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Effectiveness of digital cognitive behavioral therapy for insomnia in nurses with shift work sleep disorder: Results of a randomized controlled trial

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ABSTRACT

Background: Shift work is associated with many adverse effects on health and, in particular, affects sleep. In nurses, one of the most common forms of insomnia is shift work sleep disorder. Traditional face-to-face cognitive behavioral therapy for insomnia is often impractical for shift-working nurses due to irregular work schedules. Digital therapy presents a promising alternative to provide nurses with access to cognitive behavioral therapy for insomnia.
Objective: To investigate the effectiveness of the digital SleepCare intervention for reducing insomnia in nurses being affected by shift work sleep disorder.
Design: Randomized controlled trial.
Participants: 74 nurses affected by shift work sleep disorder.
Methods: In a two-armed randomized controlled trial, SleepCare was compared to shift work-specific psychoeducation published digitally by the German Sleep Society. The diagnosis of shift work sleep disorder was established through a clinical interview. The primary outcome was insomnia severity as measured by the Insomnia Severity Index at baseline before randomization, at 8 weeks, and 3 months after randomization. Further indicators of mental health and long-term hair cortisol concentration were evaluated as secondary endpoints.
Results: Intention-to-treat analysis of covariance showed a greater reduction in insomnia severity in the intervention group versus psychoeducation, at both post-intervention ($d = 1.11[0.7–1.6]$) and follow-up ($d = 0.97$ [0.5–1.4]), corresponding to between-group differences of 5.0 and 5.3 points on the Insomnia Severity Index, respectively. 56 % completed at least five of the six sessions and results indicated larger effects for these intervention completers with $d = 1.49$ and $d = 1.28$, respectively. Statistically significant effects were observed for sleep-related, but not other mental health indicators, for example, stress and depression. Reduced hair cortisol levels were observed post-intervention in the SleepCare group ($V = 82$, $p = .008$; $\Delta = -1.8$ pg/mg, 44 % reduction from baseline).
Conclusions: SleepCare was effective in reducing insomnia symptoms to a clinically meaningful extent and is one of the first digitally delivered programs to adapt cognitive behavioral therapy for insomnia with specific exercises to address nurses' needs for shift work. The development of effective strategies to promote treatment adherence seems necessary, as substantially larger effects were observed for intervention completers.
Registration: German Clinical Trials Register – DRKS; DRKS00027411 (https://trialsearch.who.int/Trial2.aspx?TrialID=DRKS00027411).
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What is already known

- Shift work sleep disorder, a form of insomnia, affects approximately 26 % of nurses.
- Despite indicators that digitally delivered cognitive behavioral therapy for insomnia is an effective treatment for insomnia in general, its effectiveness for nurses with shift work sleep disorder remains unclear.
- Current digital interventions show mixed results in shift workers and nurses, possibly due to a lack of shift work-specific adaptations.

What this paper adds

- Digitally delivered cognitive behavioral therapy for insomnia adapted for shift work reduced insomnia severity to a clinically meaningful extent in nurses affected by shift work sleep disorder.
- Improvement in insomnia was associated with reduced levels of long-term hair cortisol, but no effects were found for perceived stress or symptoms of depression.
- The positive feedback from nurses underscores the value of Sleep-Care's flexible digital format, which allows participation despite irregular schedules.

1. Background

Shift work, characterized by atypical working hours is essential for nurses and healthcare professionals, with approximately 40 % of nurses in Europe reporting to work in shifts (Parent-Thirion et al., 2017). The adverse effects of shift work on physical and mental health have been extensively studied, with meta-analyses finding shift work to be associated with conditions such as metabolic syndrome (Sooriyaarachchi et al., 2022), breast cancer, stroke, and diabetes (Rivera et al., 2020), as well as anxiety (Brown et al., 2020) and depression (Torquati et al., 2019). Night and rotating shifts, in particular, seem to play a major role in the development of mental health conditions, such as depression (Okechukwu et al., 2023). One of the most common negative effects of shift work is impaired sleep: shift workers report longer sleep onset latency, increased wakefulness after sleep onset (Chang and Peng, 2021), greater daytime sleepiness, and shorter total sleep duration (Huang et al., 2022; Merkus et al., 2012).

In a meta-analysis, Zeng et al. (2020) found that poor sleep quality is more prevalent among nurses working rotating and night shifts. Nurses on consecutive night shifts also report shorter sleep duration and increased fatigue compared to their off-duty days (Min et al., 2024). This may contribute to a higher risk of accidents and injuries during night compared to morning shifts (Fischer et al., 2017).

A common form of insomnia in shift workers is shift work sleep disorder, defined as insomnia and/or excessive sleepiness, associated with the work schedule for at least one month (American Academy of Sleep Medicine, 2014). Shift work sleep disorder is characterized by a disrupted circadian rhythm, resulting in misalignment (Kecklund and Axelsson, 2016). The overall prevalence of shift work sleep disorder is estimated at 26.5 % and is particularly high in nurses (Pallesen et al., 2021).

In addition to work-related factors such as irregular and backward-rotating shift schedules that contribute to the development of shift work sleep disorder (Di Muzio et al., 2021), individual risk factors, such as gender and domestic responsibilities are also relevant (Booker et al., 2018).

First-line treatment for insomnia is typically face-to-face cognitive behavioral therapy for insomnia (Riemann et al., 2023), which includes psychoeducation, sleep hygiene, stimulus control therapy, sleep restriction therapy, cognitive strategies, and relaxation therapy. However, due to limited availability and irregular work schedules, nurses struggle to attend face-to-face cognitive behavioral therapy for insomnia. Digital therapy could offer an alternative, providing increased accessibility and flexibility in time and location. In recent years, meta-analyses have demonstrated the effectiveness of digital cognitive behavioral therapy for insomnia in general (Simon et al., 2023; Soh et al., 2020) and digital therapy specifically adapted to the general working population (Behrendt et al., 2020; Brückner et al., 2024). Vallières et al. (2024) reported high attrition rates for a face-to-face intervention for shift workers and recommended considering digital interventions. For example, Dumarkaite et al. (2023) found beneficial effects of an online stress management intervention for nurses.

Despite these positive effects of general and work-related cognitive behavioral therapy for insomnia, two recent meta-analyses found no clinically meaningful effects in shift workers, analyzing a total of 10 randomized controlled trials and non-randomized studies, and 33 randomized controlled trials, respectively (Reynolds et al., 2023; Takano et al., 2023). Primary studies were characterized by considerable heterogeneity, with only four randomized controlled trials. Most importantly, Reynolds et al. (2023) called for a stronger adaptation of cognitive behavioral therapy for insomnia to the specific demands of shift work. Such modifications could include shift work-specific information about circadian rhythm, promoting circadian adaptation (e.g., through light exposure and/or light avoidance), clockwise shift progression, sleep hygiene, anchoring sleep, and scheduling naps (Wickwire et al., 2017).

