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Efficacy of a Transdiagnostic Sleep and Circadian Intervention for Outpatients With Sleep Problems and Depression, Attention Deficit Disorder, or Bipolar Disorder: A Randomised Controlled Trial

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ABSTRACT

This study aimed to investigate the efficacy of a Danish adaption of a transdiagnostic sleep and circadian intervention, combining cognitive behavioural therapy for insomnia with chronotherapy. A randomised controlled trial enrolling 88 outpatients with depression, attention deficit disorder, or bipolar disorder suffering from insomnia or circadian rhythm disorders was conducted. Patients with insomnia and/or circadian rhythm disorders were randomised to either an intervention group receiving six individual sessions of a transdiagnostic sleep and circadian intervention or a control group receiving sleep hygiene education at a single session. Primary outcome was sleep quality and insomnia severity. Secondary outcomes were well-being, personal recovery, work ability, perceived overall health, sleep efficiency, sleep onset latency, wake after sleep onset, nocturnal awakenings, and sleep medication consumption. Data were collected via validated questionnaires, actigraphy, and sleep diaries, with assessments at baseline, week 2, and 6; actigraphy and sleep diaries were recorded continuously over the 6-week period. The intervention group statistically significantly improved sleep quality ($p < 0.001$), reduced insomnia severity ($p < 0.001$), and increased well-being ($p = 0.002$), personal recovery ($p = 0.037$), work ability ($p < 0.001$), and perceived overall health ($p = 0.004$) from baseline to week 6 compared to the control group. Actigraphy and sleep diary analyses revealed no statistically significant differences between the groups. In conclusion, the transdiagnostic sleep and circadian intervention was effective for both patients with insomnia and circadian rhythm disorders comorbid with depression, attention deficit disorder, or bipolar disorder. It resulted in improved sleep quality, a reduction in insomnia, and enhanced well-being, personal recovery, work ability, and overall health perception.

1 | Introduction

Sleep problems are highly prevalent in patients with mental disorders, affecting 50% across diagnoses (Roth et al. 2006). Insomnia, defined by difficulties initiating or maintaining sleep with associated daytime impairment, is observed in 32% (Seow et al. 2018). Among patients with depression, up to 90% experience low sleep quality (Tsuno et al. 2005)- Similarly, 43%–80% of adults with attention deficit disorders experience insomnia symptoms (Wynchank et al. 2017), while 80% of individuals with bipolar disorder report sleep disturbances between episodes (Harvey et al. 2005).

Insomnia negatively affects physical health (Cappuccio et al. 2011, 2010), mental health (Baglioni et al. 2011), and quality of life (Léger et al. 2012). It also has significant daytime consequences, including an increased risk of accidents, reduced work ability, and impaired daily performance (Lian et al. 2014; Walsh 2004). Furthermore, in patients with mental disorders, sleep disturbances are associated with greater symptom severity and less treatment benefits (Kallestad et al. 2012).

The relationships between insomnia and depression, attention deficit disorder, and bipolar disorder are considered bidirectional in terms of onset, course, and treatment (Baglioni et al. 2011; Geoffroy et al. 2015; Ritter et al. 2015; Sivertsen et al. 2012; Snitselaar et al. 2017; Wynchank et al. 2017). Therefore, addressing sleep problems is essential. International guidelines recommend cognitive behavioural therapy for insomnia (CBT-I) as the first-line treatment for chronic insomnia, (Edinger et al. 2021; Riemann et al. 2017, 2023). CBT-I is a multi-component treatment encompassing sleep restriction, stimulus control, sleep hygiene education, relaxation training, and cognitive methods (Baglioni et al. 2022). In patients with insomnia and comorbid mental disorders, CBT-I is effective in reducing insomnia severity (large effect size) and the comorbid disorder (medium effect size) (Hertenstein et al. 2022).

Real-life sleep problems in mental health patients are often complex, consisting of interwoven symptoms of insomnia, hypersomnia, and circadian rhythm disorders (Harvey et al. 2016). Circadian disruption, most frequently with a delayed circadian rhythm, is observed in patients with depression, attention deficit disorder, and bipolar disorder, causing daytime impairment (Bauducco et al. 2020; Harvey et al. 2005; Snitselaar et al. 2017; Takaesu 2018) and social jetlag (Foster et al. 2013), while symptoms of hypersomnia are common in bipolar disorder (Harvey et al. 2005; Meyer et al. 2020) and depression (Geoffroy et al. 2018). These complex sleep problems are addressed in a transdiagnostic sleep and circadian intervention (TranS-C) developed by Harvey and Buysse combining CBT-I with chronotherapy (light exposure and interpersonal social rhythms therapy) and motivational interviewing (Harvey and Buysse 2018). This approach provides a comprehensive treatment for insomnia, hypersomnia, and circadian rhythm disorders, and the intervention can be tailored and applied to patients across mental health disorders.

The effect of the TranS-C intervention, delivered as individual treatment, has been investigated in two randomised controlled trials (RCTs.). In an RCT from 2019 including adolescents with a broad spectrum of mental illnesses and eveningness chronotypes, significant effects were observed in sleep and circadian parameters (Harvey et al. 2018), most of which were maintained at 6-month follow-up (Dong et al. 2020) and some at 12-month follow-up (Dong et al. 2020). In an RCT from 2021, a significant effect on sleep and circadian parameters, along with improvement in psychiatric symptoms and functional impairment, was found in adult outpatients with severe mental illness and was maintained for up to 6 months of follow-up except for functional impairment (Harvey et al. 2021). In a recent RCT from 2024, a group-based version of the TranS-C intervention was investigated in adult patients with depression, where reductions in sleep and circadian disruptions, along with depressive symptoms, were found and maintained until 3 months of follow-up (Yau et al. 2024).

