



# Stress management versus cognitive restructuring in trauma-affected refugees—A pragmatic randomised study

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## ABSTRACT

The aim of this randomised trial was to compare the effectiveness of stress management (SM) versus cognitive restructuring (CR) in trauma-affected refugees. The intention-to-treat sample comprised 126 refugees with PTSD (SM = 62, CR = 64). The treatment consisted of 16 sessions of psychotherapy with manualised SM or CR in addition to 10 sessions with a medical doctor (psychoeducation and pharmacological treatment). The primary outcome was PTSD symptom severity (Harvard Trauma Questionnaire). Secondary outcomes were symptoms of depression and anxiety (Hopkins Symptom Checklist-25, Hamilton Depression and Anxiety Ratings), quality of life (WHO-5), functioning (Global Assessment of Functioning, Sheehan Disability Scale), pain (Visual Analogue Scale) and somatisation (Symptom Checklist). There was no difference in the primary outcome between groups. A significant group difference was found on the Hamilton Anxiety Rating with the SM group improving more than the CR group (effect size 0.46) indicating that methods in SM could potentially be helpful in this population.

## 1. Introduction

In mid-2015 the number of refugees worldwide was the highest in 20 years (UNHCR, 2016). A systematic review by Steel et al. found that the proportion of refugees suffering from trauma-related mental health problems, such as post-traumatic stress disorder, is as high as 30% (Steel et al., 2009). Thus, the demand for effective treatment for this group is expected to increase rapidly over the coming years. We also know that trauma-affected refugees often show a complex symptom pattern probably reflecting the long time period with traumatic events, the high number of traumatic events experienced as well as the characteristics of the trauma (Palic et al., 2016; Teodorescu et al., 2012). Furthermore, research shows that post-migratory stressors are related to mental health in trauma-affected refugees and probably challenges treatment outcome (Carswell et al., 2011; Sonne et al., 2016a).

The most recent Cochrane reviews on PTSD treatment highlight pharmacological treatment with selective serotonin reuptake inhibitors (Stein et al., 2009) and promising psychotherapeutic approaches, including trauma-focused cognitive behavioural therapy (TFCBT) and stress management (non-TFCBT) as well as eye movement desensitisation and reprocessing (EMDR) (Bisson and Andrew, 2007). The evidence for combining pharmacological treatment and psychotherapy is

still scarce (Hetrick et al., 2010).

The increase in number of treatment-seeking trauma-affected refugees and the complex symptomatology call for a need for evidence-based effective treatment options for this population. So far, rather few treatment outcome studies have been carried out on trauma-affected refugees, and to a large extent services for trauma-affected refugees rely on treatment outcome studies carried out in other trauma-affected populations (Carlsson et al., 2014). The critique of some of the treatment outcome studies on trauma-affected refugees includes rather small samples, limited data on comorbidities, and selected samples in specialised settings (Crumlish and O'Rourke, 2010; Nosè et al., 2017). However, in recent years high-quality treatment outcome studies on trauma-affected refugees are emerging (Buhmann et al., 2016; Sonne et al., 2016b; Stenmark et al., 2013). So far, the studies on psychotherapy carried out specifically on trauma-affected refugees have shown promising results for narrative exposure therapy (NET) in various settings as well as for culturally adapted CBT (Hinton et al., 2004; Nosè et al., 2017). In a randomised clinical trial carried out at the Competence Centre for Transcultural Psychiatry (CPT), the setting of the present trial, a small advantage to psychopharmacological treatment (sertraline) versus CBT was observed. It is possible that the superiority of psychopharmacological treatment compared to CBT reflects

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that some parts of the CBT offered in this study were unsuitable for the population (Buhmann et al., 2016). The clinicians using the psychotherapy manual during this trial experienced several challenges such as a need to focus on ongoing stressors and not only past trauma as well as difficulties in disclosing and separating thoughts, feelings, bodily sensations and behaviours (Buhmann et al., 2016; Vindbjerg et al., 2014). The design and content of the present trial was influenced by these results as well as studies pointing to stress management (SM) as a promising intervention for PTSD (Bisson and Andrew, 2007). A hypothesis that SM would be superior to classical CBT in trauma-affected refugees was based on the assumption that SM would meet the challenges in psychotherapy mentioned above. Firstly, the rationale for the therapy would be easy to explain to the patients and secondly, the sessions would allow for a focus on current problems rather than past trauma. The choice of SM for the present trial and the development of the manual has been described previously in detail (Vindbjerg et al., 2014). The aim of this study was therefore to compare the effectiveness of CBT with a focus on stress management (SM) or cognitive restructuring (CR) in a clinical sample of trauma-affected refugees.

## 2. Methods

### 2.1. Setting

The Competence Centre for Transcultural Psychiatry (CTP) is a public outpatient clinic for trauma-affected refugees serving the Mental Health Services in the Capital Region of Denmark (Carlsson et al., 2014).

