Integrated vs Sequential Treatment for PTSD and Addiction

**Purpose**

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

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
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<tbody>
<tr>
<td>PTSD</td>
<td>Behavioral: Prolonged Exposure</td>
</tr>
<tr>
<td>Substance Addiction</td>
<td>Behavioral: Motivational Enhancement Therapy</td>
</tr>
</tbody>
</table>

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)

**Detailed Description:**

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 imaginative 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.
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 lead 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**

Responsible Party: VA Office of Research and Development

ClinicalTrials.gov Identifier: NCT01211106 History of Changes

Other Study ID Numbers: ZDA1-03-W10

Study First Received: September 27, 2010

Last Updated: May 23, 2016

Health Authority: United States: Federal Government
<table>
<thead>
<tr>
<th>Keywords provided by VA Office of Research and Development:</th>
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<tbody>
<tr>
<td>Treatment</td>
<td>PTSD</td>
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<tr>
<td>Addiction</td>
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<tr>
<td>Additional relevant MeSH terms:</td>
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<tr>
<td>Behavior, Addictive</td>
<td>Impulsive Behavior</td>
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<td>Substance-Related Disorders</td>
<td>Chemically-Induced Disorders</td>
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<tr>
<td>Compulsive Behavior</td>
<td>Mental Disorders</td>
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ClinicalTrials.gov processed this record on August 16, 2016