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Efficacy Study: Comparison of an Insomnia Therapy Developed for Shift Workers with the Standard Treatment (Cognitive Behavioral Therapy for Insomnia) in an Online Group Setting. RCT With an Active Control Group, Completer Analysis

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Efficacy Study: Comparison of an Insomnia Therapy Developed for Shift Workers with the Standard Treatment (Cognitive Behavioral Therapy for Insomnia) in an Online Group Setting. RCT With an Active Control Group, Completer Analysis

Running Head: Tailored Insomnia Therapy for Shift Workers

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Abstract: *Background.* Shift workers are at increased risk for insomnia or shift work disorder. The standard treatment (cognitive behavioral therapy for insomnia) is challenging for this group. Although there are new promising approaches, they are still considered inadequate. *Aims and objectives.* For this study, a tailored treatment was developed that replaces regularity interventions with methods from other disorders such as anxiety or depression. This approach is also intended to shift the focus away from disturbed sleep. *Methods.* A randomized controlled trial (RCT, completer analysis) was conducted. Therefore, linear mixed models were utilized to compare two active conditions (treatment as usual vs. tailored therapy) at three measurement points (pre-, post-treatment, 3-month follow-up). Primary outcomes are sleep quality, insomnia severity, sleep onset latency, and total sleep time. Secondary outcomes are anxiety, depression, tension, concern, emotional instability. Non-inferiority or equivalence tests were also performed. *Results.* The newly developed treatment approach is equivalent to standard care. Both resulted in significant and stable improvements in all variables. Thus, only the main effect across measurement points is significant, not the group or the interaction. *Outlook.* Attrition rates and compliance should be considered in further studies and the treatment should be revised according to these results. The approach of improving sleep with implicit interventions should be pursued further, as it seems well suited to shift workers and their specific needs.

Keywords: insomnia; shift work; tailored treatment; efficacy study; implicit treatment

1. Introduction

Shift work has been linked to a number of adverse effects, including an elevated risk of insomnia and shift work disorder (SWD; see overview in Grünberger et al., 2024a).

The most effective method for treating insomnia in the general population is cognitive behavioural therapy for insomnia (CBT-I, Espie, 2022), which includes sleep restriction, stimulus control, cognitive restructuring of dysfunctional beliefs about sleep, psychoeducation, sleep hygiene and relaxation (e.g., Espie, 2022). However, the implementation of CBT-I for shift workers is complex and challenging, as a significant proportion of these interventions are based on adherence to regularity, which is hardly feasible for individuals that constantly need to re-adapt their rhythmicity due to rotating shifts (Tout et al., 2024). Therefore, modified rules of sleep hygiene and tipps for shift workers have been provided (Järnefelt & Spiegelhalder, 2022; Kalkanis et al., 2023; Shriane et al.,

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2023). These consist of scheduled naps, exposure to natural light/light therapy in line with working hours, and the use of sunglasses after night shift.

However, these recommendations for shift workers have predominantly focussed on managing daytime sleepiness or enhancing adaption of circadian rhythms, as criticised by Ell at al. (2024). Nevertheless, these approaches do not address insomnia, despite the necessity of its treatment and the absence of a gold standard therefore (Ell et al., 2024). To resolve this issue, CBT-I has been adapted to meet the specific needs of shift workers somewhat better. Efficacy studies on this are only partially generalizable due to sample characteristics, have methodological weaknesses or show ambivalent results (cf. Ell et al., 2024; Reynolds et al., 2023), as follows.

Järnefelt et al. (2012) found rather modest effects, which already occurred between waiting period and start of the intervention. Since individuals with primary insomnia benefited to a greater extent than those with SWD, the authors assess CBT-I for this group insufficient and encourage a stronger focus on its cognitive components. A subsequent RCT (Järnefelt et al., 2020) found little difference between CBT-I (self-help or group setting) and a sleep hygiene intervention. Again, individuals with SWD showed less benefit than those with primary insomnia, which also applies to improvements in depression and anxiety.

A comparison of an adapted CBT-I with an active control intervention (low glycemic index diet, sample of nurses, Booker et al., 2022) found no significant differences between the conditions. Both interventions showed efficacy in reducing insomnia severity, improving sleep hygiene, and psychological well-being. Jang et al. (2020) also observed significant improvements, although they did not include a control group. In addition, the intervention was developed specifically for firefighters and included techniques to address specific complaints of this occupational group, such as nightmares.

Given these findings, it is not surprising that the efficacy of adapted CBT-I for shift workers is often ambivalent: CBT-I is effective for alleviating psychological and emotional problems caused by shift work, but not for sleep problems per se (Kalkanis et al., 2023); use of the standard or slightly adapted form is insufficient for shift workers (Reynolds et al., 2023); a meta-analysis failed to demonstrate a reduction in insomnia symptoms in shift workers with CBT-I (Takano et al., 2023).

Previously, insomnia in shift workers was mainly attributed to circadian misalignment (see Grünberger et al., 2024a). More recently, research has focused on cognitive factors that are also relevant to the development and maintenance of primary insomnia. These were investigated in a sample of shift workers (Bastille-Denis et al., 2020). Individuals with SWD showed increased negative cognitive activity before sleep (in line with the model proposed by Harvey, 2002), dysfunctional beliefs (particularly within the worry/helplessness subscale) and selective attention to sleep-threatening stimuli. However, they did not differ from good sleepers on catastrophising and difficulty falling asleep. It has been suggested that future interventions for shift workers should target these specific factors (Bastille-Denis et al., 2020).

A recent approach (Vallières et al., 2024) adapted CBT-I interventions for daytime and nighttime sleep separately. Insomnia severity and TST (total sleep time) for day and night sleep improved, cognitive arousal, anxiety, depression, and dysfunctional beliefs about sleep decreased. All participants achieved partial or complete remission. However, this intervention appears to be complex and lengthy (14–22 weeks), and also demanding: it requires adherence to a daytime and nighttime sleep window, and in case of awakening after sleep onset, individuals should get up but remain in darkness.

