Research paper

Stress management versus cognitive restructuring in trauma-affected refugees — A follow-up study on a pragmatic randomised trial

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ABSTRACT

Background: There is a lack of research and consensus with respect to long-term effective treatments for trauma-affected refugees. The purpose of this follow-up study of a randomised clinical trial was to investigate the effectiveness of Stress Management (SM) versus Cognitive Restructuring (CR) in treating trauma-affected refugees, six and 18 months post-treatment, respectively.

Methods: From a total of 126 refugees with PTSD, the intention-to-treat sample in the original trial, 74 patients were present at the six-month follow-up (SM; n = 37, CR; n = 37) and 34 patients at the 18-month follow-up (SM; n = 14, CR; n = 20). During the trial, the patients had been offered a total of 16 psychotherapy sessions and 10 sessions with a medical doctor.

Results: Mixed regression analyses at six and 18-month follow-up showed a non-significant small reduction in PTSD symptoms at both follow-up points with no significant between-group differences between the two psychotherapeutic interventions. Statistically significant between-group treatment effects were, however, observed with the patients receiving SM having significantly reduced symptoms of somatisation measured by the Symptom Checklist (β = 0.40), depression (β = 0.29) and anxiety (β = 0.37) (measured by the Hamilton Depression and Anxiety ratings) at 18 months post-treatment compared to the CR group.

Limitations: Limitations to the present study include the dropout rate at follow-up(s).

Conclusions: The findings suggest that the consolidation of coping strategies including relaxation, attention-diversion and behavioural activation in SM appears to be more beneficial than CR in reducing long-term somatisation, depression and anxiety symptoms for this population.

1. Introduction

According to the United Nations High Commissioner for Refugees (UNHCR), the number of refugees worldwide reached its record at the end of 2019 with 26 million refugees (UNHCR, 2020). Refugees have often been exposed to traumatic experiences or stressful events, such as persecution, imprisonment, torture and traumatic loss of loved ones prior to migration (Norris et al., 2011; Schweitzer et al., 2006). As a consequence, this population is prone to develop severe mental health disorders, of which posttraumatic stress disorder (PTSD) is the most common (Fazel et al., 2005) and is significantly comorbid with depression and anxiety (Toodorescu et al., 2012). Overall, refugees are about 10 times more likely to develop PTSD than the general population (Fazel et al., 2005). With the increased number of refugees suffering from mental health disorders worldwide, the need for advancing our knowledge on effective interventions for this population is increasing.

In treating PTSD, trauma-focused cognitive behavioural therapy (TF-CBT) is generally the recommended first line treatment (Watkins et al., 2018). Several studies have also pointed to the direction of other psychotherapeutic methods, including eye movement desensitisation and reprocessing (EMDR) and stress management (SM), as effective treatments (e.g. Bisson and Andrew, 2007). Additionally, pharmacological treatment with SSRI (sertraline, paroxetine, venlafaxine and fluoxetine) has shown significant effects in the treatment of PTSD (Hoskins et al., 2000).
While the trauma-focused approach is well-documented as a first-choice psychological treatment for PTSD in general (American Psychological Association, 2017; National Institute for Clinical Excellence, 2018), studies have questioned whether this holds true for the trauma-affected refugee populations as well (Nickerson et al., 2011). One major criticism of trauma-focused psychotherapy for trauma-affected refugees is the lack of focus on the refugees’ daily psychosocial stressors. The situation of resettling in a new country often co-exists with lower levels of social support, discriminative experiences, feelings of uncertainty regarding the well-being of family members left behind and the concomitant acculturative challenges (Miller and Rasmussen, 2010; Schick et al., 2018). As refugees experience these additional post-migration stressors, it has been argued that subsequent interventions must consider and address these challenges as well (Kartal et al., 2018). Furthermore, compared to the general PTSD population, trauma-affected refugees with PTSD are also characterised by having a higher trauma load and trauma exposure over a longer period of time, challenging therapy focusing on single traumatic experiences and increasing the risk of developing complex PTSD (Carlsson et al., 2014; Hyland et al., 2018). Particularly for refugees with PTSD, further research on treatment effects including non-trauma focused interventions is warranted.

