ISRCTN16144716 https://doi.org/10.1186/ISRCTN16144716

Innovative treatments for the recovery implementation program

Submission date
04/12/2025

Recruitment status
Recruiting

Registration date
16/12/2025

Overall study status
Ongoing

Last Edited
28/08/2026

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Depression and posttraumatic stress disorder (PTSD) are debilitating conditions with immeasurable social and economic costs, affecting the lives of hundreds of millions of people annually. Unfortunately, current treatment options for these conditions are often inadequate to meet Veterans' needs. Therefore, innovative evidence-based treatment options are needed to improve Veteran experience, outcomes, and mental health services.

This project will implement innovative evidence-based treatments for trauma-related conditions and treatment-resistant depression that improve Veteran care by addressing VA priorities of suicide prevention, outcomes, access, whole health, quality, value, and efficiency. The study involves the implementation of two evidence-based practices (EBP): 1) Mantram Repetition Program, a meditation-based approach to reduce PTSD symptoms, and 2) Ketamine Therapy for treatment-resistant depression and suicidality.

The study aims to first work with clinicians, operational staff, and Veterans to understand local needs and challenges so strategies can be tailored for successful and lasting implementation of evidence-based practices (EBPs). Next, it will introduce two EBPs at 16 sites using a stepped-wedge randomized design testing an implementation strategy bundle, including assessments, workshops, training, and facilitation. Finally, the study will evaluate how well the EBPs perform using RE-AIM measures (Reach, Effectiveness, Adoption, Implementation, and Maintenance), assess cost-effectiveness, and identify factors that help or hinder success. It will also create practical resources, such as playbooks, workshops, and training, to support long-term sustainability and wider adoption across the system.

Who can participate?
VHA medical facilities that want to implement the Mantram Repetition Program and/or Ketamine Therapy.

What does the study involve?
Using two stepped-wedge randomized design studies, the EBPs will be implemented across sites to improve multiple high-priority quality/impact domains guided by the Practical Robust Implementation and Sustainability Model (PRISM). A novel implementation strategy will be used

to bundle 1) iterative PRISM assessment (iPRISM), 2) Modified Rapid Process Improvement Workshops (RPIW), 3) training, and 4) Implementation facilitation. The impact of the two EBPs will be evaluated using multiple data sources as well as analytical methods. Quantitative and qualitative data will be collected longitudinally across pre-implementation, implementation, and sustainment, which will include survey, interview, adaptation, engagement, economic, and service outcome data.

What are the possible benefits and risks of participating?
While there is no direct benefit to participation in this study, the project hopes to identify and enhance best practices for mental health treatment for Veterans and to learn how best to implement cutting-edge clinical care programs.

Potential risks associated with participation in the study are 1) loss of confidentiality and 2) feeling discomfort answering survey/interview questions during participation. Such risks are not likely and would not lead to serious consequences.

Where is the study run from?
VA San Diego Healthcare System in San Diego, USA.

When is the study starting and how long is it expected to run for?
January 2026 to September 2030.

Who is funding the study?
The VA Quality Enhancement Research Initiative (QUERI), USA.

Who is the main contact?
Dr James Pittman, PhD, LCSW, James.Pittman@va.gov

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr James Pittman

Contact details
3350 La Jolla Village Drive
La Jolla
United States of America
92161
+1 (858)-750-9246
James.Pittman@va.gov

Additional identifiers

electronic Research Administration (eRA) Commons application number
1I50HX004145

Project ID

QUE 25-011

Study information

Scientific Title
Innovative Treatments for Recovery Implementation Program: a randomized quality improvement program implementing innovative evidence-based treatments for Veterans with trauma related conditions and treatment resistant depression to improve care by addressing VA priorities of suicide prevention, clinical outcomes, access, whole health, quality, value, and efficiency.

Study objectives
1) Pre-implementation: Engage clinical, operational, and Veteran partners to gather perspectives on local context to optimize strategies for the implementation and sustainability of the Mantram Repetition Program (MRP) and Ketamine Therapy (KT).
2) Implementation: Implement these two evidence-based practices (EBP) across 16 sites using two cluster randomized stepped-wedge design studies and a multicomponent implementation strategy bundle (i.e. iPRISM Assessment, Rapid Process Improvement Workshops [RPIW], training, and facilitation).
3) Sustainment: Evaluate RE-AIM outcomes (i.e., Reach, Effectiveness, Adoption, Implementation, and Maintenance) aligned with national performance quality standards, as well as the cost-effectiveness of the EBPs. Identify key multi-level contextual facilitators and barriers for their implementation and sustainment using the Practical Robust Implementation and Sustainability Model (PRISM) and a mixed-method analytic approach. Develop sustainment and scale-up capacity for the EBPs by creating multilevel strategies and products (e.g., playbooks, workshops, trainings) for each EBP to support enterprise dissemination and uptake.

Ethics approval required
Ethics approval not required

Ethics approval(s)

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Uncontrolled

Assignment
Sequential

Purpose
Health services research

Study type(s)
Treatment, Other

Health condition(s) or problem(s) studied
Implementation of evidence-based treatments for posttraumatic stress disorder and treatment-resistant depression.

Interventions
Current interventions as of 28/08/2026:

These studies are part of a multicenter step-wedged randomized hybrid type-2 implementation effectiveness mixed-methods quality improvement program.