The high attrition rate in this study may be related to this, but other studies of adapted forms of CBT-I (see Reynolds et al., 2023) have also reported rates above 20%. This is usually attributed to lower compliance in this group (Kalkanis et al., 2023) or to scheduling difficulties in face-to-face settings. Nevertheless, it is recommended that the cognitive components of therapy, including dysfunctional beliefs, should be further investigated (Vallières et al., 2024).

A digital, guided form of CBT-I was developed in collaboration with experts and affected nurses (Ell et al., 2024; sample 80% female, nurses only). The treatment reduced the ISI value (Insomnia

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Severity Index, Gerber et al., 2016) by approximately five points, which is more than observed in many other studies (cf. Reynolds et al., 2023). This outcome is attributed to the comprehensive integration of all CBT-I components and the provision of personalized support. However, it is noteworthy that participants may have perceived the cognitive elements as the most beneficial aspect of the intervention, while the sleep restriction component was perceived as the most challenging. The personal support provided in this study consisted of individualized, written feedback. As is the case with numerous other studies referenced in this article, no improvements were observed in the actigraphy data. It is noteworthy that the remission rate was only 39%, which may be related to the fact that the MCID (minimal clinical important difference) of the ISI, which is +/-6, was not achieved on average. The authors report a low dropout rate of 17.4%, while other sources cite figures of 20% as high. It is notable that only 69.6% of participants completed all six sessions, which is described as high engagement in the intervention. This assessment is particularly noteworthy given that this is a digital, self-study intervention for which no appointments are required, suggesting that the effort is minimal.

In summary, CBT-I can be utilized in an adapted form for shift workers. The findings of recent studies are encouraging. However, behavioral interventions (e.g., sleep restriction) have been found to be less effective and more challenging to implement in this group, whereas cognitive interventions have been identified as a promising avenue of research. Nevertheless, the high rate of attrition in numerous studies indicates that the needs of the target population have not yet been fully addressed.

It is well established that an excessive focus on (disturbed) sleep is a significant contributor to the maintenance of sleep disorders per se (e.g., cognitive insomnia model by Harvey, 2002; attention-intention-pathway by Espie et al., 2006). These mechanisms, including the attempt to force oneself to fall asleep, should also develop in shift workers if the insomnia becomes chronic.

It can be concluded that the already low compliance (Kalkanis et al., 2023) may be further reduced, as many strict rules must be followed throughout the entire 24-hour period by using separate time windows for day and night sleep and sleep hygiene. This predicament could potentially exacerbate the emphasis on (disturbed) sleep. The extant guidelines encompass behaviors and factors that are partially beyond the control of shift workers, such as lighting in the workplace. Anchor sleep times, which are based on regularity, have been a subject of extensive prior discussion.

This has led to the formulation of a novel therapeutic rationale, which posits that sleep should be accorded a reduced priority, especially within the context of therapeutic interventions. Conversely, therapeutic interventions should be oriented towards factors that affect sleep and can be influenced by therapeutic intervention. A preliminary study (cf. Grünberger et al., 2024a) identified anxiety, depression, concern, emotional stability, tension, and attitudes towards shift work as factors that merit further investigation.

Present study. In addressing the known reduced compliance of shift workers, we endeavored to consider the applicability and their specific needs by adapting the wording and by taking different work schedules into account. The efficacy of the newly developed treatment manual was assessed in the present study by addressing the following research questions: First, does the treatment lead to significant improvements in sleep, even though sleep is only implicitly addressed? Second, do personality factors, psychological well-being, and attitudes toward sleep also show improvement over the course of therapy? Third, are these improvements stable over three months? Fourth, how does the efficacy of the treatment compare to standard CBT-I?

2. Methods

2.1. Method and Design

A randomized controlled trial was conducted with a cluster/ad hoc sample. Subjects suffering from sleep disorders and engaged in shift work were assigned to either of two conditions through a computer-generated random numbers in series. CBT-I-S was designated as the experimental condition, while CBT-I, the standard treatment, was implemented as active control group. The

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comparison of the efficacy of the two conditions over three measurement points followed the approach of a completer analysis.

Because of challenges related to participant recruitment, the initially planned passive control condition (sleep diary only) had to be discontinued. Consequently, the interval between screening and pre-measurement was extended to several months in some cases, thereby creating an opportunity to compare the ISI values between these two measurement points. This served as a control measure, indicating a pseudo control group (i.e., waiting list control, see also results and discussion).

2.2. Sampling and Participants

The inclusion criteria encompassed a primary insomnia or SWD (ISI ≥ 15), engagement in shift work (2-, 3-shift system or permanent night shift) for ≥ 30 hours per week, aged 18–65 years, and sufficient German language skills. Exclusion criteria included sleep-apnea syndrome, restless-legs syndrome, chronic pain, acute addiction, affective or anxiety disorder, psychotic, bipolar, schizo-affective disorder, each in severe form.

An a-priori power estimation was conducted using G*Power 3.1.9.7 (Faul et al., 2007). For the within-between interaction (two conditions, three measurement points), a small effect size (0.1), $1-\beta = 0.80$, $p = .01$ (4 outcome variables) and a correlation among repeated measures of 0.7, a total sample size of $N = 142$ was required.

2.3. Sampling and Procedure

Participants were recruited throughout Austria and Germany between the 21st of June 2023 and the 1st of February 2024. The study was advertised with flyers, on which access to the consent form for participation was provided on the study website. Moreover, the study was disseminated to approximately 200 companies/institutions with shift work, and a total of 7,000 doctors were contacted via email and telephone to inform their patients about the study. The participating medical professionals included general practitioners, sleep physicians, occupational physicians, and psychiatrists. Finally, the appeal was disseminated via social media, regional newspapers and their online offerings, and radio interviews. To surmount potential obstacles, a supplementary incentive of €50 was offered as remuneration for exertion. Following a nine-month recruitment period, 142 individuals completed the screening questionnaire, thus concluding the recruitment phase.

Potential participants were provided with comprehensive information about the nature and scope of the study via the website. Following their acceptance of the conditions, participants were directed to the screening questionnaire. If inclusion criteria were met, the participants were contacted via telephone to arrange a virtual appointment via MS Teams for the selection diagnostics. Following the successful completion of this additional selection procedure, the participants were assigned to either the CBT-I-S or CBT-I condition and subsequently contacted once more for a briefing on scheduling and the general procedure.

