Torture, 2024, 34(2), 79-94
https://doi.org/10.7146/torture.v34i2.141339 *Research paper*

Imagery rehearsal therapy and mianserin for trauma-affected refugees: Follow-up of a randomized controlled trial

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Key points of interest

- Follow-up studies on effective treatments for trauma-affected refugees are limited.
- Improvement during treatment for trauma-affected refugees may be maintained at six-month follow-up post-treatment.
- Add-on treatment with Imagery rehearsal therapy or mianserin was not superior to treatment as usual at six-month follow-up post-treatment.

Abstract

Introduction: In order to identify the efficacy of treatment interventions for trauma-affected refugees follow-up studies are highly warranted. Hence, the overall aim of this study was to examine the efficacy of sleep-enhancing treatment, IRT and mianserin, in a sample of 219 trauma-affected refugees at six-month follow-up post-treatment. *Methods*: Data were derived from a four-armed randomized controlled trial in a sample of trauma-affected refugees with PTSD. All four arms received Treatment as Usual (TAU), an interdisciplinary treatment approach: one group received solely TAU, serving as a control group, whereas the remaining three groups were active-treatment groups receiving add-on treatment with either IRT, mianserin, or a combination. Mixed models were used to analyze the combinations of the two treatment factors (IRT vs. non-IRT and mianserin vs non-mianserin) and time (baseline vs follow-up and post-treatment vs follow-up) for the primary outcome sleep quality and for several secondary outcome measures. *Results:* A total of 36.7% of the participants had been exposed to torture and 44% had been imprisoned. The only significant effect of IRT was on well-being (measured with WHO-5), where IRT showed higher improvement in well-being six months post-treatment (p =.027). There was no significant effect of mianserin on any of the outcome measures. *Discussion:* This follow-up study found improvements from baseline to post-treatment on sleep quality and most of the secondary outcome measures that were maintained for all treatment conditions at the six-month follow-up assessment. A limitation of the study was that a high proportion (53.4%) of the participants did not attend the follow-up evaluation. The results indicate that add-on IRT-treatment and add-on mianserin-treatment were not superior to TAU at six-month follow-up post-treatment.

Keywords: IRT, Sleep, PTSD, treatment, refugee

Introduction

There are currently 82.4 million forcibly displaced persons worldwide; 20.7 million are refugees. This number is increasing rapidly since Russia's invasion of Ukraine, where UNHCR has estimated that more than 6.5 million people have been forced to flee their home (UNHCR, 2022). Many refugees have experienced psychological and physical trauma related to war, imprisonment, torture, and loss of loved ones that may lead to significant distress resulting in severe mental and physical health problems (Bogic et al., 2015; Miller & Rasmussen, 2016). These pre-migration traumas are often accompanied by post-migration stressors such as reduced social networks, new societal rules, and cross-cultural challenges while integrating into countries of settlement (Li et al., 2016; Miller & Rasmussen, 2016). Thus, refugees are of particular concern to mental health practitioners since this population presents a complex and heterogeneous mental health conditions with lower recovery rates than other trauma-affected populations (Crumlish & O'Rourke, 2010; Ter Heide & Smid, 2015). The most common mental health disorder for refugees is PTSD (Giacco et al., 2018; Williams et al., 2011), commonly co-occurring with depression and anxiety (Abu Suhaiban et al., 2019). The estimated prevalence of PTSD in refugee populations is approximately 30%, and refugees are about ten times more likely to develop PTSD than the general population (Fazel et al., 2005; Steel et al., 2009). Furthermore, refugees frequently present a more complex symptom pattern, often meeting the criteria for complex PTSD (Hyland et al., 2018). Despite the size of the problem, treatment for trauma-affected refugees is not adequately explored within the field of psychiatry (Carlsson et al., 2014; Nordbrandt et al., 2015; Giacco et al., 2017; Turrini et al., 2019; Tribe et al., 2019; Thompson et al., 2018; Nosè et al., 2017; Kip et al., 2020; Uphoff et al., 2020). Studies investigating the efficacy of psychotherapy for PTSD among refugees are limited (Morina & Sterr, 2019; Nordbrandt et al., 2020). However, meta-analyses indicate that trauma-focused therapies may be effective, although there is heterogeneity in the studies' findings (Kip et al., 2020; Lambert & Alhassoon, 2015). Furthermore, studies examining the effectiveness of pharmacological treatment for trauma-affected refugees are scarce (Sonne et al., 2017). Thus, adequate treatment of this population remains a challenge, and identifying effective psychotherapeutic and psychopharmacological treatments for trauma-affected refugees in a western setting is of utmost importance.

Problems with poor sleep quality, including difficulties initiating or maintaining sleep and nightmares, are part of the diagnostic criteria for PTSD according to ICD-10 World Health Organization, 2016). Studies indicate that 70-91% of individuals diagnosed with PTSD experience trouble falling or staying asleep (Maher et al., 2006) and the prevalence of nightmares is high in PTSD-patients, with estimates ranging from 50-70% and 40-50% (Leskin et al., 2002; Ohayon & Shapiro, 2000). Until recently, sleep disturbances have been conceptualized as a secondary PTSD-symptom, expected to resolve once the primary symptoms have been treated. Contrary to this view, research has shown that disturbed sleep is often a residual symptom after completed PTSD treatment (Spoormaker & Montgomery, 2008). One study discovered that insomnia was a residual complaint in 13 out of 27 participants after PTSD was successfully treated with trauma-focused CBT (Zayfert & DeViva, 2004). Therefore, it has been debated whether sleep disturbances constitute a core rather than a secondary feature of PTSD, where poor sleep is likely to maintain and exacerbate PTSD symptom severity. According to this view, it is recommended that sleep-focused treatment is incorporated into standard treatment for PTSD (Spoormaker & Montgomery, 2008). Research investigating the link between PTSD and sleep-enhancing treatment among refugees is scarce, especially studies examining the long-term efficacy of sleep-enhancing psychiatric interventions (Sandahl et al., 2017).

