Eye movement desensitisation and reprocessing therapy *v.* stabilisation as usual for refugees: randomised controlled trial

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Background
Eye movement desensitisation and reprocessing (EMDR) therapy is a first-line treatment for adults with post-traumatic stress disorder (PTSD). Some clinicians argue that with refugees, directly targeting traumatic memories through EMDR may be harmful or ineffective.

Aims
To determine the safety and efficacy of EMDR in adult refugees with PTSD (trial registration: ISRCTN20310201).

Method
In total, 72 refugees referred for specialised treatment were randomly assigned to 12 h (9 sessions) of EMDR or 12 h (12 sessions) of stabilisation. The Clinician-Administered PTSD Scale (CAPS) and Harvard Trauma Questionnaire (HTQ) were primary outcome measures.

Results
Intention-to-treat analyses found no differences in safety (one severe adverse event in the stabilisation condition only) or efficacy (effect sizes: CAPS –0.04 and HTQ 0.20) between the two conditions.

Conclusions
Directly targeting traumatic memories through 12 h of EMDR in refugee patients needing specialised treatment is safe, but is only of limited efficacy.

Declaration of interest
A.d.J. reports receiving personal fees from teaching activities and from books about trauma and its treatment (including EMDR). He is a board member of the Dutch EMDR Association and the EMDR Europe Association.

Experiences of war and organised violence in combination with post-migration stressors[1] leave asylum seekers and refugees in Western countries at relatively high risk of developing post-traumatic stress disorder (PTSD).[2,3] PTSD in adult refugees has been shown to pose a burden not only for individuals and their families,[4] but also for communities at large.[5] Psychological treatment for refugees with chronic PTSD, although imperative, is a great clinical challenge.[6] According to evidence-based guidelines for the treatment of adults with chronic PTSD, trauma-focused cognitive–behavioural therapy (TFCBT) and eye movement desensitisation and reprocessing (EMDR) therapy should be offered to all patients with this disorder.[7,8] With refugee patients the experience-based recommendation is often made that trauma-focused treatment should be preceded or even replaced by stabilisation.[7,9] Trauma-focused therapy *per se*, especially for refugees living in unstable conditions, has been suggested to cause unmanageable distress[10] and to be inappropriate and ineffective.[7] Nevertheless, systematic reviews of the psychological treatment of refugees have shown TFCBT and narrative exposure therapy (NET) to be safe and efficacious with refugees in various social conditions.[10–12] However, no full, high-quality randomised trials of EMDR therapy with refugees have yet been conducted. To determine the safety and efficacy of EMDR therapy in traumatised refugees, we designed a trial in which adult asylum seekers and refugees with chronic PTSD were randomly assigned to either EMDR therapy or stabilisation. In line with a pilot study[13] and evidence-based guidelines, our first hypothesis was that EMDR therapy would not differ from stabilisation in the occurrence of harms (defined as symptom increase and drop-out related to symptom increase). Our second hypothesis was that EMDR therapy would be more efficacious than stabilisation in reducing trauma-related symptoms (PTSD, anxiety and depression) and improving quality of life.

Method

The trial was performed at Foundation Centrum '45, a highly specialised Dutch centre for diagnostics and treatment of psychotrauma resulting from persecution, war and violence. Centrum '45 receives national referrals of patients considered too complex to be treated in their own municipalities. Participants were enrolled at two out-patient teams for refugees (in the towns of Oegstgeest and Diemen). Patients judged eligible for participation were asked by their intake therapists if they wished to receive any information about the study and, upon consent, were informed about the study by a research associate. Both treatments were presented as aimed at diminishing PTSD symptoms: EMDR through desensitisation of traumatic memories, stabilisation through enhancement of coping with PTSD symptoms and stressful circumstances in the here-and-now. Those willing to participate signed an informed consent form and were then interviewed with the MINI International Neuropsychiatric Interview (MINI)[14] to formally check inclusion and exclusion criteria. Data collection took place from September 2009 until August 2012. The trial was approved by the medical ethics committee of the University of Leiden. Trial registration: NARCIS (Dutch National Academic Research and Collaborations Information System) OND1324839; ISRCTN20310201.

Study entry criteria

Refugees who applied for treatment at Centrum '45 were eligible for participation if they were at least 18 years of age, met the criteria for a PTSD diagnosis according to the DSM-IV-TR,[2] and asked for individual therapy to diminish their PTSD symptoms. Patients who had at some point claimed asylum in

The Netherlands – irrespective of whether their claim had been met or rejected or was still under consideration – were defined as 'refugee'. Patients were excluded if they had disorders that acutely threatened their mental or physical health (i.e. depression with high suicidal intent or psychotic features, psychotic disorder, bipolar disorder and severe self-harm or eating disorders) or that interfered with their ability to participate (i.e. alcohol or substance dependence and cognitive disorders). No restrictions were placed on either refugee status or language proficiency. No other psychotherapeutic treatment could take place during the study, and psychotropic medication had to be kept stable from 2 months before treatment until the post-treatment assessment. For those participants who developed high suicidal intent, a psychotic disorder or another serious psychiatric disorder during the study, a psychiatric consultation was prescribed during which the necessity of prescribing or changing psychotropic medication (using a medication protocol) and of discontinuation of the intervention were to be evaluated.