Of the 142 subjects who completed the screening, 76 proceeded to the interview and briefing stage (see Figure 1). Due to a combination of attrition and inadequate attendance, the final sample size was reduced to $N_{total} = 55$. At the study's commencement, an equal number of subjects were assigned to both conditions; however, subsequent attrition resulted in 31 participants remaining in the CBT-I condition and 24 participants in the CBT-I-S condition.

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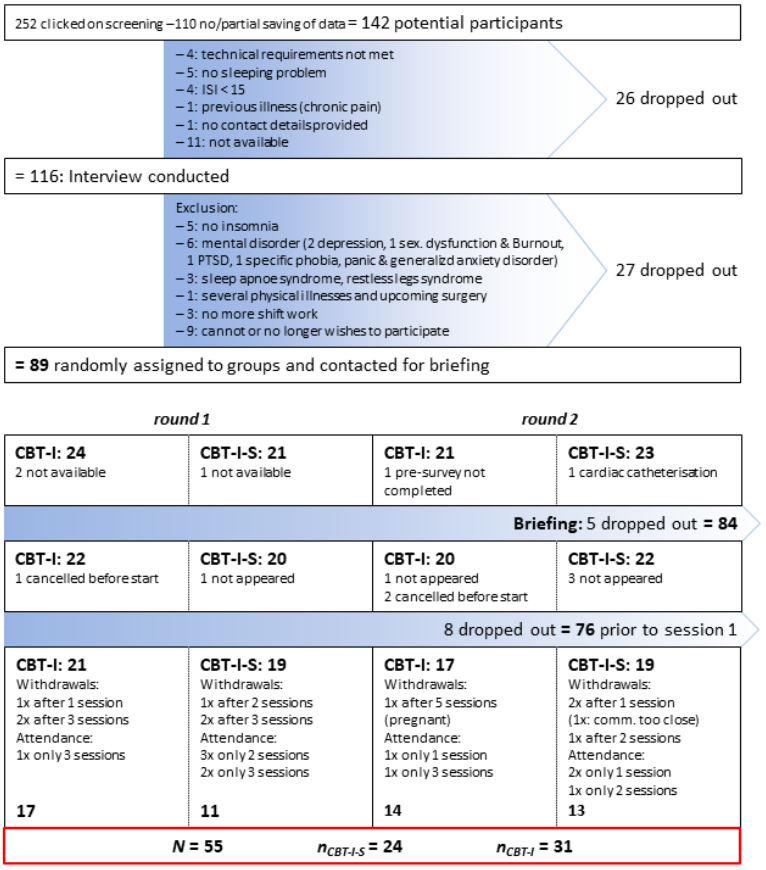

Figure 1. Flowchart.

2.4. Setting and Conditions of Implementation

We decided to implement a group therapy setting that was administered as a webinar via MS Teams, given the documented efficacy of online CBT-I (Espie et al., 2012). Individuals engaged in shift work often experience a heightened sense of social isolation (Cheng & Drake, 2018), thereby underscoring the potential for constructive group interactions and dialogues. The therapeutic intervention was meticulously structured into seven sessions, each spanning 90 minutes. To ensure ethical principles were upheld, the sessions were overseen by a trainer who was prepared to intervene in the event of any adverse developments. Due to the potential scheduling difficulties, two groups per condition (CBT-I-S vs. CBT-I) commenced in the same week, thus offering an alternative date for each session.

Given that only four of the seven sessions were mandatory, the study website provided access to all content in video and text formats to account for any potential missed appointments. The trainers were instructed to verify whether absent participants had viewed and understood the content.

The trainers were experienced Master students in Psychology from the University of Salzburg, who specialized in Clinical Psychology and had already completed a clinical training. All trainers underwent extensive training in the subject matter and the respective manual. The program's comprehensive nature was overseen by a team of supervisors, who, in addition to being psychologists, were also certified cognitive-behavioral therapists.

To ensure the comparability of both treatments, the procedures were meticulously designed to mirror each other as closely as possible. Each of the seven units was initiated with a brief discussion about the current mood and experiences or problems with the content of the previous session. Thereafter, the focus was shifted to the teaching of the methods, and the session concluded with a homework exercise.

Ten days prior to the first session, the link to the pre-survey was furnished. Following the completion of the survey, participants were provided with reading material pertaining to CBT-I-S or

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a sleep diary for CBT-I, as delineated in the respective treatment manuals. The seven weekly sessions commenced with the trainers and study management being available by telephone or email to respond to queries and address technical issues. Following the final session, the post-survey link was distributed, accompanied by a request for prompt completion. Three months later, a follow-up survey was distributed via email.

2.5. Data Collection

Self-report data was collected via online questionnaires (LimeSurvey) at three measurement points: (T1) pre-measurement ten days prior to the first session; (T2) post-measurement following the final session; (T3) follow-up measurement three months after the final session. An online screening (T0) and an interview were carried out in advance to verify the in- and exclusion criteria. The endpoint variables, questionnaires, and subscales utilized at each measurement point are presented in Table 1.

Table 1. Endpoint variables, instruments, and measurement points.

Content/Endpoint variable	*T0: Screening*	*Interview*	*T1: Pre*	*T2: Post*	*T3: Follow-up*	*Instrument / reference*
Screening and interview: in-/exclusion criteria						
Age, sufficient German language skills, technical requirements, previous illnesses, insomnia (since ≥ 3 months, ≥ 3x/week; **ISI** ≥15), weekly working hours ≥ 30, shift work, contact details	x					In-house developed items; ISI (Insomnia Severity Index), Gerber et al., 2016
Screening for mental disorders		x				Mini-DIPS (Diagnostisches Interview psychischer Störungen), Margraf & Cwik, 2017
Insomnia or SWD, no other sleep disorder like Restless-Legs Syndrome, Sleep-Apnoe Syndrome		x				SIS-D-5: in-house development based on - SIS-III-R (Strukturiertes Interview für Schlafstörungen nach DSM-III-R, Schramm et al., 1991), - DSM-5 (American Psychiatric Association, 2013), - SCID-5-CV (Beesdo-Baum et al., 2019). SS-Q (Shift-specific questions), Järnefelt & Spiegelhalder, 2022
Attitude towards shift work			x			Own item: "Do you like working shifts? Yes, I don't mind / No, but I have to"
Chronotype			x			rCSM (reduced Composite Scale of Morningness), Randler, 2008
Demographics						
Age, gender, federal state, marital status, years of shift work, profession, shift system			x			In-house developed items