A meta-analysis of the relatively few studies that have been conducted concluded that Imagery Rehearsal Therapy (IRT) is the first-choice psychological treatment for nightmares (Augedal et al., 2012). IRT is an adapted CBT targeting nightmares by restructuring disturbing dreams. Furthermore, two studies have demonstrated promising long-term effects of IRT in non-refugee populations. One study has shown long-lasting effects of IRT in reducing sleep-problems, anxiety- and depression symptoms in a population with heterogeneous mental disorders, although the study did not include a control group (Swart et al., 2013). Another study found a clinically meaningful reduction in nightmare severity among chronic nightmare sufferers at 3 and 30 months follow-up compared to a wait-list control (Krakow et al., 1993).

There is a paucity of studies examining the long-term effects of sedating antidepressants in treating sleep disturbances and PTSD symptoms. Mianserin is a sedating noradrenergic and serotonergic antidepressant, commonly used to treat depression (Sandahl, et al., 2021). A study found that sleep improved the most following treatment combining sertraline with mianserin (in addition to receiving trauma-focused CBT) from baseline to follow-up. The authors suggest that this may be attributable to mianserin's use due to its acknowledged effect on sleep disturbances. However, the study did not include a control group (Buhmann et al., 2015). Furthermore, a study has examined mirtazapine, similar to mianserin in receptor profile, and found that combining sertraline and mirtazapine

may be clinically advantageous in reducing PTSD symptoms, relative to sertraline treatment alone at post-treatment (Schneier et al., 2015). However, the study did not include a follow-up assessment investigating the long-term effects.

This article is a follow-up study to the original trial conducted by Sandahl et al. (2021), investigating the effects of IRT and mianserin six months after end of treatment. Sandahl et al. (2021) conducted an RCT investigating the effect of a psychotherapeutic (IRT) and psychopharmacological treatment (mianserin) targeting sleep disturbances in a population of 219 trauma-affected refugees. The original trial hypothesized that sleep-enhancing add-on treatment with IRT and mianserin would be superior to TAU on the primary outcome, Pittsburgh Sleep Quality Index (PSQI), measuring sleep quality post-treatment (Sandahl et al., 2021). However, the study did not find add-on treatment with IRT or mianserin to be more effective than TAU on the primary or secondary outcomes, except the Sheehan Disability Scale (SDS), measuring level of functioning, where IRT was superior to TAU (Sandahl et al., 2021).

Follow-up studies on effective treatments for trauma-affected refugees are limited, face methodological challenges, and often only have short follow-up durations (Bolton, 2018). In order to identify the efficacy of treatment interventions for trauma-affected refugees follow-up studies are highly warranted. Hence, the overall aim of this study was to examine the efficacy of sleep-enhancing treatment, IRT and mianserin in 219 refugees with PTSD, sleep disturbances, and nightmares at six-month follow-up post-treatment.

Materials and methods

Study Design

The original trial was a four-armed randomized controlled trial (RCT), with an allocation ratio of 1:1:1:1, where the block size was unknown to the investigator. The study used a 2 (IRT vs non-IRT) x 2 (mianserin vs non-mianserin) factorial design: **1)** Treatment as usual (TAU), **2)** TAU and add-on treatment with mianserin **3)** TAU and add-on treatment with IRT **4)** TAU and add-on treatment with both IRT and mianserin. In this follow-up study, there will be referred to the following four treatment-conditions: non-IRT, non-mianserin, IRT, and mianserin. The IRT treatment condition comprises Groups 3 & 4 listed above, and the mianserin treatment condition combines Groups 2 & 4. The Non-IRT treatment condition is composed of Groups 1 & 2, and finally, the non-mianserin group is a mix of 1 & 3. The randomization was stratified by gender.

Participants

The data were collected – and participants recruited – at the Competence Centre for Transcultural Psychiatry (CTP), a specialized outpatient mental health facility treating trauma-affected refugees. A total of 219 participants were recruited, of whom 102 attended the follow-up assessment, six months post-treatment. Power calculations and inclusion and exclusion criteria for the original trial are reported by Sandahl et al. (2017) and Sandahl et al. (2021).

Assessment

All participants were screened in a 2-3-hour pre-treatment interview with a medical doctor, documenting the patient's history with trauma, psychiatric, and social background. Using a standardized interview-form, sociodemographic data were collected, which among other things, included questions regarding the number of years in the host country, educational level, and affiliation to the labour market.

To confirm the presence of a PTSD diagnosis and other related comorbid disorders, part of SCAN (Schedules for Clinical Assessment in Neuropsychiatry) and the ICD-10 research criteria were applied in the baseline interview.

Treatment and assessment were conducted in the participants' desired language, and trained interpreters were available if needed. The interpreters were affiliated with CTP and were experienced with psychotherapy, psycho-educational sessions, and questionnaires.

Treatment Modalities

Treatment as usual (TAU): The participants were all offered TAU. TAU was an interdisciplinary treatment approach comprising pharmacological treatment (according to standard pharmacological treatment practice at CTP), physiotherapy, psychoeducation, and manual-based CBT, covering 6-8 months. The psychologists at CTP used CBT interventions from the second wave (Prolonged Exposure Therapy) and the third wave (ACT). TAU was divided into two parts: 1) 2-4 months of treatment managed by a medical doctor (6 sessions) and physiotherapist (8 sessions), and 2) 4-8 months of treatment provided by a medical doctor (4 sessions) and psychologist (16 sessions) (for further details on the TAU condition, cf. Sandahl et al., 2017 and Sandahl et al., 2021).

Imagery rehearsal therapy (IRT): IRT is a treatment-method specifically targeting problems with sleep and nightmares. In the study, IRT was integrated into six therapy sessions and administered by a psychologist supervised and trained for this specific method. IRT consists mainly of three parts: 1) psychoeducation and cognitive restructuring, 2) visualizing and pleas-

ant representation exercises, and 3) rewriting nightmares and exercises of new representations (Sandahl et al., 2017).

Mianserin: The participants in the mianserin groups received 10 mg. of mianserin from the treating medical doctor. Depending on the effect and side effects, the dose could be increased successively to a maximum dosage of 30 mg. Medication adherence was gauged directly by measuring the concentration of mianserin in the blood after phase one and phase two (post-treatment). This objective measure was supplemented with subjective patient self-reports, where the participants were asked to report whether they had taken their medication as prescribed (Sandahl et al., 2017).

