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Integrated vs Sequential Treatment for PTSD and Addiction

This study is ongoing, but not recruiting participants.

Sponsor:
VA Office of Research and Development

Information provided by (Responsible Party):
VA Office of Research and Development

ClinicalTrials.gov Identifier:
NCT01211106

First received: September 27, 2010
Last updated: May 23, 2016
Last verified: May 2016
History of Changes

Purpose

The investigators are examining different treatment strategies of helping patients with PTSD and addiction.

Condition	Intervention
PTSD Substance Addiction	Behavioral: Prolonged Exposure Behavioral: Motivational Enhancement Therapy

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Single Blind (Outcomes Assessor)
Primary Purpose: Treatment

Official Title: Integrated vs Sequential Treatment for PTSD and Addiction Among OEF/OIF Veterans

Further study details as provided by VA Office of Research and Development:

Primary Outcome Measures:

- substance use and PTSD symptoms [Time Frame: 16 weeks] [Designated as safety issue: No]

Estimated Enrollment: 200
Study Start Date: February 2011
Estimated Study Completion Date: December 2016
Primary Completion Date: March 2016 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Arm 1: Integrated Conditions The investigators hypothesize that Veterans in the integrated conditions will show greater reductions in substance abuse and PTSD symptom severity at the end of treatment	Behavioral: Prolonged Exposure Although almost every form of psychotherapy has been advocated for PTSD, all evidence-based psychotherapies for PTSD are CBT programs that include variants of exposure therapy (Prolonged Exposure), cognitive therapy (CT), stress inoculation training (SIT), **eye movement desensitization and reprocessing** (**EMDR**), or combinations of these procedures. Exposure therapy involves helping PTSD sufferers to gradually confront distressing trauma-related memories and reminders to facilitate successful emotional processing of the trauma memory and reduction of associated distress. Most exposure therapy programs include both imaginable confrontation with the traumatic memories and in vivo exposure to trauma reminders. Behavioral: Motivational Enhancement Therapy Motivational Interviewing (MI) is defined as a client-centered, directive method for enhancing intrinsic motivation to change by exploring and resolving ambivalence. MI is characterized by its spirit, which is defined as collaboration with the client, evocation of the client's own perceptions, goals, and values, and respect for the client's autonomy.

Detailed Description:

The investigators hypothesize that Veterans in the integrated conditions will show greater reductions in substance abuse and PTSD symptom severity at the end of treatment and at 6 and 9 month follow-ups. The investigators further hypothesize that offering Veterans PE at the onset of treatment in the integrated condition will leader to greater retention and satisfaction than in the sequential treatment design.

Eligibility

Ages Eligible for Study: 18 Years to 65 Years (Adult)
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Male or female Persian Gulf Era veterans between 18-65 years old. Older individuals are unlikely to have served in Iraq or Afghanistan.
- Current diagnosis of PTSD (symptom duration > 3 months) with clinically significant trauma-related symptoms, as indicated by a score of at least 50 on the PCL
- Current abuse or dependence on alcohol, stimulants such as cocaine, opioids, including prescription opioids or benzodiazepines. Subjects must report using on average at least 10 out of 30 days prior to signing consent. Of note: subjects can be abusing or dependent upon nicotine or marijuana but these will not be considered sufficient for inclusion
- Provides informed consent
- Speaks and reads English

Exclusion Criteria:

- Current suicidal or homicidal ideation with intent and/or plan that, in the judgment of the investigator, should be the focus of treatment
- Meets current DSM-IV criteria for bipolar affective disorder, schizophrenia or any psychotic disorder
- Has unstable or serious medical illness, including history of stroke, seizure disorder, or unstable cardiac disease
- History of moderate or severe traumatic brain injury (TBI)
- Participation in Prolonged Exposure Therapy in the last 6 months.
- Initiation of a new psychotherapy program in the last 2 months.
- Active participation in a formal addiction treatment program. Actively engaged is defined as any visit in the program in the prior month and pending future appointments for the treatment of addictions
- Change in psychotropic medication in the 1 month prior to treatment except for the use of oxazepam for alcohol detoxification or a taper of a previously used benzodiazepine.
- Therapeutic use of a benzodiazepine greater than the equivalent of more than 40 mg of diazepam (see chart) at the time of randomization.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT01211106

Locations

United States, Minnesota

VA Medical Center, Minneapolis
Minneapolis, Minnesota, United States, 55417

United States, Pennsylvania

Philadelphia VA Medical Center, Philadelphia, PA
Philadelphia, Pennsylvania, United States, 19104

Sponsors and Collaborators

VA Office of Research and Development

Investigators

Principal Investigator: David W. Oslin, MD Philadelphia VA Medical Center, Philadelphia, PA

More Information

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Keywords provided by VA Office of Research and Development:
Treatment
PTSD
Addiction

Additional relevant MeSH terms:
Behavior, Addictive
Substance-Related Disorders
Compulsive Behavior
Impulsive Behavior
Chemically-Induced Disorders
Mental Disorders

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