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Sleep variables						
Sleep quality (PSQI total) „subjective sleep quality“ (SSQ, comp. 1) SOL: sleep-onset latency (item 2) TST: total sleep time (item 4) sleep efficiency (comp. 4)			x	x	x	PSQI (Pittsburgh Sleep Quality Index), Riemann & Backhaus, 1996
ISI: Insomnia Severity	x ≥15		x	x	x	ISI (Insomnia Severity Index), Gerber et al., 2016
DS: Daytime sleepiness			x	x	x	ESS (Epworth Sleepiness Scale), Bloch et al., 1999
MZS: Dysfunctional beliefs about sleep			x	x	x	MZS (Meinungen zum Schlaf Fragebogen), Weingartz & Pillmann, 2009
Importance of sleep			x	x	x	Own item: „How important is your sleep to you?“ 1: It's not important to me, I don't think about my sleep. 2: I only think about my sleep occasionally. 3: Sleep has a normal significance for me, as for most people. 4: I think about my sleep more often than others. 5: I structure my life in a way that ensures my sleep is not compromised.
Cognitive and somatic arousal before sleep			x	x	x	PSAS (Pre-Sleep Arousal Scale), Gieselmann et al., 2012
SHI: Sleep hygiene			x	x	x	SHI (Sleep Hygiene Index), Mastin et al., 2006, own translation
Psychological and personality factors						
Anxiety, Depression, mental well-being (HADS-D total)			x	x	x	HADS-D (Hospital Anxiety and Depression Scale), Herrmann-Lingen et al., 2011
Emotional stability (C), tension (Q4), concern (O)			x	x	x	16 PF-R (16 Personality Factor Test, revised version), Schneewind & Graf, 1998
Feedback on therapy: - Categorical item 1-5 - Option for open feedback					x	Please rate how helpful the training was for you overall: 1 - The training did not help me at all 2 - 3 - Somewhat helpful. Sleep and well-being have improved, but there are still complaints. 4- 5 - Very helpful! I sleep much better and feel better overall

See Grünberger et al. (2024b) for more details on the questionnaires. Mini-DIPS and SIS-D-5 were conducted as interviews via MS Teams, all other instruments were integrated into the online surveys via LimeSurvey.

2.6. Treatment Manuals

CBT-I: standard manual (treatment-as-usual). To employ CBT-I as treatment as usual, it was necessary to adapt a manual to align with the specific requirements of this study, e.g., the online

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group setting. The interventions were meticulously curated in accordance with the contemporary recommendations outlined by Espie (2022) and were derived from a range of recognized standard manuals (see Table 2 for a detailed list). It is noteworthy to mention that certain interventions necessitated adaptation to ensure feasibility for shift workers. However, these adaptations were kept to a minimum. For instance, the sleep restriction intervention was presented in its original form but it was emphasized that shift workers should prioritize the length of the sleep window over its timing. In light of the potential challenges associated with the interventions, it is recommended that shift workers select those elements that they perceive as feasible.

Table 2. *CBT-I.*

Sessions	*Contents*	*Quoted / based on / adapted from …:*
After pre-survey	Sleep diary (to keep until the last session)	Scharfenstein & Basler, 2004a
1.	Introduction to the programme, psycho education, implementation of relaxation method	Binder et al., 2020, pp. 49–52, 75–78, 95–96; Espie, 2022; Crönlein, 2013
2.	Introduction to sleep restriction, calculation of the first sleep window	Müller & Paterok, 2010, pp. 87–97
3.	Deepen sleep restriction, repeat relaxation	Müller & Paterok, 2010, pp. 101–103; Espie, 2022
4.	Stimulus control, adaptation of the sleep window, repeat relaxation	Espie, 2022, pp. 22–25
5.	Sleep hygiene, sleep hygiene check; adaptation of the sleep window, repeat relaxation	Binder, et al., 2020, pp. 135–141; Espie, 2022
6.	Cognitive restructuring of dysfunktional thoughts about sleep	Binder et al., 2020, pp. 174–177
7.	Sharing experiences, reviewing sleep diaries, relapse prevention, goodbye	Scharfenstein & Basler, 2004b, pp. 189–190

CBT-I-S: shift-specific manual (experimental condition). To address the issue of reduced compliance (Kalkanis et al., 2023), all interventions based on regular rhythms have been eliminated. It is crucial to emphasize that this therapeutic modality was meticulously developed for the specific demographic of shift workers, with a comprehensive consideration of their unique requirements. To this end, it was deemed necessary to deviate from the standard wording, for example, by referring to the "main sleep phase" rather than to "night sleep".

To ensure that the disturbed sleep within the therapy does not garner undue attention, while guaranteeing that no pertinent information is withheld, the sleep education was provided prior to the commencement of the therapy for self-study. In the preliminary session, the material was reviewed, and the therapy rationale was derived from it: The program's primary focus was on indirect addressing of sleep issues, a deliberate strategy that is expected to ensure its efficacy.

In subsequent sessions, interventions were primarily derived from manuals that have proven efficacy for other disorders, such as anxiety and depression. The methods originate primarily from cognitive behavioral therapy, but also from positive psychotherapy (see Table 3). It is noteworthy that the explanation of these methods did not involve the use of sleep examples. The interventions

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were meticulously designed to address feelings of resignation and helplessness related to insomnia, with the aim of enhancing self-efficacy expectations through learning methods.