Another source of heterogeneity has been the choice of control group. While the commonly used waitlist is valuable in various settings, it can reduce internal validity, particularly in studies where minimal interventions, such as psychoeducation, are readily available to help-seekers. Individuals in a waitlist condition may proactively seek help from freely available accessible psychoeducation resources (Lim et al., 2023), increasing the risk of treatment-diffusion bias, as evidence suggests beneficial effects of psychoeducation (Furukawa et al., 2024; Van Straten et al., 2018). However, incorporating available psychoeducation as a comparator has not yet been implemented in most studies of cognitive behavioral therapy for insomnia for shift workers (Reynolds et al., 2023).

Almost all intervention studies on insomnia specific cognitive behavioral therapy use patient-reported outcome measures, such as the Insomnia Severity Index (Simon et al., 2023). While these measures provide direct insight into the patient experience from a psychosocial perspective, adding surrogate biological markers may enhance understanding of the intervention's effects at a biological level (Botschek et al., 2023), thereby better reflecting the biopsychosocial model of health. Among biological markers, cortisol is particularly relevant, as higher levels have been observed in patients with insomnia (Dressle et al., 2022). Cortisol is assumed to link physiological arousal and sleep through prolonged activation of the hypothalamic–pituitary–adrenal (HPA) axis, making it difficult for individuals with insomnia to fall and remain asleep (Dressle et al., 2022; Riemann et al., 2010). At the same time, poor sleep affects cortisol regulation (Abell et al., 2016), suggesting bidirectional effects between sleep and cortisol (El Mlili et al., 2021). While most studies on shift workers have used salivary cortisol to assess arousal levels, reflecting short-term changes in cortisol on a daily or hourly basis (Grosser et al., 2022), early epidemiologic studies focused on hair cortisol in shift workers (Zhang et al., 2020). Unlike salivary, urinary, or plasma cortisol levels, hair cortisol reflects long-term cortisol levels, indicating prolonged activation of the stress system over weeks (Stalder et al., 2017; Stalder and Kirschbaum, 2012). Therefore, hair cortisol has been proposed as a valuable outcome measure for psychological interventions in general (Botschek et al., 2023), and for sleep disorders in particular (El Mlili et al., 2021). Moreover, it may be a particularly promising biomarker for studying alongside digital interventions, as participants can easily collect hair samples themselves at home, without scheduling an appointment or visiting a laboratory. This method also avoids the need for multiple sample collection, as is required for salivary cortisol (Domes et al., 2019; Enge et al., 2020). This preserves the advantages of digital interventions;

namely, flexibility in time and location. While initial randomized controlled trials included hair cortisol to evaluate interventions for depression and post-traumatic stress disorder (Botschek et al., 2023), to date there is no published evidence for insomnia treatments (El Mlili et al., 2021).

To the best of our knowledge, no randomized controlled trial has yet been published comparing a digital cognitive behavioral therapy for insomnia intervention adapted for shift-working nurses against psychoeducation. Therefore, we evaluated the effectiveness of the digital cognitive behavioral therapy for insomnia intervention SleepCare for nurses with shift work sleep disorder at reducing insomnia severity compared to publicly available psychoeducation for shift work sleep disorder. A secondary aim was to assess home-collected scalp hair cortisol as an outcome measure and to determine whether changes in hair cortisol reflect the effects of cognitive behavioral therapy for insomnia on patient-reported outcomes.

2. Methods

2.1. Trial design

The study was a two-arm, parallel randomized controlled trial comparing the internet-based intervention SleepCare with a digital psychoeducational self-help guidebook for shift workers affected by insomnia.

2.2. Participants

Inclusion criteria were: (a) 18–65 years old (b) working at least 50 % full-time as a registered nurse or licensed geriatric nurse in acute care hospitals or residential care facilities, (c) working shifts, including night shifts, and (d) affected by shift work sleep disorder as diagnosed by a researcher in a semi-structured telephone interview. Exclusion criteria were (a) current psychotherapeutic treatment for insomnia, (b) any other patient-reported DSM-V mental disorder, (c) increased risk of suicide (Beck's Depression Inventory-II score at question 9 $>$ 1), (d) serious or unstable organic disease that could influence sleep or any other sleep disorder according to the International classification of sleep disorders (American Academy of Sleep Medicine, 2014), (e) use of any sleep-influencing medication in the two weeks prior to the study or during participation, (f) previous experience with insomnia specific cognitive behavioral therapy, or (g) concurrent participation in any other health training to improve sleep. Individuals were not excluded if they were unable to provide hair samples for biological evaluation (e.g., because of short hair). Participants were recruited between May 2022 and July 2023, primarily through hospitals and residential care facilities. Nurses who expressed interest in the project website were invited to a telephone interview to assess eligibility and provide further information about the terms and conditions of participation and informed consent. The diagnostic interview to assess shift work sleep disorder consisted of a detailed review of shift-related sleep patterns, the Shift Work Disorder Screening Tool (Barger et al., 2012), and screening for other sleep-related disorders. If eligible, participants were sent an online baseline questionnaire and informed consent form. Participants were informed in advance that it would take approximately 30 min to complete the questionnaire, and they were allowed to pause the questionnaire and complete their responses later.

2.3. Interventions

SleepCare is a digital, guided training based on cognitive behavioral therapy for insomnia for nurses working in shifts, modified to meet the needs of their specific work situation. The intervention was positively evaluated in a randomized controlled pilot trial (Ell et al., 2024), which was followed by the present definitive trial. The content of each intervention module is described in the Online Supplement Table S1.

SleepCare consists of six modules, each averaging 60 min, recommended for completion at a pace of one per week. After each module, participants received individualized written feedback from a psychological e-coach following a standardized manual. This handbook served as a framework for prioritizing session, provided examples and explained outlined guidelines for feedback delivery. Within this framework, e-coaches were instructed to respond as personally as possible. The intervention included all components of cognitive behavioral therapy for insomnia: Psychoeducation, sleep hygiene, stimulus control therapy, sleep restriction therapy, cognitive strategies, and relaxation therapy (Riemann et al., 2023). Adaptations to the specific situation of shift workers in a healthcare context included adding existing recommendations for adjusting circadian rhythms (e.g., wearing sunglasses on the way home after night shifts) and improving symptoms of fatigue (e.g., taking targeted naps). Sleep restriction therapy was tailored to the individual shifts and recommendations were provided for anchoring sleep (Wickwire et al., 2017). Addressing the impact of shift work on social relationships (Vitale et al., 2015), one module focused on social factors, such as balancing sleep, work, and time with family and other social contacts. A description of the shift-specific adaptations of cognitive behavioral therapy for insomnia is provided in Supplement Table S1.

The control group received psychoeducation in the form of the official digital guidebook from the German Sleep Society for shift workers affected by insomnia, which is freely available online (German Sleep Society, 2021).

The guidebook covers three main areas: (1) Psychoeducation on sleep, chronobiology, shift work, and common sleep disorders in shift work; (2) Information about circadian rhythm disturbances and their physical and psychological effects on health; and (3) Treatment options including evaluation of individual shift schedules adjusted to chronotype when possible, promoting clockwise shift progression, anchoring sleep with some overlap even on off days, advice on strategic napping, information about prescription of sleep medications, guidance on the use of stimulants and melatonin, light therapy recommendations, general sleep hygiene practices (such as maintaining a low bedroom temperature, establishing regular bedtime rituals, and using the bedroom only for sleeping), and specific dietary advice for different shift schedules.

