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CLINICAL RESEARCH ARTICLE

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Treating sleep disturbances in refugees and asylum seekers: results from a randomized controlled pilot trial evaluating the STARS group intervention

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ABSTRACT

Background: Sleep disturbances are highly prevalent in traumatized refugees and often persist despite treatment, and adapted scalable interventions are needed. The group intervention 'Sleep Training adapted for Refugees' (STARS) is a culturally- and context-sensitive approach based on evidence-based treatments for sleep disturbances (e.g. CBT-I, IRT). This study evaluated the feasibility, acceptability, and effectiveness of STARS.

Method: A randomized-controlled trial (STARS vs. waitlist) with 47 young male Afghan refugees was conducted in a routine clinical setting (DRKS-ID: DRKS00024419) with pre-, post- and 3-month follow-up assessments. The primary outcome was insomnia severity (Insomnia Severity Index); secondary outcomes included PTSD, anxiety and depression symptoms, nightmares, coping with nightmares, fear of sleep, selected sleep diary measures, and quality of life. The data were analysed using mixed models.

Results: Adherence to STARS was high (dropout = 17.4%, average attended sessions = 77%) as was client satisfaction ($M_{CSQ-4} = 12.74$, $SD_{CSQ-4} = 2.08$). A medium to large significant effect of time was observed for insomnia severity ($d = 0.96$) and most secondary measures (except nightmares and fear of sleep). However, there was no significant interaction with condition at post-treatment for the primary outcome ($d = 0.29$) and most secondary outcomes; the only exceptions were increased coping with nightmares, decreased daytime sleep, and time in bed.

Conclusions: STARS appears feasible for treating sleep disturbances in traumatized refugees in a routine clinical setting, showing moderate to large within-group effects. However, it was not superior to the waitlist, likely due to unexpected improvements in the waitlist group. Adjustments to STARS may enhance its efficacy. Further research is needed to determine how STARS can be a scalable add-on treatment for sleep disturbances in traumatized refugees and asylum seekers.

Trial registration: German Clinical Trials Register identifier: DRKS00024419..

Tratamiento de las alteraciones del sueño en refugiados y solicitantes de asilo: Resultados de un ensayo piloto controlado aleatorizado que evalúa la intervención grupal STARS

Antecedentes: Las alteraciones del sueño son altamente prevalentes en los refugiados traumatizados y a menudo persisten a pesar del tratamiento, por lo que se necesitan intervenciones adaptadas y escalables. La intervención grupal 'Entrenamiento del Sueño Adaptado para Refugiados' (STARS, por sus siglas en inglés) es un enfoque cultural y contextualmente sensible sustentado en tratamientos basados en evidencia para las alteraciones del sueño (por ejemplo, CBT-I, IRT). Este estudio evaluó la viabilidad, aceptabilidad y efectividad de STARS.

Método: Se realizó un ensayo clínico controlado aleatorizado (STARS vs. lista de espera) con 47 jóvenes refugiados afganos en un entorno clínico rutinario (DRKS-ID: DRKS00024419) con evaluaciones antes, después y a los 3 meses de seguimiento. El resultado primario fue la gravedad del insomnio (Índice de Severidad del Insomnio); los resultados secundarios incluyeron síntomas de TEPT, ansiedad y depresión, pesadillas, afrontamiento de las pesadillas, miedo a dormir, medidas seleccionadas del diario de sueño y calidad de vida. Los datos fueron analizados utilizando modelos mixtos.

Resultados: La adherencia a STARS fue alta (deserción = 17.4%, sesiones asistidas promedio = 77%) al igual que la satisfacción de los clientes (MCSQ-4 = 12.74, SDCSQ-4 = 2.08). Se observó un efecto significativo de mediano a grande del tiempo para la gravedad del insomnio (d = 0.96) y la mayoría de las medidas secundarias (excepto pesadillas y miedo a dormir).

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PALABRAS CLAVE
Insomnio inducido por trauma; solicitantes de asilo; dificultades en la vida postmigración; pesadillas; ECA; desplazamiento forzado; miedo a dormir

HIGHLIGHTS

- A context- and culture-sensitive group sleep intervention for traumatized refugees and asylum-seekers was feasible in a routine clinical setting.
- Client satisfaction and acceptance were high, indicating successful adaptation of evidence-based sleep interventions.
- Insomnia severity and most secondary outcomes were significantly reduced post-treatment and at follow-up, yet no superiority to waitlist was found.
- Further research is needed to refine STARS and explore scalable, effective treatments for sleep disturbances in this population.

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Sin embargo, no hubo interacción significativa con la condición después del tratamiento para el resultado primario ($d = 0.29$) ni para la mayoría de los resultados secundarios; las únicas excepciones fueron un mayor afrontamiento de las pesadillas, disminución del sueño diurno y tiempo en la cama.
Conclusiones: STARS parece ser viable para tratar las alteraciones del sueño en refugiados traumatizados en un entorno clínico rutinario, mostrando efectos moderados a grandes dentro del grupo. Sin embargo, no fue superior a la lista de espera, probablemente debido a mejoras inesperadas en el grupo de lista de espera. Es posible que ajustes en STARS mejoren su eficacia. Se necesita más investigación para determinar cómo STARS puede ser un tratamiento complementario escalable para las alteraciones del sueño en refugiados traumatizados y solicitantes de asilo.

1. Introduction

Sleep disturbances and insomnia are extremely prevalent in treatment-seeking refugees and asylum seekers (RAS) with up to 99% reporting sleep disturbances and nightmares (Lies et al., 2019; Richter et al., 2020). Sleep disturbances are known to transdiagnostically contribute to the development and maintenance of psychopathology (Harvey, 2008); in RAS samples they are especially strongly correlated with posttraumatic stress disorder (PTSD), depression, and anxiety, and health outcomes (Baskaran et al., 2023). Two recent systematic reviews and one 'call to action' independently outline the importance of effective treatment for sleep disturbances in RAS (Baskaran et al., 2023; Jou & Pace-Schott, 2022; Richter et al., 2020).

However, treatment of sleep disturbances in RAS is facing three major challenges: (1) a high overall symptom burden and comorbidity, primarily with PTSD and depression (Blackmore et al., 2020), (2) an ongoing stressful living situation and restrained access to (mental) healthcare (Jou & Pace-Schott, 2022), and (3) culturally and contextually varying concepts of illness and healing that may need specific adaptations for interventions (Kühlmeyer et al., 2019).

The first challenge entails the need to treat the primary diagnosis, for example, trauma-related disorders using trauma-focused interventions (American Psychological Association, 2017). Therefore, sleep-related symptoms are typically addressed as one among many symptoms, often leading to unsatisfactory results. Importantly, sleep disturbances have been shown to often persist despite successful treatment of PTSD (Pruiksma et al., 2016) emphasizing the need to complement treatment for RAS with specific sleep interventions (Weber & Wetter, 2022). Further, sleep-related problems in RAS are complex, ranging from insomnia (i.e. problems initiating or maintaining sleep with daytime impairment), to (posttraumatic) nightmares and fear of sleep (Dumser et al., in preparation). Evidence-based treatments for both insomnia and nightmares have shown promising results as add-on in PTSD treatment in clinical samples (Walters et al., 2020). For nightmares, the recommended treatment following treatment guidelines, is Imagery Rehearsal Therapy (IRT; Morgenthaler et al., 2018). During IRT, patients are instructed to rescript the story of the nightmare during wakefulness and rehearse this new story in imagination. However, a study on IRT as an add-on for RAS did not show increased effectiveness compared to treatment-as-usual. In addition, it had a high dropout rate of 61% (Sandahl et al., 2017). This might possibly be due to reduced motivation and treatment satisfaction when only nightmares are addressed rather than the full range of sleep-related symptoms. A combined intervention targeting insomnia, nightmares, and fear of sleep might better meet RAS' needs.