### 2.2. Participants

In order to be offered treatment at the clinic, the following requirements must be fulfilled: being at least 18 years old, being a refugee or family reunified with a refugee, having obtained asylum in Denmark, having trauma-related mental health problems, having been referred by a general practitioner, psychiatric practitioner or medical doctor at a hospital and being motivated for treatment. Furthermore, patients with current substance abuse (ICD-10 F1x) were not offered treatment.

#### 2.2.1. Eligibility criteria

All patients admitted to the clinic from 15th June 2011–31st March 2012 and fulfilling the eligibility criteria were invited to participate in the study (Fig. 1). The eligibility criteria for this study were: belonging to the clinic's target group, having a history of at least one severe psychological trauma (typically imprisonment with torture, organised violence, persecution or war experiences), fulfilling the diagnosis of PTSD according to ICD-10 research criteria (WHO Collaborating Centre for Research and Training in Mental Health, 1996) and giving informed consent. The exclusion criteria were having a psychotic disorder (ICD-10 F2x and F30.1–30.9) or a need for admission to a psychiatric ward at the pre-treatment assessment.

### 2.3. Procedure

All patients referred to CTP were invited to a one- to two-hour pre-treatment assessment with a medical doctor / psychiatrist (henceforth referred to as the medical doctor) at CTP. During the pre-treatment assessment the medical doctors obtained trauma and medical, including psychiatric, history as well as sociodemographic data. Diagnosis of PTSD, depression and enduring personality change after catastrophic experience was determined through a clinical interview followed by entering ICD-10 criteria for each of the diagnoses into a diagnostic algorithm. Psychotic and bipolar disorders were excluded using the Schedules for Clinical Assessment in Neuropsychiatry (SCAN) (WHO, 1999). If the patients fulfilled the eligibility criteria and accepted to participate in the trial, they signed an informed consent and

were then randomised to one of the two treatment groups. Patients who fulfilled the inclusion criteria, but who did not wish to participate in the study were offered treatment as usual (TAU), which was similar to the treatment provided to the group offered CR. All patients in need of an interpreter received this assistance and if possible the same interpreter was used throughout the treatment. All interpreters involved in the trial were introduced to the study including the ratings used. See Fig. 1 for a flow chart of the study participants.

### 2.4. Interventions

For both the SM and the CR group, the treatment programme was planned to last 6–7 months. Participants in both groups were offered a total of 10 sessions with a medical doctor and 16 sessions of psychotherapy with a psychologist. Furthermore, at the start of the treatment, all participants were offered a session with a social worker to assess the social situation and assist in contacting relevant Danish authorities when needed. The sessions with the medical doctor followed a manual and included psychoeducation on predefined topics such as PTSD, sleep, social relations as well as psychopharmacological treatment when needed, following a predefined algorithm. The first choice of psychopharmacological treatment was sertraline gradually increased by 25–50 mg to a maximum dose of 200 mg. Participants who reported sleep problems were offered mianserin in doses of 10–30 mg at night, with doses titrated weekly by 10 mg. Participants who did not wish to receive psychopharmacological treatment or received appropriate psychopharmacological treatment at the time of referral to CTP were included in the study but with no alterations in the pharmacological treatment.

All psychotherapists were trained psychologists and carried out both SM and CR in order to avoid a therapist effect. When possible, the participants had the same psychotherapist throughout the trial. The duration of the psychotherapy sessions was 45–60 min. Separate manuals were developed for the psychotherapy offered for SM and CR respectively. The content of these manuals is described below and has been described in detail by Vindbjerg et al. (2014). In order to ensure compliance with the content of the manual, all psychotherapists participated in monthly manual supervision throughout the study.

Psychoeducation topics covered, psychotherapeutic methods used and compliance with medical treatment were recorded at each session to determine compliance with the treatment programme.

#### 2.4.1. Stress management (SM)

The most common SM programme for PTSD is Stress Inoculation Training (Meichenbaum, 2007). According to this programme, and following the view of Lazarus and Folkman, pathological stress is caused by an insufficient ability to cope with stress and anxiety (Lazarus and Folkman, 1984). The primary goal of the therapy is to help patients acquire and consolidate a number of coping skills. Thus, the sessions focus on learning and applying new coping skills. The SM manual used in this study included the following techniques: (1) relaxation, (2) attention diversion and (3) behavioural activation. Relaxation consisted of a combination of breathing exercises, body relaxation and visualisation exercises. Attention diversion involved shifting focus away from unwanted or uncomfortable thoughts, feelings or impulses. The aim of behavioural activation was to offer techniques to break a vicious circle of inactivity. Among the techniques used were visualisation and activity planning.

#### 2.4.2. Cognitive restructuring (CR)

The CR manual consisted mainly of psychoeducation and cognitive restructuring of negative thoughts resulting from traumatic experiences and exposure. The structure of the CR manual was based on a number of themes for the therapist to select from, based on clinical evaluation and the capabilities and needs of the patient. Each theme consisted of psychoeducation, suggestions for interventions as well as suggestions

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