2.4. Outcomes

Data were collected online at baseline (T1), post-intervention (8 weeks after randomization, T2), and 3 months after randomization (T3). The 3-month follow-up period was determined based on ethical considerations to minimize waiting time for participants in the control group to receive a potentially beneficial treatment (Kazdin, 2021), and to allow for comparability with other digital sleep intervention studies (Reynolds et al., 2023; Van der Zweerde et al., 2019). Hair cortisol measurements were taken at baseline and 8 weeks, but not at T3, as a sample of 2 cm in length was required. Given a growth rate of 1 cm per 4 weeks, the interval between measurement times was too short (Loussouarn et al., 2005). Participants received a kit containing everything they needed to take hair samples themselves at both time points and return samples to the university. Cortisol analyses were performed by an independent, specialized laboratory.

2.4.1. Primary outcome

The primary outcome was insomnia symptom severity post-intervention (8 weeks), measured using the German version of the Insomnia Severity Index (Bastien et al., 2001). The scale contains seven items, each answered on a 5-point (0–4) Likert scale with a range for the total score of 0–28. The reliability and ranges of all the utilized questionnaires are provided in Online Supplement Table S2. According to Morin et al. (2011), change scores on the Insomnia Severity Index greater than 4.65, 8.35, and 9.89 points were considered slight, moderate, and marked improvement or deterioration, respectively. Partial remission was defined as a score of 8–10 and complete remission as a score < 8 (Morin et al., 2011). Corresponding numbers needed to treat for an additional beneficial outcome (NNTB) and number needed to treat for an additional harmful outcome (NNTH) were calculated (Schünemann et al., 2024).

2.4.2. Secondary outcomes

To further assess sleep complaints and sleep-related attitudes, the following questionnaires were used: Daytime sleepiness was assessed using the Epworth Sleepiness Scale (Johns, 1991), consisting of eight items describing situations in which participants rate their likelihood of dozing off or falling asleep. Arousal before sleep was assessed by the cognitive subscale of the Pre-Sleep Arousal Scale (Nicassio et al., 1985), with eight items describing symptoms that typically occur before sleep, such as worry or anxious thoughts. Sleep-related cognitions toward sleep were measured using the Dysfunctional Beliefs And Attitudes About Sleep Scale (Morin et al., 2007) which includes 16 items across four subscales. Shift work disorder was assessed using the four-item Shift Work Disorder Screening tool (Barger et al., 2012), where participants answered questions about their likelihood of falling asleep at work during nonstandard shifts over the past month. To assess the impact of shift work on different domains of life of participants, we employed a self-designed questionnaire with 11 items addressing various domains of life, including social activities, energy levels, and cognitive abilities.

Regarding non-sleep-related outcomes, stress was measured using the 10-item version of the Perceived Stress Scale (Klein et al., 2016) and depression using the 15-item version of the Center for Epidemiological Studies' Depression Scale (Hautzinger et al., 2012), with a clinical depression threshold score of 16 (Lehr et al., 2008). To assess work-related rumination, we utilized the cognitive irritation subscale of the Irritation Scale (Mohr et al., 2006). Work ability was assessed using the Work Ability Index (Ahlstrom et al., 2010), which asks nurses to rate their current work ability compared to their lifetime best. To assess individuals' subjective expectations regarding future employment prospects, the 3-item scale by Mittag et al. (2006) was used. Absenteeism and presenteeism were measured as the total numbers of sick days in the past four weeks and days with impaired productivity due to work-related sleep problems, respectively.

In terms of workplace characteristics, external effort and rewards were assessed using the short version of the Effort-Reward Imbalance Questionnaire by Siegrist et al. (2009). User satisfaction with the intervention was assessed at T2 using the German version of the Client Satisfaction Questionnaire (Boß et al., 2016).

2.4.3. Cortisol measurements

Participants were instructed during the screening telephone interview on how to collect scalp hair samples. Additionally, detailed written instructions with step-by-step photographs together with an instructional video demonstrated the sampling technique. Hair strands were cut by the participants or an assisting person with scissors as close to the scalp as possible at the back of the head. Hair cortisol was determined in the first 1 cm scalp-adjacent hair segment, assumed to reflect cumulative cortisol secretion over the past four weeks (Loussouarn et al., 2005). Cortisol concentrations were assessed using liquid chromatography–tandem mass spectrometry (LC–MS/MS) as described in Gao et al. (2013). To validate sample quality, the laboratory conducted parallel analyses of both cortisol and cortisone levels, as these glucocorticoids maintain a dependent relationship where cortisol gets converted into cortisone (Stalder et al., 2017). This dual analysis served as a quality control measure, allowing for the identification of potential sampling anomalies.

2.5. Sample size

For our sample size calculation, we followed DELTA2 guideline recommendations for specifying the target difference (Cook et al., 2019). When specifying a realistically achievable effect, the focus was on evidence from trials adhering to the intention-to-treat (ITT) principle, as the results account for study and intervention attrition. Considering meta-analytic evidence on the effect of digital cognitive behavioral therapy for insomnia (Seyffert et al., 2016), we assumed that a post-intervention difference of 3 points in insomnia severity between the two groups was both a clinically-relevant and realistic effect. Assuming a standard deviation of 4.5 points (Thiart et al., 2015), this results in a minimal clinically-important difference between groups of $d = 0.66$ post-intervention. Under these assumptions, a total sample size of $N = 74$ was necessary to detect the effect with 80 % power and a two-tailed significance level of 5 %.

2.6. Randomization

Participants were randomly assigned to either the intervention or the psychoeducation control condition using a computer-generated randomization list with a 1:1 ratio and block size of ten. Randomization was performed by an independent researcher not otherwise involved in participant recruitment, intervention admission or data collection of the study. Blinding of participants and e-coaches was not feasible. To reduce the risk of bias, fully automated data collection and a secondary analysis by an independent statistician was employed. Participants in the SleepCare group received immediate access to the intervention, while those in the control condition received a digital guidebook and were granted access to the intervention three months later. All participants had unrestricted access to care as usual.

2.7. Statistical methods

Data analysis was performed using R, version 4.1.1., according to a pre-specified analysis plan, and employing the intention-to-treat principle. Missing data mechanisms were assessed using explorative analyses of variables predicting missingness, and Little's MCAR test. Missing data were then estimated with multiple imputations, with 20 estimates calculated for each missing value (Sterne et al., 2009). Sociodemographic variables, the grouping variable, and baseline data on the primary and secondary outcomes were used in the imputation model. Study completer analysis was performed as a sensitivity measure, as well as mixed model analysis. For the main and secondary analyses, we performed analysis of covariance (ANCOVA) as recommended by O'Connell et al. (2017), including respective baseline scores as a covariate. Furthermore, methodological research by Wang et al. (2019), Schminder et al. (2010) and Egbewale et al. (2014) has demonstrated that ANCOVA is a robust method across different data distributions, violations of assumptions, and is appropriate to account for baseline differences.

Between-group Cohen's d values were calculated using pooled estimated marginal means and standard deviations. To account for potential non-normal distributions, non-parametric statistics were performed to analyze hair cortisol level.