The second major challenge for mental health interventions in the context of (forced) migration are ongoing postmigration living difficulties (PMLD). PMLDs such as insecure visa status, limited access to the labour market and unemployment, or precarious accommodation contribute to the maintenance and aggravation of mental health disorders (Hajak et al., 2021). In particular, collective refugee facilities (e.g. shared bedrooms with up to six people, limited privacy, restrictions to lock bedrooms, lack of space apart from the bed itself) are associated with higher levels of psychopathology, including insomnia symptoms, nightmares and fear of sleep (Dumser et al., in preparation). Furthermore, access to the healthcare system is often restricted and there is a shortage of specialized mental health care practitioners (Jou & Pace-Schott, 2022). In this context, key components of Cognitive Behavioral Therapy for Insomnia (CBT-I), the gold-standard treatment for insomnia (Riemann et al., 2017), such as bedtime restriction and stimulus control, might be difficult to apply in their original form (e.g. due to multiple bed dorms).

Third, sleep interventions may lack sufficient adaptations regarding culturally diverse and marginalized groups (Alcántara et al., 2021), although these can enhance treatment motivation and effectiveness (Kühlmeyer et al., 2019).

To overcome these significant challenges, the authors developed an integrative programme by

combining evidence-based sleep interventions. They tailored this programme to be culturally and contextually sensitive (general approach, non-culture-specific), taking into account diverse backgrounds – such as educational levels, rural or urban settings – and the current living situations, (e.g. PMLD), that RAS encounter. The resulting *Sleep Training adapted for Refugees (STARS)* aims to be a scalable intervention for adult and adolescent RAS. Like many sleep and RAS interventions (Baglioni et al., 2022; Kananian et al., 2020; Koch et al., 2020), STARS is designed as a group intervention for greater scalability. This study examined STARS in a sample of young male Afghan refugees, the second largest RAS group in Germany (German Federal Office for Migration and Refugees, 2023), who face a high mental health burden (Alemi et al., 2014).

2. Objective

The major objective of this study was to investigate the feasibility, acceptability, and effectiveness of the adapted sleep group intervention STARS among treatment-seeking Afghan refugees and asylum seekers using a randomized controlled trial design in a routine clinical setting. We hypothesized that STARS improves insomnia symptoms and has a beneficial effect on nightmare severity, fear of sleep, PTSD, anxiety, and depressive symptoms, as well as on quality of life when compared to waitlist control. Furthermore, we hypothesized that treatment gains are maintained at 3 months after the treatment.

3. Methods

3.1. Design

The study was designed as a single-centre, block-randomized, parallel-group trial (intervention vs. waitlist; 1:1). It was approved by the Research Ethics Committee at LMU Munich (08_2020_Dumser_a) and registered with the German Register for Clinical Trials (www.drks.de; DRKS00024419).

3.2. Participants

Participants were recruited through standard referral routes as well as through additional advertisements for the specific sleep-focused treatment offered at Refugio München, a psychosocial treatment centre for refugees and asylum seekers in Munich, Germany.

3.2.1. Inclusion criteria

Inclusion criteria were (1) being a refugee or asylum-seeker, (2) self-reported sleep disturbances, (3) Dari-speaking, (4) male gender, (5) being able to stay at study location for at least six months, (6) willingness for stable medication 4 weeks prior to T1 and during the study period. Due to potential cultural barriers, we offered only same-gender (i.e. male) groups. Inclusion criteria were not based on specific diagnoses as STARS is a transdiagnostic intervention.

3.2.2. Exclusion criteria

Exclusion criteria were (1) presenting with severe psychiatric symptoms that cannot be handled in a group intervention setting e.g. acute suicide risk, severe dissociation, acute psychotic or manic symptoms, substance dependance, aggressive behaviour, (2) pre-diagnosed schizophrenia, bipolar disorder or substance dependance, (3) severe physical illness, (4) pre-diagnosed severe cognitive impairment, or (5) currently receiving psychological treatment.

3.3. Sample

Participant flow is shown in Figure 1. The sample primarily consisted of adolescent and young adult (M_{age} 23.53, $SD = 5.11$, range: 16–35), single (87%) men from Afghanistan. Education level varied (0–18 years, $M = 7.61$, $SD = 4.75$), with 26% having limited literacy. Most participants had an insecure asylum status (79%), 53% were accommodated in collective housing, and 45% shared bedrooms with non-family members. Trauma and medication data are summarized in Supplementary Tables S2 and S3. Burden of psychopathology was high with most participants scoring above the cut-offs for PTSD (81%; ≥ 33 points), nightmare disorder (57%; ≥2 on each item) and insomnia (87%; ≥15 points). Sleep diaries indicated highly disturbed sleep with an average of 6.53 ($SD = 2.37$) hours of total sleep time, 1.46 h ($SD = 1.33$) sleep onset latency, and 1.97 ($SD = 1.69$) nightmares per week. Participants of the intervention and control condition did not differ in pre-treatment characteristics or levels of psychopathology, except for average sleep onset latency (Table 1).

3.4. Measures

All measures used in the current study were available in German and were translated into Dari and back-translated in accordance with gold standard translation practices (Bontempo, 1993). Outcomes were based on the standard research recommendation for insomnia (Buysse et al., 2006). Sociodemographic information and traumatic history were assessed with the Essener Trauma Inventory (ETI; Tagay et al., 2006), a 17-item list of potential traumatic events.

3.4.1. Primary outcome

The Insomnia Severity Index (ISI) assessed sleep-related symptoms as primary outcome. It is a valid, reliable, brief (7 items; range: 0–28), easy-to-

