

EMDR versus stabilisation in traumatised asylum seekers and refugees: results of a pilot study

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Background: Traumatized asylum seekers and refugees are clinically considered a complex population. Discussion exists on whether with this population treatment guidelines for post-traumatic stress disorder (PTSD) should be followed and Trauma-Focused Cognitive-Behavioural Therapy (TF-CBT) or Eye Movement Desensitisation and Reprocessing (EMDR) should be applied, or whether a phased model starting with stabilisation is preferable. Some clinicians fear that trauma-focused interventions may lead to unmanageable distress or may be ineffective. While cognitive-behavioural interventions have been found to be effective with traumatized refugees, no studies concerning the efficacy of EMDR with this population have been conducted as yet.

Objective: In preparation for a randomised trial comparing EMDR and stabilisation with traumatized refugees, a pilot study with 20 participants was conducted. The objective was to examine feasibility of participation in a randomised trial for this complex population and to examine acceptability and preliminary efficacy of EMDR.

Design: Participants were randomly allocated to 11 sessions of either EMDR or stabilisation. Symptoms of PTSD (SCID-I, HTQ), depression and anxiety (HSCL-25), and quality of life (WHOQOL-BREF) were assessed at pre- and post-treatment and 3-month follow-up.

Results: Participation of traumatized refugees in the study was found feasible, although issues associated with complex traumatization led to a high pre-treatment attrition and challenges in assessments. Acceptability of EMDR was found equal to that of stabilisation with a high drop-out for both conditions. No participants dropped out of the EMDR condition because of unmanageable distress. While improvement for EMDR participants was small, EMDR was found to be no less efficacious than stabilisation. Different symptom courses between the two conditions, with EMDR showing some improvement and stabilisation showing some deterioration between pre-treatment and post-treatment, justify the conduct of a full trial.

Conclusion: With some adaptations in study design, inclusion of a greater sample is justifiable to determine which treatment is more suitable for this complex population.

Keywords: *Complex trauma; PTSD; feasibility; trauma-focused therapy; torture; cross-cultural psychiatry; randomised*

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At the end of 2008, there were 16 million asylum seekers and refugees worldwide (UNHCR, 2009). Many refugees are exposed to potentially

traumatising situations during several phases of their journey: surviving war or organised violence, including imprisonment and torture; becoming fugitives; leaving

their home country, often to stay in refugee camps before being granted a right to stay in a country of settlement; and experiencing the stresses of resettlement and discrimination (Silove, Tarn, Bowles, & Reid, 1991). Consequently, their chances of developing post-traumatic stress disorder (PTSD; American Psychiatric Association, 1994) are high: in western countries, refugees are 10 times more likely to have PTSD than general populations (Fazel, Wheeler, & Danesh, 2005). Clinically, traumatised refugees are often regarded as a “complex” population. This complexity may refer to the nature of their traumatic experiences (e.g., McIvor & Turner, 1995), symptoms of complex PTSD (e.g., Courtois, 2004), and complex social circumstances (e.g., Laban, Gernaat, Komproe, Schreuders, & De Jong, 2004).

A discussion exists concerning the treatment this complexity calls for (e.g., Nickerson, Bryant, Silove, & Steel, 2011). Trauma-Focused Cognitive-Behavioural Therapy (TF-CBT) and Eye Movement Desensitisation and Reprocessing (EMDR) are recommended as treatments of choice for PTSD in adults (Bisson et al., 2007). Some clinicians, such as Başoğlu (2006), argue that despite all complexities PTSD treatment guidelines should be followed with traumatised asylum seekers and refugees. Others (e.g., National Institute of Clinical Excellence [NICE], 2005) argue that with this population a phased model may be appropriate, in which treatment initially focuses on the establishment of safety, emotional stabilisation, and a trusting relationship. Trauma-focused therapy, at this stage, is considered “inappropriate and ineffective” although “there is no trial evidence to support this contention and it therefore reflects a pragmatic approach” (NICE, 2005, p. 120). Some clinicians fear that trauma-focused therapy may lead to unmanageable distress in refugees (Nickerson et al., 2011), especially in asylum seekers. A recent study on psychotherapy with refugees (Kruse, Joksimovic, Cavka, Wöller, & Schmitz, 2009) points out the need for a randomised design in which the efficacy of trauma-focused therapy is compared with the efficacy of stabilisation therapy. While a review of PTSD treatments for asylum seekers and refugees (Crumlish & O’Rourke, 2010) shows evidence for the efficacy of narrative exposure therapy (NET) and TF-CBT, no studies concerning the efficacy of EMDR with this population have been conducted as yet.