Table 3. *CBT-I-S.*

Sessions	*contents*	*Partly in-house development, partly quoted / based on / adapted from …:*
After pre-survey	Reading material: Psychoeducation on healthy sleep, insomnia, and treatment options	AASM, 2014; Baglioni et al., 2022; Crönlein, 2013; Espie et al., 2006; Pollmächer et al., 2020; Müller & Paterok, 2010; Scharfenstein & Basler; 2004b; Kerkhof, 2018
1.	Introduction to therapy Discussion of the reading material Derivation of the therapeutic rationale Effects of attitudes towards shift work	Crönlein, 2013; Harvey, 2002; Espie et al., 2006; Åkerstedt et al., 2022; Axelsson et al., 2004
2.	Presentation and discussion of the concept of „shift work tolerance“; Current recommendations for shift workers; positive activities (e.g., social, family, etc.); daily structure for each shift (early, late, night shift): recognize opportunities ‘despite shift work’; find an individual relaxation method	Reinberg & Ashkenazi, 2008; Saksvik et al., 2011; Shriane et al., 2023; Järnefelt & Spiegelhalder, 2022; Schaub et al., 2013; Espie, 2022
3.	Central methodologies are employed: Systematic problem solving, acceptance, resource orientation.	Teismann et al., 2012
4.	(Depressive) rumination: Gratitude-/Happiness-Diary; grumbling/worrying stop; relaxation picture	Teismann et al., 2012; Feld & Rudy, 2017; Spiegelhalder et al., 2011
5.	Anxiety / concern: decatastrophising, reality check	Becker & Margraf, 2002
6.	Mood: positive activities, success spoilers, ABC-scheme, cognitive restructuring of dysfunctional (depressive) thoughts	Pitschel-Walz et al., 2003; Schaub et al., 2013
7.	Sharing experiences, emergency kit, relapse prevention, feedback and goodbye	Scharfenstein & Basler, 2004b

2.7. Statistical Analyses

The statistical evaluation is conducted as a completer analysis, as post- and follow-up data are unavailable for subjects who dropped out and, in some cases, for those with an insufficient number of attendances.

The employment of both the chi-squared (χ^2) and the t-tests was undertaken to ascertain whether there were any statistically significant group differences prior to the administration of the respective interventions. To make a comparison between the two interventions throughout the three measurement points, linear mixed models were computed, and the correction of p-values followed Benjamini and Hochberg (1995; Hemmerich, 2016).

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Non-inferiority and equivalence tests are necessary to determine whether the CBT-I-S treatment approach was equivalent, superior, or inferior to the established CBT-I treatment (Wellek & Blettner, 2012). The minimal clinically important difference (MCID) is the threshold value that was employed. For the PSQI, this is ±3 (Cao et al., 2023) and for the ISI, ±6 (Yang et al., 2009). The interpretation of the correlation coefficients and effect sizes aligns with the recommendations provided by Cohen (1988).

Finally, the participants' feedback was analysed quantitatively and qualitatively.

All statistical calculations were executed using SPSS 29 (IBM, 2022) or Jamovi (The Jamovi Project, 2022).

3. Results

3.1. Sample

The final sample included 55 participants (67.74% male) with a mean age of 41.62 years (SD = 9.30). The participants had been employed in shifts for approximately 15 years (M = 15.26 years, SD = 10.53). The majority of the participants were Austrian (83.64%).

The ISI average score at the time of pre-measurement was 15.00 (SD = 3.87), which is precisely the lower limit of clinical relevance of insomnia and the inclusion criterion of ≥ 15. This classification is further validated by the PSQI, which yielded an M = 9.64 (SD = 2.92), demarcating the threshold between poor sleepers (6-10) and those diagnosed with chronic insomnia (>10). For an explanation of these low values, please refer to the comparison between screening (M_{ISI} = 23.78, SD = 3.67) and pre-measurement in the context of the waiting list control group and discussion.

The average SOL is M = 38.25 minutes (SD = 22.90), and the TST is M = 5.69 hours (SD = 1.21). A comprehensive account of all distinctive values, encompassing the entire sample and the two conditions individually, is presented in the Supplementary Materials.

The SS-Q identified 24 participants in the total sample with SWD (12 each), 31 with primary insomnia (12 in CBT-I-S, 19 in CBT-I condition). The diagnostic interview identified 34 individuals with SWD (17 each), 21 with primary insomnia (7 in CBT-I-S, 14 in CBT-I). The discrepancy between the classifications derived from these two methods is statistically significant, $\chi^2(1) = 5.43$, $p = .02$, *Cramer's V* = 0.31. This discrepancy was observed exclusively in the total sample and not in the individual subgroups. Given these findings, it seems impractical to present the results separately for SWD and primary insomnia.

3.2. Power

Due to the fact that the sample size was smaller than originally intended, a post-hoc power analysis was conducted (G*Power 3.1.9.7; Faul et al., 2007) using the actual parameters and sample size. The analysis yielded an F-ratio of 2.28. When this was corrected for alpha (p = .001) and when the correlation among repeated measures (r = .7) was considered, the power (1–β) was determined to be at least .99, even for the smallest effect that was observed (16 PF-R, tension: $\eta^2_{partial}$ = .10, converted into f for G*Power). Furthermore, even in the scenario where the correlation between repeated measures is reduced to 0.13, the power (1–β) remains at 0.80.

An a priori power analysis with the actual values would have resulted in a maximum sample size of N = 22. Therefore, the current results are highly power-supported.

3.3. A Priori Group Differences

The findings from the t-tests and the χ^2-tests confirmed that there were no significant differences between the CBT-I-S and CBT-I groups prior to treatment (see supplementary material).

3.4. Waiting List Control Group

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The mean interval between screening and pre-survey was M = 68.35 days (SD = 43.88) with no significant difference between the CBT-I-S and CBT-I groups, $t(53) = 0.32$, $p = .747$.

The ISI values (N = 55) are as follows: M = 23.78, SD = 3.67 in the screening and M = 15.00, SD = 3.87 in the pre-measurement. The mean difference is M_{diff} = 8.78, SD_{diff} = 3.77, which is statistically significant, $t(54) = 17.30$, $p < .001$, $d_z = 2.33$. However, the correlation between the length of the waiting period and the extent of the ISI reduction was not significant, $r(53) = –.019$, $p = .889$.

