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Testing implementation of Cognitive Behavioral Therapy- Promoting Resilience and Support for Mental Health (CBT-PRISM)

Submission date
01/10/2025

Recruitment status
Recruiting

Registration date
13/10/2025

Overall study status
Ongoing

Last Edited
09/10/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[X] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Veterans who are lesbian, gay, bisexual, queer/questioning, trans, and other related identities (LGBTQ+) have disproportionate risk for poor mental health outcomes and suicide. LGBTQ+ veterans face unique barriers to accessing care. Tailored cognitive behavioral therapy has a strong evidence base for improving mental health among LGBTQ+ individuals. This evidence-based psychotherapy (EBP) is ready for use, but it has not yet been implemented widely in VHA. This EBP was adapted as CBT-PRISM (Cognitive Behavioral Therapy - Promoting Resilience and Support for Mental Health) in the current study to meet the unique needs of LGBTQ+ Veterans who receive care through VHA. The objective of this project is to use an implementation-effectiveness trial design to test provider- and Veteran-level outcomes linked with an Enhanced Implementation Package to increase adoption and sustainment of CBT-PRISM. The study includes the following specific aims: 1) To refine an Enhanced Implementation Package for improving uptake of CBT-PRISM; 2a) To conduct a multi-site randomly allocated trial of 12 facilities comparing a Standard Implementation Package to an Enhanced Implementation Package; 2b) To qualitatively examine determinants of implementation across sites through provider and patient interviews; and 3) To estimate the number of patients reached and effectiveness of the Enhanced Implementation Package between the two arms of the study.

Who can participate?
Twelve Veterans Health Administration facilities that meet the inclusion criteria and are selected may participate in the study.

What does the study involve?
This trial includes 12 facilities equally randomly allocated to receive either a Standard Implementation Package (internal facilitation, live virtual training for clinicians, free therapist treatment manuals, and clinical consultation/community of practice) or an Enhanced Implementation Package (Standard Implementation plus 6 implementation strategies focused on Veteran-centered health equity). The primary implementation outcome is adoption, as

measured by the rate of psychotherapists delivering at least one session of CBT-PRISM. Effectiveness outcomes include clinically significant change in depression (primary) and likelihood of self-injurious thoughts or behaviors (secondary).

What are the possible benefits and risks of participating?
Enhanced implementation strategies may help better integrate social drivers of health into daily operations. Please note that this is a hybrid type III implementation-effectiveness trial. Hence, delivery of the evidence-based psychotherapy (CBT-PRISM) within treatment sessions is not part of the study protocol.

Where is the study run?
The primary site running the study is the Durham Veterans Affairs Health Care System in Durham, NC, USA.

When is the study starting and how long is it expected to run for?
Activities with randomized facilities begin 01 Oct 2025. Clinician training in CBT-PRISM begins 01 Feb 2026, with an anticipated start for clinicians delivering the CBT-PRISM to patients on or after 01 Apr 2026. The active implementation period with facilities will run until 01 Apr 2027, and the sustainment period with facilities will run until 01 Oct 2027.

Who is funding the study?
The Department of Veterans Affairs, Health Services Research & Development, USA.

Who is the main contact?
Sarah M. Wilson, PhD, Principal Investigator, sarah.m.wilson@va.gov

Contact information

Type(s)
Scientific, Principal investigator

Contact name
Dr Sarah Wilson

ORCID ID
https://orcid.org/0000-0002-1028-6028

Contact details
VA Durham Health Care, Veterans Affairs
508 Fulton St
Durham
United States of America
27705
+1-919-286-0411 ext. 17-7914
sarah.m.wilson@va.gov

Type(s)
Public

Contact name
Dr Hollis Weidenbacher

ORCID ID
https://orcid.org/0000-0002-8108-4204

Contact details
VA Durham Health Care, Veterans Affairs
508 Fulton St.
Durham
United States of America
27705
1-919-286-0411 ext. 17-7377
hollis.weidenbacher@va.gov

Additional identifiers

Protocol serial number
CIRB 1781791

Study information

Scientific Title
Equity-focused implementation of LGBTQ-affirmative cognitive behavioral therapy: a hybrid implementation-effectiveness trial

Acronym
DELVE

Study objectives
The objective of this project is to use a hybrid type III implementation-effectiveness trial design to test provider- and Veteran-level outcomes associated with an Enhanced Implementation Package aimed at increasing the adoption and sustainment of CBT-PRISM (Cognitive Behavioral Therapy - Promoting Resilience and Support for Mental Health). The study includes the following specific aims: 1) to refine an Enhanced- Implementation Package for improving uptake of CBT-PRISM; 2a) To conduct a multi-site cluster-randomized trial of 12 facilities comparing a Standard Implementation Package to an Enhanced Implementation Package; 2b) To examine determinants of implementation across sites qualitatively; and 3) To estimate the reach and effectiveness of the Enhanced Implementation Package among LGBTQ+ Veterans between implementation arms.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 19/04/2025, Department of Veterans Affairs, VA Central Institutional Review Board (810 Vermont Avenue, NW ORD 14RD, Washington, DC, 20420, United States of America; 800-698-2411; VACentralIRB@va.gov), ref: 24-12

Primary study design
Interventional

Study design
Hybrid Type III implementation effectiveness trial

Study type(s)
Other

Health condition(s) or problem(s) studied
Access to tailored evidence-based treatment for depression and self-injurious thoughts or behaviors among U.S. military veterans who identify as LGBTQ+.