In response to this discussion, a randomised trial comparing the efficacy of EMDR and stabilisation with asylum seekers and refugees is currently being conducted at our institute. As refugees are sometimes thought unfit for participation in such trials (because of insufficient fluency or lack of refugee status; e.g., Paunovic & Öst, 2001) and as no studies on EMDR with this population were available when designing this trial, we conducted a pilot study. Objective of the pilot study was to answer

three questions: is participation in a randomised trial feasible for this complex population; is EMDR an acceptable treatment for this population; and which preliminary conclusions can be drawn on efficacy of EMDR with this population?

Method

Setting and sample

The pilot study was conducted at Foundation Centrum ’45, a Dutch centre for the treatment of psychotrauma disturbances resulting from persecution, war, and violence. Participants were asylum seekers and refugees of at least 18 years old who had recently been referred for treatment (refugees have been granted temporary or permanent refugee status in the Netherlands, while asylum seekers are still awaiting a final decision). A sample size of 20 was deemed sufficient to allow a comparison of findings to those of other pilot studies or small efficacy studies with refugees (e.g., Hinton et al., 2004, sample size 12; Paunovic & Öst, 2001, sample size 20). Eligibility was judged during a standard intake interview and a clinical interview consisting of the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I) Module PTSD (Dutch version by Van Groenestijn, Akkerhuis, Kupka, Schneider, & Nolen, 1998) and parts of the Mini International Neuropsychiatric Interview (MINI; Dutch version by Overbeek, Schruers, & Griez, 1999). In order to ensure inclusion of a sufficient number of patients within a reasonable time frame, patients were included who met the DSM-IV criteria for PTSD, or who met this diagnosis but for one C-criterion (i.e., patients suffering from so-called “Lowered-Avoidance-Criterion-PTSD”; e.g., Schützwohl & Maercker, 1999). Patients were excluded whose main diagnosis demanded care in another setting or who suffered from serious comorbid depression (with psychotic features and/or high suicidal intent), psychotic disorder, bipolar disorder, substance dependence, or eating disorder.

Participants were recruited from March until October 2007. Forty-six patients met inclusion criteria. Of these, 10 were excluded because of substance abuse, high suicidal intent, or psychotic disorder. Sixteen patients refused participation: four patients did not want to be treated with EMDR, two patients did not want to be treated with stabilisation, three patients did not want to attend (bi)weekly sessions, and seven patients refused for other reasons (preferring treatment as usual, wanting treatment only by intake therapist, breaking off contact, or not wanting to be interviewed by a research assistant). No significant demographic or clinical differences were found between participants and those refusing participation.

Characteristics for the final sample are described in Table 1. All asylum seekers were randomly assigned to

Table 1. Baseline demographic and clinical characteristics of intent-to-treat sample

Variable	EMDR (<i>n</i> = 10)	Stabilisation (<i>n</i> = 10)
	<i>n</i> / <i>M</i> (<i>SD</i>)	<i>n</i> / <i>M</i> (<i>SD</i>)
<i>Demographic characteristics</i>		
Male	5	7
Age	40.00 (9.31)	43.00 (7.93)
Residency status granted	7	10
Duration of stay in the Netherlands in years	10.10 (4.31)	10.30 (3.53)
Married	3	8
No education/primary school only	3	6
Employed	3	3
<i>Clinical characteristics</i>		
Duration of PTSD in years	8.90 (6.77)	6.13 (3.33)
Comorbid depression	8	5

the EMDR condition. Participants originated from Afghanistan (4), Algeria (1), Angola (1), Bosnia (4), Iran (2), Iraq (6), Lebanon (1), and Turkey (1). The average number of kinds of traumatic events experienced by the participants personally (i.e., excluding those events witnessed or heard of, as measured with the Harvard Trauma Questionnaire, Mollica et al., 1996a) was 10 in both conditions. Murder or unnatural death of family or friend (19/20), and physical or psychological torture (14/20) were reported most frequently; rape or sexual abuse were not reported.

Design

A mixed groups experimental design was used with two treatment conditions. Blocking was applied, with blocks of the latest two patients who had satisfied inclusion criteria. Participants were assigned to their experimental group using simple randomisation through flipping a coin: the outcome (EMDR for heads, stabilisation for tails) was assigned to the patient lowest in the alphabet. An independent research associate performed randomisation.