Measures

Participants filled out self-report questionnaires and observer ratings at baseline, post-treatment, and at follow-up. Several of the applied self-administered rating scales and observer ratings had been used previously, and in several different settings, for evaluating the outcome of treatment in trauma-affected refugees. However, the validity in refugee samples has only been studied for a few of the included instruments (Mollica et al., 1992).

Primary outcome measure: The Pittsburgh Sleep Quality Index (PSQI; Insana et al., 2013) is a validated self-report questionnaire for evaluating subjective sleep quality and the severity of sleep disturbances. The measure consists of 19 items combined to form seven component scores of sleep: sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medications, and daytime dysfunction, each weighted equally from 0-3 points. The seven component scores are added to obtain a global PSQI-score ranging from 0-21 points, which differentiates good sleep (PSQI total score ≤5) from poor sleep (PSQI total score >5).

Secondary outcome measurements, self-administered rating scales: The Harvard Trauma Questionnaire (HTQ; (Mollica et al., 1992)) part IV is a self-administered rating scale measuring traumatic experiences and PTSD symptom severity consisting of 16 items with a score range from 1 to 4, where 1 is the best score. HTQ is the most prevalent scale for evaluating PTSD symptoms in refugees. The HTQ was originally developed for use with refugees and the scale is perceived as reliable in a clinical refugee sample.

Disturbing Dreams and Nightmare Severity Index (DDNSI; (Krakow et al., 1993)) is a 5-item self-report inventory assessing the frequency and severity of nightmares and disturbing dreams. The global score ranges from 1 to 37, where 1 is the best score.

Hopkins Symptom Checklist (HSCL-25; (Kleijn et al., 2001)) is a validated self-administered symptom inventory that contains 25 questions measuring symptoms of anxiety and depression on a scale from 1 to 4, where 1 is the best score.

Sheehan Disability Scale (SDS; (Arbuckle et al., 2009)) is a five-item self-rated questionnaire measuring functional impairment regarding family, work, and social networks on a scale from 0 to 10 where 0 is the best score).

The World Health Organisation Well-being Index (WHO-5; (Topp et al., 2015)) is a five-item self-rated questionnaire, assessing subjective psychological well-being during the last two weeks. The global score ranges from 0 (worst possible) to 100 (best possible).

Secondary outcome measurements, observer rating scales

Global Assessment of Functioning – Symptoms (GAF-S) and Functioning (GAF-F) are widely used, observer rating scales used to evaluate the degree of psychiatric symptoms and global functioning in adults on a scale between 0 (worst) and 100 (best) (Bastin et al., 2013).

Data Analysis

Data were analyzed using STATA/SE 16.1 for windows. The baseline characteristics and descriptive data were analyzed using T-tests and one-way ANOVA.

Mixed models were used to analyze the combinations of the two treatment factors (IRT vs. non-IRT and mianserin vs non-mianserin) and time (baseline vs follow-up and post-treatment vs follow-up). Main effects and interaction-effects are reported in table 2 (baseline vs follow-up) and table 3 (post-treatment vs follow-up). This analysis is acceptable due to a non-significant interaction between mianserin and IRT. Furthermore, the assumptions of parametric tests were met: the data were normally distributed, and the data are independent. Homoscedasticity was tested with the Cameron–Trivedi decomposition, and the normality of the residuals was tested with the Shapiro–Wilk test; both tests indicated that the two criteria were reasonably well met.

Using Stata's *margins*-command, means and differences for baseline and post-treatment ratings were estimated. The *contrast*-command was used to determine interaction-effects and to test group differences.

Robust standard errors were used in the mixed model analyses, and the main analysis was performed with an intention-to-treat (ITT) sample. The mixed-model analyses were repeated on a reduced per-protocol sample.

Results

A total of 110 participants were randomized to add-on treatment with IRT and 108 participants were randomized to add-on treatment with mianserin. As table 1 illustrates, a total of 102 participants attended the 6-months follow-up assessment, which corresponds to 46% of the 219 participants enrolled in the study at baseline.

Pre-Treatment Characteristics

We distinguish between the follow-up group, comprising participants attending the follow-up evaluation, and the non-follow-up group, referring to those 117 participants that did not participate in the follow-up assessment.

The majority of the participants in the follow-up group originated from Iraq (*n*= 26 / 26.8%) and Syria (*n*=28 / 28.9%), were diagnosed with comorbid depression (*n*=68, 87.2%), had a trauma dating back further than ten years (*n*=60

Table 1. *Pre-treatment characteristics*

	Non follow-up sample (n = 117)	*Follow-up sample (n = 102)*
Demographic information	**Mean (SD*)**	
Age	42.2 (10.9)	47.0 (9.1)
Years since arrival in Denmark	13.8 (9.6)	12.7 (9.7)
	N (%)	
Male gender	60 (51)	50(49)
Female gender	57 (49)	52 (51)
Country of origin		
Afghanistan	13 (11.8)	13 (13.4)
Iran	9 (8.2)	10 (10.3)
Iraq	28 (25.5)	26 (26.8)
Lebanon	9 (8.2)	6 (6.2)
Syria	30 (27.3)	28 (28.9)
Other	21 (19)	21 (27.3)
Refugee camp before arrival in DK	21 (23.6)	21 (27.3)
Danish Asylum Centre	57 (68.7)	40 (67.8)
Trauma history		
War	106 (96.4)	99 (99)
Torture	35 (35.5)	33 (36.7)
Imprisonment	43 (41.4)	40 (44)
Soldier	26 (26.5)	21 (23)
Sexual harassment	10 (14)	13 (17.1)
Violence from relatives	37 (42)	23 (30.3)
Cranial traumas	30 (36.6)	32 (38.1)
> 10 years since the trauma	66 (73.3)	60 (72.9)
Psychosocial status		
Needing translater during the therapy sessions	40 (56.3)	55 (79.1)
Affiliation to the labour market / studying	32 (33.6)	34 (38.6)
Income from labour	6 (5.8)	7 (7.5)
Living alone all the time	15 (14.3)	13 (14)
Education > 10 years from home country	45 (43.3)	42 (45.2)
Work experience in Denmark	56 (54.9)	40 (42.4)
Diagnoses (ICD-10) additional to PTSD		
Depression	81 (95.3)	68 (87.2)
Enduring personality change after catastrophic experience (F62.0)	5 (10.4)	2 (5)
Functional impairment since 10 years	10 (8.6)	14 (17.3)
Previous treatment		
Previously admitted to psychiatric hospital	11 (11.2)	12 (13)
Any psychopharmacological treatment at baseline	67 (59.3)	75 (76.5)

* SD, Standard Deviation

/ 72.9%), and had lived at a Danish asylum centre (n=40 / 67.8%). A total of 36.7% (n=33) of the participants in the follow-up groups had been exposed to torture and 44% (n=40) had been imprisoned.