Trial design

A two-arm design was used in which participants were randomly assigned to either 12 h (9 sessions) of EMDR therapy or 12 h (12 sessions) of stabilisation as usual. To create maximum ecological validity, the recommended session length of EMDR and stabilisation was preserved,[7] and conditions were equated on number of treatment hours rather than number of sessions. Twelve treatment hours is considered a minimum to reach improvement in multiply traumatised patients.[7]

Blocked, simple randomisation was conducted with the latest two participants who had satisfied the inclusion criteria at the same study site forming a block. Participants were assigned to their experimental group through flipping a coin: the outcome (EMDR therapy for heads, stabilisation for tails) was assigned to the participant lowest in the alphabet. An independent research associate who was not otherwise involved in the inclusion process performed randomisation. As both the EMDR condition and the stabilisation condition contained active treatment elements, the design was complemented with a naturalistic waitlist condition to control for time (see online supplement DS1). Primary outcome measures consisted of the change in PTSD symptom severity and diagnosis, both clinician-rated (Clinician-Administered PTSD Scale, CAPS)[15] and self-administered (Harvard Trauma Questionnaire, HTQ).[16] Secondary outcome measures were changes in anxiety and depression (Hopkins Symptom Checklist, HSCL-25)[17] and quality of life (World Health Organization Quality of Life Assessment, WHOQOL-BREF).[18] Harms were defined as an increase in PTSD symptoms of at least ten points on the CAPS[19] and premature termination of the study treatment because of symptom increase. All instruments were administered before treatment (T_1), 2 weeks post-treatment (T_2) and at a 3-month follow-up (T_3). After T_2, participants converted to care as usual.

Interventions

EMDR therapy is a trauma-focused treatment that consists of several steps including treatment planning, preparing the patient for trauma-focused treatment, desensitisation and reprocessing, and evaluation. During desensitisation and reprocessing (which is considered the main active element) a focus on a traumatic image and the thoughts, sensations, feelings and memories that it elicits, is combined with an attention-demanding task such as tracking the therapist's fingers with the eyes.[20] The EMDR condition started with three 60 min sessions dedicated to treatment planning and preparation (including discussing study

course and use of interpreters, discussing the patient's explanatory model and subsequently providing psychoeducation on PTSD and EMDR, and making a timeline of traumatic experiences and symptoms). Traumatic memories that were expected to lead to the greatest remission of PTSD symptoms were selected for desensitisation. The preparatory sessions were followed by six 90 min desensitisation sessions, using the Dutch version of the EMDR protocol.[21] Stabilising interventions were proscribed. The EMDR condition was performed by seven clinical psychologists, one physician/psychotherapist and two psychotherapists. Only therapists who had earlier in their career completed an accredited advanced EMDR course participated. Their average experience in EMDR therapy was 5.3 years (s.d. = 2.9). They received monthly supervision by a licensed EMDR supervisor.

The stabilisation condition consisted of 12 sessions of 60 min stabilisation as usual. In phase-oriented treatment for PTSD, the first phase or stabilisation phase is aimed at enhancing safety, control over symptoms and socio-psychological competencies through interventions such as emotion regulation and relational skills building, stress management and cognitive restructuring; processing of traumatic memories is left until the second phase.[9] Stabilisation as usual, rather than a structured form of stabilisation, was chosen as a control condition to reflect the regular non-structured stabilisation offered in European mental healthcare centres for refugees.[22,23] Therapists were asked to select stabilising interventions to match their patient's needs. Exposure to traumatic memories was proscribed. Stabilisation was performed by three clinical psychologists, five psychotherapists, one physician/systemic therapist, one psychiatrist, one social psychiatric nurse, two psychiatrists in training and one psychotherapist in training. Those therapists participated who regularly conducted stabilising interventions in their usual care. Their mean number of years of experience in working with traumatised refugees was 9.9 (s.d. = 5.5), which did not differ from EMDR therapists' experience (mean 9.00, s.d. = 5.5; $t(22) = -0.41$, $P = 0.75$). Stabilisation therapists received monthly supervision from a registered cognitive–behavioural and family therapy supervisor/trainer with a specialisation in trauma therapy.

For both conditions, therapist manuals were designed with information on the study methods (such as study design and rules for drop-out), study treatment (such as pre- and proscribed elements), the medication protocol and camera use (manuals available from the authors on request). To assess treatment integrity, treatment sessions were videotaped. For the EMDR condition, a detailed treatment fidelity scale was put together consisting of the scale used in a Dutch EMDR trial[24] and additional prescribed, proscribed and non-specific elements. For the stabilisation condition, a brief treatment fidelity scale was designed containing prescribed, proscribed and non-specific elements. All interventions were delivered in Dutch when possible and translated by registered interpreters (physically present or by telephone) when necessary.

Measures

PTSD severity and diagnosis were measured by the CAPS and the HTQ. The CAPS yields frequency and intensity scores (ranging from 0 to 4) for all PTSD symptoms according to the DSM-IV-TR in the past week. A symptom was considered present if its frequency was rated as at least 1 and its intensity as at least 2.[25] To capture full PTSD severity, interviewers referred to clusters of war or persecution experiences rather than to one index traumatic event. The HTQ consists of three parts: one on traumatic events, one on DSM-IV trauma symptoms, and one on other trauma symptoms. Scores for the symptom parts range from 1 (not at

all) to 4 (extremely). Anxiety and depression were measured using the HSCL-25, which uses the same scale. Quality of life was measured by the WHOQOL-BREF, which measures four domains of quality of life (physical, psychological, social relationships, and environment) on a scale of 1–5 (a higher score indicating a higher quality of life). All of these instruments have good psychometric properties and are widely used in transcultural research.[26–29]

Interpreters were used whenever the participant did not speak Dutch and the instrument was not available in the participant's native language. To maximise participant understanding of the questionnaires while minimising dependency on individual interpreters' skills, where possible we used questionnaires in the participant's native language that had been carefully translated by our institute (HTQ, HSCL)[30] or by the WHOQOL Group (WHOQOL-BREF).[18] Interviews were administered by trained Master's students in psychology who were kept masked to treatment condition by having limited access to participant data and by asking participants not to reveal treatment content. They received monthly supervisions of their CAPS ratings using videotaped interviews. Participants received a gift coupon at T_2 and a box of chocolates at T_3.