Interventions

Both treatment conditions consisted of 11 weekly or biweekly sessions. Both started with three preparatory sessions to establish a working alliance, conduct a case conceptualisation and agree on treatment goals. The use of an interpreter and consent to videotaping of sessions were discussed. The explanatory model of the patient was explored and psychoeducation was given on PTSD and the treatment condition.

The EMDR condition continued with a resource development and installation exercise (Korn & Leeds, 2002). The next seven sessions were aimed at reducing disturbance associated with the most troubling traumatic memory, following the Dutch version of the EMDR protocol (De Jongh & Ten Broeke, 2003; Shapiro, 1995). EMDR sessions lasted 90 min, 60 of which were dedicated to EMDR per se. The EMDR condition was performed by two psychotherapists, one psychiatrist, and two health care psychologists. All EMDR therapists were trained at EMDR level II and received monthly supervisions by a registered EMDR-supervisor/trainer.

The EMDR Fidelity Scale (Korn, Zangwill, Lipke, & Smyth, 2001) was used to assess EMDR treatment adherence, ranging from 0 (*no adherence*) to 3 (*adherence very good*). Treatment adherence was rated by the EMDR-supervisor after conclusion of the study, with the dual objective of determining treatment adherence for the pilot study and giving recommendations for adherence improvement for the main study. For each participating therapist, one EMDR protocol was rated.

Patients in the stabilisation condition continued with eight sessions of stabilisation. A therapist manual was designed containing information on study design and guidelines on therapy content. Pivotal to the stabilisation condition was a focus on the “here-and-now”: exposure to traumatic memory was proscribed. In that sense it was comparable to present-centred therapy used as a control condition by Schnurr et al. (2007), but therapists were more directive. The aim of stabilisation was defined as the establishment of safety in physical, cognitive-behavioural, interpersonal, and social areas of functioning, as advocated by Herman (1992). Physical safety refers to the enhancement of physical well-being and diminishing of PTSD-related physical complaints, through interventions aimed at the body (e.g., relaxation exercises or instructions for self-care) and the environment (e.g., resettlement assistance). Cognitive-behavioural safety refers to enhancement of control over cognitive, behavioural, and emotional aspects of PTSD, e.g., through attention exercises or sleep hygiene. Interpersonal safety refers to the ability to bond with others including the therapist, e.g., through discussing cognitions on therapeutic trust. Social safety refers to the ability to use social support and social institutions, e.g., through applying for permission to work. In order to increase generalisability of the study findings, therapists were asked to conduct “stabilisation as usual”, selecting stabilisation interventions from therapeutic orientations they were most familiar with and which they deemed most appropriate to their patient’s therapeutic goals. Sessions lasted 60 min and were conducted under monthly supervision by a registered cognitive-behavioural and family therapy supervisor/trainer with a specialisation in trauma therapy. The stabilisation condition was performed by one clinical

psychologist, one physician/psychotherapist, one physician, and two social-psychiatric nurses.

In order to systematically assess therapy content, a “stabilisation menu” (Meichenbaum, 1985) was provided in which possible interventions were listed, derived from authors such as Herman (1992), Linehan (1993), Meichenbaum (1985), and Van der Hart and Nijenhuis (1999). Therapists were asked to tick off applied interventions after each session. A stabilisation fidelity scale was designed containing items on session goals, content of interventions, proscription of trauma exposure interventions, session length and frequency, medication, and working alliance (in line with recommendations by Barber, Triffleman, & Marmar, 2007). The scale ranged from 0 (*no adherence*) to 10 (*excellent adherence*). Treatment adherence was rated by the stabilisation supervisor after conclusion of the study, for the same reasons as using the EMDR supervisor in determining EMDR treatment fidelity. For each participating therapist, one therapy was rated.

A medication protocol was used. Patients were required to have been on a stable dose for at least 2 months before their pre-treatment assessment. In accordance with clinical guidelines for the treatment of PTSD (NICE, 2005), no medication was prescribed for participants during the study unless they developed serious depressive symptoms. Medication already used at intake was maintained until the post-treatment assessment. Psychotropic medication was used by eight participants in the EMDR condition and nine participants in the stabilisation condition.

Therapists in both conditions were experienced clinicians who had worked with traumatised asylum seekers and refugees for an average of 16.5 years. All participants received care as usual after the post-treatment assessment.