Research investigating psychotherapeutic treatments for refugees with PTSD is still in its early stages. Direct comparisons of different treatments are scarce. Due to non-randomised designs, small sample sizes and highly specific samples, the generalisability of previous findings is likely to be limited (Nicholl and Thompson, 2004). However, large high-quality randomised studies have been emerging recently (Carlsson et al., 2018; Sarkadi et al., 2020).

Currently, culturally adapted cognitive-behavioural therapy (CA-CBT) (Hinton et al., 2012; Hinton et al., 2004) has shown promising evidence in the treatment of refugees with PTSD. Furthermore, a previous systematic review by Crumlish and O’Rourke, (2010) stated that narrative exposure therapy (NET) might be the best-supported intervention for this population, although the review described several limitations with the NET studies, with small sample sizes being the most prominent concern. Moreover, methods such as cognitive restructuring (CR), often applied in CBT, in which the focus lies on changing the destructive thought patterns that resulted from the traumatic event(s), have shown to be effective in the treatment of this population (Lambert and Alhassoon, 2015).

Research has called for controlled trials to investigate the effectiveness of non-trauma focused therapies in the treatment of trauma-affected refugees, to further understand the treatment effects of such modalities (Nickerson et al., 2011). One non-trauma focused therapy is stress management (SM), which comprises training in coping strategies including relaxation, attention-diversion and behavioural activation (Vindbjerg et al., 2014). To study differences in treatment effects between SM and more traditional cognitive restructuring (CR), a randomised trial directly comparing SM and CR with trauma-affected refugees was carried out at Competence Centre for Transcultural Psychiatry (CTP; 2011-2012). The post-treatment results showed no difference between the groups regarding the primary outcome of PTSD symptoms. However, a significant group difference was found on the Hamilton Anxiety Rating, where the group receiving SM showed larger treatment effect (Carlsson et al., 2018).

The importance of follow-up studies is well documented (Palic and Eikhl, 2011). However, follow-up studies on effective treatments for trauma-affected refugees are scarce and if conducted, are mostly of short follow-up durations and face methodological quality challenges (Morina and Sterr, 2019; Nashe et al., 2019). Thus, to date, there remains a strong need to identify interventions with long-term effects for trauma-affected refugee populations.

The aim of the present study was therefore to test the long-term effects of SM and CR, six and 18 months after end-treatment, in the population of trauma-affected refugees participating in the trial described by Carlsson et al., (2018). As stress management (SM) comprises training in coping strategies and focuses on current problems rather than past trauma, it was assumed that SM could meet the challenges that refugees often experience with on-going daily stressors. Furthermore, given the diversity of refugees’ backgrounds, not everyone would be able to comprehend traditional Western therapeutic frameworks easily (Carlsson et al., 2014). SM is a more straightforward approach that could enable the circumvention of such comprehension problems.

2. Methodology

2.1. Trial design

The trial was a pragmatic randomised clinical trial with planned post-treatment assessment and six and 18 months follow-ups. The pragmatic design of this study primarily consisted of broad inclusion criteria and only few exclusion criteria. A manualised flexible intervention was offered at an outpatient clinic to reflect the outcomes of real-world mental health practices. Through randomisation, participants were assigned to one of the two psychotherapies: SM or CR.

2.2. Participants and procedure

Inclusion criteria for the trial participants were: aged 18 years or older, being a refugee or a family member reunified with a refugee, being granted asylum in Denmark, suffering from at least one severe psychological trauma, having a PTSD diagnosis based on a clinical interview in accordance with ICD-10 research criteria (World Health Organization, 1993), being motivated to receive treatment and being referred to CTP by a general practitioner, psychiatrist practitioner or medical doctor at a hospital. The exclusion criteria were as follows: patients admitted to a psychiatric ward, suffering from a psychotic disorder (ICD - 10 F2x and F30.1-30.9) or current substance abuse (ICD-10 F1x).

An informed consent form was signed by patients who fulfilled the inclusion criteria and agreed to participate in the trial and included consent for participation in the follow-ups.