T-tests of the participants' socio-demographics indicated no significant group difference between the non-follow-up sample and follow-up sample regarding gender, years since the arrival to the host country, country of origin, affiliation to the labour market, education level, income, and whether they were living alone all the time. Likewise, analyses of pre-treatment psychopathologies (additional to PTSD) and trauma history discovered no significant differences between the non-follow-up and follow-up groups. Finally, the follow-up and the non-follow-up group did not differ significantly regarding the number of attended psychotherapeutic sessions.

Differences between participants in the follow-up and non-follow-up groups revealed a significant age difference, difference regarding the usage of a language translator in the therapy session with a mean age of 42.2 in the non-follow-up group and a mean age of 47.0 in the follow-up group. The usage of a language translator in the therapy sessions similarly differed in the two groups, where the non-follow-up group (n= 55 / 79.71%) used a translator more often than the follow-up group (n=40/ 56.3%). Finally, the analysis demonstrated a significant difference between the two groups regarding medication, where the non-follow-up group included participants with more concurrently prescribed medicines at baseline (n= 67 / 59.3% vs. n=75 / 76.53%).

Comparing The Non-Follow-Up And Follow-Up Group

Table 1 illustrates the non-follow-up and follow-up group's observed mean score on several outcome variables at baseline and post-treatment. As table 1 shows, the two groups were comparable concerning their scores on almost every outcome measure at baseline and post-treatment, indicating that the participants attending follow-up did not differ from the non-follow-up group. The similarity between the two groups implies that we can expect patterns of missing data to be random in the follow-up assessment.

Primary Analysis

Tables 2 and 3 illustrate the mixed model regression analyses with main and interaction effects of IRT and mianserin at three different assessment times, baseline vs. follow-up, and post-treatment vs follow-up. The observed mean and standard error (SE) of pre- and follow-up scores for IRT & non-IRT and mianserin & non-mianserin are presented in table 2, whereas the observed mean and SE of post-treatment and follow-up scores are presented in table 3. Tables 2 and 3 contain three different p-values, describing: **1)** main effects (ME) of IRT/non-IRT and mianserin/non-mianserin, indicating whether symptoms change significantly over time in each of these treatment conditions. **2)** difference p-value, referring to whether treatment conditions differ at baseline, post-treatment, and follow-up. **3)** interaction effects, describing whether the treatment conditions result in significantly different changes over time.

Primary outcome, PSQI

Main effects: There was a significant difference between baseline and follow-up at the PSQI-score for all treatment conditions: IRT (p = 0.002), non-IRT (p = 0.005), mianserin (p = 0.003) and non-mianserin (p = 0.003), signalling better subjective sleep quality over time. The difference between baseline and follow-up did not reach the Minimal Clinically Important Difference (MCID) of 2.5 scale points on PSQI. However, the difference between baseline and follow-up for the IRT treatment condition was close to the MCID (2.26 scale points).

There were no significant main-effects between post-treatment and follow-up for either of the treatment conditions on the PSQI-score.

Interaction effects: There were no interaction-effects between time (baseline and follow-up) and treatment conditions, indicating that IRT (p = 0.60) and mianserin (p = 0.99) did not improve subjective sleep quality more than non-IRT and non-mianserin. Likewise, the analysis did not find an interaction effect between time (post-treatment and follow-up) and treatment condition (p = 0.74).

Secondary Outcomes For The IRT-Treatment Condition

Main effects: There was a significant difference between baseline and follow-up for all secondary outcome variables for the IRT treatment condition, indicating overall improvement of symptoms and functioning. Furthermore, there was a significant main effect of non-IRT from baseline to follow-up in the following outcome variables: HTQ, HSCL-25, and a marginally significant effect on GAF-S (p = 0.055).

There was a significant main effect of the IRT-treatment condition on the time post-treatment vs follow-up on two outcome variables: HSCL, which signals fewer symptoms of anxiety and depression at follow-up assessment, and GAF-S that is showing a greater level of functioning at follow-up than at post-treatment assessment. Furthermore, the analysis revealed a significant difference from post-treatment to follow-up on the non-IRT group at DDNSI.

Interaction effects: Using the mixed model, the interaction between time (measured either as the difference between base-

line and follow-up scores or between post-treatment and follow-up), and treatment condition (IRT vs non-IRT) was only significant for the WHO-5 outcome variable ($p = 0.027$) when comparing baseline and follow-up. Thus, there was a significantly larger improvement in well-being in the IRT treatment condition than in the non-IRT treatment condition from baseline to follow-up.