Measures

The Mini International Neuropsychiatric Interview (MINI; Sheehan et al., 1998) is a structured clinician-rated interview to screen for DSM-IV axis-I disorders. Despite its short and simple design, it has been found to be highly sensitive and highly specific (Sheehan et al., 1998). In this study, only those parts of the MINI were used that concerned exclusion criteria: depression with psychotic features or high suicidal intent, bipolar disorder, alcohol and drug dependence, psychotic disorder, and anorexia and bulimia nervosa.

All other instruments were applied at pre-treatment (T1), post-treatment (T2) and 3-month follow-up (T3). The primary outcome measure consisted of PTSD symptomatology as measured by the SCID-I (Van Groenestijn et al., 1998) and the Harvard Trauma Questionnaire (HTQ; Mollica et al., 1996a). Secondary outcome measures consisted of symptoms of anxiety and depression according to the Hopkins Symptom Checklist

(HSCL-25; Mollica et al., 1996b), and quality of life as measured by the World Health Organisation Quality of Life questionnaire (WHOQOL-BREF; WHOQOL Group, 1998).

The SCID-I module PTSD is a clinician-rated interview with good psychometric qualities (Lobbestael, Leurgans, & Arntz, 2011; Zanarini et al., 2000), used to determine presence and severity of a DSM-IV PTSD diagnosis. In this study, B-, C-, and D-criteria for PTSD rated as present were added to form a continuous variable with a range from 0 to 17. The interview was administered in Dutch by trained, blind assessors; interpreters were used when necessary. Inter-rater reliability was 100% on PTSD diagnosis and 92% on individual items. Blindness was maintained in 33 out of 44 assessments (70%).

The HTQ, HSCL-25, and WHOQOL-BREF are self-report questionnaires that are widely used with this population and are available in many different languages. All three have good psychometric properties (for the HTQ and the HSCL-25, see Hollifield et al., 2002; for the WHOQOL-BREF, see Skevington, Lotfy, & O’Connell, 2004, and WHOQOL Group, 1998). Questionnaires were administered in the patient’s native language if possible; interpreters were used when necessary. 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*). DSM-IV symptoms and other symptoms are added to yield a total score. A cut-off score of 2.45 is used to indicate likelihood of PTSD. The HSCL-25 consists of two parts: one on anxiety and one on depression. Scores range from 1 (*not at all*) to 4 (*extremely*). A cut-off score of 1.75 is used to indicate likelihood of a clinical diagnosis. The WHOQOL-BREF measures four domains of quality of life: physical, psychological, social, and environment. Scores range from 1 to 5, with different meanings attached to scores for different domains. At T2 and T3 the participants were given a small present in appreciation of their time and effort.

Data analysis

Statistical analyses were performed with SPSS 18.0 for Windows. Kolmogorov-Smirnov tests were used to examine normality of distribution for continuous demographic and clinical variables at baseline; consequently, independent samples T-tests were used to check for differences at baseline between participants and those who refused participation (selection bias), and between drop-outs and completers. Sample size was too small to use χ^2 tests for categorical variables.

Because of the small sample size, GLM Repeated Measures rather than a more sophisticated method of analysis was selected to test the effect of intervention. The

assumptions of sphericity and equality of variance were checked using Mauchly's test and Levene's test, respectively. When the assumption of sphericity was violated, Greenhouse-Geisser corrections were administered.

Results

Assessments

Assessments were challenging to most participants. Linguistic difficulties resulted in eight participants needing an interpreter during assessments and three needing extensive help with filling in the questionnaires. Seven participants experienced physical pain during assessments and had to take frequent breaks or asked to sit on the floor. Seven participants were emotionally upset resulting in crying, anxiety, and dissociation. Two participants felt embarrassed by questions on sexual functioning (WHOQOL-BREF). Two participants were unable to organise transportation and had to be assessed outside of the institute.

Treatment adherence

Interpreters were used in therapy sessions with six patients (three in each condition). Seven participants (35%) refused to have their treatment sessions video- or audiotaped despite explanations by their therapists about confidentiality and the offer to film only the therapist and not the participant. Reasons given for refusal mainly pertained to worries about the breaching of confidentiality. EMDR treatment adherence as rated by the EMDR Fidelity Scale was adequate ($M = 2.22$; $SD = .46$).

Stabilisation treatment adherence as rated by the stabilisation fidelity scale designed for this study was also adequate ($M = 8.14$; $SD = .81$). A focus on cognitive-behavioural functioning and social functioning was most frequently chosen. Interventions most frequently reported were psychoeducation, exploration of troubling cognitions and behaviour, and relaxation exercises.