The 126 participants who took part in the trial pre-treatment assessment and defined the intention-to-treat sample are described in Table 1. All these participants were invited to participate in the six and 18-month post-treatment assessments. Out of the 126 participants, 74 (59%) attended the six months follow-up, and 34 (27%) patients attended the 18-month follow-up, as illustrated in Fig. 1. Participants who did not show up for a follow-up assessment at CTP, but completed self-administered rating scales by post were excluded in the present study, due to lack of information regarding life-events and treatment between the follow-up periods and due to non-completion of the observer-rating scales.

The trial and the follow-up study were conducted in accordance with the Helsinki Declaration II and were approved by the Danish Data Protection Agency and the Danish Ethical Committee of Science (H-4-2011-020) and registered in ClinicalTrial.gov (NCT01362543).

2.3. Interventions

In total, 10 sessions with a medical doctor and 16 sessions of psychotherapy with a psychologist were offered to all participants. Moreover, the participants were offered sessions with a social worker if needed. Characteristics of the completed treatment are presented in Table 1. The medical doctors provided manualised sessions with psychoeducation on predetermined areas, such as social relations, sleep and PTSD and when necessary, initiated psychopharmacological treatment.

All psychologists treated both SM and CR patients to prevent confounding by therapist effects and, if possible, treated the same patients
in the first publication on the trial (Carlsson et al., 2018).

2.4. Life events at follow-up

Information about life events since last assessment was obtained for the follow-up participants, by the use of a locally adapted shorter version of the Recent Life Events (RLE) (Paykel, 1997). The interview covered 28 life events in seven subcategories: serious problems with close relationships, socioeconomic and legal problems, serious illness, accidents and assaults, illness and death of close relatives, positive life events, and political events (concern about political situation(s) in host/home country).

2.5. Outcome measures

The primary outcome measure in the trial was PTSD symptom severity, measured by the Harvard Trauma Questionnaire (HTQ; Mollica et al., 1992), part IV. The secondary outcomes were anxiety and depression symptoms assessed by both the Hopkins Symptom Checklist-25 (HSCL-25; Kleijn et al., 2001; Mollica et al., 1987) and the Hamilton Anxiety and Depression Ratings Scales (HAM-A and HAM-D; Bech et al., 1986; Vindbjerg et al., 2019). Secondary outcomes measures also included somatisation items from the Symptom Checklist (SCL-somatisation; Derogatis, 1994), pain on a visual analogue scale (VAS; Olsen et al., 2007), well-being on the WHO-5 (Topp et al., 2015), level of functioning using Sheehan Disability Scale (SDS; Sheehan and Sheehan, 2008), and the Global Assessment of Functioning, (GAF-S and GAF-F; Schwartz, 2007).

These self-administered ratings (HTQ, HSCL-25, SCL-somatisation, VAS and WHO-5) and observer-ratings (HAM-A/D, GAF-S/F) were completed at the pre-treatment assessment (pre-treatment) and at the end of treatment (post-treatment). Subsequently, participants were invited to an interview where the same ratings were administered at six and 18 months post-treatment. At the follow-up assessments the interview and observer ratings were carried out by trained raters consisting primarily of medical students. These raters, blinded to the assessment time point and the intervention group carried out the HAM-A and HAM-D ratings at all time points.

All the self-administered questionnaires were available in five different languages: Danish, English, Bosnian, Arabic and Farsi. All rating scales have been used in previous randomised clinical trials at CTP. The rating scales have been translated and back-translated to increase accuracy and validity of the scales. In case the participants did not understand any of the above mentioned languages or were illiterate, an interpreter translated the questionnaires during the sessions.

