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Trauma-focused CBT Versus EMDR in the Treatment of Posttraumatic Stress Disorder

The recruitment status of this study is unknown because the information has not been verified recently.

Verified October 2013 by VU University of Amsterdam.
Recruitment status was Recruiting

Sponsor:
VU University of Amsterdam

Information provided by (Responsible Party):
Paul M.G.Emmelkamp, VU University of Amsterdam

ClinicalTrials.gov Identifier:
NCT00716638

First received: July 14, 2008
Last updated: October 31, 2013
Last verified: October 2013
History of Changes

Purpose

This study will evaluate the effectiveness of trauma-focused cognitive behaviour therapy (TF-CBT) versus **eye movement desensitization and reprocessing** (**EMDR**) in the treatment of trauma survivors with post-traumatic stress disorder (PTSD). Patients will be randomly assigned to TF-CBT or **EMDR**. Follow-up assessments will be conducted at 3 and 12 months post-treatment. In addition to comparing the efficacy of the two protocols, an additional focus will lie on identifying predictors for treatment outcome.

Condition	Intervention	Phase
Stress Disorders, Post-Traumatic	Behavioral: Trauma-focused Cognitive Behavior Therapy Behavioral: **Eye Movement Desensitization and Reprocessing** (**EMDR**)	Phase 2 Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Intervention Model: Factorial Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: Trauma-focused CBT vs. **EMDR** in the Treatment of Posttraumatic Stress Disorder

Resource links provided by NLM:

MedlinePlus related topics: Post-Traumatic Stress Disorder Wounds and Injuries

U.S. FDA Resources

Further study details as provided by VU University of Amsterdam:

Primary Outcome Measures:

- PTSD symptom severity: (a) interviewer rating (PSS-I); (b) self-report (PDS) [Time Frame: Assessed at post-treatment, 3 months and 12 months follow-up] [Designated as safety issue: No]

Secondary Outcome Measures:

- Depressive symptom severity (Beck Depression Inventory, BDI) [Time Frame: assessed at post-treatment, 3 months and 12 months follow-up] [Designated as safety issue: No]
- Severity of anxiety symptoms (Beck Anxiety Inventory, BAI) [Time Frame: assessed at posttreatment, 3 months and 12 months follow-up] [Designated as safety issue: No]
- Trauma-related appraisal (Posttraumatic Cognitions Inventory, PTCI) [Time Frame: post-treatment] [Designated as safety issue: No]

Estimated Enrollment: 90
Study Start Date: July 2008

Estimated Study Completion Date: July 2014
Estimated Primary Completion Date: July 2014 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Treatment group 1 Trauma-focused Cognitive Behavior Therapy (TF-CBT)	Behavioral: Trauma-focused Cognitive Behavior Therapy This intervention comprises 10 sessions of trauma-focused cognitive behavior therapy for PTSD with the components (a) prolonged imaginal exposure, (b) in vivo exposure, and (c) cognitive restructuring.
Experimental: Treatment group 2 **Eye Movement Desensitization and Reprocessing** (**EMDR**)	Behavioral: **Eye Movement Desensitization and Reprocessing** (**EMDR**) This intervention comprises 10 sessions of **EMDR** according to the standard protocol.

Eligibility

Ages Eligible for Study: 18 Years to 70 Years (Adult, Senior)
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- A full diagnosis of PTSD according to the DSM-IV or subthreshold PTSD (criteria for intrusive re-experiencing are fulfilled and either three avoidance/numbing symptoms or two hyperarousal symptoms are present)
- PTSD is related to one or more single-event traumas and participants have a clear memory of this event/these events (sufficient for constructing scenes to be used in exposure)
- Age between 18 and 70
- Sufficient fluency in Dutch to complete treatment and research protocol
- If participants are using anti-depressants, they need to be on a stable dose for at least 2 weeks before the beginning of treatment and remain on this dose throughout the treatment.

Exclusion Criteria:

- Dementia or other severe cognitive impairment
- Psychosis
- Depression with suicidal ideation
- Bipolar disorder
- Borderline Personality Disorder
- Anti-social personality disorder
- Substance dependence
- Current use of tranquilizers
- Exposure to prolonged and/or chronic trauma ("type-II-trauma")

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: NCT00716638

Contacts

Contact: Thomas Ehring, PhD +31-20-5256858 ext 6858 t.w.a.ehring@uva.nl

Locations

Netherlands

PsyQ **Recruiting**
Zaandam, Netherlands, 1500 AE

Sponsors and Collaborators

VU University of Amsterdam

Investigators

Principal Investigator:	Paul MG Emmelkamp, Professor	University of Amsterdam, The Netherlands
Study Director:	Thomas Ehring, PhD	University of Amsterdam, The Netherlands

More Information

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Health Authority:	Netherlands: Independent Ethics Committee

Additional relevant MeSH terms:

Disease	Pathologic Processes
Stress Disorders, Traumatic	Trauma and Stressor Related Disorders
Stress Disorders, Post-Traumatic	Mental Disorders

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