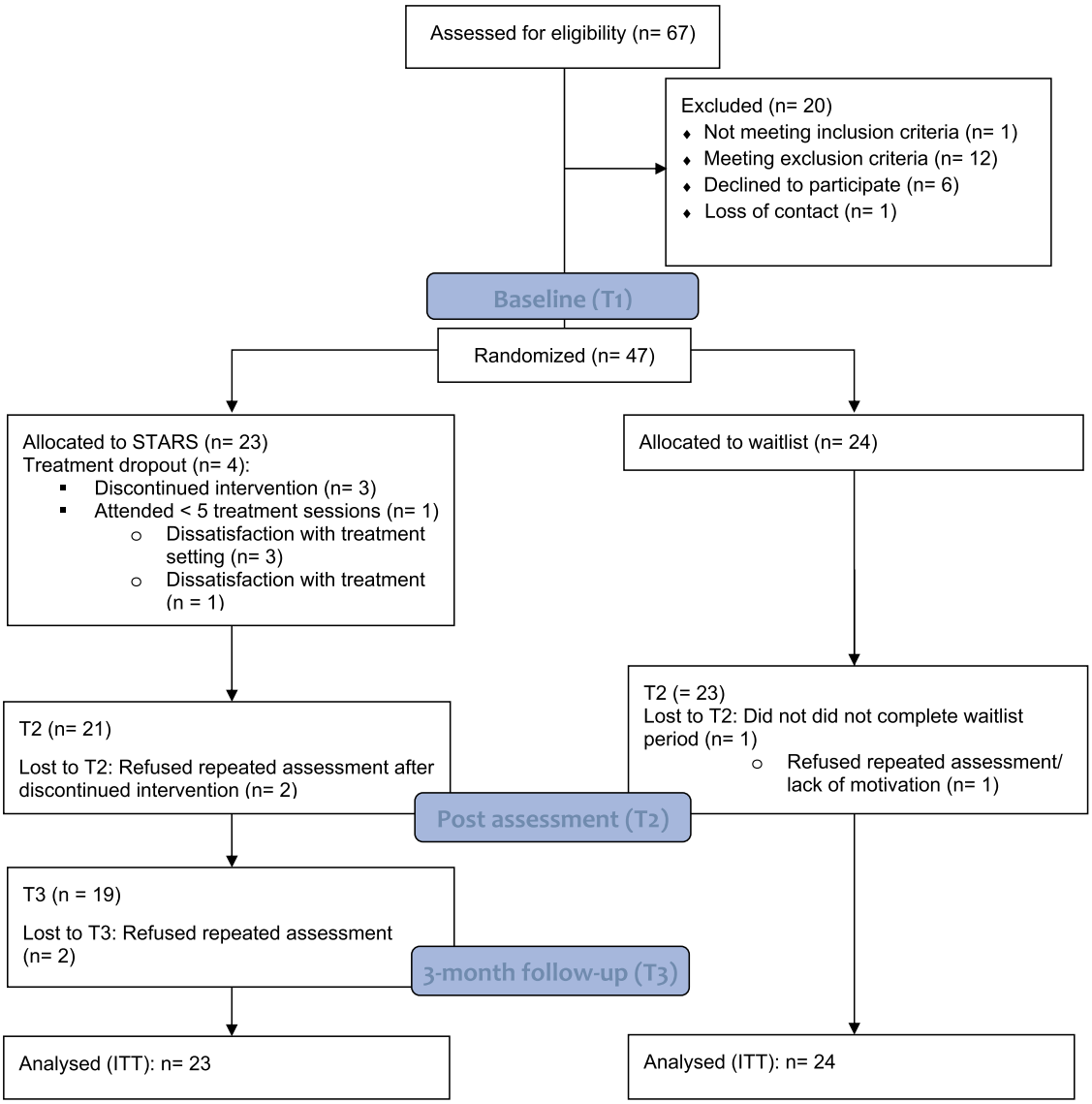

Figure 1. Study design and CONSORT flow of participants.

administer and change-sensitive self-rating questionnaire (Morin, 1993). Validated clinical cut-offs are: 0–7 no, 8–14 subthreshold, 15–21 moderate, and 21–28 points severe insomnia (.73<α<.85, in the current sample across three measurement timepoints).

3.4.2. Secondary outcomes

A minimal version of the consensus sleep diary was used (Lies et al., 2020). The following variables were obtained for one week following each assessment timepoint: total sleep time (TST), sleep onset latency (SOL), time spent in bed (TIB), wake time after sleep onset (WASO), naps during the day, and number of awakenings. Sleep efficiency (SE) was calculated by dividing TST by TIB.

Further sleep-related secondary outcomes included (1) the Nightmare Disorder Index (NDI; Dietch et al., 2020) (5 items; 5-point Likert scale); (2) the Coping with and Appraisal of Nightmares Scale (CAN; Gieselmann et al., 2020) (3-item subscale, 5-point Likert scale); (3) the Fear of Sleep Inventory – Short Form (FOSI-SF; Pruiksma et al., 2014) (13-item scale, 5-point Likert scale).

Further transdiagnostic constructs were assessed using (1) the Hopkins-Symptom-Checklist-25 (HSCL-25; Glaesmer et al., 2014) (anxiety and depression symptoms, 25 items, 4-point Likert scale); (2) the PTSD checklist for DSM-5 (PCL-5; Blevins et al., 2015) (20 items, 5-point Likert scale); (3) the EUROHIS-QOL-8 item index (Braehler et al., 2007) assessing quality of life and (4) the Client Satisfaction Questionnaire (CSQ-4; Attkisson, 2020) (4-item version, 4-point Likert scale). Internal consistency for the measures was generally good (0.76<α<0.96, across measures and timepoints), except for the NDI (0.59<α<0.72, across three timepoints).

3.5. Adherence

Therapist's adherence with the treatment manual was assessed with a checklist designed specifically for each session of the STARS manual. It was rated by the co-

Table 1. Pre-treatment characteristics.