Despite promising results in these three studies, we need more RCTs conducted in different settings, with different outcomes and with a spectrum of disorders to establish the clinical range and efficacy of the intervention. Therefore, this study aimed to investigate the efficacy of a Danish adaptation of the TranS-C intervention, which consists of six individual sessions over 6 weeks, delivered by an interdisciplinary team. The efficacy of the TranS-C intervention was investigated in patients with insomnia and/or circadian rhythm disorders comorbid with depression, attention deficit disorder, or bipolar disorder. The primary study outcomes focused on changes in sleep. However, a range of secondary outcomes related to patients' daily (daytime) functioning was included to assess the impact of this sleep intervention on their everyday lives.

2 | Materials and Methods

The reporting of this trial adheres to the CONSORT Statement for Randomised Trials of Nonpharmacologic Treatments (Boutron et al. 2008), and the trial was performed according to the published protocol (Kragh et al. 2024).

2.1 | Study Design

This trial has a randomised, controlled, nonblinded parallel group design. It was conducted between May 2022 and May 2024 at the outpatient clinic, House of Psychiatry, organised under the Department of Affective Disorders, Aarhus University Hospital Psychiatry, Denmark. The recruited patients referred for treatment of sleep problems received concurrent treatment for their mental disorder at the referring outpatient clinic or by their general practitioner.

2.2 | The Inclusion Criteria Were

- A diagnosis of F32-33 Depressive episode, Recurrent depressive disorder, F90 Disturbance of activity and attention (ADHD, ADD), or F31 Bipolar affective disorder, according to the International Classification of Diseases, 10th version (ICD-10) (World Health 1993)
- Age ≥ 18 years

- Insomnia Severity Index (ISI) score ≥ 14
- Sleep problems for 3 months, with one or more of the following criteria fulfilled three times a week or more:
  - Sleep onset latency (SOL) ≥ 30 min
  - Wake after sleep onset (WASO) ≥ 30 min
  - Total sleep time ≥ 11 h per day
  - Displaced circadian rhythm: sleep onset earlier than 8:00 pm or later than 2:00 am
  - Irregular circadian rhythm defined by bedtime varying by ≥ 3 h throughout the week.

2.3 | The Exclusion Criteria Were

- Acutely increased suicide risk according to the Central Denmark Region's suicide risk assessment guideline
- Active substance abuse (F10–19)
- Sleep problem primarily attributed to inadequate treatment of physical diseases affecting sleep (e.g., chronic pain condition)
- Unstable social situation (e.g., homeless)
- Shift work (≥ 2 times a week for the past 2 months)
- Pregnancy and breast-feeding
- Participation in other psychiatric research interventions.

2.4 | Procedures

Patients referred for treatment of sleep problems at the House of Psychiatry were screened for inclusion and exclusion criteria during their first consultation by a research group member. Relevant, interested patients were then given thorough information about the study, orally and in writing. They were offered a 2-day reflection period before deciding whether to participate. After a research group member obtained informed consent, baseline data were collected, and patients were randomised into two parallel groups: the intervention group or the control group. The study period lasted 6 weeks, with follow-up visits scheduled at weeks 2 and 6. A window of ±7 days from the planned follow-up visits was permitted.

2.5 | Intervention Group

The intervention group received the TranS-C intervention, which consisted of six individual sessions over 6 weeks, each lasting 60 min. The sessions were conducted by a team of nurses, a physiotherapist, an occupational therapist, a mental health educator, and a psychologist. These professionals had undergone a minimum of a two-day intensive theoretical sleep course to enhance their knowledge and skills in the field of sleep. Subsequently, they received peer-to-peer training from this paper's first and second authors. The six sessions, with adjustable order and emphasis, covered the following content:

1. Anamnesis, assessment, and introduction to a sleep diary (see Data S1)
2. Introduction of behavioural elements: Sleep restriction, sleep compression, stimulus control therapy, and/or phase advance. Setting treatment goals and planning wind-down activities before bedtime, as well as invigorating activities for the morning (Harvey and Buysse 2018). Sleep restriction was applied by setting the sleep window based on self-reported total sleep time plus 30 min, with a minimum time in bed of 5 h (6.5–7 h for patients with bipolar affective disorder). The position of the sleep window was determined by patient preference, and time in bed was extended when sleep efficiency was ≥ 85%.
3. Education about normal sleep, sleep problems, and circadian rhythm. Planning how daylight (and possibly light therapy) could be integrated into daily routines. All patients were encouraged to seek light exposure in the morning as soon as possible after awakening, such as by going for a walk or drinking their morning coffee outside on the terrace or indoors near a window. Furthermore, they were provided with guidance on optimising sleep hygiene and social rhythms (Harvey and Buysse 2018)
4. Introduction of cognitive techniques (e.g., scheduled worry, gratitude diary, and behavioural experiments) (Harvey and Buysse 2018)
5. Introduction to relaxation training (e.g., progressive muscle relaxation)
6. Evaluating goals and planning for the prevention of sleep problem relapse

Between sessions, patients practised the methods introduced on their own. During the winter season, they could borrow and use a light therapy lamp with 10,000 lx white light (Uplift Technologies Inc., Dartmouth, NS, Canada). They were instructed to use the lamp in the morning for 30 min. In the summer season, they were encouraged to seek daylight in the morning. Patients received their sleep diagnoses during the sessions.

2.6 | Control Group

At baseline, control group patients received individual sleep hygiene education in a single session, during which they were presented with "10 Tips for Better Sleep" (see Data S2). They were given a flyer containing these ten tips on promoting better sleep practices. They were instructed to work independently with these tips for 6 weeks while waiting for the transdiagnostic sleep treatment. As a stand-alone intervention, sleep hygiene education has been shown not to affect insomnia (Morin et al. 1994), and it was therefore chosen as the control group intervention.

