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REVIEW

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The management of sleep disturbances in children with attention-deficit/hyperactivity disorder (ADHD): an update of the literature

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ABSTRACT

Introduction: Sleep disorders represent an important comorbidity in individuals with ADHD. While the links between ADHD and sleep disturbances have been extensively investigated, research on the management of sleep disorders in individuals with ADHD is relatively limited, albeit expanding.

Areas covered: The authors searched PubMed, Medline, PsycInfo, Embase+Embase Classic, Web of Sciences databases, and clinicaltrials.gov up to 4 January 2024, for randomized controlled trials (RCTs) of any intervention for sleep disorders associated with ADHD. They retained 16 RCTs (eight on pharmacological and eight on non-pharmacological interventions), supporting behavioral intervention and melatonin, and nine ongoing RCTs registered on clinicaltrials.gov.

Expert opinion: The pool of RCTs testing interventions for sleep disorders in individuals with ADHD is expanding. However, to inform clinical guidelines, there is a need for additional research in several areas, including 1) RCTs based on a precise phenotyping of sleep disorders; 2) pragmatic RCTs recruiting neurodevelopmental populations representative of those seen in clinical services; 3) trials testing alternative interventions (e.g. suvorexant or light therapy) or ways to deliver them (e.g. online); 4) sequential and longer-term RCTs; 5) studies testing the impact of sleep interventions on outcomes other than sleep; 6) and implementation of advanced evidence synthesis and precision medicine approaches.

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KEYWORDS
Sleep; insomnia; ADHD; randomized; treatment

1. Introduction

Attention-deficit/hyperactivity disorder (ADHD) is the most common neurodevelopmental disorder, affecting around 5% of school age children [1] and at least 2.5% of adults [2] worldwide. ADHD is defined by a persistent pattern of impairing and developmentally inappropriate symptoms of inattention and/or hyperactivity/impulsivity [3–5]. If untreated, ADHD increases the risk of a series of negative outcomes, including impaired school, emotional and social functioning, lower quality of life, as well as increased risk of accidental injuries, substance misuse, criminal acts, premature death, and suicide [6].

ADHD results in substantial societal costs, with excess cost attributable to ADHD of $122.8 billion ($14,092 per adult) in the U.S.A. [7] and similar burden in other countries. For instance, in Australia, total social and economic cost of ADHD in 2018–2019 have been estimated at $12.76 billion, with productivity costs making up 81% of the total financial cost, followed by deadweight losses (11%), and health system costs (4%) [8]. Furthermore, a systematic review found that health system costs were higher in children with ($722–$11 555 per patient) than in those without ADHD ($179-$3646), including direct medical cost ($5319 for children with compared with $1152 for those without ADHD).

ADHD is highly comorbid with other disorders. One of the most frequently comorbid disorders are sleep disorders, alongside other neurodevelopmental disorders, as well as oppositional defiant, conduct, mood, anxiety, substance use disorders.

Clinicians have been familiar with the relationship between ADHD and sleep problems for a long time. In 1957, Laufer and

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Article highlights

- The association between ADHD and sleep disturbances has been extensively investigated
- Research on the management of sleep disorders in individuals with ADHD is limited
- To date, 16 randomized controlled trials (RCTs) on the treatment of sleep disturbances in ADHD have been published
- Evidence supports behavioral interventions and melatonin
- Other types of non-pharmacological and pharmacological treatments are currently not supported by strong evidence.

This box summarizes key points contained in the article.