Drop-out

In both conditions, five patients dropped out of the study (50%). In the EMDR condition, one patient dropped out because of satisfaction with symptom reduction (after a total of four sessions) and one patient did not want to speak about the past (four sessions). One therapist considered EMDR unsuitable for all three assigned patients because of current stress and cultural factors (all drop-outs during the preparatory sessions). Amongst the drop-outs was one asylum seeker. In the stabilisation condition, two patients dropped out because of satisfaction with symptom reduction (three and eight sessions), one because of dissatisfaction with symptom reduction (eight sessions), one because of an increase of symptoms (one session), and one patient missed too many therapy sessions (four sessions). No significant demographic or

clinical differences were found between drop-outs and completers.

Statistical outcomes

Table 2 presents the outcomes per participant for the intent-to-treat sample. Attempts to assess drop-outs failed with four EMDR participants and two stabilisation participants. Of those for whom all assessments were available, three out of five participants in the EMDR condition lost their PTSD diagnosis versus no (out of eight) participants in the stabilisation condition. Because of the substantial number of missing assessments, Table 3 shows completers' analyses only of outcome measures for continuous variables at T1, T2, and T3.

Primary outcomes

Primary outcome measure was PTSD psychopathology as rated by the SCID and the HTQ. No significant change in symptomatology occurred in either condition. Changes in symptomatology were however, significantly different between the two conditions both on HTQ DSM-IV items and on total HTQ items. Fig. 1 shows the course in symptoms for both conditions on HTQ DSM-IV items, with EMDR participants showing some improvement and stabilisation participants showing some deterioration between T1 and T2. Symptom decline in the EMDR condition did not reach below the cut-off score of 2.45 for PTSD. Interaction between treatment and time explained variance to a large extent (Cohen, 1988, suggests the following interpretation of partial eta squared: .01 small, .09 medium, and .25 large).

Secondary outcomes

On secondary outcomes also, changes in symptomatology failed to reach significance in either condition. Changes did differ significantly between the two conditions with regard to HSCL-25 anxiety items and depression items and with regard to social aspects of quality of life (WHOQOL-BREF; a higher score meaning a higher quality of life). Again, EMDR participants showed some improvement and stabilisation participants showed some deterioration between T1 and T2 and the amount of variance explained was large.

Discussion

Traumatised asylum seekers and refugees are clinically considered a complex population. Discussion exists on whether with this population treatment guidelines for PTSD should be followed and TF-CBT or EMDR should be applied, or whether a phased model should be followed starting with stabilisation. In a pilot study with 20 traumatised asylum seekers and refugees, the feasibility of conducting a randomised trial with this population, acceptability of EMDR to the participants, and preliminary efficacy of EMDR were examined.

Table 2. Outcomes per participant

Variable	Time	EMDR																							
		Completers					Drop-out					Stabilisation													
		P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P11	P12	P13	P14	P15	P16	P17	P18	P19	P20				
PTSD diagnosis	T1	PTSD	PTSD	PTSD	PTSD	PTSD	PTSD	PTSD	PTSD	LAC	LAC	LAC	LAC	LAC	PTSD	PTSD	PTSD	PTSD	LAC	LAC	PTSD	LAC	PTSD	PTSD	
	T2	No	PTSD	PTSD	PTSD	PTSD	PTSD	PTSD	PTSD						PTSD	PTSD	PTSD	PTSD			LAC	PTSD	PTSD	PTSD	
	T3	No	PTSD	No	PTSD	No	PTSD	No	PTSD	PTSD					PTSD	PTSD	PTSD	PTSD			PTSD	PTSD	PTSD	PTSD	
SCID-I positive items	T1	11	13	11	14	15	14	15	14	10	14	12	14	10	9	16	11	12	15	14	10	12	15	9	13
	T2	3	13	10	14	14	14	14	14						14	14	10	15	15	11	11	9	15	15	
	T3	0	15	5	16	11	16	11	11	14	15	15	15	11	15	15	11	15	13	13	10	9	17	15	
HTQ DSM-IV	T1	2.9	3.1	2.3	3.1	3.6	3.2	3.2	3.2	2.6	2.5	2.7	2.4	2.4	2.7	3.1	2.9	2.6	1.7	2.7	3.6	2.6	3.1		
	T2	1.9	2.8	2.0	3.3	2.7	2.7	2.7	2.7			3.1	3.0	2.9	2.8	2.9	2.8	3.4	2.6	2.6	3.3	3.3			
	T3	1.7	3.1	1.9	3.5	2.5	2.5	2.5	2.5	2.8	2.8	3.1	3.0	3.4	2.9	3.5	2.9	3.5	2.1	2.1	3.8	3.5			
HTQ total	T1	3.0	2.8	2.4	2.9	3.2	3.0	2.8	3.4	2.2	2.2	2.5	2.2	2.4	2.5	2.2	2.4	2.2	1.4	2.3	3.3	2.2	3.1		
	T2	1.9	2.6	1.8	3.2	2.4	2.4	2.4	2.4			2.5	2.7	3.1	2.3	3.0	2.3	3.0	2.3	2.3	3.0	3.0	3.5		
	T3	1.6	2.9	2.0	3.2	2.4	2.4	2.4	2.4	2.4	2.4	2.8	2.5	2.5	2.6	2.8	2.3	2.8	2.3	2.3	3.2	3.2	3.3		