	Total sample ($N = 47$)	STARS ($n = 23$)	Waitlist ($n = 24$)	Statistics comparison STARS vs. waitlist
	M (*SD*; range) or *N* (%)			
Demographics				
Age ($n = 47$)	23.53 (5.11; 16–35)	24.13 (5.11; 16–33)	22.96 (5.15; 16–35)	$t(44.945) = -0.783$; $p = .438$
Time since arrival in Germany (years; $n = 47$)	3.75 (3.1; 0.17–11.58)	3.44 (3.53; 0.17–11.58)	4.04 (2.67; 0.25–7)	$W = 318.5$, $p = .371$
Education (years; $n = 45$)[1]	7.61 (4.75; 0–18)	8.28 (5.22; 0–18)	6.9 (4.21; 0.5–15)	$t(43) = -0.975$; $p = .335$
Psychosocial status				
Insecure asylum status ($n = 47$)	37 (79%)	20 (87%)	17 (71%)	$\chi^2(1) = 0.987$; $p = .287$
Unaccompanied Refugee Minor at arrival in Germany ($n = 47$)	17 (36%)	8 (35%)	9 (38%)	$\chi^2(1) = 0$; $p = 1$
Currently unoccupied[2] ($n = 47$)	16 (34%)	9 (39%)	7 (29%)	$\chi^2(1) = 0.170$; $p = .680$
Accommodation ($n = 47$)				
Collective acc. centres	25 (53%)	14 (61%)	11 (46%)	$\chi^2(3) = 2.540$; $p = .548$
Private	5 (11%)	2 (9%)	3 (13%)	
Youth welfare	16 (34%)	6 (26%)	10 (42%)	
Other	1 (2%)	1 (4%)	0	
Shared bedroom[3] ($n = 47$)	21 (45%)	11 (48%)	10 (42%)	$\chi^2(1) = 0.017$; $p = .773$
Marital status: single ($n = 47$)	41 (87%)	20 (87%)	21 (88%)	$\chi^2(1) < .001$; $p = .772$
Literacy ($n = 46$)[1]				
None/ Partial	12 (26%)	6 (26%)	6 (26%)	$\chi^2(2) = 1.091$; $p = .580$
Full	34 (74%)	17 (74%)	17 (74%)	
Trauma history				
Number of different traumatic events ($n = 46$)[1]	6.08 (2.33; 0–10)	6.64 (1.91; 3–9)$^{n = 14}$	5.42 (2.68; 0–10)$^{n = 12}$	$W = 60$, $p = .218$
Psychopathology				
ISI sumscore ($n = 47$)	19.26 (5.1; 6–28)	18.61 (4.42; 8–28)	19.88 (5.7; 6–28)	$W = 325.5$, $p = .295$
PCL sumscore ($n = 47$)	47.42 (16.61; 7–72)	46.24 (14.55; 19-72)	48.55 (18.63; 7-71)	$W = 324.5$, $p = .307$
NDI sumscore ($n = 47$)	12.21 (5.07; 0–20)	12.09 (5.07; 0–18)	12.33 (5.17; 0–20)	$W = 279$, $p = .957$
CAN mean score ($n = 46$)[1]	1.57 (0.87; 1–4.67)	1.52 (0.94; 1–4.67)	1.61 (0.82; 1–4.6)	$W = 314$, $p = .252$
FOSI sum score ($n = 47$)	18.82 (13.89; 0–52)	16.96 (13.54; 0–44)	20.6 (14.29; 0–52)	$W = 328$, $p = .273$
HSCL total mean ($n = 47$)	2.75 (0.67; 1.08–3.84)	2.7 (0.59; 1.56–3.84)	2.8 (0.74; 1.08–3.56)	$W = 326.5$, $p = .287$
EUROHIS sum score ($n = 45$)	12.93 (6.18; 3–24)	11.82 (6.17; 3–24)	14 (6.13; 4–24)	$t(42.888) = 1.189$; $p = .241$
Clinical cut-offs				
ISI clinical cut-off ($n = 47$)				n/a
No	2 (4%)	0	2 (9%)	
Sub-threshold	4 (9%)	4 (17%)	0	
Moderate	25 (53%)	14 (61%)	11 (46%)	
Severe	16 (34%)	5 (22%)	11 (46%)	
Exceed PCL clinical cut-off for Probable PTSD ($n = 47$)	38 (81%)	17 (74%)	21 (88%)	$\chi^2(1) = .660$; $p = .773$
Meet NDI criteria ($n = 47$) for Probable Nightmare Disorder	27 (57%)	14 (61%)	13 (54%)	$\chi^2(1) = .029$; $p = .865$
Medication				
Psychopharmaceutic treatment at intake ($n = 47$)	27 (57%)	14 (61%)	13 (54%)	$\chi^2(1) = 0.029$; $p = .865$
Sleep diary				
TST (min)	370.17 (132.96)$^{n = 199}$	377.69 (129.12)$^{n = 103}$	362.1 (137.06)$^{n = 96}$	$t(193.72) = -0.824$; $p = .411$
TIB (min)	529.58 (138.24)$^{n = 199}$	526.56 (145.38)$^{n = 103}$	532.81 (130.84)$^{n = 96}$	$t(196.76) = 0.319$; $p = .750$
SE	0.7 (0.2)$^{n = 199}$	0.72 (0.16)$^{n = 103}$	0.68 (0.23)$^{n = 96}$	$W = 4768.5$, $p = .666$
SOL (min)	87.31 (79.8)$^{n = 199}$	90.05 (72.58)$^{n = 103}$	84.38 (87.18)$^{n = 96}$	$W = 4203$, $p = .067$
WASO (min)	27.88 (37.11)$^{n = 199}$	25.78 (34.59)$^{n = 103}$	30.14 (39.7)$^{n = 96}$	$W = 5349.5$, $p = .308$
Day sleep (min)	21.57 (51.11)$^{n = 198}$	29.61 (57.33)$^{n = 103}$	12.84 (41.96)$^{n = 95}$	$W = 4131.5$, $p = .007$**

Notes: STARS = Sleep Training adapted for Refugees, Waitlist = control group. Statistics indicate significant overall differences between groups. [1]data not available for all randomized participants; [2]occupation including employment and school attendance; [3]excluding shared rooms with family members; Abbr.: SD = standard deviation, ISI = Insomnia Severity Index, PCL = PTSD Checklist for DSM-5, NDI = Nightmare Disorder Index, CAN = Coping and Appraisal of Nightmares Subscale, FOSI = Fear of Sleep Inventory – Short Form, HSCL = Hopkins-Symptom Checklist-25, EUROHIS = EUROHIS-Quality of Life-8 item version, TST = total sleep time, TIB = time in bed, SOL = sleep onset latency, WASO = wake after sleep onset, SE = sleep efficiency. **$p \leq .01$.

therapists who were neither one of the authors of the manual nor part of the study team. After each treatment session, session components was checked if carried out according to the manual (e.g. reviewing treatment tasks from previous session = 1 point, introducing relaxation technique = 1 point) adding up to a maximum of 10 points per session.

3.6. Procedure

The study was carried out between April 2021 and June 2023. Interested individuals were invited to a 1.5 h screening appointment, received oral and written information, and were screened for inclusion and exclusion criteria. All participants and (if under 18 years of age) their guardians/parents provided written informed consent. Participants were recruited in four cohorts (range of cohort size: 11–13 participants). After recruitment of at least 10 eligible participants, each participant was re-invited to an assisted self-report session and received instructions for the sleep diary to be completed for one week. Participants were then randomly assigned to STARS or waitlist by a computer-generated block randomization list (Sealed Envelope Ltd., 2021) using random block sizes of 2 and 4 unknown to the investigator. The randomization list was implemented into REDCap, an electronic data capture tool hosted at the University of Munich (Harris et al., 2019), by an independent third party and remained hidden to study staff.

Bias through participants' potential unfamiliarity with questionnaires or lack of reading/writing skills was minimized by the assistance of trained master students and interpreters if necessary. All participants completed the assessments at pre-treatment (T1) and post-treatment (T2). Participants in the STARS condition further completed a follow-up assessment 3-months after the post-assessment (T3).

3.7. Trial conditions

All participants were allowed to continue their prior medication on a stable dose, with changes to medication only being allowed when medically necessary. Participants in both conditions were provided with basic social counselling using the routine infrastructure of the psychosocial treatment centre if pressing social issues arose during the study participation (e.g. acute asylum process-related questions). Beyond incorporating a minimum of social work, participants in neither of the conditions were receiving additional treatment at the psychosocial treatment centre during study participation.

3.7.1. Sleep training adapted for refugees

STARS is a manualized group intervention aiming to improve sleep disturbances for RAS. The manual consists of 10 weekly 90-minute sessions combining and adapting evidence-based interventions for differential aspects of sleep disturbances (Dumser et al., 2023). The intervention was developed based on three main sources of existing evidence-based treatments: (1) CBT-I (Riemann et al., 2017) as the gold-standard treatment for insomnia, (2) IRT (Poschmann & Competence Center for Transcultural Psychiatry, 2017) as recommended treatment for nightmares, and (3) Trans-C (Harvey & Buysse, 2018), a transdiagnostic modular treatment approach for sleep disturbances.

An initial pilot group ($N = 6$) consisting of young Afghan men was conducted in the adaptation process prior to this trial (Dumser et al., 2023). Several adaptations were included following these initial qualitative and quantitative information on feasibility of both manual (e.g. change of order in sessions, incorporation of material) and study procedures (e.g. refraining from a full diagnostic interview to limit participant burden). An overview of the final STARS content can be found in Table 2. The full STARS manual can be downloaded via this link: https://www.refugio-muenchen.de/wp-content/uploads/media/pdf/stars_manual_english.pdf.

