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Trial record **16 of 19** for: EMDR
◄ Previous Study | Return to List | Next Study ►

Treatment of Posttraumatic Stress Disorder (PTSD) in Adult Survivors of Early Chronic Interpersonal Trauma

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:
NCT01443182

First received: September 27, 2011
Last updated: October 31, 2013
Last verified: October 2013
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Purpose

Eye movement desensitization and reprocessing (**EMDR**) and trauma-focused cognitive-behavioural therapy (TF-CBT) have both been found to be effective in treating post-traumatic stress disorder (PTSD) following single-event traumas and to be more effective than pure anxiety management or stabilization treatments. However, much less is known about the efficacy of the different treatment approaches in survivors of repeated or chronic interpersonal trauma. Recent evidence suggests that a combination of stabilization treatment + TF-CBT is efficacious in this population. Although **EMDR** is also often used in survivors of chronic interpersonal trauma, evidence on its efficacy are still poor. The aim of the current study is to compare the efficacy of (1) stabilization + TF-CBT and (2) stabilization + **EMDR** using a randomized controlled trial in a routine clinical setting.

Condition	Intervention	Phase
Posttraumatic Stress Disorder (PTSD)	Behavioral: STAIR Behavioral: MPE Behavioral: **EMDR**	Phase 2

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

Official Title: Treatment of PTSD in Adult Survivors of Early Chronic Interpersonal Trauma

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:

- Clinician Administered PTSD Scale (CAPS) [Time Frame: Pre- (baseline) and post-assessment (after treatment termination) and 3 month follow up (3 month after post assessment and 12 month follow up))] [Designated as safety issue: No]
- Posttraumatic Diagnostic Scale (PDS) [Time Frame: Pre- (baseline) and post-assessment (after treatment termination) and 3 month follow up (3 month after post assessment and 12 month follow up). Before each treatment session] [Designated as safety issue: No]

Secondary Outcome Measures:

- Beck Depression Inventory (BDI) [Time Frame: Pre- (baseline), after the first 8 treatment sessions and post-assessment (after treatment termination) and 3 month follow up (3 month after post assessment and 12 month follow up))] [Designated as safety issue: No]

- Beck Anxiety Inventory (BAI) [Time Frame: Pre- (baseline), after the first 8 treatment sessions and post-assessment (after treatment termination) and 3 month follow up (3 month after post assessment and 12 month follow up))] [Designated as safety issue: No]
- Dissociative Experiences Scale (DES) [Time Frame: Pre- (baseline), after the first 8 treatment sessions and post-assessment (after treatment termination) and 3 month follow up (3 month after post assessment and 12 month follow up))] [Designated as safety issue: No]
- Difficulties in Emotion Regulation Scale (DERS) [Time Frame: Pre- (baseline), after the first 8 treatment sessions and post-assessment (after treatment termination) and 3 month follow up (3 month after post assessment and 12 month follow up))] [Designated as safety issue: No]
- Inventory of Interpersonal Problems (IIP) [Time Frame: Pre- (baseline), after the first 8 treatment sessions and post-assessment (after treatment termination) and 3 month follow up (3 month after post assessment and 12 month follow up))] [Designated as safety issue: No]

Estimated Enrollment: 90
Study Start Date: September 2011
Estimated Study Completion Date: September 2015
Estimated Primary Completion Date: September 2014 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: STAIR + MPE A two-phased treatment with Skills Training in Affective and Interpersonal Regulation (STAIR) in Phase 1 en modified prolonged exposure (MPE) in Phase 2	Behavioral: STAIR Skills Training in Affective and Interpersonal Regulation Behavioral: MPE Modified prolonged exposure (MPE)
Active Comparator: STAIR + **EMDR** a two-phase treatment Phase 1: Skills Training in Affective and Interpersonal Regulation (STAIR) Phase 2: **Eye Movement Desensitization and Reprocessing** (**EMDR**)	Behavioral: STAIR Skills Training in Affective and Interpersonal Regulation Behavioral: **EMDR** **Eye movement desensitization and reprocessing**

Eligibility

Ages Eligible for Study: 18 Years to 65 Years (Adult)
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- meeting DSM-IV criteria for PTSD
- having experienced repeated or chronic interpersonal trauma (e.g., sexual or physical abuse)
- at least 18 years of age
- having sufficient fluency in Dutch to complete treatment and research protocol
- participants using prescribed anti-depressant medication are required 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:

- psychiatric problems that may interfere with the study participation or that require more intensive care than can be offered in the present study, including dementia, psychotic symptoms, depression with suicidal ideation, full-blown borderline personality disorder, substance dependence
- current use of tranquilizers

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: NCT01443182

Locations

Netherlands

PsyQ **Recruiting**
Zaandam, Netherlands
Contact: Ingrid Wigard +31-75-6814420
Principal Investigator: Ingrid Wigard

Sponsors and Collaborators

VU University of Amsterdam

Investigators

Study Chair: Thomas Ehring, PhD VU University of Amsterdam

Study Chair: Katharina Meyerbröker VU University of Amsterdam

More Information

Responsible Party:	Paul M.G.Emmelkamp, Professor, VU University of Amsterdam
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Additional relevant MeSH terms:
Stress Disorders, Traumatic
Stress Disorders, Post-Traumatic
Trauma and Stressor Related Disorders
Mental Disorders

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