Interventions
Facilities are randomized using constrained randomization to one of two implementation arms: 1) Standard Implementation Package, or 2) Enhanced Implementation Package. The Standard Implementation Package includes the following strategies: internal facilitation, live virtual training for clinicians, free therapist treatment manuals, and clinical consultation/community of practice. The Enhanced Implementation Package includes all strategies from the Standard Implementation Package in addition to the following strategies: process to build infrastructure support, external facilitation to build within-organization and local community interrelationships, local CBT-PRISM referral champions, internal facilitator learning collaborative, and electronic health record audit and feedback of treatment delivery. Both implementation packages will be delivered across an 18-month Implementation Period.

Intervention Type
Behavioural

Primary outcome(s)
The extent to which an Enhanced Implementation Package improves the adoption and sustainment of the evidence-based psychotherapy (provider-level main outcomes) is measured through the following variables:
1. Primary Adoption Outcome, defined as the rate of practicing psychotherapists delivering at least one session of CBT-PRISM measured using electronic health record data from patients within the healthcare system in the 18-month Implementation Period.
2. Primary Sustainment Outcome, defined as the rate of practicing psychotherapists delivering at least one session of CBT-PRISM measured using electronic health record data from patients within the healthcare system in the 6-month Sustainment Period

Key secondary outcome(s)
1. Reach Outcome: Receiving CBT-PRISM, defined as the proportion of LGBTQ+ veterans with electronic health record depression diagnosis receiving at least one session of CBT-PRISM across implementation arms, measured using electronic health record data from patients within the healthcare system during the 18-month Implementation Period and during the 6-month Sustainment Period.
2. Effectiveness Outcome: Documentation of clinically significant improvement in depression symptoms, defined as the proportion of LGBTQ+ veterans with an electronic health record depression diagnosis with a clinically significant decrease in depression symptoms, measured pragmatically using electronic health record data from health system patients. Clinically significant change on health system symptom measurement tools (Patient Health Questionnaire-9; PHQ-9) will be quantified using the Reliable Change Index during the 18-month Implementation Period and 6-month Sustainment Period.

3. Effectiveness Outcome: Likelihood of having documented self-injurious thoughts or behaviors, measured pragmatically using electronic health record data of health care system patients, adjusting for pre-implementation levels of self-injurious thoughts or behaviors.

Completion date
30/07/2028

Eligibility

Key inclusion criteria
Facility (primary participants, unit of randomization) Inclusion Criteria:
1. Availability and willingness of one internal implementation facilitator (devoting up to 3 hours /week for 18 months)
2. Site leadership (Chief of Staff or Associate Chief of Staff for Mental and Behavioral Health Services) is willing to sign an agreement confirming willingness for the internal facilitator, trainers, and facility training, and (if randomized to the Enhanced Condition) willing to interact with study personnel for at least one meeting.
3. In the event that more than 12 facilities apply for inclusion in the study, inclusion will be prioritized by several factors, including number of Mental Health Service full-time employees (to ensure sufficient sample size of clinicians), representativeness across facility complexity classifications, and representativeness across rural/urban locations.

Provider Electronic Health Record Cohort Inclusion Criteria (not enrolled):
1. Non-specialty practicing psychotherapist at included study facility
2. Delivered psychotherapy within the measurement period

Patient Electronic Health Record Cohort Inclusion (not enrolled):
1. Identified as LGBTQ+ using validated natural language processing algorithm from electronic health record notes from 2019 to present.

Participant type(s)
Patient, Employee, Other

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Facility-Level Exclusion Criteria (primary participants, unit of randomization):
1. Facility using Cerner as its electronic health record system
2. Internal Facilitator not available
3. Facility leadership unwilling to support implementation

Provider Electronic Health Record Cohort Exclusion Criteria (not enrolled):
1. Not a practicing psychotherapist at an included study facility
2. Did not deliver psychotherapy within the measurement period

Patient Electronic Health Record Cohort Exclusion (not enrolled):
1. Not identified as LGBTQ+ using validated natural language processing algorithm from electronic health record notes from 2019 to present.

Date of first enrolment
01/10/2025

Date of final enrolment
01/04/2027

Locations

Countries of recruitment
United States of America

Study participating centre
Durham Veterans Affairs Medical Center
508 Fulton St
Durham
United States of America
27705

Sponsor information

Organisation
Veterans Health Administration

ROR
https://ror.org/05eq41471

Funder(s)

Funder type
Not defined

Funder Name
U.S. Department of Veterans Affairs

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, Veterans' Administration, VA, USDVA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
There are no plans to share non-aggregate data.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan			09/10/2025	No	No