Denhoff [9] stated that "*Generally, the parents of hyperkinetic children* [who would currently be referred to as children with ADHD] *are so desperate over the night problems that the daytime ones pale in significance*." By contrast, research on this relationship has historically lagged behind, as reflected in the lack of focus on sleep in previous classification systems and clinical guidelines for the diagnosis and management of ADHD. For instance, whilst 'restless sleep' was listed among the symptoms for diagnosing ADHD in the DSM-III (1980) [10], it was then removed in DSM-III-R (1987) [11] and there was no mention of sleep in the DSM-IV(TR) ADHD criteria [12,13]. Likewise, previous clinical guidelines/guidance documents, such as the 2007 ADHD Practice Parameters of the American Academy of Child and Adolescent Psychiatry (AACAP) [14], overlooked the association between ADHD and sleep problems. However, over the past 15 years or so there has been an exponential rise in empirical studies demonstrating a link between ADHD and sleep, and the relevance of assessing sleep in individuals with ADHD has been highlighted in more recent classification systems (e.g. DSM-5) and guidelines, e.g. the 2019 guidelines of the American Pediatric Association (APA) [15]. Importantly, key ADHD guidelines do to generally include specific recommendations on the treatment of comorbid sleep disorders. Importantly, a large body of evidence has been statistically pooled in several meta-analyses, confirming the cross-sectional association between ADHD and alterations in subjective as well as, to a less extent, objective sleep parameters (e.g [16,17]).

A recent study [18] leveraging data from the Swedish registries found that among individuals with ADHD ($N = 145\,490$, 2.25% of the total cohort), 7.5% had a diagnosis of a sleep disorder diagnosis, and 47.5% had been prescribed a pharmacological treatment for sleep.

While the association between ADHD and sleep disorders is well established and supported by meta-analytic evidence, the body of research on the management of sleep disorders in individuals with ADHD is more limited, albeit growing.

In 2013, a group of North American experts in ADHD and sleep published a guidance paper [19] proving recommendations for the management of sleep disorders in children and adolescents with ADHD. The recommendations were based on a total of 139 original articles on sleep and childhood ADHD, including 22 on treatment of sleep disturbances. However, at the time, the number of randomized controlled trials (RCTs) was limited: two RCTs [20,21] of melatonin for sleep onset delay and one RCT [22] of L-Dopa for restless legs syndrome (RLS). Two ongoing RCTs [23,24] of behavioral intervention were also identified. Based on this body of evidence and on clinical expertise, the group concluded that 1) behavioral interventions should be considered as first-line treatment of insomnia, although further evidence from randomized controlled trials (RCTs) was needed to prove their efficacy in ADHD; 2) in terms of pharmacological treatments, RCTs support the use of melatonin to reduce sleep-onset delay, whereas there was more limited evidence for other medications.

Since then, additional RCTs have been published. Here, we reviewed the available body of RCTs that may inform clinical decision-making for the management of sleep disorders in individuals with ADHD.

2. Methods

Even though this article was not originally intended as a systematic review with a formal appraisal of the level of evidence, we conducted a comprehensive search in PubMed, Ovid databases (Medline, PsycInfo, Embase +Embase Classic) and Web of Sciences databases, up to NaN Invalid Date , with no limitations in terms of language. We used the following search terms and syntax (adapted for each electronic database): (ADHD or attention-deficit or attention deficit or attention-deficit hyperactivity disorder or hyperkinetic syndrome or hyperkinetic disorder) AND (sleep or insomnia) AND (random* or trial* or RCT). We retained RCTs, regardless the level of blinding, of any intervention (pharmacological or non-pharmacological) for the management of sleep disorders (any) in individuals (any age) with a formal diagnosis of ADHD and any sleep disorder. We also searched clinicaltrials.gov, using the terms ADHD and (insomnia or sleep) for any RCT not captured by the search in the electronic databases.

3. Review of the evidence

From a pool of 3253 potentially eligible references retrieved from the electronic databases, we retained 16 RCTs, reported in 25 references. The full lists of included and excluded studies, after checking the full text (with reasons for exclusion), are reported in Appendix 1 and 2, respectively. The search in clinicaltrials.gov found: nine RCTs with no results available (in children: NCT03263156: parent-based sleep intervention; NCT02871674: behavioral sleep intervention; NCT04723719: blended CBT; NCT06007742: pediatric tuina (body massage); NCT04180189: weighted blanket; NCT00566371 and NCT00252278: atomoxetine; NCT01393574: melatonin vs methylphenidate in adults: NCT03015636: adjusted CBT-i); one RCT with results but not statistics available (NCT02638168: evening dose of methylphenidate); and one RCT that was terminated (original enrollment estimated: $n = 40$; actual enrollment: $n = 29$) (the study is also reported in [25]).