2.7 | Data Collection and Assessment

Sociodemographic variables were collected for each patient at baseline (week 0), and they completed the following questionnaires at baseline and weeks 2 and 6:

- The Pittsburgh Sleep Quality Index (PSQI) measures sleep quality (Buysse et al. 1989), with scores ranging from 0 to

21. A score of "0" indicates no difficulty, while "21" indicates severe difficulties.

- The Insomnia Severity Index (ISI) measures the subjective experience of insomnia severity, with scores ranging from 0 to 28. Higher scores indicate more severe insomnia (Bastien et al. 2001).
- The WHO-5 Well-Being Index (WHO-5) measures well-being on a scale ranging from 0 to 100. Higher scores indicate greater well-being (Bech 2004).
- The INSPIRE-O (INSPIRE) consists of five short questions that measure personal recovery on a scale, with scores ranging from 5 to 25. Higher scores indicate greater personal recovery (Moeller et al. 2024).
- The Work Ability Index (WAI) measures work ability (de Zwart et al. 2002). A score of 0 indicates the lowest likelihood of the person taking on a job, while a score of 10 indicates the highest likelihood.
- The EQ-VAS is the second part of the questionnaire EQ-5D-5L (Williams 1990), a widely used measure of health status used to compute QALYs for use in health economic analyses. The EQ-VAS consists of a visual analogue scale (VAS) on which patients rate their perceived health from 0 (worst imaginable health) to 100 (best imaginable health). The first part of EQ-5D-5L, the descriptive system, assesses health in five dimensions: mobility, self-care, usual activities, pain/discomfort, anxiety/depression. Each dimension has five responsive levels: no problems, slight problems, moderate problems, severe problems, and extreme problems/unable to perform. Only the second part of the questionnaire will be reported in this study.
- Patients wore actigraphs (Actiwatch MotionWatch 8 from CamNtech Ltd., Cambridge, UK) around the clock for all 6 weeks. They were instructed to wear the actigraph on their non-dominant wrist and to press the event marker when they intended to sleep ("lights out"). The MotionWare Software (version 1.2.28, CamNtech Ltd.) was used to analyse actigraphy data, with a 30-s epoch selected. Additionally, patients completed a sleep diary daily. Sleep efficiency (SE), SOL, WASO, and nocturnal awakenings (NWAKE) were calculated using data from both actigraphy and sleep diary entries and will be reported separately. Daytime sleep was not recorded or controlled for.
- SE is defined as total sleep time (TST) divided by time in bed (TIB)×100. In actigraphy, TST was calculated by the Motionware software, and TIB was defined as the period from when the patient pressed the event marker at "lights out" until they got out of bed (as registered in the sleep diary). If patients forgot to press the event marker, their sleep diary entry for "lights out" was used. If both entries were missing, the beginning of low activity before sleep onset was chosen. The time for getting out of bed was determined from the sleep diary entry. If this data was missing, the onset of activity after sleep offset was used instead. In the sleep diary, SE was calculated using the TST and TIB data recorded by the patient.
- SOL is the time from lights out to first sleep onset. In actigraphy, SOL was calculated based on the patient's event mark for "lights out" and the first sleep onset measured by the Motionware software. In sleep diaries, SOL was calculated based on the patient's registered "lights out" and falling asleep time.
- In actigraphy, WASO is the total time awake between initial sleep onset and the final morning awakening in minutes. In sleep diaries, patients reported how long their nocturnal awakenings lasted.
- NWAKE is reported by measurements from actigraphy referred to as numbers of "wake bouts" per night. In sleep diaries, patients estimated their number of NWAKEs.

Regular use of sleep aid medication (melatonin, promethazine, zolpidem, zopiclone) was assessed using records from the electronic health system, while *pro re nata* (PRN) medication use was tracked through sleep medication entries in the sleep diaries. Quetiapine consumption was included in the analyses because most patients used it as a sleeping aid.

Data was entered and securely stored in the Research Electronic Data Capture (REDCap) (Harris et al. 2009).

2.8 | Outcomes

2.8.1 | Primary Outcomes

Changes in sleep quality (PSQI) and insomnia severity (ISI) assessed at weeks 2 and 6.

2.8.2 | Secondary Outcomes

Changes in well-being (WHO-5), level of personal recovery (INSPIRE), work ability (WAI), overall health perception (EQ-VAS), SE, SOL, WASO, NWAKE (actigraphy, sleep diaries), and consumption of regular and PRN sleep medication (electronic health record, sleep diaries) in weeks 2 and 6.

The nighttime sleep frame in actigraphy and sleep diary data was defined as the sleep period occurring during a 16-h night interval (from 20:00 h to 11:59 h). Sleep periods starting and ending between 12.00 and 19.59 were excluded.

2.9 | Randomization

Patients were randomised into the two study groups in a 1:1 ratio using blocks randomization with varying block sizes of 4, 6, and 8. An independent service provider set up randomization in REDCap. A research group member was informed about the allocation when pressing the randomization button in REDCap, and then patients were introduced to either the intervention or control group. Blinding of allocation was not possible due to the nature of the intervention.