2.6. Statistical analyses

All statistical analyses were conducted in STATA version 16.0 (Stata Press, 2019) and were based on all 126 patients, who completed the rating scales at the trial pre-treatment assessment (i.e., intention-to-treat sample). Further supplementary analyses were conducted with a reduced sample, consisting only of completers (i.e., had eight or more sessions with psychotherapy). Pre-treatment characteristics and group differences were analysed with t-tests for continuous measures, and chi-square test for categorical variables. Treatment and life events between the follow-up periods were also analysed with chi-square tests. For each outcome, mixed model regression analyses included main effects of psychotherapy group and of time (pre-treatment, six and 18-month post-treatment) as well as the interaction between these two factors. The analyses were conducted by using STATA’s “mixed” command, followed by “margins” and “contrasts”. The fit of the model was assessed using the log likelihood ratio statistic and covariances were assumed to be unstructured. The mixed model included condition (the two intervention groups), time (the four assessment points), and the interaction between these two factors as fixed effects in addition to a random
The mixed models were based on all available data, including pre-treatment, post-treatment, six-month, and 18-month assessments. Time was treated as a qualitative variable with four levels corresponding to (pre-treatment, post-treatment, six and 18-months post-treatment), respectively. A significant interaction between psychotherapy group and time would indicate that the difference between the two psychotherapy groups differs over time (reflecting group differences in change between pre-treatment and follow-up scores). In this case the significance of differences in mean scores between the two groups can be tested at each follow-up, and differences between pre-treatment mean scores and each follow-up mean score can be tested for each psychotherapy group. However, as the tests of group differences in mean scores do not adjust for pre-treatment scores, linear regression analyses were conducted to analyse the adjusted differences in mean between the SM.
and CR groups at the six-month and 18-month follow-up assessments. For all outcomes, the post-treatment follow-up scores (six and 18-month) were treated as the outcome and the pre-treatment scores and intervention group as predictors, using structural equation modeling (SEM) and Full information maximum likelihood to handle missing data.

3. Results

3.1. Characteristics of the study population

A description of the intention-to-treat sample at pre-treatment and follow-up assessments is presented in Table 1. Preliminary regression analyses, t-tests and chi-squared tests of the patients’ socio-demographics, pre-treatment psychopathologies, medication and trauma history indicated no significant group difference between SM and CR at any of the assessments and similarly no differences between the patients at follow-ups compared to the intention-to-treat sample.

3.2. Treatment

Compared to all patients at the pre-treatment assessment, the patients present at the six-month follow-up, \( t(197) = -2.44, p = .016 \) and the 18-month follow up, \( t(78) = -2.85, p = .005 \) had a significantly longer multidisciplinary treatment course during the trial. Similarly, compared to all patients at the pre-treatment assessment, those present at follow-up were also characterised by having participated in more psychotherapy sessions during trial: \( t(197) = -2.44, p = .016 \) for patients present at the six-month follow-up, and \( t(195) = -2.41, p = .017 \) for patients present at the 18-month follow-up. However, comparing the CR and SM groups present at the follow-up(s), no significant differences were found with regard to number of sessions with medical doctors, months in multidisciplinary treatment or psychotherapy sessions during trial. The percentage of patients receiving antidepressants, most commonly sertraline and mianserin, at the six and 18-month follow-ups were 78% and 79%, respectively, with no significant group difference. Significantly more patients in the CR group required an interpreter in psychotherapy (78%) compared to the SM group (51%) at six-months present at the follow-up(s), no significant differences between the CR and SM groups present at the 18-month follow up.

3.3. Outcome

The primary outcome rating scale (HTQ), was completed by a total of 32 patients at the pre-treatment assessment, and by 32 patients at the 18-month post-assessment. Regarding the secondary outcomes there were between 66 and 72 participants who completed the six-month post-treatment ratings. Lastly, for the 18-month post-treatment, between 31 and 33 patients completed the secondary outcome ratings, with an exception of the SDS rating scale, which was completed by 28 patients. No significant pre-treatment group differences was found on any of the outcome variables.

At the six-month follow-up only two patients out of 66 no longer met the diagnosis of PTSD, both patients belonging to the SM group. However, these two patients relapsed at the 18-month follow-up. Only one patient out of 32 patients at the 18-month follow-up no longer met the diagnosis of PTSD, this patient belonging to the CR group.