Statistical analysis

Sample size was calculated with the power analysis program G*Power version 2 for Windows (Erdfelder, Faul and Buchner at the University of Trier, Germany, www.psycho.uni-duesseldorf.de/aap/projects/gpower/). Power calculations were based on outcomes of our pilot study, which resulted in a medium effect size between EMDR and stabilisation on the HTQ.[13] For the main study, a sample size of 36 patients per condition was needed (using a power of 0.80, a two-sided significance level of 0.05 and three repeated measures) to detect a medium between-treatment effect size at T_3. In response to reviews of our pilot study, in the final analyses we used a statistically more advanced variation of the planned analysis strategy (Bayesian latent growth modelling instead of repeated measures analysis), which the sample size allowed for.[31]

Treatment fidelity, interrater reliability and demographic and clinical variables were analysed with SPSS version 20.0 for Windows. Chi-squared and t-tests were conducted to check for demographical and clinical differences between participants and those who refused to participate as well as between the two treatment conditions. Mean scale and subscale scores were computed, allowing for a maximum number of three missing values in the HTQ and HSCL and following the questionnaire manual rules for missing values for the WHOQOL-BREF. Chi-squared tests (for treatment condition, gender, refugee status, drop-out, use of an interpreter and work status) and t-tests (for age, distance from home to treatment centre, and CAPS score at baseline) were conducted to explore relationships between missing values and demographic and clinical variables.

Data were then converted to Mplus version 7 (Muthén and Muthén at University of California, www.statmodel.com/). Bayesian estimation was used in all analyses with the default settings in Mplus with regard to prior specifications.[32] Bayesian analysis enables full intent-to-treat analysis as missing data are automatically imputed. For the burn-in and convergence criteria we used a minimum of 20 000 iterations after which the Gelman-Rubin convergence criterion[32] was used to monitor convergence with a cut-off value of 0.01. Additionally, to ensure convergence was reached, we checked the trace-plots manually. In Bayesian statistics, credibility intervals are used to indicate the 95% probability that the estimate will lie between the lower and upper value of the interval. A treatment effect can be assumed

to be present when the credibility interval does not include zero. A difference in treatment effect between conditions can be assumed to be present when credibility intervals between conditions do not overlap. As a measure of effect size between conditions we divided the difference between the linear slopes by the square root of the linear slope's variance (which is equal for the two conditions).[33]

Finally, to analyse individual changes in post-traumatic stress scores over time and to identify predictors in the separate treatment conditions, we applied a multigroup latent growth model to the data. Latent growth modelling (LGM) enables an examination of individual growth trajectories for each condition, allowing participants to have a different starting point (i.e. a random intercept model) and a different growth rate (i.e. a random slope model). The R-squared statistic provides the proportion of variance in post-traumatic stress symptoms that is explained by the latent growth factors. The posterior predictive P-value was checked as an indication for model fit (outcome files available from the authors on request).

Results

Participants

Participant flow during the trial is depicted in Fig. 1. The flow diagram includes all patients who met inclusion criteria at intake, i.e. before they were informed about the study and formally interviewed.[34] Although the inclusion of 72 participants was planned, 2 participants who terminated their participation before the first treatment session, unaware of which condition they had been assigned to, were replaced as it was clear that no post-treatment data could be obtained for them.

Chi-squared and t-tests revealed no significant demographic or clinical differences between participants and those who refused to participate (data available from the authors on request). Table 1 shows demographic and clinical characteristics for the two groups at baseline (see online Table DS1 for a version of this table that details a wider range of demographic characteristics). The EMDR group was found to contain significantly fewer female participants than the stabilisation group. Types of traumatic experiences most frequently reported in the HTQ were being close to death (60/72, 83%), murder of family or friend (54/72, 75%) and threatened with torture (52/72, 72%). Drop-out numbers for the two groups were comparable, with 6 EMDR participants (16.7%) and 8 stabilisation participants (22.2%) discontinuing the intervention ($\chi^2(1, n = 72) = 0.36$, $P = 0.55$). One participant, in the stabilisation group, terminated treatment prematurely because of symptom increase (attempted suicide). In both groups, asylum seekers and those in the country illegally were no more likely to drop out of treatment than participants with a refugee status (EMDR therapy: $\chi^2(1, n = 36) = 0.05$, $P = 0.83$; stabilisation: $\chi^2(1, n = 36) = 0.05$, $P = 0.83$).

Treatment integrity and content

Treatment integrity was rated by four trained graduate-level research assistants. We randomly selected 12.5% of all treatment sessions for rating of treatment fidelity. Interrater agreement was determined for the first three ratings for both conditions. As this was consistently high (Cronbach's $\alpha = 0.95$ for EMDR and 1.0 for stabilisation), interrater agreement was deemed to be satisfactory and was not monitored thereafter.