LAC = Lowered Avoidance Criterion PTSD.

Table 3. Analysis of variance for completers

Variable	Time	EMDR (n = 5)		Stabilisation (n = 5)		Interaction effect	
		M	SD	M	SD	F(2, 36)	Effect size ^a
SCID-I positive items	T1	12.80	1.79	13.60	2.07	1.61	0.17
	T2	10.80	4.66	13.00	2.35		
	T3	9.40	6.80	13.80	1.79		
HTQ DSM-IV	T1	3.01	0.47	2.74	0.27	5.92*	0.42
	T2	2.54	0.56	3.04	0.25		
	T3	2.55	0.77	3.16	0.26		
HTQ total	T1	2.85	0.32	2.36	0.16	5.99*	0.43
	T2	2.37	0.58	2.71	0.32		
	T3	2.43	0.65	2.85	0.38		
HSCL anxiety	T1	2.92	0.66	2.76	0.23	4.68*	0.36
	T2	2.50	1.00	3.02	0.52		
	T3	2.44	0.88	3.18	0.33		
HSCL depression	T1	3.04	0.38	2.80	0.16	3.67*	0.32
	T2	2.47	0.66	3.04	0.43		
	T3	2.71	0.79	2.80	0.22		
WHOQOL physical	T1	2.60	0.84	2.37	0.54	1.50	0.16
	T2	2.80	0.51	2.20	0.37		
	T3	2.71	0.48	1.97	0.26		
WHOQOL psychological	T1	2.13	0.48	2.23	0.45	1.39	0.15
	T2	2.37	0.48	2.13	0.66		
	T3	2.23	0.61	1.80	0.46		
WHOQOL social	T1	2.40	0.86	3.07	0.49	9.55**	0.54
	T2	2.87	0.90	2.33	0.53		
	T3	2.60	0.89	2.23	0.57		
WHOQOL environment	T1	2.73	1.03	3.13	0.54	1.16	0.13
	T2	3.05	0.60	3.08	0.47		
	T3	2.90	0.81	2.90	0.61		
WHOQOL general	T1	2.50	0.79	1.60	0.65	0.09	0.01
	T2	2.50	0.94	1.70	0.45		
	T3	2.20	0.91	1.40	0.55		

^aPartial eta squared.

* $p < 0.05$.

** $p < 0.001$.

Feasibility

Feasibility of the study was supported by the study setting, which provided highly experienced therapists for both conditions and allowed for the random allocation of participants to their treatment conditions (unlike, for example, the study by Kruse et al., 2009). A representative sample of refugee patients was included—including participants without a refugee status and participants needing interpreters (unlike the studies by Paunovic & Öst, 2001 and Kruse et al., 2009).

Feasibility was influenced by issues related to the complexity of the study population. Pre-treatment attrition was 57%: 35% of eligible participants refused participation and 22% met exclusion criteria. This number is considerably higher than pre-treatment attrition rates of 35%–37% mentioned in a review on PTSD treatment studies by Spinazzola, Blaustein, and Van der Kolk (2005). In their study with traumatised refugees, Paunovic and Öst report a pre-treatment attrition of 14 out of 34 clients (41.2%) who were referred from other