The face-to-face group intervention was conducted by either the first or the last author of the manual (clinical psychologists, one of them specialized in CBT) with support of a second psychologist in training at Refugio München (all female). The psychological team underwent biweekly supervision. All groups were assisted by a trained interpreter for Dari. The group size ranged from five to seven participants.

After having completed treatment, participants in the intervention group did not receive further psychological treatment and were asked to remain with stable medication until follow-up.

3.7.2. Waitlist

Participants in the waitlist condition received no intervention during the study period but were offered treatment after the post-assessment. If participants received psychological interventions during their waiting period, they were excluded from the data analysis.

Table 2. Content of STARS sessions.

N°	Sessions
1	Establishing group cohesion, goal setting
2	Sleep rhythm & sleep hygiene
3	Sleep in a complicated environment
4	Dealing with worry and rumination during the night
5	Sleep and stress: Establishing a wind-down routine
6	Dealing with nightmares I: Skills to decrease arousal
7	Dealing with nightmares II: Anxiety and fear of sleep
8	Dealing with nightmares III: Positive imagery
9	Improving daytime functioning
10	Consolidation and celebration

3.8. Statistics

Power calculations and sample size. A priori sample size calculation was performed using G*Power (Faul et al., 2014). The analysis resulted in 34 participants needed to detect a medium effect size of $f = 0.25$ (Koch et al., 2020; Koffel et al., 2015) with $\alpha = 0.05$ (two-sided) and a power of $\beta = 0.8$ for the Condition × Time interaction from pre- to post-treatment. We expected a dropout-rate of 30% from previous studies in the same context (Koch et al., 2020). Therefore, we aimed for a total required sample size of 48 participants.

Data analysis. Statistical analyses were performed using R (R Core Team, 2023). Both intent-to-treat and per-protocol analyses were performed. For the per-protocol analyses dropouts at each timepoint were omitted resulting in $n_{T2} = 44$, $n_{T3} = 42$. Differences in pre-treatment characteristics between groups were tested using t-tests/Wilcoxon's test and qui-squared/Fisher's exact test. Due to the nested design structure, all hypotheses were tested using linear mixed modelling (LMM) implementing the *lme4* package (version 1.1–34; Bates et al., 2014). Each model had a two-level structure, with repeated assessments (level 1) within subjects (level 2). Models were estimated with maximum-likelihood estimation and included fixed effects for group, time, and their interaction as well as a random intercept for subjects. Random slopes were not included due to overparameterization.

To investigate long-term treatment effects, piecewise linear multilevel models were performed only within the STARS condition to account for differences in the intervention and follow-up period using the *nlme4* package. Dummy coded segments of time were specified for a segment investigating differences from pre- to post-treatment (0 = pre-treatment, 1 = post-treatment and follow-up) and for a segment investigating differences between post-treatment to follow-up (0 = pre- and post-treatment, 1 = follow-up). Again, each model had a two-level structure, with repeated assessments (level 1) within subjects (level 2). Models were estimated with maximum-likelihood estimation and included a random intercept for subjects. Inclusion of a random effect for time was not warranted based on the model fit indices (Bayesian Information Criterion and Akaike Information Criterion) and the likelihood-ratio test.

Effect sizes (Cohen's *d*; Cohen, 2013) were calculated by dividing the observed means by the pooled standard deviation of the total sample at baseline. For the within-group differences (1) $d_{within} = (M_{pre} - M_{post})/SD_{total\text{-}pooled\text{-}pre}$ and for the between-group effect sizes(2) $\Delta d_{STARS\text{-}WAITLIST} = [(M_{preSTARS} - M_{postSTARS}) - (M_{preWAITLIST} - M_{postWAITLIST})]/SD_{total\text{-}pooled\text{-}pre}$ was used. For the primary outcome, we additionally calculated the reliable change index (RCI; Jacobson & Truax, 1991) as follows: $RCI = \frac{M\text{post} - M\text{pre}}{\sqrt{2 * SE2}}$ and $SE = SD\text{pre} * \sqrt{1 - \alpha}$. When the change exceeded 1.96 points it was considered reliable.

4. Results

4.1. Treatment outcomes

Primary Outcome. We found a significant main effect of time from pre- to posttreatment ($\beta = -3.18$; $CI = -4.19$ – (-1.45), $p = .001$; Table 3), yet no significant interaction between time and condition ($\beta = -1.46$; $CI = -4.92$ – (-2.01), $p = .405$). Effect size for the interaction indicated a small effect ($\Delta d_{STARS\text{-}WAITLIST} = 0.29$; $CI_d = -0.28$–0.86). Descriptive results on the primary outcome, insomnia severity (ISI), are visualized in Figure 2.

The mean ISI score decreased below the ISI clinical cut-off (≥15) at posttreatment in the STARS condition (Table 4). Reliable change indices in the per-protocol-sample showed no significant difference between conditions with 4 out of 21 participants (19%) in the STARS and 4 out of 23 participants (17%) in the waitlist condition showing reliable change in insomnia symptoms posttreatment.

Secondary Outcomes. Analyses revealed significant main effects of time for all secondary questionnaire measures (see Table 3). However, the Condition × Time interaction was significant only for the coping with nightmares subscale (CAN; $\beta = 3.91$; $CI = 1.50$–6.32, $p = .002$; $\Delta d_{STARS\text{-}WAITLIST} = -1.49$; $CI_d = -0.85$ – (-2.14)) reflecting significantly better coping with nightmare skills posttreatment in the STARS condition. Further, analyses using sleep diary data yielded significant Condition × Time interactions only for time in bed (TIB; $\beta = -61.40$; $CI = -104.90$ – (-17.90), $p = .006$; $\Delta d_{STARS\text{-}WAITLIST} = 0.08$) and daytime sleep ($\beta = -34.72$; $CI = 57.12$ – (-12.32), $p = .002$; $\Delta d_{STARS\text{-}WAITLIST} = 0.63$). Descriptive results of secondary outcomes are visualized in Supplementary Figures S2 and S3.

Long-term effects. For the piecewise analysis within the STARS condition, a large significant within-group effect for insomnia severity was found from pre- to posttreatment ($\beta = -3.91$; $CI = -6.14$ – (-1.68), $p = .001$; $d_{T1\text{-}T3} = 0.96$; Table S5) that remained stable to follow-up. Further, 7 out of 19 participants (30%) in the STARS condition showed reliable change regarding their insomnia symptoms to follow-up. For secondary outcomes, piecewise models yielded large significant within-group effects from pre- to posttreatment for PTSD symptoms, symptoms of depression and anxiety, coping with nightmares, and quality of life (see

Table 3. Results of the linear mixed effects model for all dependent variables in the intention to treat (ITT; $n = 47$) sample and effect sizes in the per-protocol (PP; $n_{T2} = 44$) sample.