Figure 1 summarizes the screening process. Tables 1 and 2 report the key characteristics of RCTs (retrieved by electronic databases) of pharmacological and non-pharmacological treatments, respectively.

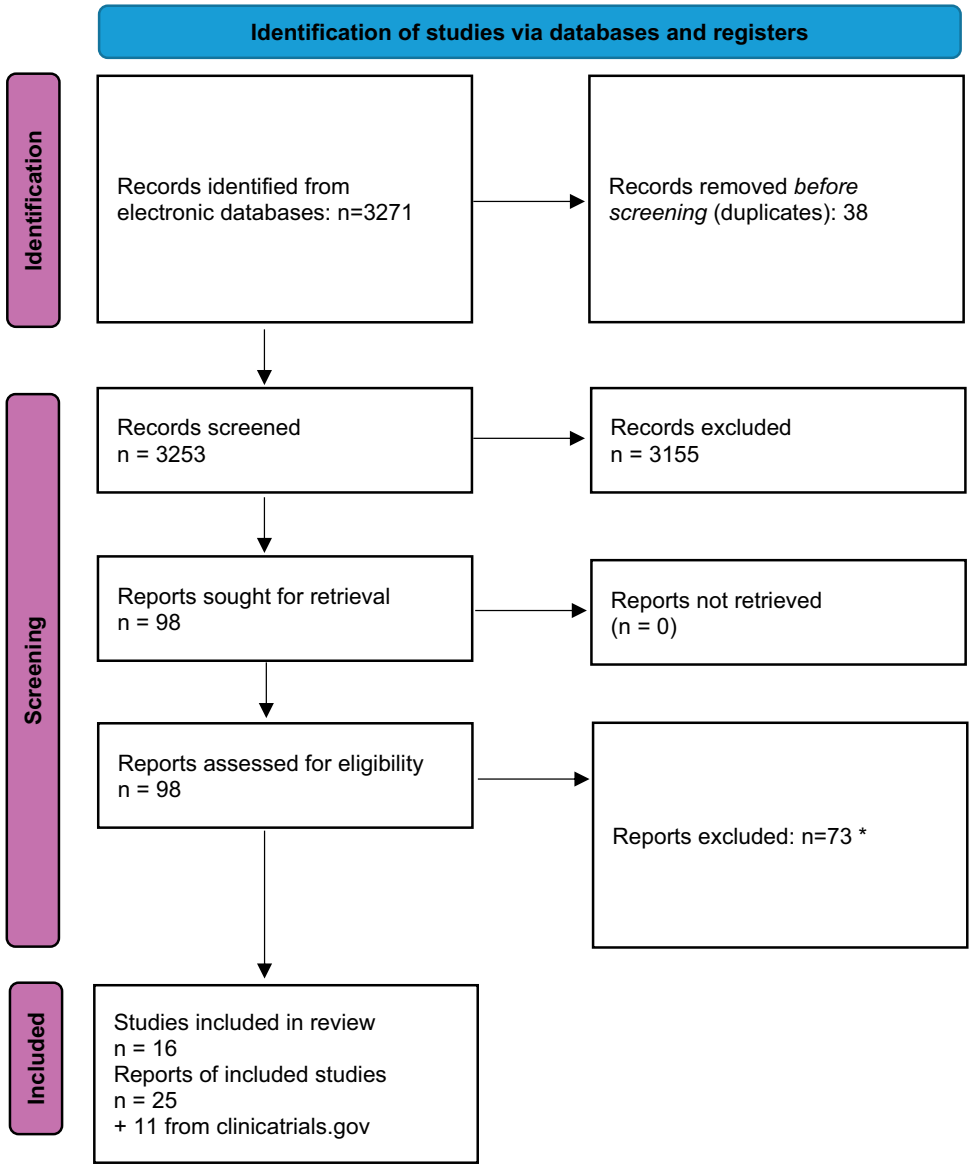


Figure 1. Flow diagram of the selection process of the articles included in the review.
*See Appendix 2 for a comprehensive list of reasons for exclusion.