Furthermore, according to the reliable change index (RCI) for HTQ between pre-treatment and post-treatment, a total of 21 patients (19%) experienced a significant improvement in PTSD symptoms, 10 patients (18%) from the SM group and 11 patients (20%) from the CR group. Additionally, 81 patients (73%) experienced no change, 41 patients (75%) from the SM group and 40 patients (71%) from the CR group. Lastly, a total of 9 patients (8%) experienced a significant worsening in PTSD symptoms, 4 patients (7%) belonging to the SM group and 5 patients (9%) belonging to the CR group. The RCI between pre-treatment and six-month follow-up further indicated a total of 16 patients (23%) with a significant improvement in PTSD symptoms, 6 patients (18%) belonging to the SM group and 10 patients (27%) belonging to the CR group. Meanwhile, 49 patients (69%) experienced no change, 25 patients (74%) from the SM group and 24 patients (65%) from the CR group. Finally, 6 patients (8%) experienced a significant worsening, 3 patients (9%) belonging to the SM group and 3 patients (8%) belonging to the CR group.

At the 18-month follow-up assessment, the RCI for HTQ indicated a total of 10 patients (31%) with a significant improvement, 3 patients (23%) from the SM group and 7 patients (37%) from the CR group. A total of 19 patients (59%) experienced no change in PTSD symptoms between pre-treatment and the 18-month follow-up, 10 patients (77%) from the SM group and 9 patients (47%) from the CR group. Lastly as determined by the RCI, 3 patients (9%) experienced a significant worsening, all 3 patients (16%) belonging to the CR group.

Table 2 illustrates the mixed model regression analyses with the main and interaction effects of the two psychotherapies with the time of assessment, indicated a non-significant interaction effect on the primary outcome HTQ at six (\( p = .441, d = .019 \)) and 18-month post-treatments (\( p = .724, d = .014 \)). However, a significant interaction between the psychotherapy groups and time of assessment was evident on the SCL-somatisation outcome scores (\( p = .024, d = 1.01 \)) and HAM-A scores (\( p = .014, d = 0.86 \)) at the 18-month follow-up, with the SM group emerging as superior to the CR group in reducing somatisation and anxiety symptoms. The significant interactions reflected a significant within-group change in SCL scores between pre-treatment and the 18-month follow-up in the SM group only (\( p = .047, d = 0.89 \)) and similarly a significant within-group change in HAM-A scores between pre-treatment and the 18-month follow-up in the SM group only (\( p = .002, d = 0.73 \)).

Tests of within-group change between pre-treatment and follow-up further showed significant change for a number of outcomes, although the interaction between psychotherapy and time was non-significant. At the six-month follow-up the SM group showed a significant change from pre-treatment on the WHO-S scores (\( p = .004, d = 0.56 \)), GAF-S (\( p = .001, d = 1.19 \)) and the GAF-F scores (\( p = .003, d = 0.76 \)). At the 18-month follow-up the SM group also showed significant change from pre-treatment on HAM-D (\( p = .005, d = 0.69 \)) and GAF-S scores (\( p = .001, d = 0.89 \)).

In the CR group there were significant differences between the pre-treatment and the six-month follow-up means on the primary outcome HTQ (\( p = .023, d = 0.40 \)) and on the secondary outcomes HSCL-25 (\( p = .016, d = 0.33 \)), HAM-D (\( p = .002, d = 0.37 \)) and GAF-F (\( p = .001, d = 0.88 \)), indicating lower levels of PTSD, anxiety, depression and overall assessment of symptoms. At the 18-month follow-up the CR group showed significant change from pre-treatment on GAF-S scores (\( p = .001, d = 0.89 \)).

3.3.1. Adjustment for pre-treatment scores

SEM was used to examine the associations of the long-term treatment outcomes, adjusted for pre-scores, illustrated in Table 3. In line with the interactions observed in the mixed regression models, the statistically significant differences between the two psychotherapy groups on the secondary outcome measures SCL and HAM-A remained significant after adjusting for pre-treatment scores. The SM group displayed substantially reduced somatisation and anxiety symptom outcome scores compared to the CR group at the 18-month post-treatment. The SEM analyses further
revealed a significant group difference in HAM-D scores ($p = .016$, $\beta = 0.29$), at the 18-months post-treatment period, with the SM group having significantly reduced depressive symptoms compared to the CR group. Additionally, the SEM analyses showed a significant group difference in functional abilities measured with GAF-F ($p = .047$, $\beta = 0.18$) at the six-month assessment, with the SM group emerging as having larger improvement in functional ability. In supplementary SEM analyses conducted on a reduced sample with only patients who were considered completers (had eight or more sessions with the therapist), the group differences in SCL, HAM-D, HAM-A (18-month) and GAF-F (6-month) remained statistically significant.