		Linear Mixed Models – ITT					Effectsizes – Cohen's *d*		
Outcome	Fixed parts	*B*	*CI*	*SE*	*p*	*Marginal R2/ Conditional R2*	$d_{withinSTARS}$ T1-T2	$d_{withinWaitlist}$ T1-T2	$\Delta d_{STARS\text{-}waitlist}$
ISI	Intercept	19.24	17.68–20.81	0.79	<.001	0.110/ 0.480	0.77	0.48	0.29
	Group	−1.27	−4.40–1.86	1.57	.423				
	Time	−3.18	−4.91–(−1.45)	0.87	.001**				
	Group x Time	−1.46	−4.92–2.01	1.74	.405				
PCL	Intercept	47.40	42.59–52.20	2.53	<.001	0.079/0.669	0.54	0.57	−0.04
	Group	−2.30	−11.91–7.31	5.05	.635				
	Time	−9.42	−13.61 – (−5.23)	2.13	<.001***				
	Group x Time	−0.18	−8.56–8.21	4.25	.967				
HSCL	Intercept	2.75	2.57–2.94	0.10	<.001	0.053/0.661	0.40	0.32	0.08
	Group	−0.10	−0.47–0.28	0.19	.608				
	Time	−0.26	−0.43 – (−0.10)	0.08	.002**				
	Group x Time	−0.10	−0.43–0.23	0.17	.536				
NDI	Intercept	12.21	10.77–13.65	0.72	<.001	0.023/0.811	0.34	0.18	0.16
	Group	−0.25	−3.12–2.63	1.44	.865				
	Time	−1.31	−2.24 – (−0.38)	0.47	.006**				
	Group x Time	−0.92	−2.79–0.94	0.94	.328				
CAN	Intercept	4.68	3.82–5.54	0.43	<.001	0.259/0.321	−1.71	−0.22	−1.49
	Group	−0.31	−2.03–1.42	0.87	.724				
	Time	2.54	1.34–3.75	0.61	<.001***				
	Group x Time	3.91	1.50–6.32	1.21	.002**				
FOSI	Intercept	18.78	14.92–22.63	1.94	<.001	0.032/0.622	0.18	0.43	−0.25
	Group	−3.64	−11.36–4.07	3.88	.350				
	Time	−3.97	−7.51 – −0.43	1.78	.028*				
	Group x Time	4.03	−3.05– 11.11	3.56	.261				
EUROHIS	Intercept	13.05	11.26–14.84	0.90	<.001	0.046/0.625	−0.62	−0.20	−0.43
	Group	−2.05	−5.64–1.54	1.80	.259				
	Time	2.25	0.59–3.91	0.83	.008*				
	Group x Time	2.39	−0.93–5.71	1.67	.156				
Sleep diary									
TST	Intercept	360.62	327.73–393.51	16.73	<.001	0.010/0.433	−0.04	−0.11	0.06
	Group	30.18	−35.60–95.96	33.45	.368				
	Time	7.62	−15.00–30.23	11.50	.508				
	Group x Time	−51.40	−96.63 – −6.16	23.00	.026*				
TIB	Intercept	521.79	486.57–557.02	17.91	<.001	0.016/0.503	0.08	−0.01	0.08
	Group	11.95	−58.50–82.41	35.83	.739				
	Time	−5.25	−27.00–16.50	11.06	.636				
	Group x Time	−61.40	−104.90 – −17.90	22.12	.006**				
SE	Intercept	0.69	0.65–0.74	0.02	<.001	0.011/0.443	0.05	0.04	0.01
	Group	0.04	−0.05–0.14	0.05	.357				
	Time	0.02	−0.01–0.05	0.02	.231				
	Group x Time	−0.02	−0.08–0.05	0.03	.624				
SOL	Intercept	87.38	68.53–106.23	9.59	<.001	0.013/0.515	−0.13	−0.11	−0.01
	Group	8.00	−29.70–45.69	19.17	.677				
	Time	−15.64	−27.03 – −4.25	5.79	.007**				
	Group x Time	−10.20	−32.97–12.58	11.58	.379				
WASO	Intercept	30.58	20.83–40.34	4.96	<.001	0.019/0.528	0.40	0.21	0.18
	Group	−7.31	−26.82–12.21	9.92	.462				
	Time	−3.60	−9.40–2.20	2.95	.223				
	Group x Time	−5.36	−16.96–6.23	5.90	.364				
Day Sleep	Intercept	20.79	7.73–33.86	6.65	.002	0.026/0.309	0.46	−0.18	0.63
	Group	25.07	−1.06–51.21	13.29	.060				
	Time	−2.76	−13.96–8.44	5.70	.629				
	Group x Time	−34.72	−57.12 – −12.32	11.39	.002**				

Notes: STARS = Sleep Training adapted for Refugees, Waitlist = control group. Abbr.: *SD* = standard deviation, ISI = Insomnia Severity Index, PCL = PTSD Checklist for DSM-5, NDI = Nightmare Disorder Index, CAN = Coping and Appraisal of Nightmares Subscale, FOSI = Fear of Sleep Inventory – Short Form, HSCL = Hopkins-Symptom Checklist-25, EUROHIS = EUROHIS-Quality of Life-8 item version, TST = total sleep time, TIB = time in bed, SOL = sleep onset latency, WASO = wake after sleep onset, SE = sleep efficiency. $d_{within} = (M_{pre} - M_{post})/SD_{total\text{-}pooled\text{-}pre}$ was used and (2) $\Delta d_{STARS\text{-}WAITLIST} = [(M_{preSTARS} - M_{postSTARS}) - (M_{preWAITLIST} - M_{postWAITLIST})]/SD_{total\text{-}pooled\text{-}pre}$. * α <.05, ** α <.01, *** α <.001.

Supplementary Table S5). No significant effect emerged for NDI and FOSI. Significant effects for all retrospective self-report measures remained stable to 3 months follow-up. Further, a decrease of individuals scoring above the clinical cut-off for PTSD (baseline: 74%; follow-up: 47% at) and nightmare disorder (61% to 47%) was found.

Regarding sleep diary measures, sleep onset latency showed additional significant change from posttreatment to follow-up. Total sleep time and sleep efficiency yielded significant changes not from pre- to posttreatment, but only from posttreatment to follow-up improving SE to 80% on average (*SD* = 16%). Wake after sleep onset (WASO) did not show changes over time in both conditions.

All results remained unchanged when repeated with a per-protocol-sample ($n_{T2} = 44$, $n_{T3} = 42$; see Supplementary Table S4 and Table S5). About 35% of participants in each condition reported changes to their concomitant medication from pre- to post-treatment