3.1. Pharmacological treatments

Eight RCTs focused on pharmacological treatments. Among these, we identified two positive (i.e. with significant results in the primary outcomes favoring the active treatment) RCTs of melatonin immediate (rather than extended) release in children and adolescents. Primary outcomes were actigraphy-derived sleep onset, total time asleep, and salivary dim light melatonin onset in the first RCT [20]; and mean sleep-onset latency, SOL, recorded on sleep diary in the second [21]. An RCT in adults showed that both melatonin and melatonin plus bright light therapy, unlike placebo control, were efficacious in advancing dim light melatonin onset [26]. Another RCT [27] in adults showed that ramelteon was efficacious in maintaining an earlier sleep/wake cycle in adults with ADHD and circadian rhythm sleep disorder but had paradoxical fragmenting effects on sleep and exacerbated daytime sleepiness. A trial in children found L-dopa improved Restless Legs Syndrome/Periodic Limb Movements in Sleep (RLS/PLMS) symptoms severity compared with placebo, but had no significant effect on other sleep parameters [22]. In their RCT in children, Ashkenasi et al. [28] noted a marginally significant trend toward better sleep quality with longer patch wear times of methylphenidate. Finally, we found two negative (i.e. with negative results on the primary outcome) RCTs in children on the primary outcome, for eszopiclone [29] and zolpidem [30], both in terms of reduction in latency to persistent sleep measured by polysomnography.

3.2. Non-pharmacological interventions

Among the RCTs identified on non-pharmacological interventions, two [31,32] (from the same group in Australia) reported that behavioral sleep interventions (sleep hygiene practices and standardized behavioral strategies), delivered in two fortnightly consultations, were more effective than usual care in reducing

Table 1. Key characteristics of RCTs of pharmacological interventions for sleep disorders/disturbance in individuals with ADHD (listed in alphabetical order by study first author).