VA implementation partners are involved in the implementation of the Mantram Repetition Program (MRP) or Ketamine Therapy (KT) at one of the project sites. The two interventions administered in this study are the MRP and KT. There is no control treatment for this quality improvement project. Sites will be randomized by implementation start date.

1. Mantram Repetition Program (MRP). Mantram repetition consists of the silent repetition of a self-selected word or short phrase with spiritual meaning multiple times throughout the day. Mantram repetition is used to develop one-pointed attention, increase present moment awareness, regulate emotions, and manage distressing thoughts. The MRP is a transdiagnostic intervention, with documented positive effects on a range of outcomes, including reductions in post-traumatic stress disorder (PTSD) symptoms. The MRP can be taught in person or virtually, including by use of pre-recorded videos or by clinicians or paraprofessional; and can even be done via self-guided software application. MRP can be delivered in individual or group-based formats, typically involving a 60-minute meeting; and has been successfully delivered in 1-8 sessions. MRP is provided on an outpatient basis. For this QUERI program, MRP will be tailored to meet the unique needs of each implementation site. Background and further details on Mantram Repetition can be found here: https://www.jillbormann.com/mantram-repetition-program

2. Ketamine Therapy (KT). KT has been shown to have rapid antidepressant effects in multiple research trials, which has led to the FDA-approval as an intervention for treatment-resistant depression (TRD). The medication is administered intravenously, intramuscularly, or intranasally in a face-to-face medical appointment with qualified health providers in a range of dosages that vary in rate, length, and frequency. KT can be given in an inpatient or outpatient setting. For this project, KT will be customized to each site depending on the unique needs of each. Background and further details on KT can be found here: https://www.va.gov/formularyadvisor/DOC_PDF/CRE_Ketamine_Infusion_for_Treatment_Resistant_Depression_Rev_Oct_2025.pdf

_____

Previous interventions:

These studies are part of a multicenter step-wedged hybrid type-2 implementation effectiveness mixed-methods quality improvement program.

VA implementation partners are involved in the implementation of the Mantram Repetition Program (MRP) or Ketamine Therapy (KT) at one of the project sites. The two interventions administered in this study are the MRP and KT. There is no control treatment for this quality improvement project. Sites will be randomized by implementation start date.

1. Mantram Repetition Program (MRP). Mantram repetition consists of the silent repetition of a self-selected word or short phrase with spiritual meaning multiple times throughout the day. Mantram repetition is used to develop one-pointed attention, increase present moment awareness, regulate emotions, and manage distressing thoughts. The MRP is a transdiagnostic intervention, with documented positive effects on a range of outcomes, including reductions in post-traumatic stress disorder (PTSD) symptoms. The MRP can be taught in person or virtually, including by use of pre-recorded videos or by clinicians or paraprofessional; and can even be done via self-guided software application. MRP can be delivered in individual or group-based formats, typically involving a 60-minute meeting; and has been successfully delivered in 1-8 sessions. MRP is provided on an outpatient basis. For this QUERI program, MRP will be tailored to meet the unique needs of each implementation site. Background and further details on Mantram Repetition can be found here: https://www.jillbormann.com/mantram-repetition-program

2. Ketamine Therapy (KT). KT has been shown to have rapid antidepressant effects in multiple research trials, which has led to the FDA-approval as an intervention for treatment-resistant depression (TRD). The medication is administered intravenously, intramuscularly, or intranasally in a face-to-face medical appointment with qualified health providers in a range of dosages that vary in rate, length, and frequency. KT can be given in an inpatient or outpatient setting. For this project, KT will be customized to each site depending on the unique needs of each. Background and further details on KT can be found here: https://www.va.gov/formularyadvisor/DOC_PDF/CRE_Ketamine_Infusion_for_Treatment_Resistant_Depression_Rev_Oct_2025.pdf

Intervention Type
Mixed

Primary outcome(s)
1. Mantram repetition: The proportion of veterans who receive the EBI, and the time from referral to the first EBI visit measured using a review of VA Corporate Data Warehouse data at pre-implementation, implementation, and sustainment timepoints

2. Ketamine Therapy: The proportion of veterans with TRD who have at least one suicide risk indicator, and the number of suicide risk indicators among veterans with TRD measured using a review of VA Corporate Data Warehouse data at at pre-implementation, implementation, and sustainment timepoints

Key secondary outcome(s)
PRISM Contextual Survey Instrument and Qualitative Interviews at pre-implementation, implementation, and sustainment timepoints. Adaptation Tracking as indicated by adaptation events and cost analysis at implementation and sustainment timepoints.

Completion date
30/09/2030

Eligibility

Key inclusion criteria
1. Frontline staff
2. Clinicians
3. Operational partners
4. Supervisors/managers/leaders

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
110 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Must meet all inclusion criteria and accept the invitation to participate in the program by the study principal investigator

Date of first enrolment
05/01/2026

Date of final enrolment
01/04/2030

Locations

Countries of recruitment
United States of America

Study participating centre
VA San Diego Healthcare System
3350 La Jolla Village Drive
San Diego
United States of America
92161

Sponsor information

Organisation
Quality Enhancement Research Initiative

ROR
https://ror.org/03cdz5d08

Funder(s)

Funder type
Not defined

Funder Name
Quality Enhancement Research Initiative

Alternative Name(s)
VA Quality Enhancement Research Initiative, QUERI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available