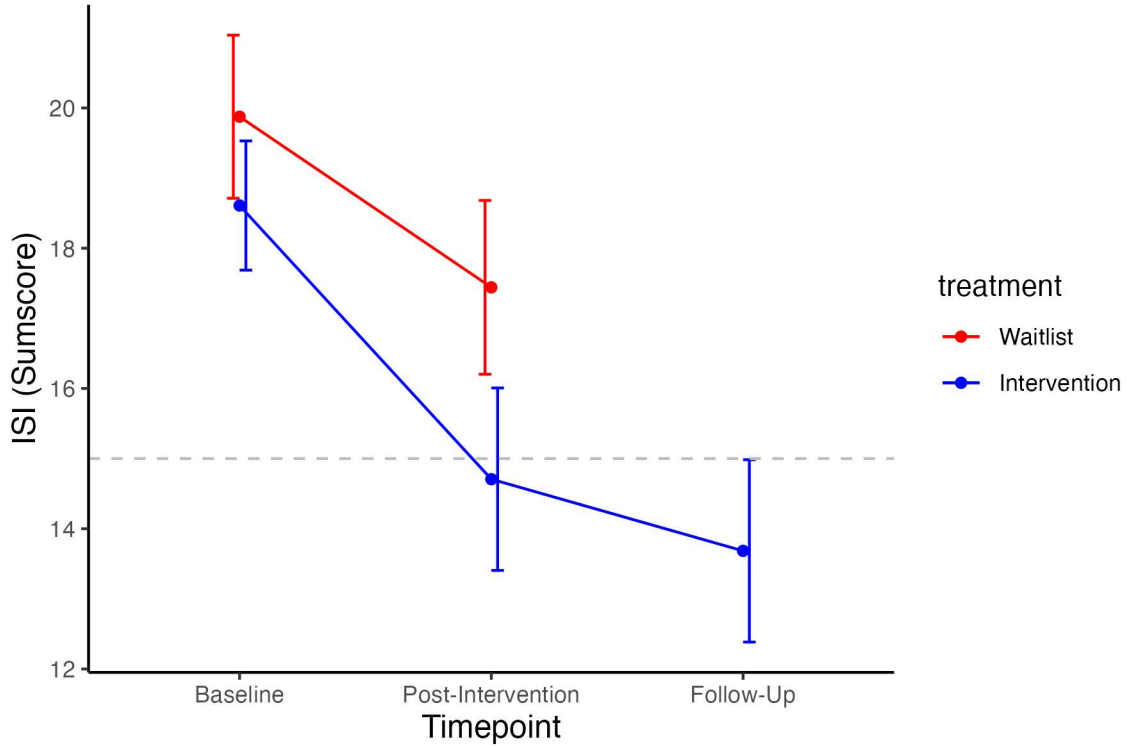

Figure 2. Descriptives of the primary outcome measure, insomnia severity (ISI) shown at baseline, after treatment, and at 3 months follow-up. The grey horizontal line refers to ISI clinical cutoff for moderate to severe insomnia ≥15.

without significant differences between conditions regarding the stability of medication ($\chi^2(1) = .015$; $p = .902$). Another 22% of the STARS condition reported changes to their medication from post-treatment to follow-up.

4.2. Treatment retention, attendance, and acceptability

Dropout was 17.4% ($n = 4$) in the STARS condition. One participant from the waitlist condition dropped out from pre- to post-treatment assessment due to a lack of motivation and meeting exclusion criteria at T2. Participants completing treatment attended an average of 7.7 out of 10 sessions ($SD = 0.4$; range: 5–10); participants dropping out attended an average of 1.7 ($SD = 0.19$) sessions. Reasons for non-attendance (43% with prior notification) were illness or quarantine, work or school obligations and other relevant appointments (e.g. asylum process-related). Participants in the STARS condition reported a high overall satisfaction with the treatment on the CSQ-4 ($M = 12.74$, $SD = 2.08$; range: 8–15). Of those participants completing treatment, two out of 19 (11%)

Table 4. Means and standard deviations by condition and timepoint.

	Pre-assessment (T1)		Post-assessment (T2)		3-Month- Follow-up (T3)	
	STARS ($N = 23$) *M* (*SD*)	Waitlist ($N = 23$) *M* (*SD*)	STARS ($N = 21$) *M* (*SD*)	Waitlist ($N = 23$) *M* (*SD*)	STARS ($N = 19$) *M* (*SD*)	STARS-Diff T1-T3
ISI	18.61 (4.42)	19.88 (5.7)	14.71 (5.96)	17.44 (5.94)	13.68 (5.67)	−4.93
PCL-5	46.24 (14.55)	48.55 (18.63)	37.18 (14.31)	38.87 (19.52)	31.79 (16.47)	−14.45
HSCL-25	2.7 (0.59)	2.71 (0.62)	2.43 (0.52)	2.58 (0.75)	2.24 (0.65)	−0.46
NDI	12.09 (5.07)	12.33 (5.17)	10.33 (4.54)	11.39 (5.57)	9.61 (5.79)	−2.48
CAN	1.52 (0.94)	1.61 (0.82)	3.02 (0.92)	1.8 (1.28)	3.44 (1.16)	1.92
FOSI-SF	16.96 (13.54)	20.6 (14.29)	14.42 (11.72)	14.58 (14.41)	15.82 (12.54)	−1.14
EUROHIS-QOL	11.82 (6.17)	14 (6.13)	15.66 (6.2)	15.22 (6.63)	16.84 (6.47)	5.02
Sleep diary	STARS ($N = 103$)	Waitlist ($N = 96$)	STARS ($N = 76$)	Waitlist ($N = 105$)	STARS ($N = 82$)	
TST (min)	377.69 (129.12)	362.1 (137.06)	384.05 (122.9)	376.51 (141.65)	414.39 (155.54)	36.7
TIB (min)	526.56 (145.38)	532.81 (130.84)	515.95 (113.87)	533.55 (141.03)	514.55 (148.99)	−12.01
SOL (min)	90.05 (72.58)	84.38 (87.18)	58.37 (48.74)	67.44 (68.38)	42.26 (43.48)	−47.79
WASO (min)	25.78 (34.59)	30.14 (39.7)	23.75 (28.34)	28.49 (32.98)	25.56 (33.87)	−0.22
Daytime Sleep (min)	29.61 (57.33)	12.84 (41.96)	6.58 (22.37)	21.86 (86.62)	4.39 (17.71)	−25.22
SE	0.72 (0.16)	0.68 (0.23)	0.75 (0.18)	0.71 (0.2)	0.8 (0.16)	0.08

Notes: STARS = Sleep Training adapted for Refugees, Waitlist = control group; Abbr.: SD = standard deviation, ISI = Insomnia Severity Index, PCL-5 = PTSD Checklist for DSM-5, NDI = Nightmare Disorder Index, CAN = Coping and Appraisal of Nightmares Subscale, FOSI = Fear of Sleep Inventory – Short Form, HSCL-25 = Hopkins-Symptom Checklist-25, EUROHIS = EUROHIS-Quality of Life-8 item version, TST = total sleep time, TIB = time in bed, SOL = sleep onset latency, WASO = wake after sleep onset, SE = sleep efficiency.

scored < 2 on a minimum of two items, which indicates dissatisfaction with the treatment according to (Pedersen et al., 2023).

Therapists' adherence to the manual was high applying on average 86% ($SD = 0.05$; range: 0.7–1) of session content.

4.3. Adverse events

There were no adverse events with a possible, probable, or definite relationship to the study intervention. Two participants in the control group reported adverse events during the waiting period (aggressive and self-harming behaviour, respectively). No serious adverse events occurred during the study period.

5. Discussion

The present study investigated the feasibility, acceptability, and effectiveness of STARS, a group intervention for sleep disturbances based on evidence-based sleep treatments and adapted for RAS. Participants reported high treatment satisfaction and attended on average 77% of sessions. The dropout rate was 17.4%, which is comparable to other RAS samples according to a recent meta-analysis (Semmlinger et al., 2021). These results indicate that STARS is highly feasible and well-accepted in a routine clinical setting.