First author, year	Age	Sleep disorder/ disturbance	Active intervention/duration	Control	Sample size	Outcomes (sleep-related)	Key findings
Ashkenasi, 2011 [28]	Mean age (SD) Sequence 1: 9.8 (1.8) y Sequence 2: 9.6 (1.8) y Sequence 3: 7.5 (2.4) y Sequence 4: 10.3 (1.8) y	Difficulty sleeping (as reported by the caregiver)	Transdermal methylphenidate patch to one of four groups with different sequences of patch application times for 4 weeks in each group	Same treatment at different sequences	Total sample: 26 Sequence 1: 6 Sequence 2: 9 Sequence 3: 4 Sequence 4: 7	*Primary outcomes*: Sleep latency (mean change in parent-reported sleep diary, Monday through Sunday of every week). *Secondary outcomes*: Total sleep time, sleep quality (mean change in parent-reported sleep diary Monday through Sunday of every week)	*Primary outcome*: No significant effects of patch wear time ($F(1, 233) = 0.34$, $p = 0.558$) *Secondary outcomes*: No significant effect on total sleep time ($F(1, 323) = 0.77$, $p = 0.382$) Marginally significant trend toward better sleep quality at longer patch wear times ($F(1,341) = 3.60$, $p = 0.059$)
Blumer, 2009 [30]	6–17 y	Insomnia	Zolpidem (0.25 mg/kg/day, to a maximum of 10 mg/ day), 6 weeks	Placebo	201 (zolpidem: 136; placebo: 65)	*Primary outcome*: Latency to persistent sleep (LPS) (PSG) *Secondary outcomes*: Clinical global impression (CGI)-I and CGI-S child scores CGI-I and CGI-S parent/guardian scores PSG variables (WASO, NAASO, TST) Safety assessment: next-day residual effects by using the Pediatric Daytime Sleepiness Scale. Rebound effects (actigraphically measured LPS and TS)	*Primary outcome*: No significant difference between treatment groups in LPS at week 4 (LS mean reduction from baseline: −20.28 minutes with zolpidem and −21.27 minutes with placebo) *Secondary outcomes*: No significant difference in Sleep efficiency, WASO and NAASO on baseline-adjusted mean changes at week 4 Greater improvement in the zolpidem group at week 4, on CGI-I and CGI-S child score (LS mean difference: 0.4 [95% CI: 0.05–0.85] and −0.64, [95% CI: −1.095 to −0.187]) CGI-S parent/guardian scores (LS mean difference: −0.55 [95% CI: −1.010 to −0.088]) but not CGI-I improved with zolpidem No rebound phenomena after treatment discontinuation 7.4% of patients discontinued zolpidem treatment due to adverse events
England, 2011 [22]	7–12 y	PLMS/RLS (in subsample)	Carbidopa/L-DOPA (250–600 mg) for 8–13 weeks	Placebo	29 with ADHD- 16 with ADHD +RLS/PLMS	PSG parameters Periodic Limb Movements in Sleep (PLMS) (using EMG) PLMS index (mean change of # PLMS/h of sleep) RLS symptoms (diagnostic criteria IRLSSG and rating scale)	L-DOPA improved RLS/PLMS symptoms severity compared with placebo ($p = .007$) L-Dopa had no significant effects on any other sleep parameters In a subsample analysis (Ferri et al. 2013), L-DOPA significantly reduced only sleep latency (Wilcoxon test: $p < 0.01$). No significant effect on any other sleep parameter

(*Continued*)

Table 1. (Continued).