Table 2. Mixed model analyses baseline vs follow-up

Rating-scale	*Treatment-condition*	*Mean pre-treatment score*	*Mean follow-up score*	*Difference (SE)*	*P-value*
PSQI	**IRT**	16.50 (0.29)	14.24 (0.73)	-2.26 (0.72)	**0.002*** (ME)
	Non-IRT	16.01 (0.28)	14.25 (0.65)	-1.76 (0.63)	**0.005*** (ME)
	Difference	0.49 (0.4)	-0.01 (0.99)	-0.51 (0.97)	
	Difference, p-value	0.22 (difference treatment condition at baseline)	0.99 (difference treatment condition at follow up)	0.604 (IE)	
	Mianserin	16.43 (0.29)	14.42 (0.72)	-2.0 (0.68)	**0.003***
	Non-mianserin	16.10 (0.28)	14.08 (0.7)	-2.02 (0.67)	**0.003***
	Difference	0.32 (0.4)	0.34 (0.99)	0.02 (0.97)	
	Difference, p-value	0.42	0.73	0.99	
HTQ	**IRT**	3.12 (0.04)	2.79 (0.08)	-0.33 (0.08)	**0.003***
	Non-IRT	3.11 (0.04)	2.87 (0.08)	-0.23 (0.07)	**0.002***
	Difference	0.01 (0.06)	-0.09 (0.11)	-0.1 (0.11)	
	Difference, p-value	0.88	0.42	0.36	
	Mianserin	3.13 (0.04)	2.9 (0.07)	-0.22 (0.07)	**0.003***
	Non-mianserin	3.1 (0.04)	2.77 (0.08)	-0.33 (0.08)	**<0.001****
	Difference	0.03 (0.06)	0.14 (0.11)	0.12 (0.11)	
	Difference, p-value	0.63	0.19	0.28	
HSCL-25	**IRT**	3.02 (0.04)	2.72 (0.08)	-0.38 (0.07)	**<0.001****
	Non-IRT	2.95 (0.05)	2.64 (0.08)	-0.23 (0.08)	**0.003***
	Difference	0.07 (0.07)	-0.07 (0.11)	-0.14 (0.11)	
	Difference, p-value	0.32 (0.4)	0.52	0.18	
	Mianserin	2.99 (0.05)	2.74 (0.08)	-0.25 (0.07)	**0.001***
	Non-mianserin	2.98 (0.05)	2.62 (0.08)	-0.36 (0.08)	**<0.001****
	Difference	0.02 (0.07)	0.12 (0.11)	0.1 (0.11)	
	Difference, p-value	0.80	0.29	0.33	

Rating-scale	*Treatment-condition*	*Mean pre-treatment score*	*Mean follow-up score*	*Difference (SE)*	*P-value*
WHO-5	**IRT**	16.16 (1.48)	29.95 (2.93)	13.78 (2.56)	**<0.001****
	Non-IRT	18.59 (1.61)	22.6 (3.42)	4 (3.57)	**0.26**
	Difference	-2.43 (2.18)	7.35 (4.5)	9.77 (4.41)	
	Difference, p-value	0.26	0.1	**0.027***	
	Mianserin	17.3 (1.62)	27.9 (3.66)	10.49 (3.44)	**0.002***
	Non-mianserin	17.4 (1.46)	24.79 (2.68)	7.28 (2.8)	**0.009***
	Difference	-0.07 (2.18)	3.14 (4.6)	3.21 (4.49)	
	Difference, p-value	0.97	0.5	0.47	
DDNSI	**IRT**	17.13 (0.7)	14.44 (1.01)	-2.69 (1.16)	**0.020***
	Non-IRT	16.15 (0.74)	14.77 (1.03)	-1.39 (1.12)	**0.21**
	Difference	0.97 (1.02)	-0.33 (1.48)	-1.30 (1.65)	
	Difference, p-value	0.34	0.82	0.43	
	Mianserin	16.16 (0.7)	13.67 (0.99)	-2.48 (1.12)	**0.027***
	Non-mianserin	17.11 (0.74)	15.5 (1.05)	-1.61 (1.16)	**0.17**
	Difference	-0.95 (1.02)	-1.82 (1.48)	-0.87 (1.65)	
	Difference, p-value	0.35	0.22	0.6	
SDS	**IRT**	22.94 (0.57)	19.04 (1.17)	-3.89 (1.19)	**0.001***
	Non-IRT	21.03 (0.63)	19.38 (1.25)	-1.64 (1.24)	**0.19**
	Difference	1.91 (0.85)	-0.34 (1.72)	-2.25 (1.73)	
	Difference, p-value	0.024*	0.84	0.19	
	Mianserin	22.54 (0.61)	19.67 (1.28)	-2.83 (1.35)	**0.04***
	Non-mianserin	21.45 (0.58)	18.72 (1.14)	-2.7 (1.08)	**0.01***
	Difference	1.09 (0.85)	0.96 (1.18)	-0.13 (1.75)	
	Difference, p-value	0.2	0.17	0.94	
GAF-F	**IRT**	51.58 (0.8)	55.66 (1.94)	4.08 (2.06)	**0.048***
	Non-IRT	51.57 (0.74)	52.01 (1.92)	0.45 (2.01)	**0.83**
	Difference	0.02 (1.08)	3.65 (2.71)	3.63 (2.86)	
	Difference, p-value	0.99	0.18	0.2	
	Mianserin	51.82 (0.76)	53.61 (1.69)	1.77 (1.78)	**0.32**
	Non-mianserin	51.33 (0.77)	52.01 (1.93)	2.76 (2.27)	**0.23**
	Difference	0.49 (1.08)	0.5 (2.72)	-0.99 (2.86)	
	Difference, p-value	0.65	0.85	0.73	

Rating-scale	*Treatment-condition*	*Mean pre-treatment score*	*Mean follow-up score*	*Difference (SE)*	*P-value*
GAF-S	**IRT**	50.58 (0.57)	56.72 (1.37)	6.14 (1.5)	**<0.001****
	Non-IRT	51.38 (0.51)	55.15 (1.87)	3.76 (1.96)	**0.055**
	Difference	-0.81 (0.77)	1.57 (2.3)	2.38 (2.46)	
	Difference, p-value	0.29	0.5	0.33	
	Mianserin	50.85 (0.52)	55.9 (1.59)	5.03 (1.7)	**0.003***
	Non-mianserin	51.10 (0.57)	55.99 (1.7)	4.87 (1.80)	**0.007***
	Difference	-0.25 (0.77)	-0.09 (2.32)	0.16 (2.47)	
	Difference, p-value	0.74	0.97	0.95	

PSQI, 1–21 (1 best score); HTQ, 1–4 (1 best score); HSCL-25 ,1–4 (1 best score); WHO-5, 0–100 (100 best score); DDNSI, 1–37 (1 best score); SDS, 0–10 (0 best score); GAF-F, 0–100 (100 best score).
Abbreviations: IRT, imagery rehearsal therapy; SE, standard error; PSQI, Pittsburgh Sleep Quality Index; HTQ, Harvard Trauma Questionnaire; HSCL25, Hopkins Symptom Checklist-25; WHO-5, Well Being Index; DDNSI, Disturbing Dreams and Nightmare Severity Index; SDS, Sheehan Disability Scale; GAF-F/-S, Global Assessment of Functioning (function/symptoms).The table presents mixed-model estimates of means, SE, p-values and effect size. The p-values are presented for differences in pre-treatment and post-treatment scores and changes over time between the add-on treatment condition and the no add-on condition corresponding to the interaction of each treatment with time. *p ≤ .05.