2.8. Ethics approval

The study was approved by the Ethics Committee of Leuphana University Lüneburg (Reference No. EB-Antrag_202108–10-Lehr_Sleepcare, September 8, 2021) and the trial was registered at the German Clinical Trials Registry (DRKS-ID: DRKS00027411, March 9, 2022). Informed consent was obtained from all participants prior to participation.

3. Results

3.1. Baseline data

Fig. 1 depicts the flow of participants. Of the 168 individuals who

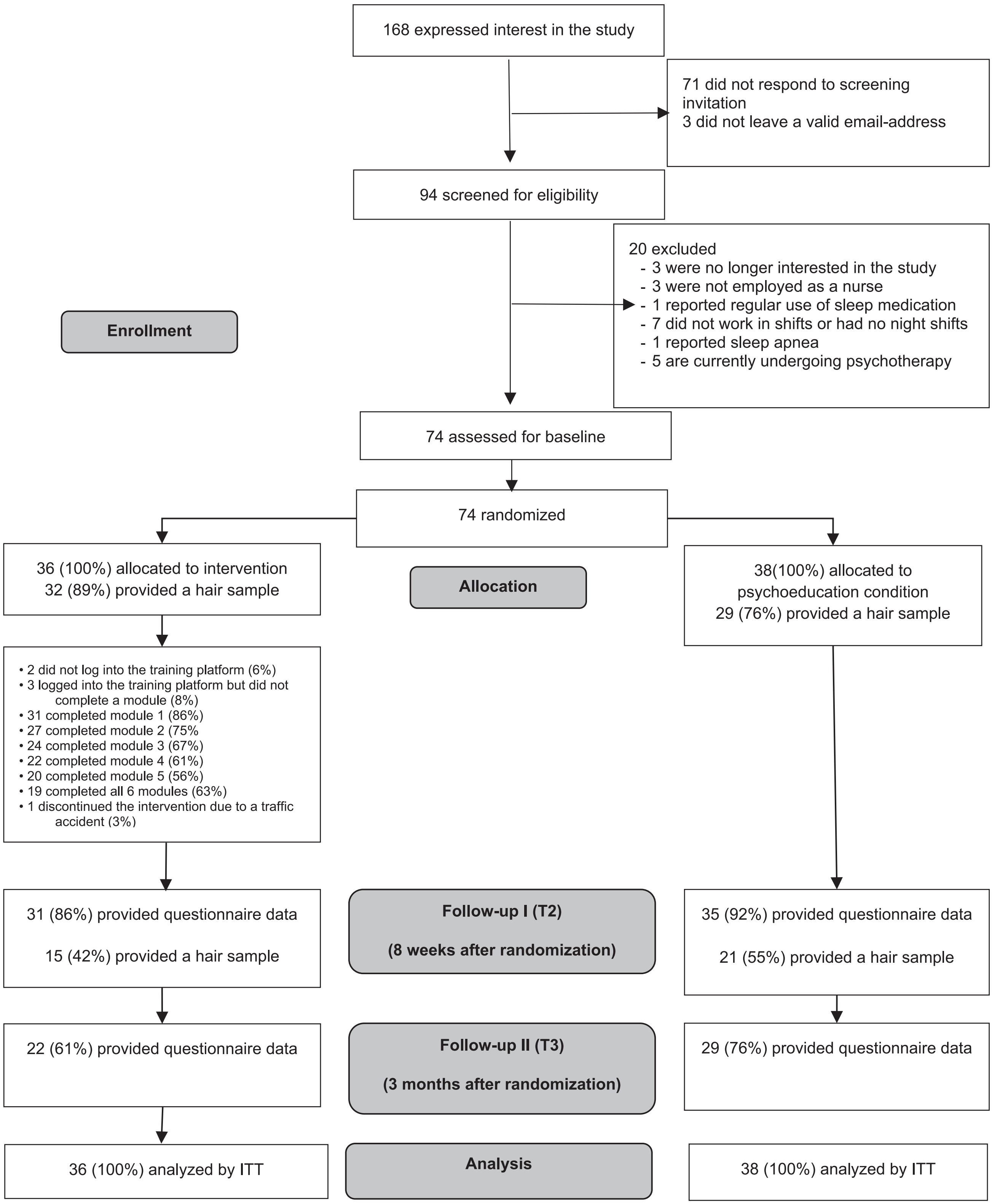

Fig. 1. Flow of participants.

expressed interest in participating, 94 were screened by telephone interview. The 74 eligible individuals completed the baseline questionnaire, among whom 36 and 38 were randomized to the intervention and control group, respectively. Participants averaged 43.8 years old (SD = 12.0, range: 23–61), were predominantly female (N = 63; 85.1 %), and generally had a long history of shift work (21.0 years), relative to general years of work experience (23.7 years); 52.7 % reported symptoms of insomnia for over five years. The vast majority (91.9 %) reported an adverse situation at work, in terms of an effort-reward imbalance. Half of all participants (N = 37) worked in a three-shift system and 23.0 % (N = 17) worked irregular shifts. Baseline characteristics are summarized in Table 1.

Table 1
Demographic characteristics: means/outcomes, standard deviations/percentages at baseline.

		Total (N = 74)		SleepCare (n = 36)		Education (n = 38)	
		N/M	%/SD	n/m	%/SD	n/m	%/SD
Age (M/SD)		43.8	12.0	41.4	12.7	46.2	10.9
Gender	Male	10	13.5	4	11.1	6	11.4
	Female	63	85.1	31	86.1	32	84.2
	Other	1	1.4	1	2.8	0	0
Relationship	Single/unmarried	20	27.0	10	27.8	10	26.3
	Married or in a partnership	43	58.1	21	58.3	22	57.9
	Divorced or widowed	11	14.9	5	13.9	6	15.8
Children	Yes, living in the same household	30	40.5	10	27.8	20	52.6
	Yes, living in another household	15	20.3	8	22.2	7	18.4
	No	29	39.2	18	50.0	11	28.9
Caregiving for relatives	Yes	9	12.2	4	11.1	5	13.1
Educational degree	Secondary school/primary school	20	27.0	10	27.8	10	26.3
	Middle school	43	58.1	21	58.3	22	57.9
	High-school	11	14.9	5	13.9	6	15.8
Nursing qualification	Vocational nursing training	57	77.0	27	75.0	30	78.9
	Technical school degree	17	23.0	9	25.0	8	21.1
Employment	Work experience in years (*M/SD*)	23.7	12.4	22.1	13.4	25.2	11.3
	Shift work experience in years (*M/SD*)	21.0	13.2	19.8	13.4	22.2	13.1
	Managerial position	17	23.0	8	22.2	9	23.7
	Work hours per week (*M/SD*)	36.9	9.2	35.9	10.4	37.8	8.1
	Percentage of night shifts (*M/SD*)	23.7	18.6	26.4	22.1	21.1	14.4
	Working in a three-shift system	37	50.0	19	52.8	18	47.4
	Working irregular shifts	17	23.0	6	16.7	11	28.9
	Effort-reward imbalance[a]	68	91.9	34	94.5	34	89.5
Mental health	Moderate to severe insomnia[b]	58	78.4	30	83.3	28	73.7
	Depressive symptoms[c]	33	44.6	20	55.6	13	34.2
	Severe sleepiness[d]	11	14.9	8	22.2	3	7.9
	Sleep complaints in years (*M/SD*)	3.5	0.7	3.5	0.6	3.4	0.7
	Insomnia symptoms for 1–5 years	30	40.5	13	36.1	17	44.7
	Insomnia symptoms for over 5 years	39	52.7	21	58.3	18	47.4
Previous use of a treatment in the last month	Medication	5	6.8	1	2.8	4	10.5
	Psychotherapy	4	5.4	3	8.3	1	2.6
	Other kind of mental health prevention	12	16.2	5	13.9	7	18.4
Subjective expectations regarding future employment prospects	1.5× greater risk of early retirement[e]	49	66.2	22	61.1	27	71.1
	2× greater risk of early retirement[e]	21	28.4	12	33.3	9	23.7
	8× greater risk of early retirement[e]	4	5.4	2	5.6	2	5.3

