers' panels who received a PTSD guideline-recommended medication (either a selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI)) from the year pre-intervention relative to the year post-intervention, measured using patient notes.

**Secondary outcome measures**

Subgroup analyses comparing prescribing behavior between training participants and non-participants at the intervention sites.

**Overall study start date**

07/12/2011

**Completion date**

01/05/2017

**Eligibility****Key inclusion criteria**

sites where leadership agreed to study participation

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

8 sites, 4 in each arm, approx. 33,500 patient records

**Key exclusion criteria**

not applicable

**Date of first enrolment**

01/03/2012

**Date of final enrolment**

22/09/2015

## **Locations**

### **Countries of recruitment**

United States of America

### **Study participating centre**

#### **Minneapolis VA Health Care System**

Minneapolis, MN

United States of America

55417

### **Study participating centre**

#### **Edward Hines Jr. VA Hospital**

Hines, IL

United States of America

60141

### **Study participating centre**

#### **VA Boston Healthcare System**

Boston, MA

United States of America

02132

### **Study participating centre**

#### **VA Connecticut Healthcare System**

West Haven Campus

West Haven, CT

United States of America

06516

### **Study participating centre**

#### **Phoenix VA Health Care System**

Phoenix, AZ

United States of America

85012

## **Sponsor information**

**Organisation**

Minneapolis VA Health Care System

**Sponsor details**

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**Sponsor type**

Government

**Website**

<http://www.minneapolis.va.gov/>

**ROR**

<https://ror.org/02ry60714>

**Funder(s)****Funder type**

Government

**Funder Name**

Health Services Research and Development

**Alternative Name(s)**

VA Health Services Research and Development Service, VA HSR&D, Veterans Health Administration HSR and D, HSR&D

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United States of America

**Results and Publications**

**Publication and dissemination plan**

We intend to publish the primary paper later this year, in a high-impact peer-reviewed journal, using an implementation evaluation framework.

**Intention to publish date**

31/12/2022

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are not expected to be made available due to:

The outcome data consists of medication prescriptions ordered by individual providers and received by individual patients. The prescribing database, which includes identifying information of providers and patients, is too large to obtain informed consents and HIPAA authorizations. Public disclosure of the final study data containing PII and/or PHI would be inconsistent with the IRB approved waiver of informed consent and HIPAA authorization that was obtained.

**IPD sharing plan summary**

Not expected to be made available