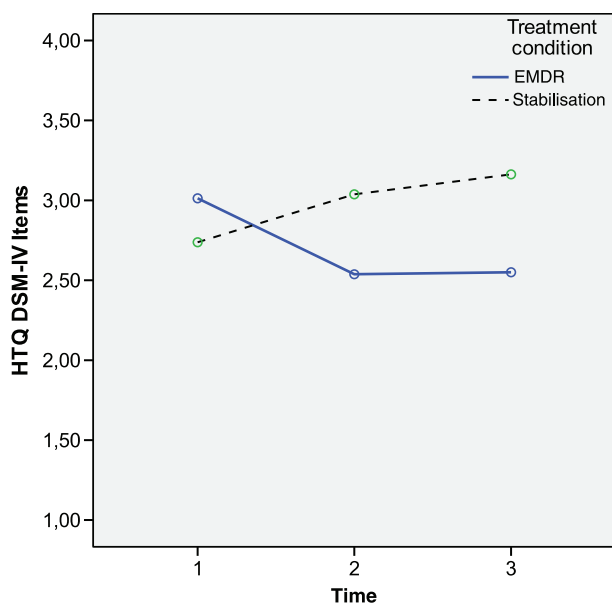


Fig. 1. Estimated marginal means of HTQ DSM-IV.

psychiatric units for participation: seven (22%) seemingly because of patient refusal; seven (22%) for not meeting inclusion criteria and/or meeting exclusion criteria. The higher refusal rate encountered in the present study might be accounted for by the fact that participants were recruited upon intake in the institute rather than being referred especially for study participation. Both the Paunovic and Öst study and the present study suggest that low therapeutic trust may limit the feasibility of participating in a clinical trial for traumatised asylum seekers and refugees. Examples of reasons given for refusal were that the patient is reminded of a torture setting by the interview (Paunovic and Öst) and the patient wants treatment only by intake therapist (present study). This finding is in line with Herman's (1992) theory on complex PTSD, which states that in complexly traumatised patients, therapeutic trust should be developed rather than assumed to exist at the outset of treatment.

Thirty-five percent of participants refused to have their treatment sessions video- or audiotaped. Compared to other experiences with PTSD efficacy studies, this percentage can be considered high (Jacques Barber, personal communication). In line with the complex PTSD criterion of "inability to trust" (Van der Kolk, Roth, Pelcovitz, Sunday, & Spinazzola, 2005), reasons given for refusal mainly pertained to worries about the breaching of confidentiality. This finding may structurally limit the feasibility of videotaping study sessions with traumatised asylum seekers and refugees, and thus complicate the rating of treatment fidelity with this population. In the main study, the protocol has been adapted and research associates rather than study therapists will ask for taping permission, as they might be better able to explain the

importance of taping and precautions taken to ensure confidentiality.

Assessments were challenging to most participants due to language difficulties, physical pain, emotional distress, and embarrassment by questions on sexuality. Research on the HTQ, HSCL-25, and WHOQOL-BREF has mainly focused on reliability and validity of these measures (e.g., Hollifield et al., 2002), rather than on the feasibility of using them with populations who may have little schooling and limited literacy. In the present study, participants were aided with filling in the questionnaires by using symbols such as smiles to help them understand response options. The physical pain observed during assessments may be perceived as part of complex trauma symptomatology. Pain and somatic complaints are frequently reported by refugees, especially survivors of torture (e.g., Turner & Gorst-Unsworth, 1990). The emotional distress observed in some participants seems to be higher than that reported in studies with other traumatised populations (Carter-Visscher, Naugle, Bell, & Suvak, 2007) and several participants needed encouragement to finish their assessments and attend future assessments. Finally, the embarrassment caused by questions about sexuality may be culture-specific and enhanced by the presence of interpreters. Embarrassment or distrust may have potentially led participants to not report rape or sexual abuse on the HTQ (e.g., Tankink & Richters, 2007). The many difficulties encountered during assessments suggest that psychological assessments with this population should be limited in time and be performed with cultural sensitivity and with minimal reference to traumatic memories and complaints. This leaves room for only a limited number of measurements (e.g., 5 in our main study versus 11 in a study with traumatised veterans by Schnurr, Friedman, Lavori, and Hsieh, 2001, in which participant burden was carefully taken into account).

Acceptability

In this study, a treatment intervention was considered unacceptable if it led to either refusal to participate or to drop-out. Acceptability of treatment interventions was equal across conditions. Both EMDR and stabilisation were deemed undesirable treatments to some patients, leading to refusal to participate. Drop-out in both conditions was equally high, suggesting that neither of the two conditions was more acceptable to the participants than the other. No participants dropped out of the EMDR condition because of high levels of psychological distress, nor did asylum seekers have a higher chance of dropping out from the EMDR condition than refugees.

