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Eye movement desensitization and reprocessing (EMDR) versus stabilisation in the treatment of traumatised asylum seekers and refugees

Submission date
17/09/2012

Recruitment status
No longer recruiting

Registration date
08/10/2012

Overall study status
Completed

Last Edited
22/02/2016

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Traumatised asylum seekers and refugees are often clinically considered a complex population. Many of them suffer from posttraumatic stress disorder (PTSD), which may be related not only to traumatic experiences but also to current stressful situations, such as an insecure residency status. For the psychological treatment of single traumatic events, Eye Movement Desensitization and Reprocessing (EMDR) and Cognitive-Behavioral Therapy (CBT) are considered "treatments of choice", meaning that they should be offered to patients with PTSD. Both are treatments that involve confrontation with traumatic memories. Whether these treatments also work well with asylum seekers and refugees has been a question of debate. It is considered "good clinical practice" to use a phased model of treatment with these patients, in which treatment initially focuses on psychosocial stabilisation and only later, if at all, on the traumatic memories. There are however indications that this group could benefit from early EMDR, without first undergoing a long stabilisation phase. The study has been designed to answer the question: is EMDR better than stabilisation in reducing posttraumatic symptoms in traumatised asylum seekers and refugees? The aim of the study is to improve the treatment of traumatised asylum seekers and refugees. Considering previous study outcomes, we expect that EMDR will work better than stabilisation.

Who can participate?
Participants will be adult asylum seekers and refugees who suffer from PTSD and who have applied for outpatient treatment.

What does the study involve?
In this study, participants will be randomly assigned to either 12 hours of EMDR or 12 hours of stabilisation. Another group of patients will be asked to participate in a waitlist condition. The study aims to include 108 participants. Participants will answer interview questions and questionnaires on trauma symptoms, anxiety and depression, quality of life, and ways of coping with stressful situations.

What are the possible benefits and risks of participating?
The study has been ethically approved and no side effects are expected from participating. Participation brings no specific benefits. Patients who decide not to participate are entitled to the usual care.

Where is the study run from?
The study is run from Centrum 45, which is a Dutch psychotrauma expert centre.

When is the study starting and how long is it expected to run for?
The study has started in September 2009, and we expect to finish it by the end of 2012.

Who is funding the study?
The study is partially funded by ZonMW, the Netherlands organization for health research and development, and updates on the progress of the study may be found on their website, www.zonw.nl (add /en/ for information in English).

Who is the main contact?
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Study website
http://www.centrum45.nl/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NARCIS OND1324839

Study information

Scientific Title
Eye movement desensitization and reprocessing (EMDR) versus stabilisation in the treatment of traumatised asylum seekers and refugees: a randomised controlled trial

Study objectives
Eye movement desensitization and reprocessing (EMDR) will be more efficacious than stabilisation or waiting list in reducing post-traumatic stress, anxiety and depression, and increasing quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethical Committee, University of Leiden, 25/07/2007, ref: P06.211

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Post Traumatic Stress Disorder (PTSD)

Interventions
72 participants are randomly assigned to either EMDR or stabilisation as usual, and 36 participants are non-randomly asssigned to a waitinglist group.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Posttraumatic stress disorder (PTSD) as measured by the Clinician-Administered PTSD Scale (CAPS) and the Harvard Trauma Questionnaire (HTQ)

Secondary outcome measures
1. Anxiety and depression as measured by the Hopkins Symptom Checklist (HSCL-25)
2. Quality of life as measured by the World Health Organization Quality of Life Questionnaire (WHOQOL-BREF)
3. Coping styles as measured by the Cope-Easy

Overall study start date
01/09/2009

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Patients who newly apply for treatment at Centrum 45
2. Patients who have applied for asylum in the Netherlands (i.e. are asylum seekers or refugees)
3. Patients who are at least 18 years old
4. Patients who meet the criteria for a posttraumatic stress disorder (PTSD)-diagnosis according to the DSM-IV-TR (APA, 2000)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
108

Key exclusion criteria
1. Patients who suffer from serious depression (i.e. with high suicidal intent and/or psychotic features)
2. Patients who suffer from alcohol or substance dependence
3. Patients who suffer from psychotic disorder, bipolar disorder, cognitive disorders, or automutilation or eating disorders threatening their physical health.

Date of first enrolment
01/09/2009

Date of final enrolment

31/12/2012

Locations

Countries of recruitment
Netherlands

Study participating centre
Foundation Centrum '45
Diemen
Netherlands
1112 XE

Sponsor information

Organisation
The Netherlands Organisation for Health Research and Development [ZonMw] (Netherlands)

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Postbox 93 245
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Sponsor type
Government

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http://www.zonmw.nl/en/

ROR
https://ror.org/01yaj9a77

Funder(s)

Funder type
Government

Funder Name
ZonMw, ref: 100002036

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

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 of pilot study	01/05/2011		Yes	No
Results article	results	01/10/2016		Yes	No