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Results From a 24 Week Trial of EMDR Combined With Venlafaxine XR (EMDRVEN)

This study has been withdrawn prior to enrollment.

(PI was transferred to another base. No one else available to serve as PI.)

Sponsor:
Bayne-Jones Army Community Hospital

Information provided by (Responsible Party):
Bayne-Jones Army Community Hospital

ClinicalTrials.gov Identifier:
NCT02433353

First received: April 9, 2015
Last updated: January 11, 2016
Last verified: January 2016
History of Changes

Purpose

Approximately 150 active duty service members meeting Diagnostic and Statistical Manual version 5 (DSM-5) criteria for posttraumatic stress disorder (PTSD) and scoring 50 or above on the Clinician Administered PTSD Score for DSM-5 (CAPS-5) will be recruited. Qualifying participants will be randomized on a 1:1 basis to either the **eye movement desensitization reprocessing** (**EMDR**) plus venlafaxine XR group or the **EMDR** plus placebo group. Protocol will call for participants to complete 12 one-hour **EMDR** session while taking a venlafaxine XR/placebo dose of 150mg or 225mg for the entire 24 weeks. Both prescribers and therapists will be blinded and CAPS-5 assessments will be completed by an individual not involved in a participant's direct treatment. An unblinded pharmacist will dispense medication or placebo according the instructions of the prescriber and will count remaining tablets to measure compliance. All **EMDR** sessions will be recorded and will be reviewed by the principal investigator using a fidelity checklist. CAPS-5 will be administered after completion of **EMDR** and again at 6 months from the date of his/her first therapy session.

Condition	Intervention	Phase
Posttraumatic Stress Disorder	Drug: Venlafaxine XR Behavioral: **EMDR** Drug: Placebo	Phase 4

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: Results From a 24 Week, Double-blind, Placebo-controlled Trial of **EMDR** Combined With Venlafaxine XR in the Treatment of Posttraumatic Stress Disorder

Resource links provided by NLM:

MedlinePlus related topics: Post-Traumatic Stress Disorder

Drug Information available for: Venlafaxine Venlafaxine hydrochloride

U.S. FDA Resources

Further study details as provided by Bayne-Jones Army Community Hospital:

Primary Outcome Measures:

- Change in PTSD symptoms at 12 weeks measured using the CAPS-5 scale [Time Frame: 12 weeks] [Designated as safety issue: No]
  Clinician Administered PTSD Scale for DSM-5

- Change in PTSD symptoms at 24 weeks measured using the CAPS-5 scale [Time Frame: 24 weeks] [Designated as safety issue: No]
  Clinician Administered PTSD Scale for DSM-5

Secondary Outcome Measures:

- Change in depression symptoms at 12 weeks measured using the PHQ-9 scale [Time Frame: 12 weeks] [Designated as safety issue: No]
  Periodic Health Questionnaire
- Change in depression symptoms at 24 weeks measured using the PHQ-9 scale [Time Frame: 24 weeks] [Designated as safety issue: No]
  Periodic Health Questionnaire
- Percentage of participants experiencing adverse events as a measure of safety and tolerability [Time Frame: 24 weeks]
  [Designated as safety issue: No]
- Attrition percentage as a measure of safety and tolerability [Time Frame: 24 weeks] [Designated as safety issue: No]
- Change in PTSD symptoms at 12 weeks measured using the PCL-5 scale [Time Frame: 12 weeks] [Designated as safety issue: No]
  PTSD Checklist for DSM-5
- Change in PTSD symptoms at 24 weeks measured using the PCL-5 scale [Time Frame: 24 weeks] [Designated as safety issue: No]
  PTSD Checklist for DSM-5
- Presence of non-prescribed or illicit drugs on urine drug screen at 12 weeks [Time Frame: 12 weeks] [Designated as safety issue: No]
- Presence of non-prescribed or illicit drugs on urine drug screen at 24 weeks [Time Frame: 24 weeks] [Designated as safety issue: No]

Enrollment: 0
Study Start Date: January 2016
Study Completion Date: January 2016
Primary Completion Date: January 2016 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: **EMDR** + Venlafaxine XR Participants will receive 12 one-hour sessions of **EMDR** while taking venlafaxine XR 150mg or 225mg for the duration of the 6 month study.	Drug: Venlafaxine XR Serotonin norepinephrine reuptake inhibitor Other Name: Effexor Behavioral: **EMDR** psychotherapy Other Name: **Eye Movement Desensitization Reprocessing**
Placebo Comparator: **EMDR** + Placebo Participants will receive 12 one-hour sessions of **EMDR** while taking placebo 150mg or 225mg for the duration of the 6 month study.	Behavioral: **EMDR** psychotherapy Other Name: **Eye Movement Desensitization Reprocessing** Drug: Placebo Look-alike venlafaxine XR tablets containing no active drug Other Name: Sugar pill