[a] Effort-Reward-Imbalance indicated by an ERI-score > 1 (Siegrist et al., 2009).
[b] Insomnia Severity Index ≥ 15 (Bastien et al., 2001).
[c] Moderate depressive symptoms, indicated by a CES-D ≥ 16 (Hautzinger et al., 2012).
[d] Sleepiness indicated by a value ≥ 16 (Epworth Sleepiness Index).
[e] Increased risk compared to the reference group (risk = 1) of early retirement due to ill health (Mittag & Raspe, 2003).

Table 2
Means and standard deviations of outcome variables at baseline, post-intervention (8 weeks) and 3-month-follow-up.

	T1 (baseline)				T2 (8 weeks)				T3 (3 months)			
	SleepCare		Education		SleepCare		Education		SleepCare		Education	
	M	SD	M	SD	M	SD	M	SD	M	SD	M	SD
Primary outcome												
Insomnia severity	18.2	3.6	16.5	3.6	10.4	4.5	15.4	4.1	9.4	6.4	14.6	5.4
Secondary outcomes												
Sleepiness	12.5	3.8	10.2	4.1	8.6	3.5	11.0	3.3	7.3	4.7	10.8	4.3
Pre-sleep arousal	23.6	6.3	22.7	5.6	17.9	5.8	21.7	5.7	17.4	6.6	20.1	6.5
Dysfunctional beliefs	5.8	1.4	5.2	1.6	4.4	1.5	5.3	1.4	4.1	1.5	5.1	1.4
Shift work disorder	9.7	2.2	8.7	1.8	7.0	1.8	8.5	1.8	6.4	2.1	8.1	2.2
Impact of shift work	13.0	5.4	15.2	4.3	18.0	5.8	15.5	6.0	18.4	5.6	16.1	7.0
Stress	22.0	5.9	20.0	7.4	17.9	7.2	18.3	7.0	17.0	8.5	18.1	8.1
Depression	16.4	8.0	15.1	7.8	13.0	7.9	14.3	7.7	12.3	9.1	12.8	8.6
Work-related rumination	14.8	4.4	12.9	4.8	12.9	4.7	13.1	4.4	11.8	4.8	12.8	4.4
Work ability	6.5	1.9	6.7	2.0	6.8	2.0	6.8	1.9	7.1	2.6	7.1	2.3
Absenteeism	5.6	4.7	5.5	4.9	6.0	4.6	5.4	4.9	5.7	4.4	7.8	9.8
Presenteeism	9.6	6.6	7.0	5.5	6.5	5.1	8.5	5.4	4.5	2.6	8.1	8.2
Effort	11.1	1.5	10.2	1.5	10.7	1.3	10.0	1.3	10.2	2.1	9.9	1.8
Reward	16.0	3.4	16.9	2.9	16.2	2.3	16.8	2.1	17.1	3.4	16.5	3.3
Hair cortisol in pg/mg	4.8	5.2	3.5	2.6	2.7	1.5	3.5	3.1	–	–	–	–

Note: SleepCare: n = 36, Education: n = 38; Absenteeism = Number of working days with sick leave in the last 4 weeks, Presenteeism = Number of days working despite feeling unwell. pg/mg = picograms cortisol per milligram of hair.

For patient-reported outcomes, Little's MCAR test was not significant ($\chi^2(7) = 9.12$, $p = .244$), indicating that there was insufficient evidence to reject the null hypothesis of data being Missing Completely At Random. No variable was identified that predicted the absence of the primary outcome, which would have supported the assumption of Missing At Random. Data were missing for 10.8 % of participants at T2 and 31.1 % at T3 (Fig. 1). 14 % of participants did not complete any module: 2 participants (6 %) never logged into the training platform, while 3 participants (8 %) logged in but did not complete any module. 56 % of participants completed at least 5 out of 6 modules and were considered as intervention completers.

3.2. Primary outcome analysis

Intention-to-treat ANCOVA with baseline measure as a covariate showed lower levels of insomnia severity in the intervention than psychoeducation group eight weeks after randomization ($F_{1,\ 4372} = 7.9$; $p <$ .001; $\Delta = 5.0$ points; $d = 1.11$; Table 2). In terms of within-group changes, the t-test for dependent samples revealed a statistically-significant improvement in insomnia severity from pre- to post-intervention in the SleepCare group ($t(30) = 9.0$, $p < .001$, $\Delta = 7.8$ points, $d = 1.78$), also for the psychoeducation group ($t(34) = 2.5$, $p =$ .021, $\Delta = 1.1$ points, $d = 0.37$).

3.2.1. Follow-up measure

At three months, individuals in the SleepCare group reported statistically significant lower insomnia symptoms than the psychoeducation group ($F_{1,\ 109} = 4.7$; $p < .001$; $\Delta = 5.3$ points; $d = 0.97$). The t-test for dependent samples showed a statistically-significant improvement in insomnia severity to follow-up in the SleepCare group ($t(21) =$ 8.7, $p < .001$, $\Delta = 8.8$ points, $d = 1.75$), also for the psychoeducation group ($t(28) = 3.3$ $p = .004$, $\Delta = 1.9$ points, $d = 0.51$).

3.2.2. Sensitivity analyses

Sensitivity analyses for insomnia severity were conducted from various perspectives. First, effects found in the study completer sensitivity analyses were comparable to those in intention-to-treat-sample (T2: $F_{1,\ 63} = 24.5$; $p < .001$; $\Delta = 4.2$ points; $d = 0.93$; T3: $F_{1,\ 48} = 4.7$; $p < .001$; $\Delta = 5.3$ points; $d = 1.05$, see Supplement Table S3).

Second, larger effect sizes, however, were observed for intervention completers (5 of 6 completed modules), for both T2 ($F_{1,\ 50} = 17.36$; $p <$ .001; $\Delta = 5.8$ points and $d = 1.49$) and T3 ($F_{1,\ 44} = 12.75$; $p < .001$; $\Delta =$ 5.9 points, $d = 1.28$).

