EMDR vs. TF-CBT after Stabilisation in the treatment of posttraumatic stress disorder following type II trauma

Published: 17-09-2010
Last updated: 02-05-2024

(1) The study aims to investigate whether the effects of stabilization + TF-CBT on PTSD symptoms in survivors of early-onset chronic interpersonal trauma can be replicated in a routine clinical setting. (2) The study secondly aims to investigate...

Ethical review	Approved WMO
Status	Pending
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON34998

Source
ToetsingOnline

Brief title
EMDR vs. TF-CBT

Condition

- Anxiety disorders and symptoms

Synonym
posttraumatic stress disorder; psychological consequences of early-childhood traumas

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Amsterdam

Source(s) of monetary or material Support: Ministerie van OC&W,KNAW professorship to Paul MG Emmelkamp

Intervention

Keyword: CBT, EMDR, PTSD, trauma

Outcome measures

Primary outcome

The main dependent variables are

(1) the percentage of participants meeting DSM-IV criteria for PTSD according

to the Structured Clinical Interview for the DSM-IV (SCID; First, Spitzer,

Gibbon, & Williams, 1996)

(2) the PTSD symptom severity, assessed with the Clinian-administered PTSD

Scale (CAPS; Blake et al., 1995) and the Posttraumatic Diagnostic Scale (PDS;

Foa, Cashman, Jaycox, & Perry, 1997).

Secondary outcome

Secondary study parameters are:

(1) Symptom levels/clinical problems typically associated with PTSD following

early-onset chronic interpersonal trauma, namely

(a) Symptom levels of depression assessed with the Beck Depression Inventory

(BDI; Beck, Rush, Shaw, & Emery, 1979)

(b) Levels of anger, assessed with the State Trait Anger Inventory (STAXI;

Spielberger, 1991)

(c) Emotion regulation difficulties, assessed with the Difficulties in Emotion

Regulation Scale (DERS; Gratz & Roemer, 2004)

(d) Interpersonal problems, assessed with the Inventory of Interpersonal

Problems (IIP; Horowitz, Rosenberg, Baer, Ureno, & Villasenor, 1988)

(e) Dissociation, assessed with the Dissociative Experiences Scale (DES; Bernstein & Putnam, 1986)

(f) Quality of Life, assessed with the WHO Quality of Life Questionnaire (WHO-QoL; Trompenaars, Masthoff, Van Heck, Hodiamont, & De Vries, 2005)

(2) Variables shown to be involved in the maintenance of PTSD that can be expected to be reduced as a consequence of successful treatment, namely

(a) negative trauma-related appraisals, assessed with the Posttraumatic Cognitions Inventory (PTCI; van Emmerik, Schoorl, Emmelkamp, & Kamphuis, 2006)

(b) dysfunctional coping strategies (e.g., avoidance, safety behaviours, rumination, thought suppression) assess with the Responses to Intrusions Questionnaire (RIQ; Ehring, Ehlers, & Glucksman, 2006) and the Avoidance and Safety Behaviours Questionnaire (ASBQ; Ehring et al., 2006)

(c) characteristics of the trauma memory, assessed with the Trauma Memory Questionnaire (TMQ; Halligan, Michael, Clark, & Ehlers, 2003) and a narrative task

(d) social support, assessed with the Crisis Support Scale (CSS; Joseph, 1999)

Study description

Background summary

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 early-onset repeated or chronic

interpersonal trauma. Recent evidence suggests that a combination of stabilization + 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.

Study objective

(1) The study aims to investigate whether the effects of stabilization + TF-CBT on PTSD symptoms in survivors of early-onset chronic interpersonal trauma can be replicated in a routine clinical setting. (2) The study secondly aims to investigate whether the effects of stabilization + EMDR differ from those of stabilization + TF-CBT.

Study design

The study design is a randomized clinical trial, in which patients are randomly assigned to two treatments: (1) stabilization + TF-CBT and (2) stabilization + EMDR. Dependent variables will be assessed at pre-treatment, mid-treatment (following stabilization), post-treatment, 3 months post-treatment and 12 months post-treatment.

Intervention

In both conditions, participants will first receive 8 sessions of stabilization treatment according to the STAIR protocol (Cloitre, Cohen, & Koenen, 2006). In the second phase, participants will either receive 16 sessions of TF-CBT consisting of imaginal exposure to their traumatic event (modified prolonged exposure; see Cloitre et al., 2006) or 16 sessions of EMDR (Shapiro, 1995).

Study burden and risks

In both conditions, participants will receive bona fide treatments for PTSD. Content, intensity and duration of the treatment are comparable to usual clinical care for this group within PsyQ Zaandam. In order to study the effects of the treatment participants will be asked to fill in a number of questionnaires and complete interview before treatment, at mid-treatment, at post-treatment and at 3- and 12-months follow-up. The benefit for individual participants concerns the fact that they receive a bona fide treatment for their condition and that this treatment will be provided by experienced therapists who will receive additional supervision for the cases treated within the project. On a more general level, the study addresses a highly relevant topic, which has to date been under-researched. The study has the potential to greatly improve knowledge about the efficacy of treatments for PTSD following

type-II trauma.

Contacts

Public
Universiteit van Amsterdam

Roetersstraat 15
1094 JP
NL
Scientific
Universiteit van Amsterdam

Roetersstraat 15
1094 JP
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1) Meeting DSM-IV criteria for PTSD
2) having experienced repeated or chronic interpersonal trauma before the age of 14 (e.g., sexual or physical abuse)
3) at least 18 years of age
4) having sufficient fluency in Dutch to complete treatment and research protocol
5) 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

1) 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
2) current use of tranquilizers

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2010
Enrollment:	90
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL31098.018.10