2.10 | Sample Size

The power calculation was performed based on the results of a similar study (Dong et al. 2020), with PSQI as a secondary

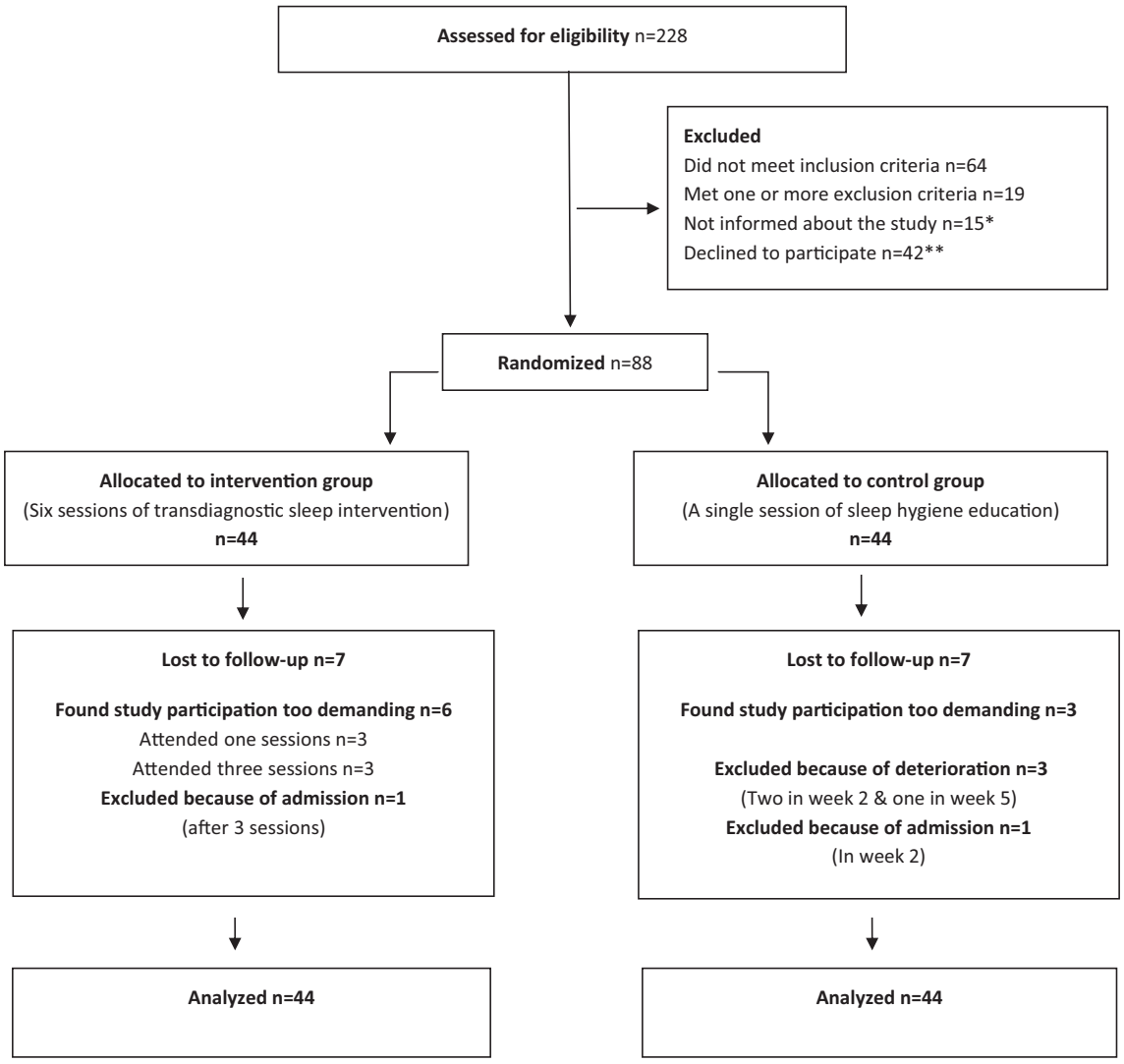
outcome, using an average effect size of 0.67. Assuming a power of 0.80, a significance level of 0.05, an expected effect size of 0.67, and a dropout rate of 25%, a sample size of $n = 44$ was calculated for each group. The expected dropout rate was based on previous experiences from a pilot project ($n = 55$) (Kragh 2021). Therefore, a total of 88 patients were included in the study.

2.11 | Statistical Methods

Baseline sociodemographic and outcome measures for all participants, stratified by intervention and control group, were described using proportions/median, and means.

The intent-to-treat method was used to examine outcome changes from baseline to weeks 2 and 6 using a linear mixed effects (LME) model with time and treatment effects as fixed effects. The LME model compared measurement differences between the intervention and control groups over time. This method is recommended for longitudinal data with missing data (Kuznetsova et al. 2017). The mixed-effects model was specified in terms of the interaction effect between time and treatment group. Outcome measures from baseline up to six were included in the model. The *p*-values from the model indicate the difference between the two treatment groups per time unit increment, conditional on the average time and treatment effect. Given the presence of repeated measures per individual and the aim to generalise beyond the sample, a model with a random intercept was fitted to account for individual differences. A random slope was not included.

The level of statistical significance was set at 0.05. Statistical analyses were performed using the statistical software R, version 4.3.1.



*Were not informed about the study to; had previously received the transdiagnostic sleep intervention (n=5), had a massive history of non-attendance (n= 9), no available researcher present at the time of referral (n=1).

** Declined due to; risk of being allocated to control group (n=12), sensitive skin, patients not wanting to wear an actigraph (n=6), timing of social events (n=4), lack of energy and somatic conditions (n=10), not stated (n=10).

FIGURE 1 | Patient recruitment and flow.

TABLE 1 | Sociodemographics and clinical variables for all participants and the control and intervention group.