For the EMDR group, 36 out of 291 sessions were rated, a third of which were taken from the preliminary sessions and two-thirds of which from the EMDR protocol sessions. The mean treatment fidelity score for the preliminary sessions was 97.0 (s.d. = 3.0) and for the protocol sessions 87.8 (s.d. = 9.2) on a scale of 0–100. For EMDR treatment completers ($n = 30$), subjective
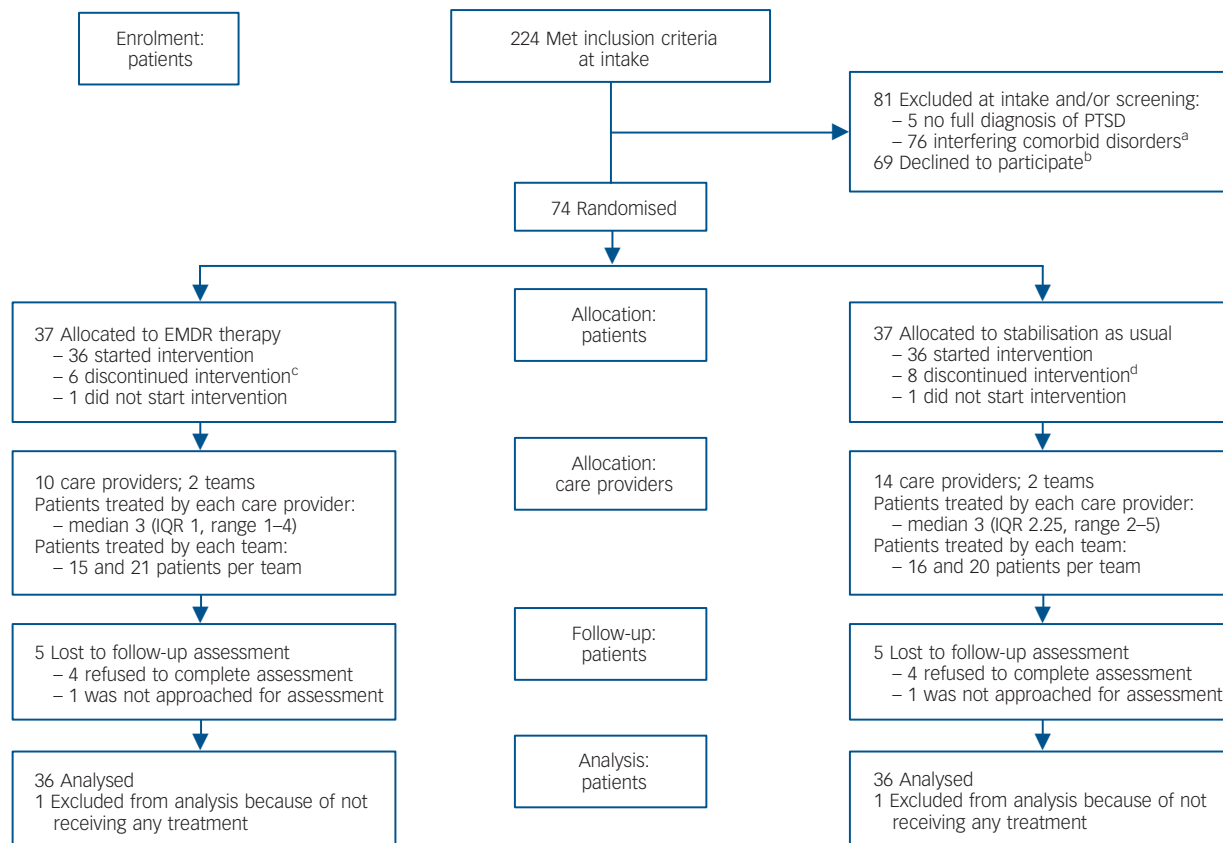
Fig. 1 CONSORT flow diagram.

EMDR, eye movement desensitisation and reprocessing; IQR, interquartile range.
a. 34 substance or alcohol dependence, 7 self-harm, 3 cognitive disorder, 5 eating disorder, 10 serious suicidal ideations, 16 psychotic disorder, 1 bipolar disorder.
b.10 did not want any help at the institute, 30 found participation too much hassle, 18 did not want trauma-focused treatment, 3 did not want stabilisation, 2 did not want treatment for post-traumatic stress disorder (PTSD), 6 refused for various study-related reasons.
c. 3 did not show up for 4 consecutive appointments; 1 thought the travel distance too great; 2 did not want to continue trauma-focused therapy.
d. 6 did not show up for 4 consecutive appointments; 1 developed high suicidal intent; 1 wanted to change to trauma-focused therapy.

unit of distress (SUD) scores decreased significantly from the start of treatment to the end of treatment (from a mean of 8.3, s.d. = 1.7 to a mean of 3.9, s.d. = 3.7, $t(29) = 7.5$, $P < 0.001$), with only 11 participants reaching the desired SUD of 0–1. Mean number of targets treated was 1.6 (s.d. = 1.0, range 1–5), with most participants (19/30, 63%) staying with one target.

For the stabilisation group, 48 out of 387 sessions were rated. The mean treatment fidelity for the stabilisation condition was 88.7 (s.d. = 8.9) on a scale of 0–100. For these 48 sessions the main interventions were registered using an intervention menu.[13] The most frequently registered interventions were discussing and teaching of coping strategies, identification and validation of

negative emotions, and active problem-solving by participant and therapist.

For three EMDR participants and three stabilisation participants a change of medication took place during the study. In most cases this entailed a new or changed prescription for antidepressants.

Reliability

To assess interrater reliability, 12.5% of all interviews (MINI and CAPS) were randomly selected, using stratification for time of assessment. Interrater reliability for the decision whether or not to include a patient in the study (using the MINI; 12.5%, 12/94) was

Table 1 Demographic and clinical characteristics before treatment[a]

	EMDR group (n = 36)	Stabilisation group (n = 36)	χ^2 (d.f.)	t-test (d.f)	P
Age, years: mean (s.d.)	43.1(10.7)	39.8 (11.9)		1.26 (70)	0.21
Women, n (%)	6 (16.7)	14 (38.9)	4.43 (1)		0.04
Types of traumatic experiences, HTQ: mean (s.d.)	13.8 (5.5)	13.7 (5.6)		0.85 (70)	0.93
Years with PTSD, mean (s.d.)	7.9 (7.2)	8.0 (6.5)		−0.41 (59)	0.97
Comorbid depression, n (%)	28 (77.8)	28 (77.8)	0.00 (1)		1.00
On psychotropic medication, n (%)	21 (58.3)	21 (58.3)	0.00 (1)		1.00
CAPS symptom severity, mean (s.d.)	74.7 (18.0)	78.3 (18.3)		−0.83 (70)	0.41
Use of interpreter during study treatment, n (%)	20 (55.6)	20 (55.6)	0.00 (1)		1.00

EMDR, eye movement desensitisation and reprocessing; HTQ, Harvard Trauma Questionnaire; PTSD, post-traumatic stress disorder; CAPS, Clinician-Administered PTSD Scale.
a. See online Table DS1 for a table that details a wider range of demographic and clinical characteristics.

excellent (a Cronbach's α of 1). Interrater reliability for the CAPS (12.5%, 25/198) was excellent for PTSD symptom severity (Cronbach's α = 0.95) and good for PTSD diagnosis (Cohen's κ = 0.78). Internal consistency for all scales was excellent, with a Cronbach's α of 0.86 for the CAPS; 0.88 for HTQ symptoms; 0.90 for the HSCL; and 0.85 for the WHOQOL-BREF.

Missing data

Out of a total database of 1944 total or mean scores (i.e. nine outcome measures administered three times with 72 participants), 186 scores (9.6%) were missing and automatically imputed for each Bayesian analysis. 'Missingness' was significantly related to drop-out, with those who ended participation prematurely being more likely to have missing data than those who completed the study ($\chi^2(1, n = 72) = 12.85$, $P < 0.001$).

