This study has been completed.

**Sponsor:**
Boston University

**Collaborator:**
National Institute of Mental Health (NIMH)

**Information provided by:**
Boston University

**ClinicalTrials.gov Identifier:**
NCT00000379

**First received:** November 2, 1999

**Last updated:** February 19, 2014

**Last verified:** February 2014

**History of Changes**

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### Purpose

The purpose of this study is to compare two treatments for post-traumatic stress disorder (PTSD): fluoxetine (an antidepressant) and Eye Movement Desensitization and Reprocessing (EMDR, a psychological treatment in which the patient is led through the memory of a traumatic experience in order to heal him/herself).

There are a variety of therapies used to treat PTSD, but the effectiveness of medication alone vs an exposure treatment, such as EMDR, has not been tested.

Patients will be assigned randomly (like tossing a coin) to one of three groups for 8 weeks of treatment. Group 1 will receive fluoxetine; Group 2 will receive EMDR; and Group 3 will receive inactive placebo. Patients will then stop treatment and have evaluations, including psychological tests, at the time treatment is stopped, 8 weeks later, and at 6 months.

An individual may be eligible for this study if he/she:

- Has PTSD and is 18 to 65 years old.

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<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
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<tbody>
<tr>
<td>Stress Disorders, Post-Traumatic</td>
<td>Drug: Fluoxetine Behavioral: EMDR</td>
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**Drug Information available for:**
Fluoxetine  Fluoxetine hydrochloride

**U.S. FDA Resources**

**Further study details as provided by Boston University:**

- **Study Start Date:** January 1999
- **Estimated Study Completion Date:** December 2003

**Detailed Description:**

To compare the short-term and long-term efficacy of two different treatment approaches in widespread use in clinical settings for treating patients with post-traumatic stress disorder (PTSD): fluoxetine (which acts directly on biological systems) vs a psychological treatment, Eye Movement Desensitization and Reprocessing (EMDR).
Reprocessing (EMDR). To clarify: 1) the differential treatment effects of these different treatment modalities; 2) whether symptom improvement is accompanied by changes in pathophysiology; and 3) the long-term effectiveness of these treatments.

In recent years a variety of treatment approaches have been shown to be effective in the treatment of PTSD. These include prolonged exposure therapies (PE), stress inoculation training (SIT), EMDR and psychopharmacological treatment with serotonin re-uptake blockers. While PE has been compared with SIT and a study is currently under way comparing cognitive-behavioral treatment with EMDR, no study as yet has compared the relative merits of pharmacotherapy alone vs an exposure treatment. While it is commonly held that, in order to recover, people with PTSD need to "process" their traumatic memories, treatments that do not involve the processing of traumatic memories (such as SIT or pharmacotherapy) may be just as effective. In clinical practice, many patients with PTSD appear to be effectively treated with pharmacological agents alone, without trauma-focused therapy.

Patients are randomly assigned to one of three conditions: 1) a double-blind psychopharmacological treatment (fluoxetine); 2) a manualized treatment which focuses on "processing" traumatic memories (EMDR); or 3) a placebo control group. After 8 weeks of active treatment, subjects are evaluated, cease treatment, and are assessed again after another 8 weeks and at 6 months in order to evaluate the long-term effects. Training raters remain blind to the subjects' treatment condition throughout the study. Treatment outcome is assessed with a multi-modal psychological and biological assessment battery including: 1) standard psychological tests for PTSD (CAPS); 2) neuroendocrine function (cortisol); and 3) psychophysiological response to traumatic scripts (pre-post changes in heart social and occupational functioning). Treatment adherence is monitored throughout the study.

![Eligibility](image)

**Ages Eligible for Study:** 18 Years to 65 Years (Adult)

**Genders Eligible for Study:** Both

**Accepts Healthy Volunteers:** No

**Criteria**

**Inclusion Criteria:**

Patients must have:

Post-Traumatic Stress Disorder (PTSD).

**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: NCT00000379

**Locations**

**United States, Massachusetts**

The Trauma Center
Brookline, Massachusetts, United States, 02446

**Sponsors and Collaborators**

Boston University
National Institute of Mental Health (NIMH)

**Investigators**

Principal Investigator: Bessel Van Der Kolk, MD

**More Information**

ClinicalTrials.gov Identifier: NCT00000379

History of Changes

Other Study ID Numbers: R01MH058363, DSIR AT-CT

Study First Received: November 2, 1999

Last Updated: February 19, 2014

Health Authority: United States: Federal Government

Keywords provided by Boston University:

Adult
Comparative Study
Desensitization, Psychologic
Eye Movements
Female
Fluoxetine
Human
Male

Additional relevant MeSH terms:

Disease

Molecular Mechanisms of Pharmacological Action

Fluoxetine vs EMDR to Treat Post Traumatic Stress Disorder (PTSD)
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ClinicalTrials.gov processed this record on August 16, 2016