Characteristics	All	Group		
		Control	Intervention	
	n = 88	*n* = 44	*n* = 44	*p*
Sociodemographics				0.660
Gender, *n* (%)				
Female	55 (62.5)	26 (59.1)	29 (65.9)	
Male	33 (37.5)	18 (40.9)	15 (34.1)	
Age				0.410
Median (IQR)	27 (24;34)	26 (24;34)	27 (23;34)	
Civil status, *n* (%)				0.243
Married/cohabiting	25 (28.4)	14 (31.8)	11 (25.0)	
Living alone	32 (36.4)	13 (29.5)	19 (43.2)	
Living at home	13 (14.8)	5 (11.4)	8 (18.2)	
Cohabiting w/roomie(s)	18 (20.5)	12 (27.3)	6 (13.6)	
Education, *n* (%)				1.000
Primary school/high school/technical education	47 (53.4)	23 (52.3)	24 (54.5)	
Short/intermediate/longer higher education	41 (46.6)	21 (47.7)	20 (45.5)	
Employment, *n* (%)				0.911
Student	11 (12.5)	—	—	
Part-time/full-time employee/flexjob[c]	12 (13.6)	5 (11.4)	7 (15.9)	
Sick leave/unemployed/internship	56 (63.6)	28 (63.6)	28 (63.6)	
Retirement/early retirement/cash benefits	9 (10.2)	—	—	
Alcohol[a], *n* (%)				—
< 10 units/week	79 (92.9)	—	—	
> 10 units/week	6 (7.1)	—	—	
Smoking[b], *n* (%)				0.187
Yes/sometimes	27 (31.0)	17 (38.6)	10 (23.3)	
No	60 (69.0)	27 (61.4)	33 (76.7)	
Clinical measures				
A diagnosis, *n* (%)				0.505
Bipolar affective disorder	13 (14.8)	5 (11.4)	8 (18.2)	
Depression	59 (67.0)	32 (72.7)	27 (61.4)	
ADHD + ADD	16 (18.2)	7 (15.9)	9 (20.5)	
Sleep diagnosis[d], *n* (%)				0.355
F51.0 (Nonorg. insomnia)	21 (23.9)	12 (27.3)	9 (20.5)	
F51.03 (Psychophysiological insomnia)	—	—	—	
F51.05 (Insomnia due to other mental disorder)	38 (43.2)	16 (36.4)	22 (50.0)	
F51.10 (Nonorg. Hypersomnia)	—	—	—	
F51.20/F51.23 (Nonorg. disorder of sleep–wake schedule/due to delayed sleep time)	21 (23.9)	12 (27.3)	9 (20.5)	

(Continues)

TABLE 1 | (Continued)

Characteristics	All	Group		
		Control	Intervention	
	n = 88	*n* = 44	*n* = 44	*p*
Duration of sleep problem				0.432
< 2 years	24 (27.3)	9 (20.5)	15 (34.1)	
2–6 years	14 (15.9)	9 (20.5)	5 (11.4)	
7–10 years	13 (14.8)	7 (15.9)	6 (13.6)	
11–40 years	37 (42.0)	19 (43.2)	18 (40.9)	
Regular medication				
Antidepressants[e]	66 (75.0)	34 (77.3)	32 (72.7)	0.806
Sleep aid medication[f]	24 (27.3)	16 (36.4)	8 (18.2)	0.094
Mood stabilisers[g]	10 (11.4)	5 (11.4)	5 (11.4)	1.000
Antipsychotics[h]	9 (10.2)	—	—	—
Medicine for ADHD[i]	21 (23.9)	9 (20.5)	12 (27.3)	0.617
Anxiety[j]	13 (14.8)	8 (18.2)	5 (11.4)	0.548

Note: '—' indicates microdata (observations < 5).
[a] $n = 85$.
[b] $n = 87$.
[c] Employment benefits for people with reduced work capacity.
[d] At the end of treatment (week 6).
[e] Agomelatin, amitriptyline, citalopram, clomipramine, duloxetine, escitalopram, mirtazapine, nortriptyline, sertraline, venlafaxine, vortioxetine.
[f] Melatonin, promethazine, zolpidem, zopiclone.
[g] Lamotrigine, lithium citrate, lithium carbonate.
[h] Olanzapine, aripiprazole, clozapine, quetiapine.
[i] Lisdexamfetamine, methylphenidate, dexamphetamine, atomoxetine.
[j] Pregabalin, oxazepam.

2.12 | Ethics

The trial was conducted following the Declaration of Helsinki—Ethical Principles for Medical Research Involving Human Subjects. The study was approved by the Ethics Committee of the Central Denmark Region, record number 1-10-72-38-22. The project complies with the General Data Protection Regulation and is registered in the internal record of research projects kept by the Central Denmark Region, record number 1-16-02-151-22. Furthermore, the study is registered with ClinicalTrials.gov, Identifier: NCT05406414.

3 | Results

3.1 | Patient Flow

In total, 228 patients were referred to sleep treatment at the House of Psychiatry between May 2022 and May 2024. After screening, 145 patients fulfilled the inclusion criteria, 42 declined to participate, 15 were not asked, and 88 were ultimately included (Figure 1). They were randomised into the intervention group ($n = 44$) and the control group ($n = 44$). Fourteen patients were excluded or lost to follow-up during the study period, with seven patients from each group, resulting in a dropout rate of 16% for both groups. In the intervention group, six patients were lost to follow-up because they found participation too demanding, and one was excluded due to hospital admission. In the control group, three patients were lost to follow-up because they found participation too demanding. Lost to follow up means both from treatment and outcome reporting. Three were excluded because of mental health deterioration, and one was excluded due to hospitalisation. Table 1 shows the sociodemographic variables, clinical measures, and regular medication. No significant differences between the groups were found. Most patients (67%) had depression, and the most common sleep diagnosis was F51.05, Insomnia due to other mental disorders. A total of 18 patients used a light therapy lamp.