The acceptability of staying in treatment as agreed was rather low, considering the high drop-out that occurred in both conditions (50%). While this rate is 3.5 times higher than rates recorded in efficacy research for psychological

therapies for PTSD, it is comparable to treatment studies for PTSD with comorbid disorders (37%–62%; Spinazzola et al., 2005)—suggesting that the complexity of the clinical picture may have led to a higher drop-out. However, the drop-out rate was also higher than in comparable studies (i.e., PTSD efficacy studies with refugees in western psychiatric settings) by Paunovic and Öst (2001; drop-out 20%) and Hinton et al. (2004, 2005; drop-out 0%). Study design and setting may have been of influence here. In the present study participants were assured of receiving care as usual at the institute after drop-out. In the Paunovic and Öst study, however, drop-out of the study meant dropping out of psychotherapy at their institute, perhaps resulting in a greater dedication to the treatment condition. Low drop-out rates in the Hinton studies may be accounted for by the fact that all participants were already in long-term treatment at the centre at which the studies were conducted and already had strong treatment alliances there.

Acceptability of EMDR to therapists rather than participants may also have influenced drop-out. Deighton, Gurriss, and Traue (2007) mention six hindrances to working through trauma with torture survivors: client's reservations, client's symptoms, and therapeutic relationship on the one hand and therapist's insecurity, fear of hurting the client, and unfavourable conditions on the other hand. The fact that one therapist thought EMDR unfit for all three assigned patients suggests that a therapist factor may have been of influence. The discussion on the advisability of working through traumatic experiences with traumatised asylum seekers and refugees, as described in the introduction, may make it harder for therapists to stick to the study protocol. Safeguarding therapists' support of the study protocol should be able to bring drop-out down in the main study.

Preliminary efficacy

With the small sample size characteristic for a pilot study, statistical outcomes should be treated as preliminary and interpreted with caution (Lancaster, Dodd, & Williamson, 2004). The contention that EMDR might be ineffective in comparison with stabilisation was not confirmed, neither was the fear that EMDR might lead to unmanageable distress. Three out of five EMDR completers lost their PTSD diagnosis versus no stabilisation completers. Neither EMDR nor stabilisation completers showed significant change in symptomatology on any continuous outcome measure. Differences in symptom change were, however, found between the two conditions on self-reported trauma symptoms, anxiety and depression, and social aspects of quality of life, with EMDR showing some improvement and stabilisation showing some deterioration between T1 and T2.

Improvement shown by EMDR completers was small in comparison to EMDR with other populations (Bisson et al., 2007) and in comparison to other trauma-focused interventions with traumatised refugees (Nickerson et al., 2011). Differences found between the two conditions justify the conduct of a full efficacy trial.

Examination and interpretation of preliminary efficacy is limited in several ways. First, a high percentage of drop-outs and a substantial number of missing assessments reduced information on treatment efficacy. In the main study, every attempt is made to bring down drop-out and follow-up early terminators. Second, in this pilot study we chose to statistically analyse only completers' results. Intent-to-treat analysis with imputation of missing data might have provided different results. Third, blindness was maintained only in 70% of SCID-interviews, thus threatening the reliability of clinician-rated outcomes. In the main study an effort is made to maintain assessor blindness by involving more research associates. Fourth, differences in session length (90 min in EMDR versus 60 min in stabilisation) further hinder conclusions on efficacy. While these differences in session length make sense clinically, in the main study treatment contact is of equal duration to allow for a comparison of efficacy based on treatment content only.

Conclusion

This pilot study is the first randomised study to examine EMDR with traumatised asylum seekers and refugees. Clinically, a comparison between EMDR and stabilisation is highly relevant. Many centres for refugee care, at least in the Netherlands, are hesitant to offer EMDR but do offer eclectic forms of stabilisation whose efficacy has not been proved.

In this pilot study, participation of traumatised refugees, including those who lack refugee status and who need an interpreter, turned out to be feasible although more complicated than with other traumatised populations. The suggestion that EMDR with traumatised asylum seekers might be inappropriate or ineffective or might lead to unmanageable distress was not confirmed. EMDR did not lead to higher pre-treatment attrition or drop-out than stabilisation, nor did EMDR prove any less efficacious. In conclusion, incorporating the improvements suggested above, it is feasible and justifiable to conduct a larger study with a similar design to more conclusively address the question of treatment efficacy.

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There is no conflict of interest in the present study for any of the authors.

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