# Efficacy and efficiency of Eye Movement Desensitisation and Reprocessing therapy versus Brief Eclectic Psychotherapy (BEP) in the treatment of post-traumatic stress disorder

| Submission date 04/08/2005          | <b>Recruitment status</b><br>No longer recruiting             | <ul> <li>Prospectively registered</li> <li>Protocol</li> </ul>     |
|-------------------------------------|---|--|
| <b>Registration date</b> 04/08/2005 | <b>Overall study status</b><br>Completed                      | <ul> <li>Statistical analysis plan</li> <li>[X] Results</li> </ul> |
| Last Edited<br>04/09/2015           | <b>Condition category</b><br>Mental and Behavioural Disorders | Individual participant data  |

# Plain English summary of protocol

Not provided at time of registration

# **Contact information**

# Type(s)

Scientific

# Contact name

Dr M Olff

# **Contact details**

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# Additional identifiers

EudraCT/CTIS number

IRAS number

### ClinicalTrials.gov number

Secondary identifying numbers NTR46

# Study information

## Scientific Title

Efficacy and efficiency of Eye Movement Desensitisation and Reprocessing therapy versus Brief Eclectic Psychotherapy (BEP) in the treatment of post-traumatic stress disorder

#### Acronym

**BEP-EMDR** 

### **Study objectives**

Eye movement desensitisation and reprocessing (EMDR) therapy is applied frequently in clinical practice as a treatment method for psychological trauma. Arguments for applying EMDR are faster symptom reduction, lower dropout and better tolerance than cognitive behavioural interventions. However, in the Netherlands a randomised controlled study determining efficacy and efficiency of EMDR has not yet been performed.

Research objectives:

1. To compare efficacy of EMDR therapy and brief eclectic psychotherapy (BEP) in the treatment of patients with post-traumatic stress disorder

- 2. To test whether EMDR is more efficient than BEP
- 3. To determine efficacy of the treatments at long-term follow up
- 4. To determine which patients benefit most from EMDR or BEP

5. To determine the effects of both treatments on comorbid psychopathology, like major depressive disorder

The overall trial end date was changed from 01/12/2006 to 01/12/2007.

On 14/02/2012 the following changes were made to the trial record:

1. The target number of participants was changed from 120 to 140.

2. The overall trial end date was changed from 01/12/2007 to 01/02/2009.

### **Ethics approval required**

Old ethics approval format

### Ethics approval(s)

Ethics approval received from the local ethics committee

### Study design

Randomised-controlled parallel-group single-blinded trial

**Primary study design** Interventional

**Secondary study design** Randomised controlled trial

# Study setting(s)

Not specified

### Study type(s)

Treatment

### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

### Health condition(s) or problem(s) studied

Mental disorders, post-traumatic stress disorder

### Interventions

EMDR is a combination of trauma exposure (desensitisation) with saccadic eye movements. When anxiety diminishes, the patient is instructed to develop more positive cognitions and link these to the trauma.

BEP is primarily a cognitive behavioral intervention, but 'eclectic' means that elements of psychodynamic and directive psychotherapy are also part of this therapy.

# Intervention Type

Other

**Phase** Not Specified

### Primary outcome measure

- 1. Impact of Event Scale Revised (IES-R)
- 2. Hospital Anxiety and Depression Scale (HADS)

### Secondary outcome measures

Structured clinical interviews are administered, as well as neuropsychological tests and other self-report measures.

# Overall study start date 01/12/2003

# Completion date 01/02/2009

01/02/2009

# Eligibility

# Key inclusion criteria

Current inclusion criteria as of 14/02/2012

One hundred and forty patients with post-traumatic stress disorder for at least one month after the traumatic experience according to Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, will be included. They are asked to participate after intake at the Outpatient Psychiatry Clinic of the Academic Medical Center/De Meren.

#### Previous inclusion criteria

One hundred and twenty patients with post-traumatic stress disorder for at least one month after the traumatic experience according to Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, will be included. They are asked to participate after intake at the Outpatient Psychiatry Clinic of the Academic Medical Center/De Meren.

#### Participant type(s)

Patient

#### Age group

Adult

**Sex** Both

**Target number of participants** 140

#### Key exclusion criteria

Severe comorbidity that would interfere with treatment
 Enhanced risk for suicide and psychotic disorders

Date of first enrolment 01/12/2003

Date of final enrolment 01/02/2009

# Locations

**Countries of recruitment** Netherlands

**Study participating centre Academic Medical Center (AMC)** Amsterdam Netherlands 1105 AZ

# Sponsor information

**Organisation** Academic Medical Centre (AMC) (The Netherlands)

Sponsor details

Emma Kinderziekenhuis P.O.Box 22660 Amsterdam Netherlands 1105 AZ

**Sponsor type** University/education

Website http://www.amc.uva.nl/

ROR https://ror.org/03t4gr691

# Funder(s)

Funder type Hospital/treatment centre

**Funder Name** Academisch Medisch Centrum

Alternative Name(s) Academic Medical Center, AMC

**Funding Body Type** Private sector organisation

**Funding Body Subtype** Universities (academic only)

**Location** Netherlands

# **Results and Publications**

**Publication and dissemination plan** Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

**IPD sharing plan summary** Not provided at time of registration

# Study outputs

| Output type     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|-----------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 01/03/2012   |            | Yes            | No              |
| Results article | results | 01/08/2015   |            | Yes            | No              |