The linear mixed model, applied across the ISI values of all four measurement points, yielded a significant main effect of measurement point, $F = 399.96$, $p = .001$, $\eta^2_{partial} = 0.88$, indicating a significant decline in ISI scores over time. Subsequent post-hoc tests revealed that all measurement points differed from each other and exceeded the MCID (+/- 6), with the exception of the difference between post and follow-up (see Figure 2, discussion, and supplements).

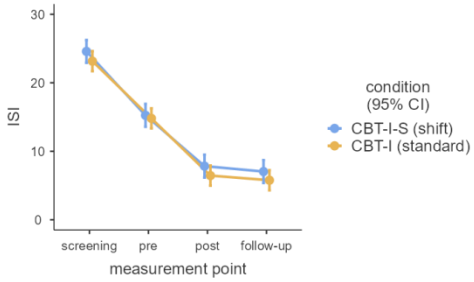

Figure 2. ISI, 4 measurement points.

3.5. Linear Mixed Models

A substantial main effect for the three measurement points was identified in both conditions across a multitude of variables (see Table 4). The effects that exhibited the least significance were observed for the importance of sleep, the somatic PSAS, and the three personality traits (concern, tension, and emotional stability). In contrast, the most pronounced effects were identified in the sleep variables, particularly in the total scores of the PSQI (see Figure 3) and the ISI (see Figure 2), followed by the MZS (see Figure 4) and the SOL (see Figure 5).

No significant main effect of the group was observed, nor was there an interaction effect. The study revealed no statistically significant differences between the CBT-I-S and CBT-I groups (refer to Table 4 for comprehensive results and further figures in the supplementary materials).

Table 4. Linear mixed models, 3 measurement points (Benjamini & Hochberg, 1995).

Variable	*Measurement point*			*Condition*			*Measurement point * Condition*		
	$F(2, 106)$	p	$\eta^2_{partial}$	$F(1, 53)$	p	$\eta^2_{partial}$	$F(2, 106)$	p	$\eta^2_{partial}$
SSQ	51.86	.003	0.49	0.30	.707	-	1.60	.336	-
SOL	56.16	.003	0.51	2.00	.298		0.21	.843	
TST	39.04	.003	0.42	0.18	.742		1.33	.408	
Sleep efficiency	40.86	.003	0.44	0.02	.904		1.79	.305	
PSQI total	80.24	.003	0.60	0.06	.843		1.10	.470	
Importance of sleep	7.36	.003	0.12	0.01	.923		0.71	.633	
MZS	64.12	.003	0.55	1.57	.341		0.42	.742	
ISI total (3t)	135.02	.003	0.72	1.18	.414		0.39	.742	

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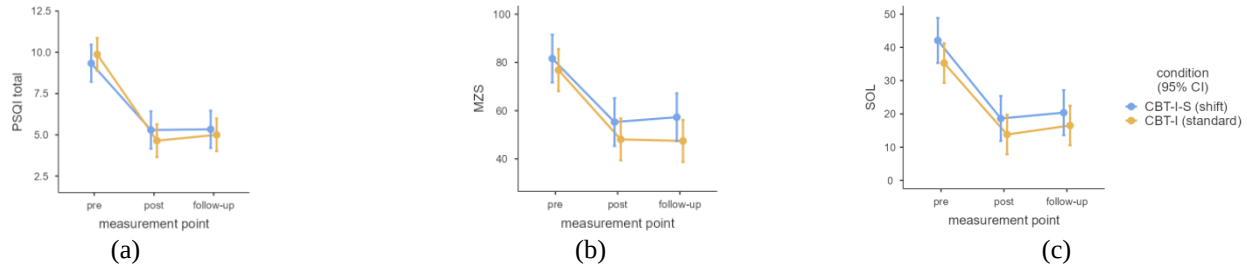
ISI total (4t) (*df* = 3/159 rsp. 1/53)	399.96	.003	0.88	1.68	.336		0.32	.843	
ESS	25.87	.003	0.33	0.25	.712		2.54	.174	
PSAS soma	6.50	.006	0.11	2.49	.225		3.56	.080	
PSAS cogn	29.69	.003	0.36	2.59	.219		1.61	.336	
PSAS total	22.62	.003	0.30	2.98	.180		3.19	.108	
SHI	21.23	.003	0.29	6.29	.041	0.11	0.60	.683	
HADS-A	20.10	.003	0.28	0.27	.711		2.55	.174	
HADS-D	15.91	.003	0.23	0.59	.592		3.00	.125	
HADS total	26.25	.003	0.33	0.50	.633		4.03	.055	
16-PF: C emo. stab.	7.29	.003	0.12	1.11	.424		1.03	.492	
16-PF: Q4 tension	5.91	.012	0.10	0.35	.683		5.42	.017	0.09
16-PF: O concern	8.81	.003	0.14	1.23	.408		2.58	.174	



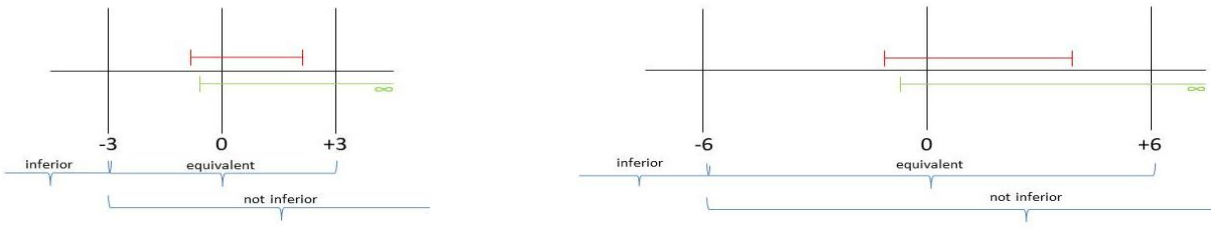
(a) (b) (c)

Figure 3 (a) PSQI total; **(b)** MZS; **(c)** SOL

3.6. Non-Inferiority/Equivalence Tests

The distribution values in the PSQI total at post-survey are as follows: $M_{CBT\text{-}I\text{-}S} = 5.29$, $SD_{CBT\text{-}I\text{-}S} = 2.56$, $s^2_{CBT\text{-}I\text{-}S} = 6.56$; $M_{CBT\text{-}I} = 4.65$, $SD_{CBT\text{-}I} = 2.80$, $s^2_{CBT\text{-}I} = 7.84$. The confidence interval for the difference in the equivalence test (Figure 6, red line) is $CI_{95\%} = [-0.83; 2.12]$, while that for the non-inferiority test (green line) is $CI_{95\%} = [-0.58; \infty]$.