3.4. Life events

Self-reported negative experiences related to societal problems, family illnesses, or serious social-relational problems between the two follow-up periods, shown in Table 4, were evenly distributed in the psychotherapy groups at follow-ups. However, the SM group were significantly more concerned about political circumstances in their home countries at the six-month follow-up $\chi^2(1, N = 41) = 6.10, p = .014$. This variable was found to be significantly associated with higher levels of PTSD symptoms, measured with HTQ, for the SM group at the six-month assessment.

The results of a chi-square test showed an unequal distribution of positive experiences in the period between end-treatment till six months post-treatment, with the group receiving SM having experienced significantly more positive experiences $\chi^2(1, N = 33) = 6.62, p = .01$. Positive experiences between the end-treatment and six months post-treatment were significantly associated with larger improvement outcomes on HTQ-25, WHO-5, S-GAF and GAF-F ratings. There was, nevertheless, no significant difference in the number of positive experiences at 18-months post-treatment. Furthermore, the patients receiving SM significantly experienced more mental/physical illnesses between six and 18 months post-treatment $\chi^2(1, N = 10) = 8.82, p < .001$. However, no association was found between rating outcomes and the frequency of experiences of physical or mental illnesses.

Finally, no significant difference was found between the groups regarding the number of psychotherapeutic, medical, or other outpatient treatments since last assessments, as illustrated in Table 4.

4. Discussion

To the best of our knowledge, this is the first follow-up study to directly compare the psychotherapeutic intervention effects of SM and CR, while simultaneously being one of the largest RCTs with trauma-affected refugees. The need to identify treatments with long-term effects for trauma-affected refugees and to look beyond traditional therapies have led to this research.

The findings of the present study demonstrate no significant long-term psychotherapeutic differences between SM and CR in relation to PTSD symptom severity. The hypothesis of SM being superior to CR in reducing long-term PTSD symptoms was thus rejected. In line with the original trial (Carlsson et al., 2018), a statistically significant group difference was observed in anxiety symptoms, where patients receiving SM had substantially lower anxiety symptoms at the 18-month post-treatment assessment. Similarly, somatisation symptoms at the...
and post-treatment. The CR group was found to have increased somatisation and anxiety symptoms between pre-post treatment and only a small decrease in depressive symptoms between pre-post treatment was detected. Similar and strengthened trends were found in the current study where the SM group experienced a substantial decrease in somatisation, depressive and anxiety symptoms with statistically significant group differences at the 18-month assessment.

The limited number of clinical trials comparing the effect of different psychotherapeutic interventions for trauma-affected refugees (Morina and Sterr, 2019) imposes a challenge to compare the findings of this current study. A study with a relatively small sample size (n = 28), comparing NET to stress inoculation training (a programme similar to SM), found a larger effect of NET in reducing PTSD symptoms at both six-months and one-year follow-ups, but the group differences were not statistically significant (Hensel-Dittmann et al., 2011). Similarly in our study, the differences between the groups in reducing PTSD symptoms were not significant at both follow-ups. Furthermore, Hensel-Dittmann et al., (2011) found no evidence of a long-term reduction in depressive symptoms for either stress inoculation training or with NET. In contrast, we found a treatment advantage of SM over CR in reducing depressive symptoms for either stress inoculation training or with NET.