The effectiveness of STARS showed mixed results. We found a significant reduction of insomnia severity over time with a large within-group effect from pre- to post-treatment ($d = 0.77$) that remained stable to follow-up ($d = 0.96$). Similarly, moderate to large changes could be observed for most secondary measures from pre- to posttreatment including reduced PTSD, anxiety and depressive symptom severity, improved coping with nightmares and quality of life, as well as wake after sleep onset and daytime sleep ($|0.40| \leq d \leq |1.71|$). However, in contrast to our hypotheses, these changes in the STARS condition were not significantly higher than in the waitlist control group. The small – and non-significant - interaction effect ($d = 0.29$) found in the current study was comparable to overall small effects found in other transdiagnostic interventions for RAS (Schäfer et al., 2023) but smaller than typically achieved by CBT-I in PTSD samples (Hertenstein et al., 2022). Only for selected secondary outcomes a superiority of the intervention over the waitlist emerged: (1) improved coping with nightmares, (2) reduced time in bed, and (3) reduced daytime sleep from pre- to posttreatment. The waitlist control group showed a significantly stronger increase in total sleep time during their waiting time. All significant effects within the STARS condition could be maintained to the 3 months follow-up, while sleep onset latency further significantly improved and total sleep time as well as sleep efficiency showed delayed significant improvement from posttreatment to follow-up. Nightmare severity and fear of sleep did not change between timepoints. Taken together, the results slightly hint towards a beneficial effect of STARS. However, effect sizes were smaller than expected given an unexpected improvement in the waitlist. Therefore, it cannot be ruled out that the finding may be due to limited power.

The symptom reduction within the waitlist condition stands in contrast to prior waitlist-controlled studies with treatment-seeking Afghan refugees (Kananian et al., 2020; Koch et al., 2020). Reasons for this unexpected effect remain speculative at this stage. One potential explanation could be improved asylum policies towards Afghan refugees in Germany following the Taliban takeover in Afghanistan in 2021 such as a decrease of rejection rates from 24% in 2019 to 0.6% in 2022 (German Federal Office for Migration and Refugees, 2023). Thus, despite probable effects of acute stress perceived shortly after the takeover, Afghans' postmigration living difficulties were gradually reduced with potential beneficial effects on mental health of the target group. In addition, it is worth noting that all participants underwent repeated extensive assessment including a total of 3 h of interviews and assisted self-report, and a full week of self-observation via a sleep diary, which may have already had interventional effects (Baglioni et al., 2022; Lies et al., 2020).

Future research is needed to test whether the STARS programme exerts a significantly better effect than low-level interventions (assessment, induction of treatment expectations, psychosocial support) implemented in our waitlist condition. To this end, larger sample sizes resulting in higher statistical power are needed. Further, future research might benefit from focusing on long-term effects (e.g. 6-month follow-up) that might be better suited to detect symptom change due to a behaviour change following the intervention (yet difficult to implement in this study population). In addition, in order to investigate potential therapeutic effects of intense diagnostic assessment, future research may consider adding an additional control condition characterized by less intensive assessment. Further, qualitative assessments of patients' experiences and their explanations for changes taking place in the control condition might help to shed light on processes underlying symptom improvement in the control group. Of note, even small to moderate effects may be clinically relevant in the context of a low-intensity group intervention provided to a population with high symptom burden and PMLD.

Nevertheless, it appears promising to further improve the STARS intervention to increase its efficacy. For example, the context-sensitive incorporation of active components of CBT-I, such as bedtime

restriction and stimulus control (Riemann et al., 2017), might need to be revised. Both components were only partially incorporated into STARS. They are known to challenge patients' adherence, need considerable expertise due to known contraindications (and therefore diminish easy dissemination among primary health care workers) and require full literacy as bedtime restriction relies on sleep diary data (Baglioni et al., 2022). Several adaptations were made to take collective housing and shared bedrooms (affecting 45% of this sample) into account. For example, instead of leaving the bed, patients in shared bedrooms with limited space, were instructed to sit at the end of their bed or use bedspreads while spending time on their beds during the day. Further, instead of a full bedtime restriction, patients were instructed to leave their bed at a regular hour according to an individualized realistic morning schedule. Therefore, the dose of these active components within STARS might have been too low. Despite the challenges, some RAS might benefit from stricter CBT-I.

Secondly, given the high comorbidity with PTSD, a stronger focus on nightmares appears necessary for some individuals. Although our results showed that coping with nightmares improved, related phenomena (e.g. fear of sleep) did not. A more personalized approach allowing for additional individual IRT (Sandahl et al., 2021) might be necessary.

Lastly, there was a high heterogeneity in individuals' responses to STARS (see Supplementary Figure S2). Furthermore, specific sleep-related topics relevant for sub-groups of patients such as (culturally influenced) sleep paralysis (Jalal, 2016), sleep-disordered breathing, shift work, or parenthood of a newborn (Baglioni et al., 2022) were not addressed. Further research should develop and evaluate modular or personalized approaches.

6. Strengths and limitations

Strengths of the current study include the routine clinical setting with highly burdened Afghan refugees using typical referral routes and few exclusion criteria while at the same time using an RCT design. Additionally, extensive assessment procedures were applied to ensure reliability and data validity.

The study had several limitations. First, the trial might have been underpowered, especially with unexpected symptom improvement in the control group. Second, authors of the STARS manual provided the treatments, raising potential bias, and independent fidelity checks via session recordings could not be conducted. Third, no interviewer assessments or objective sleep measurements were available. Further piloting is necessary to evaluate how to integrate objective ambulatory sleep measures into research with this study population. Fourth, the results are specific to young male Dari-speaking Afghans, limiting generalizability. Lastly, not all measures were validated for Afghan refugees, and the NDI showed only acceptable internal consistency, potentially missing symptom changes.

7. Conclusions

This study is the first to evaluate a scalable and potentially easy-to-disseminate treatment for sleep disturbances in RAS. Despite challenging conditions (e.g. COVID-19, Taliban takeover), the treatment showed good feasibility, high acceptability, and participant satisfaction. Contrary to our hypotheses, findings did not show significant superiority of STARS over the control group. Secondary outcomes revealed improved coping with nightmares and adherence to treatment recommendations (reduced daytime sleep and time in bed), which likely contributed to symptom reduction and better quality of life at a 3-month follow-up. Our findings cautiously suggest that STARS could be a promising intervention, but further adaptations, such as an extended dose or an individualized combined group and individual sessions approach, might be necessary. Future research and improvements could enhance its efficacy, making STARS a valuable complement to disorder-specific treatments and providing early intervention to prevent the development of psychopathology.

Open Scholarship

This article has earned the Center for Open Science badges for Open Materials and Preregistered. The materials are openly accessible at https://osf.io/dq58u/ and https://drks.de/search/en/trial/DRKS00024419.

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Disclosure statement

No potential conflict of interest was reported by the author(s).

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Data availability statement

The data that support the findings of this study will be available from the corresponding author on reasonable request from the corresponding author, BD. Due to data protection regulations, demographic information will only be shared in aggregated form. The data are not publicly available due to their high sensibility to ensure participants' privacy and following restrictions by the local Ethics Committee.

Author contributions

BD, GGW, TE and KT were involved in the design of the study. BD and TK conducted the acquisition of data. CM contributed to the statistical analysis and interpretation of data. BD drafted the manuscript, and all authors have read and approved the manuscript.

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