The distribution values in the ISI at post-survey are $M_{CBT\text{-}I\text{-}S} = 7.83$, $SD_{CBT\text{-}I\text{-}S} = 4.51$, $s^2_{CBT\text{-}I\text{-}S} = 20.32$; $M_{CBT\text{-}I} = 6.45$, $SD_{CBT\text{-}I\text{-}S} = 4.68$, $s^2_{CBT\text{-}I} = 21.86$. The confidence interval for the difference in the equivalence test (Figure 7, red line) is $CI_{95\%} = [-1.13; 3.89]$; for the non-inferiority test (green line) $CI_{95\%} = [-0.71; \infty]$.



(a) (b)

Figure 4 Non-inferiority/equivalence tests: **(a)** PSQI; **(b)** ISI

3.7. Remission Rates

Remission rates are also comparable between the two conditions, dependent on the precise definition of remission employed. (Table 5).

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Table 5. Remission rates (ISI): *Proportion of cases that showed a value below the specified threshold or above the MCID at the respective measuring point.*

		Screening (T0)	*Pre (T1)*	*Post (T2)*	*Follow-up (T3)*
ISI <15: subthreshold clinical insomnia	CBT-I-S (24)	0 (0%)	11 (45.83%)	22 (91.67%)	22 (91.67%)
	CBT-I (31)	0 (0%)	15 (48.39%)	28 (90.32%)	30 (96.77%)
ISI < 8: no clinically significant insomnia	CBT-I-S (24)	0 (0%)	1 (4.17%)	12 (50.00%)	17 (70.83%)
	CBT-I (31)	0 (0%)	1 (3.23%)	22 (70.97%)	22 (70.97%)
Difference ≥ 6 T0-T1	CBT-I-S (24)	21 (87.50%)			
	CBT-I (31)	26 (83.87%)			
Difference ≥ 6 T1-T2	CBT-I-S (24)		17 (70.83%)		
	CBT-I (31)		25 (80.65%)		
Difference ≥ 6 T2-T3	CBT-I-S (24)			2 (8.33%)	
	CBT-I (31)			2 (6.45%)	

3.8. Feedbacks

With regard to the evaluation of the treatment's overall effectiveness, as measured by the categorical question (rf. to Table 1), there was no significant difference between CBT-I-S (M = 3.96, SD = 0.91) and CBT-I (M = 3.97, SD = 1.14); $t(52.94) = -0.03$, $p = .973$.

The qualitative evaluation of the feedback also exhibited similarities between the two conditions, considering the group size and the number of feedback items. Statements classified as "helpful" were more prevalent in the CBT-I-S condition, though improvements in well-being were more often observed in the CBT-I condition. The proportion of feedback mentioning an improvement in sleep was similar in both groups.

The terms "well-prepared documents" and "pleasant group atmosphere" were mentioned exclusively by the participants in the CBT-I-S group. Negative feedback following CBT-I-S was observed to be associated, on one occasion, with the therapy rationale, and on two instances, with the unchangeability of the underlying causes, specifically the persistent shift work. Of course, this criticism cannot be attributed to the specific form of treatment. A comparable feedback item was identified in the CBT-I group, namely that a long-standing problem cannot be resolved within a three-month timeframe. It is noteworthy that the therapy was deemed "unsuitable for shift workers" exclusively by CBT-I participants (see full and categorized feedback in supplementary information).

3.9. Dropout Rates

Following the random allocation of participants to the respective conditions, CBT-I-S and CBT-I were of an equivalent size, comprising 42 individuals each. Four individuals each withdrew from the study prior to first session. Accordingly, the two conditions started with n = 38 each (cf. Figure 1).

In the standard condition (CBT-I), four individuals withdrew from the study (10.52%), three attended less than four sessions (7.89%). In the experimental condition, six participants discontinued the study (15.79%), and eight individuals attended the sessions with insufficient frequency (21.05%).

Potential explanations of the origin of these slightly higher values in the CBT-I-S condition are provided in the discussion section.

4. Discussion

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The newly developed CBT-I-S manual and the standard CBT-I both resulted in significant enhancements in subjective sleep variables, including SOL, TST, SSQ, sleep efficiency, DS, as well as PSQI total and ISI. The observed changes in the total PSQI and ISI scores exceeded the MCID (±3 and ±6, respectively), suggesting that the observed improvements were clinically significant in both therapy conditions. This finding is particularly noteworthy and encouraging, especially in light of the fact that sleep was only implicitly addressed in the CBT-I-S condition. Additionally, improvements were observed in dysfunctional attitudes towards sleep, sleep importance, pre-sleep arousal, sleep hygiene, depression/anxiety, and various personality factors, along with emotional stability and tension, in both conditions, although to a lesser extent. Notably, these enhancements demonstrated stability over the three-month follow-up period, irrespective of the specific therapy condition.

No statistically significant between-group differences were observed at any measurement points. The efficacy of the novel therapeutic CBT-I-S approach was found to be statistically equivalent to the established CBT-I treatment, and the same applies to the remission rates observed in both conditions.

A notable benefit of the novel treatment is its potential to be more accessible for shift workers compared to conventional treatment methods. The interventions employed in this study, which only implicitly address sleep, are evidently suitable for replacing interventions on regularity, such as sleep restriction. Consequently, the higher attrition rate observed in the tailored therapy group is somewhat unexpected. A review of the therapists' notes reveals that some of the observed absences were attributed to short-term assumption of duties, illness, or technical difficulties. However, given that this information was not systematically collected and some participants were absent without providing an excuse, it is not possible to assess the role of these causes and determine whether there is a difference between the groups. The scheduling of treatment sessions may also have been a contributing factor. Due to the protracted acquisition period, the commencement of treatment occurred subsequent to the initially anticipated schedule. Consequently, trainers, particularly CBT-I-S trainers, were constrained by competing commitments, impeding their ability to offer dates with the flexibility initially envisioned and agreed upon. This constraint may have led to missed appointments or withdrawals by participants.