### Table 3

<table>
<thead>
<tr>
<th>Adjusted rating</th>
<th>6 and 18 months post-treatment</th>
<th>Regression coefficient B (95% CI)</th>
<th>Beta-coefficient SE</th>
<th>Z-score</th>
<th>P</th>
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<tbody>
<tr>
<td>HTQ 6</td>
<td>0.06 (-0.15, 0.28)</td>
<td>0.06</td>
<td>0.11</td>
<td>0.57</td>
<td>.57</td>
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<td></td>
<td>0.28</td>
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<td>0.21</td>
<td>0.34</td>
<td>.74</td>
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<tr>
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<td>0.07 (-0.33, 0.47)</td>
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<td>HSCL-25 6</td>
<td>0.05 (-0.16, 0.26)</td>
<td>0.04</td>
<td>0.11</td>
<td>0.44</td>
<td>.66</td>
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<td>-0.08 (-0.42, 0.26)</td>
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<td></td>
<td>-0.13</td>
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<td>SCL-S 6</td>
<td>-0.04 (-0.32, -0.03)</td>
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<td>0.14</td>
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<td>-0.85 (-1.56, -0.13)</td>
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<td>VAS 6</td>
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<td>4.64</td>
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<td>3.27 (8.46, 14.99)</td>
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<td>0.55</td>
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<td>HAM-D 6</td>
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<td>HAM-A 6</td>
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<tr>
<td>GAF-S 6</td>
<td>1.99 (-1.46, 5.44)</td>
<td>0.11</td>
<td>1.76</td>
<td>1.13</td>
<td>.26</td>
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<td></td>
<td>0.03 (4.74, 4.80)</td>
<td>0.00</td>
<td>2.43</td>
<td>0.01</td>
<td>.99</td>
</tr>
<tr>
<td>GAF-F 6</td>
<td>3.85 (-0.05, 7.66)</td>
<td>0.18</td>
<td>1.94</td>
<td>1.98</td>
<td>.05*</td>
</tr>
<tr>
<td></td>
<td>0.43 (6.16, 7.03)</td>
<td>0.02</td>
<td>3.36</td>
<td>1.13</td>
<td>.90</td>
</tr>
</tbody>
</table>

18-month assessment yielded a statistically significant difference between the two therapies, where patients in the SM group appeared to have reduced somatisation symptoms compared to the patients in the CR group. The results of SEM analyses further revealed a group difference in depressive symptoms at the 18-month post-treatment, with the SM group reporting fewer depressive symptoms. Finally, the SM group showed significantly greater functional abilities than the CR group at six-month post-treatment, but this finding was non-significant at the 18-months follow-up assessment.

In the original trial (Carlsson et al., 2018) no changes were observed in the SM group with regard to somatisation symptoms, but a substantial decrease in depressive and anxiety symptoms was evident between pre- and post-treatment. The CR group was found to have increased somatisation and anxiety symptoms between pre-post treatment and only a small decrease in depressive symptoms between pre-post treatment was detected. Similar and strengthened trends were found in the current study where the SM group experienced a substantial decrease in somatisation, depressive and anxiety symptoms with statistically significant group differences at the 18-month assessment.
fluctuating patterns on some outcome measures, including perceived mental well-being and PTSD symptoms, were also present nine to 23-months post-treatment (Carlsson et al., 2010). Possibly, this trend could be partially explained by the chronicity of the CTP populations’ PTSD, their comorbidity and their long stay in exile, as compared to other studied refugee populations. Long symptom duration often leads to a range of psychosocial problems including unemployment, economic problems, divorce and isolation. This could in turn lead to fluctuating symptoms in varying degrees over time. Moreover, symptom relapses are usually high in patients with PTSD and comorbid disorders (Boehnlein et al., 2004; Vaage et al., 2010). Fluctuating symptom patterns at follow-ups are, thus, not unusual and may even be expected to some extent for this patient group.

The observed change in symptom levels in this study could be explained by factors other than the effect of therapies. For example, the decline in symptoms could reflect natural recovery, rather than effects of the psychotherapies in symptom alleviation. However, natural recovery would not explain the beneficial effects of SM compared to CR and appears unlikely because natural recovery usually takes place over the course of the first few weeks or months following trauma (e.g. Rothbaum et al., 1992) and most of the patients at CTP have a prolonged history of trauma-related mental health concerns (M = 14.8 years). The reduced long-term somatisation, depression and anxiety symptoms found in the group receiving SM are in line with the core components of the SM manual regarding bodily relaxation, breathing exercises and behavioural activation. Thus, it seems plausible that the observed significant differences in group change, have occurred as outcome of the psychotherapies.