Third, controlling for baseline differences and for potential confounders, several ANCOVAs, including the covariates chronicity of insomnia, age, having children or children living in the same household, yield comparable results to the primary analysis.

Fourth, regarding different methods for handling missing values, we further employed mixed models analyses (O'Connell et al., 2017) instead of multiple imputations, and the results remained stable: For the primary outcome, the group × time interactions showed significance with negative coefficients at both T2 ($\beta = -5.79$, 95 % CI [-6.21, -5.37]) and T3 ($\beta = -5.93$, 95 % CI [-6.35, -5.51]), indicating decreased insomnia severity in the intervention group compared to the control group ($p < .001$; SE = 0.21).

3.2.3. Response, improvement, and deterioration rates

The SleepCare intervention demonstrated meaningful clinical efficacy across multiple response levels. For achieving slight improvement, the number needed to treat for one additional beneficial outcome (NNTB) was NNTB = 1.77 [95 % CI: 1.33–2.64], for moderate improvement NNTB = 3.58 [2.28–8.31], and for marked improvement NNTB = 3.98 [2.46–10.36]. Regarding partial or full remission, NNTB = 4.96 [2.57–71.60] and NNTB = 8.77 [3.92–10^6] were observed at post intervention respectively. Two participants in the educational group deteriorated slightly, but no participant in the intervention group did so. No moderate or severe deterioration was observed in either groups.

Results suggest that four individuals need to participate in the SleepCare training program to see one additional individual with a moderate or marked improvement in insomnia symptoms, compared to psychoeducation. For a slight improvement, two individuals are needed. Similar effects were found at 3 months follow-up (see Supplement Table 4).

3.3. Secondary outcome analysis

Statistically significant between-group differences were found for all sleep-related outcomes with largest effects for sleepiness (T2: $d = 0.64$; T3: $d = 0.81$) and pre-sleep arousal (T2: $d = 0.61$; T3: $d = 0.75$). Further effects were found for dysfunctional beliefs about sleep (T2: $d = 0.50$, T3: $d = 0.57$) and shift work disorder (T2: $d = 0.76$, T3: $d = 0.93$), both confirmed by sensitivity analysis. For other non-sleep-related clinical outcomes, no statistically significant differences between groups were observed, although descriptive statistics indicated favorable trends in the intervention group. This was the case for stress, depression, work-related rumination, work ability, effort, and reward (Table 3) in the intention-to-treat- and study completer analyses.

3.4. Cortisol

Sixty-one participants (84.4 %) provided a hair sample at baseline, versus 36 (48.6 %) post-intervention. Among 97 data points, two values (2.1 %) had to be excluded due to measurement error or improper sample handling. Overall, 34 nurses provided complete and validated hair cortisol data both pre- and post-intervention (Supplement Table S5).

Fig. 2 shows changes in cortisol over time for both groups, with 27 % lower values for the control group at baseline. Medians in the SleepCare group were 3.74 pg/mg at T1 and 2.45 pg/mg at T2, while corresponding medians in the psychoeducation group were 2.65 pg/mg and 2.45 pg/mg at T2. Wilcoxon signed-rank testing showed a statistically significant reduction in cortisol levels from pre-to-post-intervention in the SleepCare ($V = 82$, $p = .008$; $\Delta = -1.8$ pg/mg, reduction of 44 % compared to baseline), but not the education group ($V = 114$, $p = 1$; $\Delta = -0.3$ pg/mg). Comparing change scores between groups, the Mann–Whitney U test showed a marginally, but non-statistically-significant larger reduction in the intervention group ($W = 191$, $p = .055$, 95 % CI: -0.12–2.97). The effect size r (Cureton, 1956), quantifying the effect between groups, was $r = -0.32$.

3.5. Participants' satisfaction and adherence

Participants' (N = 31) overall satisfaction with SleepCare was high, with a mean satisfaction rating at T2 of 27.3 ($SD = 3.6$ range = 20–32). Detailed results for all items assessing satisfaction are summarized in Supplement Table S6. Participants completed an average of 4.5 modules (SD = 2.1), with 50 % completing all six.

4. Discussion

4.1. Principal findings

The primary aim of this study was to compare the effects of the digital intervention SleepCare to psychoeducation in nurses diagnosed with shift work sleep disorder. Results revealed a clinically meaningful and statistically significant improvement in insomnia severity with SleepCare, evident both in intention-to-treat and sensitivity analyses, with even larger effects among intervention completers. While beneficial effects were observed for all sleep-related secondary outcomes, no statistically significant between-group effects were found for other secondary outcomes, including depression and perceived stress.

Table 3
Results of analysis of covariance with between-group differences at 8 weeks post-intervention (T2) and 3 month follow-up (T3).

Outcome	Between-groups effect T2 (8 weeks)					Between-groups effect T3 (3 months)				
	Cohens' d	SEP	95 % CI	F	*p*-Value	Cohens' d	SEP	95 % CI	F	*p*-Value
Primary outcome										
Insomnia severity	1.11	0.72	0.6–1.6	7.9	<.001	0.97	0.97	0.5–1.5	4.7	<.001
Secondary outcomes										
Sleepiness	0.64	0.57	0.2–1.1	18.3	.003	0.80	0.81	0.3–1.2	9.0	.001
Pre-sleep arousal	0.61	0.95	0.2–1.1	22.1	.004	0.75	0.53	0.1–1.1	9.6	.022
Dysfunct. beliefs about sleep	0.50	0.23	0.1–1.0	48.8	.008	0.21	0.57	0.1–1.0	27.4	.006
Shift work disorder	0.76	0.29	0.1–0.9	18.8	<.001	0.93	0.93	0.4–1.4	6.6	<.001
Impact of shift work	0.46	0.97	0.1–1.0	1.2	.075	0.40	1.03	−0.1-0.9	0.4	.125
Stress	0.07	1.16	−0.4-0.5	18.4	.832	0.16	1.36	−0.3-0.6	1.8	.556
Depression	0.17	1.29	−0.3-0.6	20.9	.457	0.07	1.46	−0.4-0.5	6.1	.801
Work-related rumination	0.02	0.75	−0.4-0.5	17.2	.853	0.18	0.75	−0.3-0.6	19.8	.302
Work ability	0.03	0.05	−0.4-0.5	11.2	.908	0.01	0.40	−0.5-0.5	5.9	.970
Effort	0.45	0.21	0.1–0.9	12.4	.013	0.14	0.32	−0.3-0.6	2.7	.552
Reward	0.19	0.36	−0.3-0.7	2.6	.307	0.12	0.56	−0.4-0.6	0.2	.640

Note: intention-to-treat sample, N = 74, 95 % CI = 95 % confidence interval, SEP = standard error of the population.