3.2 | Outcome Measures From Questionaries

Sleep quality improved statistically significantly more in the intervention group than in the control group from baseline to week 2 and week 6, as measured by PSQI. The estimated mean PSQI score in the intervention group decreased from 13.7 (CI 12.8;14.7) to 9.1 (CI 8.1;10.2) while in the control group it decreased from 13.3 (CI 12.3;14.2) to 12.4 (CI 11.4;13.5) ($p < 0.001$) (Table 2, Figure 2). The estimated mean ISI score in the intervention group decreased from 19.3 (CI 18.2;20.5) to 10.1 (CI 8.9;11.4) and in the control group it decreased from 18.7 (CI 17.5;19.8) to 16.9 (CI 15.6;18.1) ($p < 0.001$). Additionally, the intervention group demonstrated a statistically significantly higher increase in well-being, personal recovery, work ability, and overall health perception than the control group from baseline to week 6 (Table 2, Figure 2).

TABLE 2 | Estimated means for the pittsburgh sleep quality index (PSQI), insomnia severity index (ISI), WHO-5 well-being index (WHO-5), INSPIRE-O (INSPIRE), work ability index (WAI), and EQ-5D-5L scores based on the linear mixed effects model with time × treatment effect for week 0, 2, 6[a].

Scores	Intervention	p[b]	Control	p[b]	p[c]
PSQI					
Baseline	13.7 (12.8;14.7)		13.3 (12.3;14.2)		
2 weeks	11.2 (10.2;12.2)	< 0.001[b]	11.9 (10.9;12.9)	0.001[b]	0.065
6 weeks	9.1 (8.1;10.2)	< 0.001[b]	12.4 (11.4;13.5)	0.063	< 0.001[b]
ISI					
Baseline	19.3 (18.2;20.5)		18.7 (17.5;19.8)		
2 weeks	14.2 (13.0;15.4)	< 0.001[b]	16.5 (15.4;17.7)	0.001[b]	0.001[b]
6 weeks	10.1 (8.9;11.4)	< 0.001[b]	16.9 (15.6;18.1)	0.004[b]	< 0.001[b]
WHO-5					
Baseline	30.5 (25.2;35.7)		31.5 (26.3;36.8)		
2 weeks	40.0 (34.7;45.4)	< 0.001[b]	35.7 (30.3;41.0)	0.104	0.125
6 weeks	47.8 (42.2;53.3)	< 0.001[b]	37.1 (31.6;42.6)	0.033[b]	0.002[b]
INSPIRE					
Baseline	45.5 (40.2;50.7)		47.7 (42.4;52.9)		
2 weeks	46.1 (40.8;51.5)	0.749	48.5 (43.2;53.9)	0.676	0.945
6 weeks	53.0 (47.5;58.4)	0.001[b]	48.8 (43.4;54.3)	0.592	0.037[b]
WAI					
Baseline	3.5 (2.8;4.1)		3.7 (3.0;4.3)		
2 weeks	4.2 (3.6;4.9)	0.003[b]	3.7 (3.1;4.4)	0.846	0.049[b]
6 weeks	5.3 (4.6;6.0)	< 0.001[b]	4.0 (3.3;4.6)	0.269	< 0.001[b]
EQ VAS[d]					
Baseline	49.3 (43.0;55.7)		48.8 (42.5;55.2)		
2 weeks	56.3 (49.8;62.8)	0.01[b]	49.7 (43.2;56.2)	0.744	0.106
6 weeks	61.3 (54.6;68.0)	< 0.001[b]	49.4 (42.8;56.1)	0.834	0.004[b]

[a]$p < 0.05$ indicates significance how the two treatment groups diverge with the progression of time based on the linear mixed effects model and is marked with[b].
[b]Significance from baseline with the progression of time.
[c]Significance between intervention and control with the progression of time.
[d]EQ VAS is the second part of the questionnaire EQ-5D-5L. On a 0–100 scale, patients are asked to indicate their overall health on the day of questionnaire completion, from 0 (the worst imaginable health) to 100 (the best imaginable health).

3.3 | Outcome Measures From Sleep Diaries and Actigraphy

Sleep diary data showed statistically significant reductions in WASO and SOL and an increase in SE in the intervention group from week 1 to weeks 2 and 6 (Table 3). In the control group, WASO statistically significantly decreased and SE increased from week 1 to week 2, with SE also increasing at week 6. Actigraphy data showed statistically significant reductions in WASO and NWAKE from week 1 to week 2 and week 6. In the control group, the only statistically significant finding was a reduction in SOL from week 1 to week 2. No statistically significant between-group differences were found in WASO, NWAKE, SOL, and SE in either the sleep diary or actigraphy data.

In actigraphy, TIB was scored by the first author and STK. Inter-rater reliability was assessed on ten scorings using the intraclass correlation coefficient, showing 95% agreement.

3.4 | Regular and PRN Sleeping Aid Medication Consumption

Due to the small sample size in the available data for regular and PRN sleep aid medication, statistical analyses could not be performed. In total, 26 patients were prescribed regular sleep aid medication (see Table 1). They were prescribed the following medication: melatonin ($n = 24$), zopiclone ($n = 1$), promethazine ($n = 1$) and quetiapine ($n = 6$). The number of patients prescribed PRN sleep aid medication was as follows:

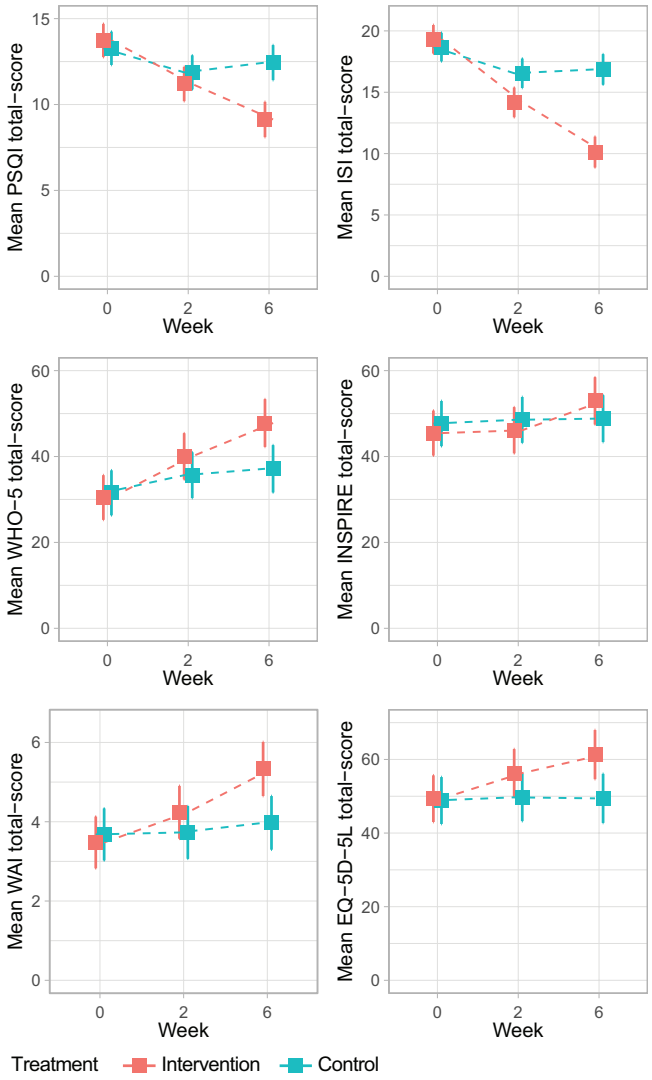


FIGURE 2 | Estimated means and 95%-confidence intervals for the pittsburgh sleep quality index (PSQI), insomnia severity index (ISI), WHO-5 well-being index (WHO-5), INSPIRE-O (INSPIRE) and work ability index (WAI) scores based on the linear mixed effects model with time × treatment effect (red: Intervention, blue: Control) for week 0, 2, 6.

melatonin ($n = 11$), zolpidem ($n = 9$), zopiclone ($n = 1$) and quetiapine ($n = 9$).

3.5 | Adverse Effects

Patients in the intervention group were asked about possible adverse effects related to the intervention at follow-up visits in weeks 2 and 6. They reported fatigue ($n = 21$ in week 2, $n = 7$ in week 6), headache ($n = 7$ in week 2, $n = 7$ in week 6), inner turmoil ($n = 8$ in week 2, $n = 5$ in week 6), and irritated eyes with the use of light therapy ($n = 7$ in week 2).

4 | Discussion

This study aimed to investigate the efficacy of a Danish adaptation of the TranS-C intervention for patients with sleep problems comorbid with depression, attention deficit disorder, or bipolar disorder. We found that the intervention significantly improved patients' sleep quality, reduced insomnia severity, and increased their well-being, personal recovery, work ability, and overall health perception. No statistically significant between-group differences were found in objective or subjective SE, SOL, WASO, or NWAKE data obtained from actigraphy and sleep diary data.

The positive effect on subjective sleep parameters (sleep quality and insomnia severity) aligns with findings from three RCTs using TranS-C (Harvey et al. 2018, 2016; Yau et al. 2024) and several RCTs investigating CBT-I efficacy for insomnia comorbid with mental health disorders (Hertenstein et al. 2022). The transdiagnostic approach may offer advantages over diagnosis-specific CBT-I manuals by addressing a broader range of sleep problems beyond just insomnia. Additionally, the intervention elements can be tailored to individual patients' needs, meeting patient demands for personalised treatment (Kristiansen et al. 2024).

By the end of the intervention, patients reported increased well-being, personal recovery, work ability, and overall health perception. A meta-analysis of CBT-I found only small to moderate effects on daytime symptoms, possibly becauseCBT-I does not directly target daytime symptoms (Benz et al. 2020). The meta-analysis concluded that future studies may benefit from incorporating therapeutic techniques that more directly address daytime symptoms (Benz et al. 2020). In our study, elements from social rhythms therapy, advancing circadian rhythms, and light therapy (natural or artificial) were added to CBT-I, which may have enhanced its efficacy in treating daytime symptoms. However, we did not investigate this, making it a relevant topic for future research.

No statistically significant between-group differences were found in SE, SOL, WASO, and NWAKE. Some of these sleep parameters also improved in the control group, and the sample size may have been too small to detect between-group differences. In a comparable but larger RCT ($n = 121$), significant differences were found in sleep diary data, while actigraphy data showed only one significant difference related to variability in waking activity count (Harvey et al. 2021). Furthermore, these outcome measures might not be ideal for measuring sleep improvements in this study design, which addressed symptoms of insomnia, hypersomnia, and circadian disorders. Adding circadian outcome measures would have been beneficial.

A strength of the study is that it was conducted within an existing clinical treatment program, enhancing its external validity and the generalisability of the study results. However, we have a fairly young study population compared to patients in mental health services in general because we included a part of our patients from a Unit for Young people with Depression (patients aged 18–25 years) in the House of Psychiatry. The study has several other limitations. Mental health outcomes were not assessed, and no follow-up was conducted after the intervention. Additionally, since the RCT was embedded within a clinical sleep treatment program (Kragh 2021), treatment had to be offered to all participants. Although a six-week wait for the control group was deemed acceptable, a longer delay of 3–6 months was not considered feasible. Furthermore, the control group received substantially less therapist contact (six

TABLE 3 | Sleep diary and actigraphy. Estimated means and 95%-confidence intervals for the sleep measures; sleep efficiency (SE), sleep onset latency (SOL), wake after sleep onset (WASO), and nocturnal awakenings (NWAKE) based on the linear mixed effects model with time × treatment effect (all) for week 1, 2, 6[a].

