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Fluoxetine vs EMDR to Treat Post-Traumatic Stress Disorder (PTSD)

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

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.

Condition	Intervention	Phase
Stress Disorders, Post-Traumatic	Drug: Fluoxetine Behavioral: **EMDR**	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Primary Purpose: Treatment

Official Title: Treatment of Outcomes of Fluoxetine vs **EMDR** in PTSD

Resource links provided by NLM:

MedlinePlus related topics: Post-Traumatic Stress Disorder

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). 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

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

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Other Study ID Numbers:	R01MH058363 DSIR AT-CT
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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
Placebos
Stress Disorders, Post-Traumatic
Treatment Outcome
Desensitization, Psychologic -- *methods
Fluoxetine -- *therapeutic use
Stress Disorders, Post-Traumatic -- *therapy
Stress Disorders, Post-Traumatic -- drug therapy

Additional relevant MeSH terms:

Disease
Molecular Mechanisms of Pharmacological Action

Stress Disorders, Traumatic
Stress Disorders, Post-Traumatic
Pathologic Processes
Trauma and Stressor Related Disorders
Mental Disorders
Fluoxetine
Serotonin Uptake Inhibitors
Neurotransmitter Uptake Inhibitors
Membrane Transport Modulators

Neurotransmitter Agents
Serotonin Agents
Physiological Effects of Drugs
Antidepressive Agents, Second-Generation
Antidepressive Agents
Psychotropic Drugs
Cytochrome P-450 CYP2D6 Inhibitors
Cytochrome P-450 Enzyme Inhibitors
Enzyme Inhibitors

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