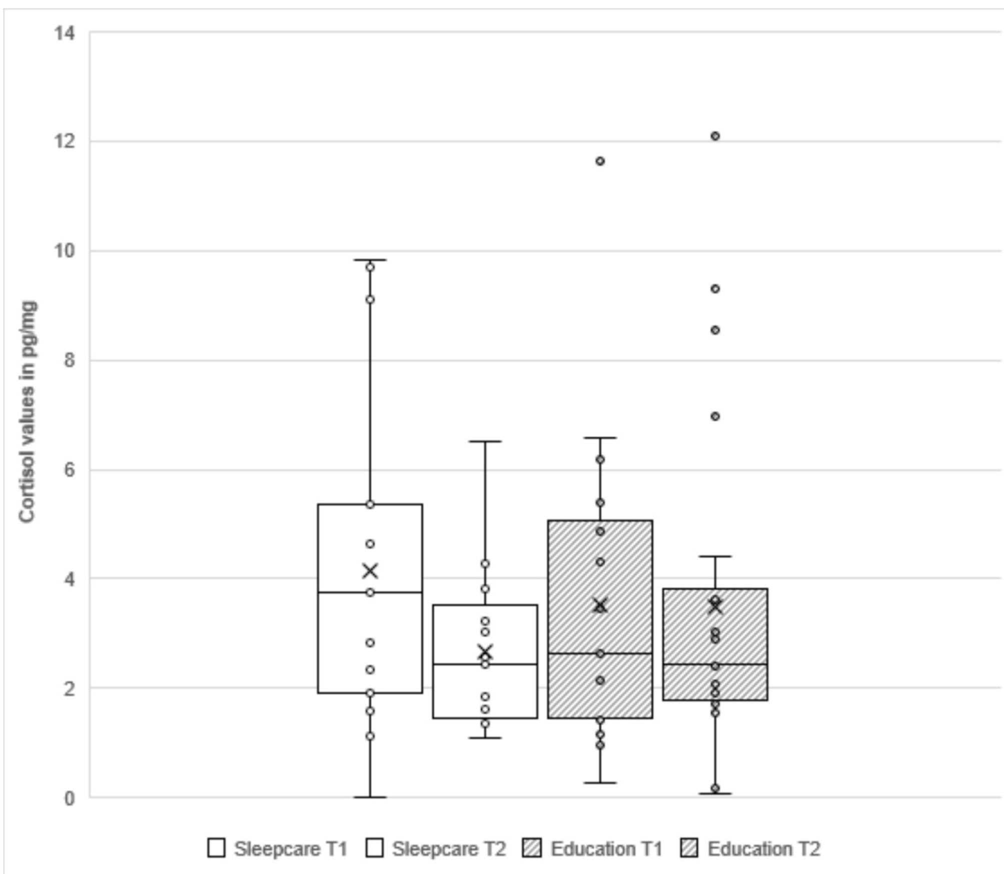

Fig. 2. Boxplots for cortisol in both groups. Data include only individuals who provided a hair sample at T1 and T2 (n = 13 in the SleepCare group and n = 21 in the education group).

4.2. Comparison with previous research

Placing these findings in context, the first key result is that the assumed clinically meaningful difference between the two interventions of 3 points on the Insomnia Severity Index was exceeded, with an observed Δ = 5 points, corresponding to an effect size $d = 1.11$. This difference surpasses the non-inferiority margin of Δ = 2 points proposed in recent literature (Benz et al., 2024), highlighting the clinical relevance of the observed improvement.

Second, these results of the present study confirm the findings of the SleepCare pilot randomized controlled trial (Ell et al., 2024), demonstrating beneficial effects on insomnia severity when compared to psychoeducation rather than non-active controls. Testing these effects in an adequately powered definitive trial is essential, as effects derived from studies with small sample sizes, such as pilot and feasibility trials, might be inflated due to sampling bias (Kühberger et al., 2014).

Third, to contextualize the study within the research literature on interventions for shift workers, despite the critical assessment of cognitive behavioral therapy for insomnia for shift workers by Reynolds et al. (2023) and Takano et al. (2023), both the pilot and current randomized controlled trial demonstrate the feasibility and effectiveness of digital therapy adapted for shift workers. A distinctive feature of our intervention was the inclusion of e-coach support through written feedback after each module, which has been uncommon in previous studies on sleep and shift work (1 of 10 studies in Reynolds et al. and 7 of 33 in Takano et al.). This additional support may have contributed to the intervention's effectiveness and high levels of satisfaction, and should be considered when comparing our results to other digital interventions, which are often delivered as self-help.

Fourth, the results are in line with prior research investigating the effectiveness of digital cognitive behavioral therapy for insomnia adapted for the general working population (Behrendt et al., 2020), employees with blurred work-life boundaries (Brückner et al., 2024), and to specific occupational groups, particularly teachers (Thiart et al., 2015).

Fifth, the observed between-group effect ($\Delta = 5$ on the Insomnia Severity Index) is consistent with results examining the effectiveness of generic online therapy on insomnia severity. Meta-analyses of digital cognitive behavioral therapy for insomnia analyzing a total of 15 and 33 randomized controlled trials respectively, identified average differences of 4.3 (Seyffert et al., 2016) and 5.0 on the Insomnia Severity Index (Soh et al., 2020) in favor of cognitive behavioral therapy for insomnia post-intervention. Comparable effects are particularly noteworthy, as most studies in these meta-analyses employed waitlist control groups, whereas the present study used publicly available psychoeducation, promoted by the respective national sleep medicine society, as a minimal intervention comparator (Heckendorf et al., 2022). This may reflect the natural help-seeking behavior of patients waiting for treatment, particularly in healthcare systems where free access to digital psychoeducation is part of public health promotion strategies (Lim et al., 2023).

Finally, these findings can also be discussed from a workplace-directed perspective. The high number of nurses experiencing effort-reward imbalance in our sample reflects the challenging working conditions faced by nurses in general (Saade et al., 2022). Notably, despite these adverse conditions, our results demonstrate that meaningful improvements in sleep can be achieved through targeted interventions, similar to findings by Nixon et al. (2022) who showed that a web-based intervention could effectively reduce stress symptoms even in employees experiencing effort-reward imbalance at work. Despite these promising effects of this worker-directed intervention, it should not be overlooked that implementing workplace-directed interventions – such as improved shift work schedules (Fox et al., 2022), promoting forward shift rotation (Di Muzio et al., 2021), and reducing adverse working conditions, such as quick returns (Vedaa et al., 2016; Hatukay et al., 2024) – could alleviate insomnia symptoms, prevent the onset of shift work sleep disorder, and even reduce the need for worker-directed interventions such as SleepCare. Shift work may serve as a valuable paradigm for the development of integrated workplace- and worker-directed interventions (Cohen et al., 2023; Rugulies et al., 2023).

Contrary to the meta-analysis by Thielecke et al. (2024), which demonstrated substantial effects of digital and worker-adapted cognitive behavioral therapy for insomnia on depression, this study found no effects on depression or its risk factors, including stress and work-related rumination. Several differences in our intervention design may account for this discrepancy. First, the present intervention primarily focused on dysfunctional beliefs about sleep as part of the cognitive component, whereas the other interventions examined by Thielecke et al. (2024) took a broader perspective by including exercises targeting the transdiagnostic risk factor of negative repetitive thinking, including metacognitive imaginations techniques or a gratitude diary (Emmons and McCullough, 2003; Wells, 2011). To maintain the overall length of the intervention, while incorporating additional therapeutic elements, future iterations could offer a more flexible, modular approach. For instance, the module addressing social factors, such as balancing sleep, work, and family time could become optional. This would allow the integration of modules targeting sleep-related and generalized repetitive negative thinking (e.g. Behrendt et al., 2020), both to reduce sleep-inhibiting arousal and the latter in addition to reduce stress and depression. Likewise, Vallières et al. (2024) concluded that interventions should specifically target "shift workers' worries rather than beliefs about sleep". Second, the present intervention placed less emphasis on fostering recreational activities to promote detachment, a worker-adapted version of antidepressant behavioral activation (Alber et al., 2023), compared to the interventions examined by Thielecke et al. (2024).