Outcomes

Primary outcomes

Table 2 describes PTSD diagnoses for the two groups at each assessment.

Numbers indicate that outcomes displayed a slightly quadratic development over time for both groups. Between T_1 and T_3, the majority of assessment completers in both groups achieved a clinically significant improvement in PTSD severity (defined as improving at least ten points on the CAPS, Table 2).[19]

In the LGM analyses, best model fit was obtained when including a quadratic slope. Table 3 shows the results of the intent-to-treat analyses for primary outcomes. Participants in both groups initially achieved a clinically significant improvement in clinician-rated PTSD severity, which was partly lost after T_2. The EMDR group significantly improved in self-reported PTSD symptoms according to DSM-IV. No significant differences between the two groups were found in either linear or quadratic slopes and effect sizes between the groups were small (for within- and between-treatment effect sizes based on unimputed data, see online Table DS2).

Secondary outcomes

No significant differences were found between the EMDR therapy and stabilisation group on any of the secondary outcome measures (Table 3). Neither intervention had a significant effect on anxiety, depression or quality of life. Quality of life, in fact, in both groups did not show uniform improvement.

Post hoc analyses

Gender

As the EMDR group contained significantly fewer female participants than the stabilisation group, we added gender as a covariate to the

LGM model. This, however, led to a decreased model fit. We therefore analysed the effect of gender on the slopes of the primary outcome measures. Low R squares for all measures and conditions showed that gender had little influence on treatment effect (online Table DS3).

Refugee status

As some clinicians argue that EMDR therapy with asylum seekers is not possible because of their insecure living conditions, we also analysed the effect of refugee status on the primary outcome measures. We divided the groups into participants with no refugee status (i.e. asylum seekers and those staying in the country illegally) and those with temporary or permanent refugee status. The direction of the effect was that participants without a refugee status, regardless of treatment group, showed more PTSD symptom reduction than participants with a refugee status. Although not statistically significant, in the stabilisation group the effect size was medium (online Table DS4).

Discussion

Main findings

In this study, no differences in safety or efficacy were found between EMDR therapy and stabilisation as usual. As previously stated, some clinicians argue that trauma-focused treatment in refugees, especially those living in unstable circumstances, may be harmful.[10] However, in this study, the EMDR and stabilisation groups had comparable numbers of participants who dropped out of treatment and participants reporting symptom increase. In fact, drop-out numbers were relatively low compared with other PTSD outcome studies.[36] Additionally, in the EMDR as well as the stabilisation group asylum seekers showed an improvement at least equal to that of refugees. Results are in line with an increasing body of evidence suggesting that trauma-focused therapy carries no risk of psychologically overwhelming refugee patients, even those in unstable conditions.[10] However, conclusions may not generalise to refugee patients who meet our exclusion criteria – notably those with psychotic disorders, substance dependence or severe suicidal ideations – although the justifiability of using these exclusion criteria in patients who are treated for these disorders has been called into question.[37]

Comparison with a non-randomised waitlist condition suggested that treating refugees with EMDR therapy is more effective than not treating them. However, contrary to expectation, EMDR therapy was found to be no more effective than stabilisation. The effect of stabilisation was similar to effects found for unstructured stabilisation in other refugee samples in Western countries.[22,23] However, the effect of EMDR therapy was lower than expected, with effect sizes for other trauma-focused therapies

Table 2 Post-traumatic stress disorder (PTSD) diagnosis and clinically significant change in PTSD severity in the eye movement desensitisation and reprocessing (EMDR) therapy and stabilisation groups

| | n/N (%) | | | |
	EMDR group	Stabilisation group	χ^2 (d.f.)	P
CAPS diagnosis	30/36 (83)	32/36 (89)		
T_1	21/33 (64)	20/29 (69)	0.47 (1)	0.50
T_2	26/32 (81)	22/31 (71)	0.08 (1)	0.78
T_3			0.92 (1)	0.34
CAPS severity change T_1–T_3			0.23 (2)	0.89
Deterioration (⩾ −10 points)	7/32 (21.9)	8/31 (25.8)		
No change (< 10 points to > − 10 points)	12/32 (37.5)	10/31 (32.3)		
Improvement (⩾ 10 points)	13/32 (40.6)	13/31 (41.9)		

CAPS, Clinician-Administered PTSD Scale.

Table 3 Intent-to-treat analyses of the effects of treatment on post-traumatic stress disorder (PTSD), anxiety, depression and quality of life in the eye movement desensitisation and reprocessing therapy (EMDR) and stabilisation group

	Intercept	Slope	Credibility interval Lower 2.5%	Credibility interval Upper 2.5%	Effect size[a]	Q slope	Credibility interval Lower 2.5%	Credibility interval Upper 2.5%	Effect size[a]
Primary outcomes									
CAPS, severity									
EMDR therapy group	74.71	−11.68	−24.91	1.12	−0.04	4.66	−1.70	10.50	−0.03
Stabilisation group	78.30	−12.75	−27.26	1.61		4.33	−2.55	10.98	
HTQ, DSM-IV									
EMDR therapy group	3.06	−0.40*	−0.74	−0.04	0.20	0.15	−0.01	0.30	−0.29
Stabilisation group	3.19	−0.25	−0.57	0.06		0.06	−0.08	0.20	
HTQ, total									
EMDR therapy group	2.85	−0.31	−0.63	0.02	0.29	0.12	−0.02	0.27	−0.38
Stabilisation group	2.90	−0.11	−0.41	0.18		0.02	−0.11	0.14	
Secondary outcomes									
HSCL, anxiety									
EMDR therapy group	2.86	−0.09	−0.43	0.25	0.09	0.02	−0.13	0.16	−0.15
Stabilisation group	3.04	−0.01	−0.45	0.43		−0.03	−0.23	0.17	
HSCL, depression									
EMDR therapy group	2.95	−0.20	−0.55	0.16	−0.03	0.06	−0.09	0.21	0.03
Stabilisation group	2.97	−0.22	−0.59	0.18		0.07	−0.09	0.23	
WHOQOL-BREF, physical									
EMDR therapy group	2.35	0.07	−0.36	0.49	0.07	−0.03	−0.23	0.16	−0.10
Stabilisation group	2.34	−0.01	−0.44	0.43		0.01	−0.18	0.21	
WHOQOL-BREF, psychological									
EMDR therapy group	2.34	0.00	−0.47	0.47	0.07	−0.03	−0.22	0.17	−0.15
Stabilisation group	2.35	−0.09	−0.61	0.44		0.04	−0.19	0.27	
WHOQOL-BREF, social relationships									
EMDR therapy group	2.71	0.05	−0.48	0.58	−0.28	−0.09	−0.33	0.15	0.22
Stabilisation group	2.56	0.38	−0.18	0.95		−0.20	−0.46	0.05	
WHOQOL-BREF, environment									
EMDR therapy group	2.99	−0.24	−0.61	0.14	−0.52	0.06	−0.11	0.24	0.38
Stabilisation group	2.68	0.22	−0.17	0.63		−0.08	−0.26	0.10	