Table 3. *Mixed model analyses post-treatment vs follow-up*

Rating-scale	*Treatment-condition*	*Mean post-treatment score*	*Mean follow-up score*	*Difference (SE)*	*P-value*
PSQI	**IRT**	14.41 (0.48)	14.08 (0.7)	-0.34 (0.54)	**0.53**
	Non-IRT	14.38 (0.44)	14.32 (0.63)	-0.07 (0.61)	**0.91**
	Difference	0.03 (0.65)	-0.24 (0.95)	-0.27 (0.82)	
	Difference, p-value	0.97	0.8	0.74	
	Mianserin	15.18 (0.44)	14.38 (0.7)	-0.8 (0.6)	**0.19**
	Non-mianserin	13.62 (0.49)	14.00 (0.63)	0.39 (0.54)	**0.47**
	Difference	1.57 (0.66)	0.38 (0.96)	-1.19 (0.82)	
	Difference, p-value	0.017*	0.69	0.15	
HTQ	**IRT**	2.88 (0.07)	2.79 (0.08)	-0.08 (0.06)	**0.2**
	Non-IRT	3.0 (0.06)	2.87 (0.08)	-0.13 (0.08)	**0.09**
	Difference	-0.12 (0.09)	-0.07 (0.11)	0.05 (0.1)	
	Difference, p-value	0.19	0.51	0.61	
	Mianserin	3.02 (0.06)	2.9 (0.07)	-0.12 (0.08)	**0.11**
	Non-mianserin	2.85 (0.07)	2.76 (0.08)	-0.09 (0.06)	**0.14**
	Difference	0.17 (0.09)	0.13 (0.11)	0.04 (0.1)	
	Difference, p-value	0.07	0.23	0.7	

Rating-scale	*Treatment-condition*	*Mean post-treatment score*	*Mean follow-up score*	*Difference (SE)*	*P-value*
HSCL-25	**IRT**	2.77 (0.08)	2.64 (0.08)	-0.13 (0.06)	**0.027***
	Non-IRT	2.86 (0.07)	2.72 (0.08)	-0.14 (0.08)	**0.07**
	Difference	-0.09 (0.01)	-0.08 (0.11)	0.01 (0.1)	
	Difference, p-value	0.38	0.49	0.90	
	Mianserin	2.89 (0.07)	2.73 (0.08)	-0.16 (0.07)	**0.028***
	Non-mianserin	2.74 (0.08)	2.62 (0.08)	-0.11 (0.06)	**0.08**
	Difference	0.16 (0.1)	0.11 (0.11)	-0.05 (0.1)	
	Difference, p-value	0.13	0.34	0.62	
WHO-5	**IRT**	26.44 (2.65)	29.35 (2.88)	2.89 (2.31)	**0.21**
	Non-IRT	24.34 (2.32)	21.24 (3.22)	-3.12 (2.85)	**0.27**
	Difference	2.1 (3.52)	8.11 (4.33)	6.01 (3.72)	
	Difference, p-value	0.55	0.06	0.11	
	Mianserin	25.63 (2.54)	27.71 (3.55)	2.00 (2.92)	**0.49**
	Non-mianserin	25.21 (2.48)	23.06 (2.5)	-2.23 (2.21)	**0.31**
	Difference	0.42 (3.56)	3.14 (4.6)	4.23 (3.72)	
	Difference, p-value	0.91	0.5	0.26	
DDNSI	**IRT**	16.40 (0.75)	14.93 (0.99)	-1.5 (1.02)	**0.14**
	Non-IRT	16.82 (0.81)	14.56 (1.01)	-2.28 (1.16)	**0.04***
	Difference	-0.42 (1.11)	0.36 (1.44)	0.78 (1.52)	
	Difference, p-value	0.7	0.8	0.61	
	Mianserin	16.68 (0.73)	13.7 (1.00)	-2.98 (1.17)	**0.01***
	Non-mianserin	16.54 (0.82)	15.75 (1.01)	-0.79 (0.96)	**0.41**
	Difference	0.13 (1.1)	-2.06 (1.45)	-2.19 (1.52)	
	Difference, p-value	0.9	0.16	0.15	
SDS	**IRT**	20.8 (0.9)	19.65 (1.09)	-1.14 (0.9)	**0.21**
	Non-IRT	21.58 (0.73)	19.35 (1.22)	-2.21 (1.18)	**0.06**
	Difference	-0.77 (1.16)	0.3 (1.65)	1.07 (1.50)	
	Difference, p-value	0.51	0.86	0.48	
	Mianserin	22.1 (0.82)	19.69 (1.26)	-2.37 (1.14)	**0.04***
	Non-mianserin	21.56 (0.73)	19.35 (1.22)	-0.97 (0.95)	**0.30**
	Difference	1.79 (1.18)	0.39 (1.67)	-1.4 (1.49)	
	Difference, p-value	0.13	0.82	0.35	

Rating-scale	*Treatment-condition*	*Mean post-treatment score*	*Mean follow-up score*	*Difference (SE)*	*P-value*
GAF-F	**IRT**	55.01 (1.26)	55.66 (1.94)	0.65 (1.78)	**0.72**
	Non-IRT	53.44 (1.14)	52.01 (1.93)	-1.43 (1.79)	**0.42**
	Difference	1.57 (1.71)	3.65 (2.71)	2.08 (2.49)	
	Difference, p-value	0.36	0.18	0.41	
	Mianserin	53.71 (1.24)	53.61 (1.69)	-0.11 (1.52)	**0.94**
	Non-mianserin	54.77 (1.17)	54.12 (1.93)	-0.67 (2.03)	**0.74**
	Difference	-1.06 (1.71)	0.5 (2.72)	0.56 (2.51)	
	Difference, p-value	0.53	0.85	0.82	
GAF-S	**IRT**	54.04 (1.15)	56.33 (1.33)	2.28 (1.0)	**0.02***
	Non-IRT	53.37 (1.06)	54.26 (1.78)	0.88 (1.89)	**0.64**
	Difference	0.67 (1.56)	2.07 (2.21)	1.4 (2.14)	
	Difference, p-value	0.67	0.36	0.51	
	Mianserin	53.42 (1.03)	55.84 (1.46)	2.42 (1.46)	**0.10**
	Non-mianserin	54.01 (1.19)	54.77 (1.69)	0.75 (1.56)	**0.63**
	Difference	-0.6 (1.58)	1.07 (2.24)	1.67 (2.14)	
	Difference, p-value	0.71	0.63	0.44	