Sleep measures	Intervention	p[b]	Control	p[b]	p[c]
Sleep diary					
SE					
Week 1	72.6 (67.8;77.4)		72.2 (67.2;77.2)		
Week 2	78.0 (73.1;82.8)	0.001[b]	77.1 (72.0;82.2)	0.005[b]	0.835
Week 6	78.1 (73.2;82.9)	0.001[b]	76.4 (71.3;81.5)	0.016[b]	0.589
SOL					
Week 1	68.0 (54.9;81.1)		66.9 (53.5;80.4)		
Week 2	48.2 (34.8;61.6)	0.005[b]	62.6 (48.8;76.4)	0.545	0.124
Week 6	48.1 (34.7;61.5)	0.005[b]	54.0 (39.9;68.1)	0.080	0.492
WASO					
Week 1	41.6 (28.7;54.5)		32.6 (19.5;45.7)		
Week 2	29.4 (16.4;42.5)	0.014[b]	20.6 (7.2;33.9)	0.018[b]	0.984
Week 6	29.2 (16.3;42.1)	0.011[b]	26.1 (12.7;39.4)	0.201	0.402
NWAKE					
Week 1	1.8 (1.3;2.3)		1.6 (1.2;2.1)		
Week 2	1.7 (1.2;2.1)	0.419	1.4 (0.9;1.9)	0.135	0.592
Week 6	1.6 (1.2;2.1)	0.218	1.5 (1.1;2.0)	0.514	0.714
Actigraphy					
SE					
Week 1	73.5 (70.9;76.1)		73.2 (70.5;75.8)		
Week 2	74.7 (72.0;77.4)	0.174	74.8 (72.1;77.5)	0.060	0.714
Week 6	75.2 (72.5;77.9)	0.052	73.9 (71.2;76.7)	0.380	0.458
SOL					
Week 1	35.8 (28.0;43.6)		34.7 (26.8;42.7)		
Week 2	30.8 (22.7;38.8)	0.183	25.9 (17.9;34.0)	0.019[b]	0.472
Week 6	29.6 (21.6;37.7)	0.101	28.7 (20.5;36.9)	0.117	0.978
WASO					
Week 1	101.3 (90.0;112.5)		104.5 (93.2;115.9)		
Week 2	92.1 (80.7;103.6)	0.031[b]	99.8 (88.3;111.3)	0.258	0.459
Week 6	88.2 (76.7;99.6)	0.002[b]	102.2 (90.6;113.9)	0.593	0.074
NWAKE					
Week 1	43.3 (39.6;47.1)		47.9 (44.1;51.7)		
Week 2	40.5 (36.7;44.4)	0.046[b]	45.8 (41.9;49.6)	0.125	0.733
Week 6	40.3 (36.5;44.2)	0.031[b]	46.9 (43.0;50.8)	0.472	0.316

[a]$p < 0.05$ indicates significance in how the two treatment groups diverge with the progression of time based on the linear mixed effects model and is marked with[b].
[b]Significance from baseline with the progression of time.
[c]Significance between intervention and control with the progression of time.

sessions vs. one session), which is a potential confounding factor. Finally, only the intervention group was asked about adverse events, whereas both groups should have been included to allow for a proper comparison. It is quite possible that fatigue, headache, inner turmoil, and other symptoms also occurred in the control group.

5 | Conclusion

The transdiagnostic sleep intervention was effective in outpatients with sleep problems comorbid with depression, attention deficit disorder, or bipolar disorder. Sleep quality improved, insomnia severity decreased, and patients' well-being, personal recovery, work ability, and overall health perception improved.

6 | Perspectives

Hopefully, these positive results can help promote further implementation of non-pharmacological sleep treatment services. This RCT study was incorporated into an existing, well-established treatment program. However, a current challenge in European healthcare is the limited implementation of CBT-I, which restricts access to evidence-based treatment for individuals with insomnia (Riemann et al. 2023). Most research on the effects of non-pharmacological sleep intervention is conducted in outpatient settings, but the lack of treatment opportunities is also well documented in hospital settings (Schneider et al. 2023). We previously conducted a pilot study to investigate the feasibility of the TranS-C intervention in hospitalised patients and concluded that a shorter intervention was needed. A potential future research project could involve testing an adapted version of the TranS-C intervention and assessing its effect in a RCT study with hospitalised patients. A study like this, along with similar upcoming studies (Schneider et al. 2020; Sheaves et al. 2018) could strengthen the knowledge of transdiagnostic, non-pharmacological sleep treatments for patients with mental disorders.

Author Contributions

Mette Kragh: conceptualization, investigation, funding acquisition, writing – original draft, methodology, validation, project administration, visualization, writing – review and editing, data curation, supervision, resources. **Henny Dyrberg:** conceptualization, investigation, funding acquisition, supervision, methodology, resources, writing – original draft. **Sanne Toft Kristiansen:** conceptualization, supervision, methodology, funding acquisition, validation, data curation, writing – original draft. **Maria Speed:** software, formal analysis, data curation, conceptualization, supervision, methodology, validation, visualization, funding acquisition, writing – original draft. **Pernille Pedersen:** conceptualization, funding acquisition, supervision, methodology, writing – original draft. **Klaus Martiny:** conceptualization, methodology, supervision, funding acquisition, writing – original draft.

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Ethics Statement

The study was approved by the Ethics Committee of the Central Denmark Region, record number 1-10-72-38-22.

Consent

Full informed consent was obtained from all study participants before enrollment in the trial.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

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

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Supporting Information

Additional supporting information can be found online in the Supporting Information section.