CAPS, Clinician-Administered PTSD Scale; HTQ, Harvard Trauma Questionnaire; HSCL, Hopkins Symptom Checklist; WHOQOL-BREF, World Health Organization Quality of Life Assessment.
a. Cohen's *d*: 0.20 small, 0.50 medium, 0.80 large.[35]
*$P<0.05$.

in refugee samples in Western countries ranging from 0.93 to 1.6 for NET[22,23] and from 2.4 to 2.6 for exposure.[10,38] A primary explanation is that the number of trauma-focused sessions was lower in this study (i.e. 6 sessions of desensitisation and reprocessing) than in comparable studies (9 for NET[22,23] and 20 for TFCBT[38]). Considering the high number of types of traumatic experiences (14 in both conditions), six sessions appear to have been insufficient to process all memories driving PTSD symptom severity. Additionally, it is possible that equalisation of number of treatment sessions rather than number of treatment hours would have resulted in differences in efficacy between the two groups, as it did in our pilot study.[13] A second explanation is that the study sample consisted of refugee patients who are relatively difficult to treat. Centrum '45 is a specialised institute that receives national referrals of patients who have insufficiently benefited from, or are expected to insufficiently benefit from, treatment within primary mental healthcare. This may be related to the complexity of their traumatic experiences (i.e. multiple, prolonged, interpersonal traumatic events often involving intentional and extreme cruelty) as well as the complexity of their present-day lives (such as being threatened with expulsion, having no financial means, being socially isolated, fearing the effects of ongoing conflict in the country of origin).[39] Comparable studies included only participants who were fluent in the language of their resettlement country[38] or who could be treated within general healthcare.[23] A third possible explanation is that TFCBT (including NET) is indeed more effective than EMDR therapy in treating refugees with chronic PTSD. The culturally sensitive rationale[40] and relatively simple protocol of NET might make this therapy easier to grasp for refugees and EMDR therapy may have some catching

up to do in those respects. A randomised controlled trial is needed to clarify this issue.

Strengths and limitations

This study is the first full trial that meets all CONSORT criteria to test the safety and efficacy of EMDR therapy in refugees with chronic PTSD. A broad range of refugee patients were engaged in this study, including patients who needed interpreters and highly vulnerable patients who were homeless, stayed in the country illegally or were listed for forced return. Both groups were treated by highly experienced therapists. Bayesian estimation allowed for full intention-to-treat analysis.

The study also has several limitations. Although all instruments used have been extensively validated in refugee or transcultural samples, not all language versions were validated, which may have compromised measurement validity. In addition, a measure of positive expectancy for both therapists and patients would have been useful to explore the influence of treatment preference on treatment outcome. Asking refugees which treatment would be preferable under which circumstances would have yielded valuable information and would have enabled refugees to contribute as experts as well as participants. Finally, inequality in number of treatment sessions between the two groups may have led to a greater risk of treatment drop-out in the stabilisation condition than in the EMDR condition.

Clinical implications

On the basis of our study it may be concluded that therapists need not refrain from offering EMDR therapy to asylum seekers or

refugees with chronic PTSD for fear of deterioration, although this conclusion may not necessarily generalise to refugees with comorbid untreated psychosis, substance dependence and high suicidal intent. Offering only a limited number of EMDR sessions, as was the case in this study, may not result in a satisfactory reduction of PTSD and comorbid symptoms. Whether EMDR therapy would show greater efficacy with refugees after a larger number of sessions, or with refugee patients who are referred to general rather than specialised mental healthcare, or when preceded by or combined with stabilising interventions, remains to be tested in future trials. This study adds to an increasing body of evidence that directly targeting traumatic memories of refugees carries no harm.

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EXTRA
CONTENT
ONLINE

Online supplement DS1

The research design did not include a randomised waitlist condition as we considered it unethical to randomly ask patients to refrain from having any psychiatric or psychotherapeutic interventions for a set period of time, and as we expected that such a request would increase refusal to participate. Instead, to control for time we chose to compare the effects of the two treatment conditions with a naturalistic waitlist condition consisting of patients who for various practical reasons did not participate in the main study (mainly because inclusion for the main study had already closed). Those patients were eligible for participation who (a) were refugees of at least 18 years old, (b) had a PTSD diagnosis, (c) had been waiting to start treatment for at least 11 weeks (i.e. equal to the time between T_1 and T_2 for the EMDR condition) and had not had any psychiatric or psychotherapeutic intervention during that time, (d) had completed a regular psycho-diagnostic assessment (consisting of the HTQ events and DSM-IV subscales and the HSCL-25) at intake and had granted permission to use this assessment for scientific purposes, and (e) did not meet the exclusion criteria for the main study. The files of patients who had been placed on the regular waitlist after intake were screened for these criteria by a research associate. Potential participants were contacted by telephone to ask if they were willing to complete an additional assessment before their first therapy session. Upon consent, the HTQ events and DSM-IV symptom subscales, as well as the HSCL-25 were administered before starting treatment. In total, 36 patients were enrolled in the waitlist condition. At the second assessment, significant differences in PTSD severity (EMDR n=32, mean 2.79, s.d.=0.54 *v.* waitlist, n=36, mean 3.17, s.d.=0.43, P = 0.002) and in anxiety (EMDR n=32, mean 2.77, s.d.=0.69 *v.* waitlist, n=36, mean 3.16, s.d.=0.66, P=0.021) were found between EMDR and waitlist, with medium effect sizes (0.77, 95% CI 0.28–1.27, and 0.57, 95% CI 0.09–1.06, respectively, calculated in SPSS). In the LGM model, medium effect sizes (ESs) for PTSD severity were also found between EMDR and waitlist (ES=0.71), and stabilisation and waitlist (ES=0.54), but these did not reach statistical significance (see online Table DS4).

