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Effective Implementation of Stress Treatments in US Department of Veterans Affairs PTSD Clinics

Submission date
19/07/2018

Recruitment status
No longer recruiting

Registration date
25/07/2018

Overall study status
Completed

Last Edited
21/09/2020

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
The US Department of Veterans Affairs (VA) uses two evidence-based psychotherapies for Post-traumatic Stress Disorder (PTSD) throughout the VA healthcare system. However, the problem is that the majority of Veterans diagnosed with PTSD do not receive one of these evidence-based psychotherapies. This project aims to address this. In this two-year quality improvement project we will look the effectiveness of an intervention to address this gap in treatment.

Who can participate?
The intervention will be tested in two VA outpatient PTSD teams from different US geographic regions that have a significant quality gap in terms of delivery of evidence-based psychotherapy to veterans with PTSD. These two intervention sites will be matched to three comparison sites each for a total of two intervention and six comparison sites.

What does the study involve?
The intervention was designed in collaboration with VA leaders who have responsibility for mental health care for VA patients with PTSD. It includes six months of toolkit-guided external facilitation to help PTSD teams improve patient access to evidence-based psychotherapies for PTSD. External facilitation involves clinicians working with an expert, knowledgeable individual to make changes to their practice to improve the quality gap, including strategies and resources to improve access to psychotherapies for PTSD. To see if our intervention works, we will examine changes in the proportion of therapy patients with PTSD who receive an evidence based psychotherapy in our intervention and comparison sites.

What are the possible benefits and risks of participating?
The benefit of participating is improved access to evidence-based psychotherapies for PTSD in the two intervention VA PTSD teams, improving their rates of delivery of these proven psychotherapy. This will further benefit and support the VA mission, improving processes of care. There are no known risks to the sites for participation.

Where is the study run from?
The study is run from the Minneapolis VA Healthcare System in Minneapolis, MN and involves 8 VA Medical Centers.

When is the study starting and how long is it expected to run for?
June 2017 to March 2020

Who is funding this study?
VA Health Services Research and Development (HSR&D) (USA)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CRE 18-002

Study information

Scientific Title
A Quasi-Experimental Implementation Trial of Toolkit Guided External Facilitation to Improve Reach of Evidence-Based Psychotherapies for Posttraumatic Stress Disorder (PTSD) in US Department of Veterans Affairs PTSD Clinics

Acronym

PERSIST 2.0

Study objectives
The Primary aim of this Quality Improvement Implementation Trial is to increase the reach of Cognitive Processing Therapy (CPT) and Prolonged Exposure (PE) in two low reach PTSD teams using external facilitation and a toolkit that bundles strategies and resources to improve reach identified through prior research. To achieve our primary aim, we will assess the effectiveness of our implementation strategy in a pre-post nonequivalent control group, quasi-experimental design. Our second aim is to conduct formative evaluation to inform facilitation activities and aid in interpretation of quantitative findings. Our third aim is to refine our implementation tools for use in future efforts to improve reach of CPT and PE to patients with PTSD.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Minneapolis VA Health Care System IRB reviewed this project and determined that the activities involved do not meet the definition of research. This project is designed for internal purposes in support of the mission of the Department of Veterans Affairs and findings are to be used within Department of Veterans Affairs to improve processes of care. All data collected pertain to quality improvement activities. 30/06/2017

Study design
Interventional non-randomised proof-of-concept improvement project with a quasi-experimental, pre-post design with non-equivalent control groups

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Post-traumatic Stress Disorder (PTSD)

Interventions
The study will have 2 intervention sites and 6 comparison sites.
The 2 intervention sites will engage in toolkit-guided external facilitation for 6 months. Each intervention site will be matched to 3 comparison sites based on available administrative data on reach of Cognitive Processing Therapy (CPT) and Prolonged Exposure (PE) (the outcome), facility and patient characteristics.
External facilitation involves having an external expert in implementation with credible

knowledge about the clinical innovation interact with the target sites in the context of a supportive interpersonal relationship to enact changes. Facilitation activities include assessment of local context, identifying and preparing a local champion, engagement of stakeholders, assistance in goal setting and action planning using a formal implementation plan, regular contact to provide technical assistance, formative evaluation, support and training for the internal change agent and preparing for sustainability. This work will be guided by a toolkit which bundles strategies and resources to improve access to evidence based therapies for PTSD that have been identified through prior research.
The 6 comparison sites will receive assistance and support for delivery of CPT and PE as usual.

Intervention Type
Behavioural

Primary outcome measure
Cognitive Processing Therapy (CPT) and Prolonged Exposure (PE) reach to therapy patients seen by the PTSD team, measured as the proportion of veterans diagnosed with PTSD during a psychotherapy appointment with a provider on the PTSD team within the 6 months before and after the intervention who receive at least one CPT or PE appointment.

Secondary outcome measures
Cognitive Processing Therapy (CPT) and Prolonged Exposure (PE) reach in other mental health teams in the facility, measured as the proportion of veterans diagnosed with PTSD during a psychotherapy appointment with a provider in any other mental health team within the 6 months before and after the intervention who receive at least one CPT or PE appointment.

Overall study start date
05/06/2017

Completion date
31/03/2020

Eligibility

Key inclusion criteria
1. Low reach PTSD team (defined as less than or equal to the national median of reach on PTSD teams during a 12-month period preceding project start)
2. Have a champion to serve as an internal change agent
3. Facility leadership support for the project

Participant type(s)
Other

Age group
Not Specified

Sex
Not Specified

Target number of participants

Two Department of Veterans Affairs PTSD teams from sites in different geographic regions of the US

Key exclusion criteria
PTSD teams that treat fewer than 500 patients in a 12 month period

Date of first enrolment
01/04/2018

Date of final enrolment
01/08/2018

Locations

Countries of recruitment
United States of America

Study participating centre
Minneapolis VA Health Care System
One Veterans Drive
Minneapolis
United States of America
55417

Sponsor information

Organisation
VA Health Services Research and Development Service

Sponsor details
810 Washington Ave, NW
Washington DC
United States of America
20420

Sponsor type
Research organisation

ROR
https://ror.org/011qyt180

Funder(s)

Funder type
Not defined

Funder Name
Department of Veterans Affairs Health Services Research and Development (USA)

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer-reviewed journal

Intention to publish date
01/08/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available, as the data is available for the US Department of Veterans Affairs to improve the quality of care. Therefore, public disclosure of the data would be inconsistent with the purpose of this work.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2020	21/09/2020	Yes	No