Eye Movement Desensitisation and Reprocessing versus stabilisation in the outpatient treatment of traumatised asylum seekers and refugees: a randomised controlled trial

Published: 13-08-2007
Last updated: 10-05-2024

To contribute to the improvement of mental health care to traumatised asylum seekers and refugees.

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

Summary

ID

NL-OMON30477

Source
ToetsingOnline

Brief title
EMDR vs stabilisation

Condition

- Anxiety disorders and symptoms

Synonym
posttraumatic stress disorder, trauma

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Centrum 45 (Oegstgeest)
Source(s) of monetary or material Support: door Centrum '45 zelf.

Intervention

Keyword: EMDR, refugees, stabilisation, trauma

Outcome measures

Primary outcome

Traumasymptoms (according to DSM-IV) as measured by the Harvard Trauma

Questionnaire (HTQ).

Secondary outcome

Diagnosis of PTSD according to the SCID module PTSD.

Comorbid symptoms (anxiety, depression), as measured by the Hopkins Symptom

Check List (HSCL-25).

Quality of life, as measured by the WHOQOL-BREF.

Study description

Background summary

Focus of study is the outpatient treatment of adult traumatised asylum seekers and refugees with Eye Movement Desensitisation and Reprocessing (EMDR) or stabilisation.
Where the treatment of type-1 trauma is concerned, EMDR and CBT are treatments of choice. It's unclear whether this also goes for the treatment of asylum seekers and refugees, who often suffer from complex trauma. It is considered good practice to work with this population according to a phased model, in which the patient is first stabilised before proceeding to traumafocused interventions. There are however indications that this population may benefit from CBT without prior stabilisation. Perhaps this is also the case with EMDR.
This research project has been designed to answer the question: what is the effectiveness of EMDR and stabilisation in reducing traumasymptoms in

traumatised asylum seekers and refugees?

Study objective

To contribute to the improvement of mental health care to traumatised asylum seekers and refugees.

Study design

This study is designed as a randomised controlled trial, comparing EMDR and stabilisation. The protocol consists of:
1. informing the patient of the research protocol and signing of informed consent form
2. clinical interview
3. when patient is included: randomised assignment to one of the two conditions
4. pretreatment assessment.
5. research treatment consisting of three preparatory sessions (taking down the patient's biography, deciding on a treatment plan); followed by 8 weekly/biweekly sessions of either EMDR or stabilisation.
6. posttreatment assessment.
7. follow-up assessment after three months.
Considering the available scientific evidence, the hypothesis is that EMDR will be more effective than stabilisation.

Intervention

EMDR condition: this condition is, under supervision, performed by EMDR-therapists trained in treating complex trauma, according to the EMDR-protocol (De Jongh en Ten Broeke, 2003). Sessions take 90 minutes and an interpreter is used when necessary.
Stabilisation condition: this is performed by psychologists/doctors, under supervision. It consists of interventions aimed at the social, emotional, cognitive and behavioural stabilisation of the patient, as described by Linehan (1993) and Meichenbaum (1985). Each session the therapist records the interventions used in a "stabilisation menu". Sessions take 60 minutes and an interpreter is used when necessary.

Study burden and risks

Interview and questionnaires take six hours per patient. The burden of the treatment itself is equal to the burden of care as usual (i.e., no extra burden). Some therapists are of the opinion that focusing on traumatic memories is emotionally burdening to asylum seekers and refugees. Research (e.g. Drozdek, 1997; Van Minnen, 2006) has shown however that traumafocused therapy is tolerable and effective with this population. Drop-out numbers with such forms of therapy are not higher than with forms of therapy which avoid focusing

on the trauma. Stabilisation is not considered burdening, because it is a form of supportive-structuring therapy. In conclusion the researchers are of the opinion that taking part in this study implies minimal risks for the participants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* the patient has been diagnosed with PTSD according to DSM-IV
* the patient asks for help concerning the reprocessing of trauma or reduction of PTSD-symptoms
* the patient is able to speak about his/her traumatic experiences

Exclusion criteria

* the patient suffers from a comorbid disorder which requires care in another setting(i.e. developmental disorder, cognitive disorder, psychotic disorder not related to PTSD, bipolar disorder, sexual disorder, antisocial personality disorder or other serious personality disorder)
* the patient suffers from a serious comorbid disorder which should be the initial focus of treatment (i.e. psychotic disorder, depressive disorder with psychotic features and/or serious suicidal ideations, eating disorder, substance dependence)

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):	01-01-2007
Enrollment:	68
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL15458.058.06