PSQI, 1–21 (1 best score); HTQ, 1–4 (1 best score); HSCL-25, 1–4 (1 best score); WHO-5, 0–100 (100 best score); DDNSI, 1–37 (1 best score); SDS, 0–10 (0 best score); GAF-F, 0–100 (100 best score).
Abbreviations: IRT, imagery rehearsal therapy; SE, standard error; PSQI, Pittsburgh Sleep Quality Index; HTQ, Harvard Trauma Questionnaire; HSCL25, Hopkins Symptom Checklist-25; WHO-5, Well Being Index; DDNSI, Disturbing Dreams and Nightmare Severity Index; SDS, Sheehan Disability Scale; GAF-F/-S, Global Assessment of Functioning (function/symptoms). The table presents mixed-model estimates of means, SE, p-values and effect size. The p-values are presented for differences in pre-treatment and post-treatment scores and changes over time between the add-on treatment condition and the non add-on condition corresponding to the interaction of each treatment with time. *p ≤ .05

Secondary Variables For The Mianserin Treatment Condition
Main effects: There was a significant main effect of the mianserin-group on the time baseline vs follow-up in the following outcome-variables: HTQ, showing fewer PTSD-symptoms, HSCL-25, indicating fewer anxiety and depression symptoms, WHO-5, reflecting subjectively better well-being, DDNSI, indicating a reduction in nightmares and bad dreams, SDS and GAF-S, signalling improved psychosocial functioning and less severe symptoms. Furthermore, there was a significant main effect of the non-mianserin-group on the time baseline vs follow-up in the following outcome variables: HTQ, HSCL-25, WHO-5, SDS, and GAF-S. Finally, there was a significant main effect of the mianserin treatment condition on time post-treatment vs follow-up on the following variables: HSCL, DDNSI, and SDS.

Interaction effects: There were no significant interactions between time (pre-treatment vs follow-up and post-treatment vs. follow-up) and treatment condition (mianserin vs non-mianserin) on any outcome variables.

Completer Analysis
In the follow-up group, 23 patients participated in four or more IRT-sessions (IRT treatment completers) whereas 14 were adherent to medication (mianserin completers). The mean dose of mianserin was 13.49 (6.23). The attendance rate (calculated as number of sessions attended/number of sessions planned)

for medical doctor sessions was 0.68. The mixed-model analyses on the reduced per-protocol sample confirmed the results of the intention-to-treat analysis showing a borderline significant difference between IRT treatment completers and non-IRT on WHO-5 when comparing baseline and follow-up.

Discussion

This follow-up study compared the effectiveness of add-on psychotherapeutic IRT treatment and add-on psychopharmacological mianserin treatment with an active control intervention on sleep disturbances in trauma-affected refugees at six months follow-up. Similarly to the original trial, data from this follow-up study did not find add-on treatment with IRT or mianserin to be superior to TAU in improving subjective sleep quality on the primary outcome measure PSQI at six months follow-up. The study's only significant difference was between IRT and non-IRT on the secondary measure, WHO-5, where IRT showed greater advantages in achieving improved well-being.

The IRT group did have a non-significant numerical advantage for every primary and secondary outcome measure from baseline to follow-up. Moreover, the number of treatment completers was low for mianserin as well as IRT.

In the following section, IRT and mianserin will be discussed separately.

Imagery Rehearsal Therapy

The study found no significant differences in sleep quality between IRT and non-IRT neither from baseline to follow-up nor from post-treatment to follow-up, indicating that add-on treatment with IRT was not superior to TAU. WHO-5 was the only secondary outcome measure, where IRT was superior to TAU from baseline to follow-up. This significant effect on WHO-5 was mainly due to an interaction between post-treatment and follow-up, where the non-IRT treatment condition experienced a reduction in well-being, whereas the well-being score was increased for the IRT treatment condition. This result differed from the original study, where the level of functioning measured on SDS was the only outcome variable, where IRT was significantly superior to non-IRT from baseline to post-treatment (Sandahl et al., 2021).

In the original trial, the IRT treatment condition had a non-statistical numerical advantage over non-IRT on the primary and secondary outcome measures. The same pattern could be seen when looking at treatment response between baseline and follow-up, but not when only looking at post-treatment to follow-up.

The non-significant difference between IRT and non-IRT can potentially be attributed to TAU treatment. Parts of TAU focus on psychoeducation about good sleep-hygiene, potentially overlapping with psychoeducation in IRT. Furthermore, a study indicates that IRT is less effective in reducing nightmare anxiety in PTSD participants than in individuals who only suffer from nightmares without a clinical diagnosis (Thünker & Pietrowsky, 2012). These factors could explain why IRT was not superior to TAU in improving sleep.

Mianserin

Add-on medication with mianserin was not superior to TAU on the primary or any of the secondary outcome measures neither from baseline to follow-up nor from post-treatment to follow-up. This aligns with the original trial (Sandahl et al., 2021), where add-on treatment with mianserin did not significantly affect PSQI or any other secondary outcome measures from baseline to post-treatment. Treatment with mianserin did have a numerical non-significant advantage on every symptomatic and functional outcome measure from post-treatment to follow-up, differing from the results found in the original study where the mianserin treatment condition was inferior to the non-mianserin treatment condition on every outcome measure.

