**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.

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<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
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</thead>
<tbody>
<tr>
<td>Stress Disorders, Post-Traumatic</td>
<td>Behavioral: Trauma-focused Cognitive Behavior Therapy</td>
<td>Phase 2</td>
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<tr>
<td></td>
<td>Behavioral: Eye Movement Desensitization and Reprocessing (EMDR)</td>
<td>Phase 3</td>
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</tbody>
</table>

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

**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 post-treatment, 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)

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<th>Arms</th>
<th>Assigned Interventions</th>
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| Experimental: Treatment group 1 | 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 | Behavioral: **Eye Movement Desensitization and Reprocessing (EMDR)**
This intervention comprises 10 sessions of EMDR according to the standard protocol. |

### Eligibility

**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**

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**Locations**

**Netherlands**

PsyQ  Recruiting
Zaandam, Netherlands, 1500 AE

**Sponsors and Collaborators**

VU University of Amsterdam

**Investigators**