Detailed Description:
Approximately 150 active duty service members meeting DSM-5 criteria for PTSD and scoring 50 or above on the Clinician Administered PTSD Score for DSM-5 (CAPS-5) will be recruited for a prospective, randomized, double-blinded, controlled trial. Participants will be recruited via referral from other providers or self-referral from recruitment fliers. CAPS-5 is considered the gold-standard for PTSD symptom assessment in research. An initial PHQ-9,PCL-5, urine drug screen, and pregnancy test will be obtained at that visit as well. Qualifying participants will then meet with a prescriber, review informed consent, draw a number for randomization, and complete the SCID-5. The participant will then meet with the pharmacist who will dispense either venlafaxine XR or placebo. Randomization will have occurred before any participants have been recruited. Randomization will consist of use of a random number generator to generate 150 numbers. The pharmacist will secretly assign half of the numbers to treatment and half to control. Numbers generated will be written on slips of paper and placed in opaque envelopes then placed in a box. Participants will then draw their own numbers and inform the researchers of the number drawn. The titration schedule for the venlafaxine XR/placebo will be 3 days at 37.5mg, 7 days at 75mg, then increasing to 150mg. The participant will meet with the prescriber after 4 weeks at 150mg to determine if an increase to 225mg is warranted based on the participants DSM-5 PTSD symptoms. Meetings with a prescriber will then occur monthly throughout the study unless side effects or other concerns require more frequent follow up. Prescriber visits will be scheduled for 30 minutes, however, visits could be completed in as little as five minutes if the medication is working well with no side effects, blood pressure remains at baseline, the participant remains adherent to both medication and therapy, and the participant raises no concerns. Participants will meet with the pharmacist on a monthly basis for pill counts. EMDR sessions will occur weekly if possible and not any less than once every 2 weeks. Two sessions are allowed in 1 week if the participant anticipates going to the field or otherwise being unavailable for regular visits. All EMDR sessions will be recorded using a camcorder and the principal investigator will review 10% of all therapy sessions (a minimum of 1 session per participant) using a fidelity checklist. CAPS-5 assessments will be completed by an individual not involved in a participant's direct treatment and will be administered after completion of EMDR and again at 6 months from the date of his/her first therapy session. A urine drug screen will be ordered with each CAPS-5. Missing data/participant drop out will be handled using last object carried forward. Comparisons between interventions will be computed using a student's T-test for single comparisons between groups or ANOVA when multiple comparisons/time points are involved. If at any point a participant requests a record of treatment, a summary of care will be provided.

Eligibility

Ages Eligible for Study: 17 Years to 70 Years (Child, Adult, Senior)
Genders Eligible for Study: Both
Accepts Healthy Volunteers: Yes

Criteria

Inclusion:

- Initial CAPS-5 score of 50 or greater
- Meeting criteria for PTSD using DSM-5 criteria
- Open to active duty US service members of all genders, races / ethnicities, religions, sexual orientations, and marital statuses
- Participants can have a history of mild TBI, past or current substance abuse, nicotine dependence, chronic pain, migraines/headaches, and most other medical illnesses not specified in exclusion section
- Participants can be taking opiates, a sleep aid, and/or prazosin for an indication of PTSD nightmares provided dosing does not exceed 15mg (men) / 9mg (women). Dosing more than once per day is not permitted

Exclusion:

- Current suicidal or homicidal ideation
- Pregnancy
- Profound hearing loss
- HIV and AIDS
- Current chemotherapy
- Primary thought disorders
- Bipolar disorder or cyclothymia
- Current substance dependence (not including nicotine)
- Current use of bupropion above 150mg daily
- Current use of mirtazapine above 15mg daily
- Current use of an SSRI
- Current use of another SNRI
- Current use of tricyclic antidepressants in doses above 50mg
- Current use of an MAO-I
- Current use of a stimulant
- Current use of a mood stabilizer/anti-epileptic for an indication of mood stability or reduction in anger
- Current use of an anti-psychotic
- Current use of lithium
- Chronic daily use of steroids
- Current use of tapentadol
- Current use of dronabinol
- Current use of ketamine

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: NCT02433353

Sponsors and Collaborators

Bayne-Jones Army Community Hospital

Investigators

Principal Investigator: Daniel J Lee, MD Bayne-Jones Army Community Hospital

More Information

Responsible Party: Bayne-Jones Army Community Hospital
ClinicalTrials.gov Identifier: NCT02433353 History of Changes
Other Study ID Numbers: Bayne-Jones
Study First Received: April 9, 2015
Last Updated: January 11, 2016
Health Authority: United States: Institutional Review Board

United States: Federal Government

Keywords provided by Bayne-Jones Army Community Hospital:
PTSD
posttraumatic stress disorder
venlafaxine
EMDR
eye movement desensitization reprocessing
antidepressant
psychotherapy

Additional relevant MeSH terms:
Stress Disorders, Traumatic
Stress Disorders, Post-Traumatic
Trauma and Stressor Related Disorders
Mental Disorders
Venlafaxine Hydrochloride
Serotonin and Noradrenaline Reuptake Inhibitors
Neurotransmitter Uptake Inhibitors
Membrane Transport Modulators
Molecular Mechanisms of Pharmacological Action
Neurotransmitter Agents
Physiological Effects of Drugs
Antidepressive Agents, Second-Generation
Antidepressive Agents
Psychotropic Drugs

ClinicalTrials.gov processed this record on August 16, 2016