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

Submission date
25/02/2019

Recruitment status
No longer recruiting

Registration date
06/03/2019

Overall study status
Completed

Last Edited
20/12/2021

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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?
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Contact information

Type(s)
Scientific

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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
Interventional

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

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Minneapolis VA Health Care System

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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