A more substantial explanation for the elevated dropout rate in CBT-I-S can be derived from trainer feedback. Initially, some participants in the CBT-I-S group exhibited considerable skepticism regarding the rationale of indirectly addressing sleep and expressed doubts about its efficacy.

This feedback underscores the imperative for subsequent applications to deliberate on potential ramifications. For instance, the rationale underpinning this approach could be articulated with greater clarity and precision. Furthermore, a less rigid approach to the exclusion of sleep from therapy may be advantageous.

The significant decrease in the ISI score between the screening and pre-surveys is a notable finding. The mean ISI value at the screening stage fell within the range associated with severe clinical insomnia (ISI ≥ 22). However, at the pre-measurement stage, the mean value was already within the moderate insomnia clinical symptom range (15-21). While this finding clearly demonstrates a waiting-list effect, it would be a simplistic argument to claim that the subsequent therapy effects would have emerged simply by keeping the participants on a waiting list. In this case, there should have been a correlation between the magnitude of the improvement and the length of the waiting period; however, this correlation was not observed.

As illustrated in Figure 2, the treatment-induced improvement exceeds the minimal clinically important difference (MCID), attaining the threshold of the lowest category of the Insomnia Severity Index (ISI), defined as "no clinically significant insomnia" (Gerber et al., 2016). The significant discrepancies observed between screening and pre-measurement results can be attributed to expectation effects, as prior research has demonstrated a positive correlation between outcome expectations and treatment effects (Frank, 1961). However, a recent meta-analysis (Constantino et al., 2018) indicates that the effects between pre- and post-treatment are typically modest, which

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contradicts the magnitude of the observed effect in the present study. The substantial waiting effect in this study could be attributed to the observation that shift workers often perceive a lack of available assistance or the perception that poor sleep is an unavoidable consequence of their work schedule. This assumption is further substantiated by the fact that a significant proportion of participants expressed their gratitude in their feedback for having the opportunity to participate in this customized treatment program. This may have led to heightened expectations, resulting in an anticipatory improvement in sleep quality.

The evaluation results indicate that the CBT-I-S group exhibited a more favorable response compared to the classical CBT-I group. Notably, the claim that the treatment was not appropriate for shift workers was made exclusively by the standard CBT-I group. This finding serves to validate the hypothesis that CBT-I-S is perceived as more suitable for shift workers.

4.1. Limitations

All data is based on self-assessment and must be considered subjective. This is due to the online setting and financial constraints, which did not allow for laboratory assessments with polysomnography recordings. A potential limitation of the statistical analysis is that some of the factors and variables are not normally distributed. However, this observation is predominantly constrained to one of the two conditions. To ensure a standardized and clear evaluation, it was decided that parametric tests should be used for the entire evaluation. We cite Pagano (2010), Rasch & Guiard (2004), and Wilcox (2012) as evidence that t-tests are relatively resilient to deviations from a normal distribution. With regard to the linear mixed models and the tests for equivalence/non-inferiority, we have opted for parametric tests due to the absence of non-parametric methods.

A notable discrepancy exists between the two instruments utilized with respect to the classification of SWD or primary insomnia. This discrepancy is regrettable, as it precludes the calculation of a group difference between the two diagnoses, which would have been highly informative. The interview instrument was developed in-house but is grounded in extensively evaluated procedures and diagnostic systems. The SS-Q was published in this abridged form by Järnefelt and Spiegelhalder (2022) and is based on an evaluated procedure (Vanttola et al., 2020).

It is regrettable that no data is available for dropouts or participants who were present for a maximum of three sessions. An intention-to-treat analysis and the examination of possible differences between dropouts and completers must therefore be reserved for future studies.

It is unfortunate that the studies, which had been cited in the introduction and which showed great promise, were not available at the time this study was planned. Had we had the opportunity to take these studies into account, the study's overall quality would have been enhanced.

4.2. Strengths

The present study is innovative and pioneering in its use of a completely new implicit approach to treat insomnia in shift workers. The findings of the study demonstrate that sleep can be improved without direct addressing of the condition. This is accomplished by adapting well-established therapy rationales to align with challenging schedules and routines. This suggests that most interventions that require regularity can be replaced, making the new therapy manual more applicable, especially for shift workers.

Conventional studies have frequently been constrained to individual occupational categories. In contrast, this study did not impose any restrictions, allowing for the generalization of its results to different occupational groups. Noteworthy strengths of the study include its high power and supra-regionality, achieved through the online setting. A significant strength of the study is its simultaneous exploration of numerous factors, including sleep in its various forms, thereby providing a more comprehensive overview of the effects.

5. Conclusions

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A comparative analysis of the efficacy of the newly developed CBT-I-S and standard CBT-I reveals that they are comparable. The former appears to be more suitable for shift workers, as it contains hardly any interventions based on regularity. However, given the inconclusive data regarding compliance and the drop-out rate in conjunction with feedback, a definitive conclusion regarding the superiority of CBT-I-S over standard CBT-I therapy cannot be drawn.

5.1. Outlook

A revision of the manual is necessary to reflect the experiences and results of the study. For example, a more detailed explanation of the rationale behind the therapy is required. Additionally, the scheduling of appointments should be more flexible, for instance, by offering one appointment in the morning and one in the afternoon, as explicitly suggested by a participant. For subsequent research, it is recommended to record compliance, inquire about the reasons for dropouts, and integrate novel approaches as proposed by Vallieres et al. (2024) and Ell et al. (2024). Distinguishing between shift work disorder (SWD) and primary insomnia would be advantageous.

Furthermore, the strategy of indirectly addressing sleep in the treatment of insomnia in shift workers merits further investigation, as it has already shown efficacy in its current form and holds considerable promise.

The findings suggest that the novel therapy is comparable to treatment as usual, indicating its feasibility in clinical practice. The program is currently being introduced to companies and institutions in collaboration with a provider of prevention services. In the event of this implementation, scientific monitoring would be advantageous.

Supplementary Materials: The following supporting information can be downloaded at the website of this paper posted on Preprints.org

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