Table DS1 Demographic and clinical characteristics before treatment	EMDR therapy	Stabilisation	Analysis			
	(n=36)	(n=36)	χ^2	t-test	d.f.	P
Demographic characteristics						
Age in years, mean (s.d.)	43.1(10.7)	39.8(11.9)		1.26	70	0.21
Female, n (%)	6(16.7)	14(38.9)	4.43		1	0.04
Education, n (%)			3.44		2	0.18
No education/primary school only	7(19.4)	13(36.1)				
Secondary school/vocational training	15(41.7)	15(41.7)				
University/academy	14(38.9)	8(22.2)				
Married, n (%)	21(58.3)	15(41.7)	2.00		1	0.16
Employment, n (%)			0.60		2	0.74
Unemployed/sickness leave	21(58.3)	24(66.7)				
Volunteer work/school	8(22.2)	7(19.4)				
Employed	7(19.4)	5(13.9)				
Country of origin, n (%)			2.78		5	0.73
Iraq	9(25.0)	8(22.2)				
Afghanistan	9(25.0)	6(16.7)				
Former Yugoslavia	3(8.3)	5(13.9)				
Other Middle Eastern countries	6(16.7)	4(11.1)				
African countries	8(22.2)	10(27.8)				
Other	1(2.8)	3(8.3)				
Refugee background, n (%)			1.74		5	0.88
Political activist	14(38.9)	16(44.4)				
Civilian victim of war/organised violence	10(27.8)	7(19.4)				
Veteran	3(8.3)	4(11.1)				
Child soldier	1(2.8)	2(5.6)				
Persecution for various reasons	2(5.6)	3(8.3)				
Combination of factors	6(16.7)	4(11.1)				
Refugee status, n (%)			0.85		1	0.36
Asylum seeker/illegal	5(13.9)	8(22.2)				
Temporary/permanent refugee status	31(86.1)	28(77.8)				
Years in the Netherlands, mean (s.d.)	10.0(5.3)	8.9(5.1)		0.88	69	0.38
Clinical characteristics						
Types of traumatic experiences (HTQ), mean (s.d.)	13.8(5.5)	13.7(5.6)		0.85	70	0.93
Years of having PTSD, mean (s.d.)	7.9(7.2)	8.0(6.5)		-0.41	59	0.97
Comorbid depression, n (%)	28(77.8)	28(77.8)	0.00		1	1.00
On psychotropic medication, n (%)	21(58.3)	21(58.3)	0.00		1	1.00
CAPS symptom severity, mean (s.d.)	74.7(18.0)	78.3(18.3)		-.83	70	0.41
Use of interpreter during study treatment, n (%)	20(55.6)	20(55.6)	0.00		1	1.00
EMDR, eye movement desensitisation and reprocessing; PTSD, post-traumatic stress disorder;						
HTQ, Harvard Trauma Questionnaire						

Table DS2 shows unimputed outcomes as calculated by SPSS. We used pre- and post-treatment means, sample sizes and paired groups t-values calculated by SPSS to calculate effect-sizes within conditions, and means, standard deviations and sample sizes at follow-up calculated by SPSS to calculate effect-sizes between conditions. Effect-sizes and 95% confidence intervals were calculated using Comprehensive Meta-Analysis version 2 for Windows (Biostat, Englewood NJ; see http://www.meta-analysis.com/index.php).

Table DS3 shows the effects of gender and refugee status on treatment outcome for both conditions.

Table DS4 shows changes in symptom severity for the two treatment conditions and the non-randomised waitlist condition.

Table DS2								

Unimputed analyses of the effects of treatment on PTSD, anxiety, depression and quality of life for EMDR therapy and stabilisation