Since comorbidity with depression and anxiety disorders is often the case in PTSD patients (e.g. Brady et al., 2000), the findings of SM being superior to CR in reducing somatisation (β = 0.40), depression (β = 0.29) and anxiety (β = 0.37) symptoms at 18 months post-treatment might have important clinical implications. As treating comorbid disorders remains an imperative, this finding is still a major step forward in targeting effective interventions for the purpose of treating trauma-affected refugees.

Furthermore, a high percentage of the patients, especially those receiving SM, reported concerns about the political circumstances in their home countries between the period end-of-treatment and six months post-treatment (56.9%) and between six months and 18 months post-treatment (70.6%). The patients reported feelings of worry, sadness and anxiety when watching or hearing about the news in their home countries. This might have acted as triggers for the patients’ PTSD and comorbid symptoms.

A significant difference between the groups in number of positive experiences at the six-month post-treatment was evident, in which case the SM group outnumbered the CR group. However, experiencing positive events could possibly be the results of the intervention, rather than being an independent factor. Thus, it is well documented how benefits of treatment can, in turn, lead individuals to perceive and remember situations as more positive and/or expose themselves to situations that are positive for them, resulting in better perception of social relationships, less avoidance-seeking and, thus, more encountering of positive events. As most of the SM group’s positive experiences involved attending social activities, experiencing better social relations and feelings of satisfaction and happiness, it seems more likely that number of positive experiences should be considered an outcome variable.

### 4.1. Strengths and limitations

As this study is a pragmatic clinical trial in which few exclusion criteria were applied, it realistically reflects the outcomes in mental health practices with similar populations. Another strength is that this study includes a variety of mental health outcomes and variables. A major limitation in this study is the dropout rate at follow-up(s), especially at the 18-month follow-up. Although both mixed regression modelling and SEM are robust in dealing with missing data, the precision of the estimates is still reduced and dropout at the later follow-ups is not necessarily random.

As the refugees originated from culturally heterogeneous groups, potential cultural bias may have had unknown ramifications for the psychometric quality of the scales. Furthermore, it was not considered possible to blind the participants or clinicians with respect to the intervention group or the time of assessment, except for the HAM-A and HAM-D scales. Additionally, the information obtained about life events between the follow-up periods could also have been influenced by recall bias.

The current sample is representative for treatment-seeking refugees with PTSD in Denmark and to a large extent other European countries. Keeping in mind the heterogeneity of the current sample and that refugee samples can vary a lot as to for example country of origin, trauma exposure including time from trauma, we encourage researchers to describe trauma-affected refugee samples as detailed as possible in order to have sufficient information to establish and discuss generalisability of results.
4.2. Perspective

In conclusion, the treatment effects of SM appear to be superior to CR in reducing somatization, anxiety and depressive symptoms 18 months after the end of treatment. As no significant group differences in PTSD symptoms were found at any of the time-points, our findings suggest that the trauma-focused approach is not necessarily the most effective therapy in treating refugees with PTSD.

For trauma-affected refugees who have suffered from mental health disorders through several of years, such as the current population, future studies of the long-term treatment effects of a treatment programme focusing on current symptoms rather than past trauma (such as SM) are needed to increase our understanding of the treatment effects of such non-trauma-focused approaches.

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Contributors

Author Maria Barhoma was the primary investigator of the study, conducted the statistical analyses and was the primary author of this paper. Author Jessica Carlson was the primary supervisor and co-investigator of this study, was part of the team designing the study, was one of the psychiatrists providing treatment during trial, and provided several critical revisions of the article. Author Charlotte Sonne was part of the team designing the study, was one of the psychiatrists providing treatment during trial, contributed with statistical tools and provided revisions to the drafts of the manuscript. Author Miriam J.J. Carlsson, J.M., Olsen, D.R., Kastrup, M., Mortensen, E.L., 2010. Late mental health examination of post-traumatic stress disorder in rape victims. J. Trauma. Stress 5, 283–299. https://doi.org/10.1007/s10926-008-9175-4.


Organization, World Health, 1993. The ICD-10 classification of mental and behavioural disorders: Diagnostic criteria for research, The ICD-10 classification of mental and behavioural disorders: Diagnostic criteria for research,