4.3. Cortisol measurement

Another aim of our study was to evaluate hair cortisol measurements as a biological measure of an internet intervention. Overall, the quality of self-collected hair samples was satisfactory, with only 2 % excluded values due to insufficient quality, comparable to findings reported by Enge et al. (2020). Baseline response rates were high, with 82 % providing hair samples shortly after personal contact with the researcher. Post-intervention, 55 % of those who completed the questionnaire submitted hair samples. This rate is considerably higher than the 23 % reported by Wekenborg et al. (2024) in an observational study using similar digital and remote data collection methods. Conversely, hair cortisol sample rates from 52 to 90 % have been reported in interventional laboratory studies involving regular contact with researchers (Botschek et al., 2023). Overall, these findings demonstrate that hair cortisol measurement can be feasibly integrated into digital intervention studies. This relatively novel method allows participants in internet interventions to maintain flexibility of time and location, reduces participation burden, and follows the biopsychosocial model for evaluating interventions. As the response rate was considerably higher after the personal telephone call with the researcher, the inclusion of an additional personal telephone call prior to the post- or follow-up intervention assessments may be a valuable strategy to reduce study dropout in future trials (Torous et al., 2020).

Regarding the intervention's effect on cortisol, the following should be considered: First, Botschek et al. (2023) noted that an intervention's effect must be strong to yield a consistent impact at a biological level. This was met in our study, as we observed substantial effects on insomnia severity. Furthermore, descriptive data and pre-post statistical comparisons, revealed that the considerable decrease in insomnia symptoms was paralleled by a statistically significant decrease in cortisol levels in the intervention group, whereas both sleep quality and cortisol remained comparably stable in the control group. These results are consistent with the assumption that cortisol indicates sleep-disruptive hyperarousal and that reducing both is essential for successful treatment (Riemann et al., 2010). It also suggests for the first time that hair cortisol not only reflects biological processes involved in the etiology of insomnia (El Mlili et al., 2021) but, potentially, successful treatment. This supports the general notion that hair cortisol may be a valuable outcome to complement patient-reported outcomes when providing or evaluating a psychological intervention (Botschek et al., 2023). Although there was a trend toward greater long-term cortisol reduction in the intervention group, this should be considered with caution. Most importantly, the cortisol analyses were likely underpowered, exacerbated by dropout and baseline differences- specifically, the education group had 27 % lower cortisol levels at baseline. Although cortisol levels were reduced by 44 % post-treatment in the intervention group and remained stable in the control group, this imbalance made it unlikely that statistically significant effects could be found. Nevertheless, this study is the first to report cortisol data in digital cognitive behavioral therapy for insomnia research on shift work sleep disorders. The change within the intervention group, in particular, may provide valuable insights for future definitive trials with cortisol as the primary outcome. Likewise, the effect sizes and attrition rates could serve as an informed estimate for future sample-size calculations and definitive trials to either confirm or reject the currently observed trend of the effect of SleepCare on hair cortisol.

4.4. Limitations

Several study limitations must be acknowledged. First, our results may not be generalizable to other shift workers, given variations in shift schedules and specific workplace conditions. Second, although meaningful effects on daytime sleepiness were observed, it cannot be concluded that the intervention increases safety for nurses and patients. To reduce the burden of participation, we did not assess accidents or treatment errors. Third, while missingness at post-intervention was low, study dropout rates were notably high in the intervention group at 3 months follow-up, a pattern observed in similar trials (Behrendt et al., 2020). Although complete-case analysis, multiple imputation and mixed models yielded comparable results, missingness limits the validity of the effects at 3 months. Fourth, the self-designed questionnaire assessing the impact of shift work of different domains of life lacks established normative data, reliability and validity statistics, which may affect the robustness of the findings. Future research on these measurement characteristics is needed to better understand the impact of shift work on different domains of life. Fifth, we were unable to verify the extent to which participants in the psychoeducation group adhered to the guidebook instructions. Sixth, a notable proportion of nurses (14 %) never initiated the intervention, despite initially expressing their intention to do so during the telephone interview. While similar non-engagement rates have been reported for other digital cognitive behavioral therapy for insomnia programs (e.g. Behrendt et al., 2020), further research is needed to understanding the underlying reasons and to develop strategies to enhance engagement.

Seventh, while data is lacking to explain the reasons for intervention dropout, substantially stronger effects were found for intervention completers, representing a best-case scenario. Thus, if the intervention is implemented in routine occupational care, it could be emphasized for motivational purposes that greater adherence is associated with better health outcomes.

Finally, although no deterioration was observed in the intervention group, potential adverse effects, such as those related to sleep restriction therapy, were not systematically measured or actively elicited. However, no adverse events were reported in communications between participants and their e-coaches.

4.5. Conclusions and future directions

In conclusion, nurses affected by shift work sleep disorder reported high satisfaction with the SleepCare intervention. Clinically meaningful effects were observed, including reduced insomnia severity, with nearly 40 % achieving remission at three months, alongside with improvement in daytime sleepiness. Patient-reported improvements in insomnia also appeared to be reflected at a biological level in hair cortisol. Future studies are needed to replicate the program's effects on long-term cortisol and should explore benefits to nurse and patient safety. When implementing SleepCare in routine care, attention must be given to comorbid depressive symptomatology, as no statistically significant effects were found for depression, work-related rumination, or stress. Additionally, workplace interventions, including improved shift schedules, remain crucial for preventing work-related sleep disorders.

CRediT authorship contribution statement

Hanna A. Brückner: Writing – review & editing, Writing – original draft, Visualization, Validation, Project administration, Methodology, Formal analysis, Data curation, Conceptualization. **Johanna Ell:** Writing – review & editing. **Lina Kalon:** Writing – review & editing, Formal analysis. **Jana Strahler:** Writing – review & editing. **Antje Ducki:** Writing – review & editing. **Dieter Riemann:** Writing – review & editing. **Claudia Buntrock:** Writing – review & editing. **Kai Spiegelhalder:** Writing – review & editing. **Dirk Lehr:** Writing – review & editing, Supervision, Resources, Methodology, Conceptualization.

Ethical statement

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008. The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional guides. The study involved human participants and was approved by the Ethics committee of Leuphana University. The ID is: EB-Antrag_202108-10-Lehr_Sleepcare.

Participants gave informed consent to participate in the study before taking part.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijnurstu.2025.105112.

Data availability

Data are available upon reasonable request: https://doi.org/10.48548/pubdata-1384. Individual participant data underlying the results reported in this article will be made available, after de-identification, to researchers who submit a methodologically-sound proposal. Those interested in further details of the analysis can contact the corresponding author.

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