Measure	Condition	T1		T2		T3		ES[a] T1-T3	ES[a] EMDR - stabilisation
		n	Mean (s.d.)	n	Mean (s.d.)	n	Mean (s.d.)	(95% CI)	(95% CI) at T3
Primary outcomes									
CAPS severity	EMDR therapy	36	74.69(18.01)	32	67.38(23.16)	32	69.94(25.07)	0.19(-0.16 to 0.54)	-0.02(-0.51 to 0.63)
	Stabilisation	36	78.25(18.34)	29	68.86(26.93)	31	69.55(25.05)	0.30 (-0.06 to 0.66)	
HTQ DSM-IV	EMDR therapy	36	3.05(0.49)	32	2.79(0.54)	31	2.86(0.58)	0.38(0.02 to 0.73)*	0.13(-0.36 to 0.63)
	Stabilisation	36	3.19(0.43)	30	2.98(0.62)	32	2.94(0.59)	0.39(0.03 to 0.75)*	
HTQ total	EMDR therapy	34	2.86(0.45)	32	2.63(0.57)	31	2.73(0.63)	0.20(-0.17 to 0.57)	0.04(-0.45 to 0.54)
	Stabilisation	34	2.90(0.51)	30	2.79(0.62)	32	2.76(0.62)	0.25(-0.11 to 0.61)	
Secondary outcomes									
HSCL anxiety	EMDR therapy	35	2.86(0.57)	32	2.77(0.69)	31	2.75(0.71)	0.02(-0.34 to 0.37)	0.10(-0.39 to 0.59)
	Stabilisation	36	3.04(0.66)	30	2.98(0.66)	32	2.89(0.69)	0.17(-0.18 to 0.52)	
HSCL depression	EMDR therapy	35	2.94(0.52)	32	2.79(0.61)	31	2.81(0.61)	0.30(-0.07 to 0.66)	-0.01(-0.50 to 0.49)
	Stabilisation	36	2.97(0.61)	30	2.80(0.66)	32	2.80(0.64)	0.26(-0.09 to 0.61)	
WHOQOL-BREF physical	EMDR therapy	36	2.35(0.60)	31	2.39(0.60)	31	2.34(0.58)	-0.10(-0.45 to 0.26)	-0.06(-0.55 to 0.44)
	Stabilisation	36	2.34(0.53)	29	2.36(0.72)	32	2.37(0.62)	0.03(-0.32 to 0.37)	
WHOQOL-BREF psychological	EMDR therapy	36	2.34(0.65)	31	2.34(0.71)	31	2.21(0.65)	-0.18(-0.53 to 0.18)	-0.17(-0.66 to 0.33)
	Stabilisation	36	2.35(0.70)	29	2.30(0.91)	32	2.33(0.77)	-0.01(-0.36 to 0.33)	
WHOQOL-BREF social relationships	EMDR therapy	36	2.71(0.80)	31	2.72(0.80)	31	2.49(0.86)	-0.32(-0.69 to 0.04)	0.04(-0.46 to 0.53)
	Stabilisation	36	2.55(0.98)	29	2.65(0.88)	32	2.46(0.87)	0.00(n.a.)	
WHOQOL-BREF environment	EMDR therapy	36	2.99(0.70)	31	2.81(0.60)	31	2.77(0.57)	-0.32(-0.68 to 0.04)	-0.06(-0.56 to 0.43)
	Stabilisation	35	2.65(0.66)	29	2.84(0.80)	32	2.81(0.65)	0.15(-0.21 to 0.50)	

EMDR, eye movement desensitisation and reprocessing; TAU, treatment as usual; CI, credibility interval; ES, effect size; CAPS, Clinician Administered PTSD Scale; HTQ, Harvard Trauma Questionnaire; DSM-IV, Diagnostic and Statistical Manual of Mental Disorders, 4th edition; HSCL, Hopkins Symptom Checklist; WHOQOL, World Health Organization Quality of Life

[a] Cohen's d: 0.20 small, 0.50 medium, 0.80 large [35]

*P<0.05, **P<0.01

Table DS3

Effects of gender and refugee status on treatment outcome for EMDR and stabilisation

	Measure	Condition	beta	SE	CI lower 2.5%	CI upper 2.5%	R^2 [a]	95% CI 0 to
Gender	CAPS total	EMDR therapy	3.36	6.95	-10.08	17.27	0.05	0.38
		Stabilisation	-1.94	4.33	-10.43	6.49	0.03	0.28
	HTQ DSM-IV	EMDR therapy	-0.06	0.17	-0.40	0.27	0.04	0.32
		Stabilisation	-0.03	0.10	-0.23	0.17	0.03	0.23
	HTQ total	EMDR therapy	-0.07	0.18	-0.43	0.28	0.04	0.29
		Stabilisation	-0.03	0.11	-0.24	0.19	0.02	0.20
Refugee status	CAPS total	EMDR therapy	0.17	6.31	-12.19	12.67	0.03	0.28
		Stabilisation	7.98	5.05	-1.74	17.98	0.14	0.55
	HTQ DSM-IV	EMDR therapy	0.13	0.15	-0.17	0.42	0.06	0.38
		Stabilisation	0.19	0.12	-0.05	0.42	0.14	0.51
	HTQ total	EMDR therapy	0.11	0.16	-0.20	0.42	0.04	0.23
		Stabilisation	0.19	0.13	-0.06	0.44	0.11	0.43

EMDR, eye movement desensitisation and reprocessing; SE, standard error; CI, credibility interval;

CAPS, Clinician Administered PTSD Scale; HTQ, Harvard Trauma Questionnaire;

DSM-IV, Diagnostic and Statistical Manual for Mental Disorders, 4th edition

[a]0.02 small, 0.13 medium, 0.26 large [35]

*P<0.05, **P<0.01

Measure	Condition	Intercept	Slope	CI		ES[a]
Table DS4 Intent-to-treat analyses of change in symptom severity for EMDR therapy, stabilisation and non-randomised waitlist						
				lower 2.5%	upper 2.5%	
Primary outcomes						
HTQ DSM-IV	EMDR therapy	3.05	-0.26*	-0.46	-0.06	EMDR - stabilisation 0.17
	Stabilisation	3.19	-0.21*	-0.41	-0.01	EMDR - waitlist 0.71
	Waitlist	3.20	-0.03	-0.18	0.12	Stabilisation - waitlist 0.54
Secondary outcomes						
HSCL anxiety	EMDR therapy	2.86	-0.08	-0.28	0.13	EMDR - stabilisation 0.05
	Stabilisation	3.04	-0.06	-0.36	0.24	EMDR - waitlist 0.40
	Waitlist	3.09	0.08	-0.14	0.28	Stabilisation - waitlist 0.35
HSCL depression	EMDR therapy	2.94	-0.15	-0.38	0.07	EMDR - stabilisation 0.00
	Stabilisation	2.97	-0.15	-0.38	0.09	EMDR - waitlist 0.23
	Waitlist	2.99	-0.06	-0.24	0.13	Stabilisation - waitlist 0.23

EMDR, eye movement desensitisation and reprocessing; HTQ, Harvard Trauma Questionnaire;

DSM-IV, Diagnostic and Statistical Manual of Mental Disorders, 4th edition; HSCL, Hopkins Symptom Checklist;

ES, effect size

[a] Cohen's d: 0.20 small, 0.50 medium, 0.80 large [35]

*P<0.05, **P<0.01

	Supplementary material can be found at: http://bjp.rcpsych.org/content/suppl/2016/02/08/bjp.bp.115.167775.DC1.html
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