The research literature regarding the efficacy of mianserin for treating PTSD and sleep disturbances is scarce and characterized by ambiguity. Similarly, this study did not provide evidence for the efficacy of mianserin compared to TAU. Another follow-up study at CTP found evidence supporting the usage of mianserin and sertraline for treating sleep disturbances from baseline to follow-up, although several methodological limitations were present. Most importantly, the study was not able to separate the effect of sertraline from mianserin (Buhmann et al., 2015). Furthermore, an RCT examining a non-refugee population found that combining sertraline and mirtazapine (a drug similar to mianserin in receptor profile) may be clinically advantageous in reducing PTSD symptoms, relative to sertraline treatment alone (Schneier et al., 2015). However, the authors did not find that mirtazapine enhanced sleep quality. Another study by Alderman et al., (2009) similarly found that mirtazapine was effective in the treatment of combat-related PTSD among military veterans, where mean scores of PTSD symptoms were reduced significantly after three months of psychopharmacological treatment. However, the study by Alderman et al., (2009) was conducted with a small sample size, without a control group, and a different population, which may explain the differing results.

An additional potentially important factor is the low number of IRT and mianserin completers. Non-adherence to treatment is a common challenge in refugee populations (Chaudri, 2004), which may be due to various factors including beliefs

about the cause of mental health disorders, barriers in the relationship between doctor/psychologist and patient, patient autonomy and social network (Kortmann, 2010).

Effects of Psychotherapy at Follow-up

This follow-up study found improvements from baseline to post-treatment on sleep quality and most of the secondary outcome measures that were maintained for all treatment conditions at the six-months follow-up assessment.

Only a few longitudinal studies have examined the effects of psychotherapeutic treatment for trauma-affected refugees at follpw-up, yielding mixed findings. A study showed no clinically significant improvement in mental health neither at the 9-month or 23-month follow-up after admission to a multidisciplinary treatment (Carlsson et al., 2010). Contrary to these studies, a study by Neuner et al. (2004), found that *Narrative Exposure Therapy* had a clinical significance on PTSD-symptoms among African refugees. More specifically, there was a significant main effect from pre-treatment to post-treatment and post-treatment to the one-year follow-up, indicating improved mental health after the end of treatment. Finally, a meta-analysis by Macedo et al. (2018) investigated the long-term effects of CBT on PTSD in a heterogeneous population. In summary, the meta-analysis did not provide conclusive evidence for a long-term treatment effect of CBT, mainly due to methodological limitations (Macedo et al., 2018). Thus, research cannot without ambiguity conclude that CBT has long-term treatment effects in any PTSD population. However, the findings of our study contribute to evidence suggesting that TAU, including trauma-focused CBT, enhances trauma-affected refugees' mental health at post-treatment, which is maintained at a six-month follow-up.

Strengths And Limitations

The key strengths of this study are its randomized design, the usage of subjective self-administered rating scales as well as observer rating scales (measuring a variety of mental health outcomes), and the initial confirmation of a PTSD diagnosis with a clinician-administered interview. The active control group design accounts for any spontaneous recovery effects while posing fewer ethical dilemmas than waiting list control.

Furthermore, another strength is that the study is a pragmatic clinical trial in which few exclusion criteria were used and without strict inclusion criteria, intentionally creating a pool of heterogeneous participants, typically treated at a trauma clinic for refugees. This increases the generalizability of the results due to the multicultural sample and the allowance of multiple comorbidities. Conversely, the cultural heterogeneity may have had a significant impact on the psychometric quality of the outcome measures, since cultural and linguistic meanings of scales can differ, potentially creating test bias resulting in unreliable results.

Several important limitations need to be considered. First, this study had a limited follow-up period of six months with a high portion of participants not attending the follow-up evaluation (53.4%), which resulted in lower power and low robustness of the results that were not powered to produce a conclusive test of efficacy.

Even though mixed regression modelling is effective in its ability to handle missing data, the accuracy of the statistical model's estimation is still reduced. Second, some participants did receive mianserin in the follow-up period due to positive drug response, which complicates the study of the psychopharmacological treatment's long-term effects, since several participants were in treatment with psychopharmacology at the follow-up assessment. Finally, the follow-up period is vulnerable to confounding environmental influences, making causal statements related to mianserin or IRT more difficult than in the trial from baseline to post-treatment.

Conclusion

To our knowledge, this is the first large-scale follow-up study examining the therapeutic and psychopharmacological treatment of sleep disturbances in trauma-affected refugees. It is essential to evaluate whether a treatment has sustained effect beyond treatment or merely works as an initial response that only lasts during the trial.

This follow-up study's primary conclusion was that sleep quality and most of the secondary outcomes improved from baseline to post-treatment and that these gains were maintained for all the treatment conditions at the six-month follow-up assessment. Furthermore, we did not find the IRT or mianserin treatment conditions superior to TAU in improving sleep disturbances or on any symptomatic and functional outcome measure (besides WHO-5) at the six-month follow-up.

This study has demonstrated that the treatment of trauma-affected refugees remains a challenge. Further research is required to examine the linkage between sleep disturbances, nightmares, and PTSD symptoms to assess whether sleep-enhancing treatment modalities, including therapeutic and psychopharmacological interventions, are useful in the future treatment of PTSD.

Contributors

Hinuga Sandahl and Jessica Carlsson designed and conducted the study. Anders Nielsen and Felix Klich performed the statisti-

cal analysis and wrote the first draft of the manuscript. Stig Bernt Poulsen advised on methodological issues. All authors contributed to and have approved the final manuscript.

Ethical Considerations statement

The RCT was approved by The Ethics Committee of the Capital Region of Denmark (H-15014503), the Danish Medicines Agency (EudraCT: 2015-004153-40) and the Danish Data Protection Agency (2012-58-0004) and was registered at ClinicalTrials.gov ID (NCT02761161), April 27, 2016.

Acknowledgements

The authors want to thank the participants and staff at CTP. The authors wish to thank Erik Lykke Mortensen for statistical consultation.

Data availability statement

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy and ethical restrictions.

Conflicts of Interest and Source of Funding

The authors declare that they have no financial or other competing interests.

This work was supported by TrygFonden (grant number 120354) and Fonden til Lægevidenskabens fremme (Foundation for Promotion of Medicine, grant number 16-319).

Treatment facilities were provided by the Mental Health Services in the Capital Region, Denmark. The design, management of the study, and interpretation of the data were entirely independent of funding.

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