First author, year	Age	Sleep disorder/ disturbance	Active intervention/duration	Control	Sample size	Outcomes (sleep-related)	Key findings
Fargason, 2011 [27]	19–65 y	Insomnia subtypes: Primary Insomnia; Circadian Rhythm Sleep Disorder, Delayed sleep phase type	Ramelteon, 8 mg/day, for 2 weeks	Placebo	Total, $n = 36$	Wrist actigraphic measures: Total sleep time, sleep start and end times, sleep onset latency, sleep fragmentation, and sleep efficiency Subjective measures: daytime sleepiness (mean change of the Epworth Sleepiness Scale (EES) Sleep quality (mean change of the Pittsburgh Sleep Quality Index (PSQI) and a Sleep-wake Diary)	Wrist actigraphic measures: Significant main effect of ramelteon ($F_{1,15} = 4.7$, $p = 0.046$). Mid-sleep time occurred 46 min earlier vs placebo Ramelteon induced a 7-min phase advance on average (mean ± SD: 7.0 ± 32.3 min). Placebo induced a 39-min phase delay on average (mean± SD: 39.2 ± 44.6 min). Ramelteon marginally, but significantly increased the sleep fragmentation score (ANCOVA, $F_{1,20}$ 6.9, $p = 0.016$) Subjective measurements Unexpected significantly higher ESS scores during ramelteon treatment vs placebo (p _> 0.017) Results on PSQI and sleep diary not reported
Sangal, 2014 [29]	Total sample Age range: 6–17 y High dose Mean age (SD): 11.3 (3.0) y Low dose Mean age (SD): 11.4 (3.0) y Placebo Mean age (SD): 11.6 (3.0) y	Insomnia	Eszopiclone high dose: 2 mg for children aged 6–11 y, 3 mg for adolescents aged 12–17 y low dose: 1 mg for children aged 6–11 y, 2 mg for adolescents aged 12–17 y for 12 weeks (+12-month open label safety study)	Placebo	High dose: $n = 160$ Low dose: $n = 163$	Primary outcome: Objective sleep parameter (reduction in latency to persistent sleep, PSG) Secondary outcomes: other PSG and actigraphy outcomes subjective sleep parameters (patient/parent reports, Pediatric Daytime Sleepiness Scale) change in daytime functioning and behavior (CGI-improvement score for insomnia) – Safety evaluations	Treatment-emergent AEs reported by 61.0%, 59.5%, and 46.0% of patients receiving high-dose eszopiclone, low-dose eszopiclone, and placebo, respectively
Van Andel, 2022 [26] (PhASE study)	Mean age (SD): 29.53 (8.66) y	Delayed sleep phase syndrome	Melatonin (MEL) 0.5 mg/day Melatonin 0.5 mg/day plus bright light therapy (MEL+ BLT) for 3 weeks	Placebo	Toral; $n = 51$ MEL: 17 MEL+BLT: 15	Primary outcome: Dim light melatonin onset (DLMO) Secondary outcome: Sleep Diagnosis List (SDL), Dutch version of the Sleep Disorders Questionnaire (SDQ)	Fist endpoint (directly after treatment): MEL advanced DLMO by 1 h 28 min ($p = .001$), and MEL plus BLT by 1h58 ($p < .001$). Placebo did not affect DLMO Two weeks after end of treatment, DLMO returned to baseline levels
Van der Heijden, 2007 [20]	Total sample Age range: 6–12 y Melatonin group Mean age (SD): 9.1(2.3) y Placebo group Mean age (SD): 9.3(1.8) y	Chronic sleep-onset insomnia	Melatonin (3 or 6 mg/day) for 4 weeks	Placebo	Total, $n = 105$	*Primary outcomes*: actigraphy-derived sleep onset, total time asleep, and salivary dim light melatonin onset (DLMO) *Secondary outcomes*: Other objective and subjective measures of sleep (actigraphy data; sleep-log data) Adverse effects recording	Sleep onset advanced by 26.9 (SD: 47.8) minutes with melatonin; delayed by 10.5 (SD: 37.4) min with placebo ($p < .0001$). Advance in dim light melatonin onset of 44.4 (SD: 67.9) min with melatonin and delay of 12.8 (SD: 60.0) min with placebo ($p < .0001$). Total time asleep increased with melatonin (19.8, SD 61.9 min) vs placebo (−13.6, SD 50.6 minutes; $p = .01$). No adverse events

(*Continued*)

Table 1. (Continued).

First author, year	Age	Sleep disorder/ disturbance	Active intervention/duration	Control	Sample size	Outcomes (sleep-related)	Key findings
Weiss, 2006 [21]	Mean age: 10.29 (range 6.5 to 14.7) y	Initial insomnia	Melatonin	Placebo	Total, $n = 19$	*Primary outcome*: Mean sleep-onset latency, SOL (recorded on somnolog) Secondary outcomes: night-to-night variability in SOL and total sleep duration on somnolog; actigraphy: mean SOL, night-to-night variability in SOL, total sleep duration Clinical Global Impression-Improvement (CGI-I) (including sleep) Safety evaluation	*Primary outcome* SOL on placebo : 62.1 min (SD = 26.6) versus 46.4 min for melatonin ($p < 0.05$) (effect size: 0.6, 95% CI not reported) *Secondary*: Melatonin superior to placebo on actigraphic measurement of SOL ($p < 0.01$) More time asleep (15.0 minutes) during melatonin treatment ($p < 0.01$) on somnolog. No significant differences in other measures No serious adverse events; no clinically significant changes in vital signs or abnormalities on physical examination

NAASO: number of awakenings after sleep onset; PSG: polysomnography; SD: standard deviation; TST: total sleep time; WASO; wakefulness after sleep onset.

the proportion of children with moderate-to-severe sleep problems, as rated by parents/caregivers. Additional analyses of [31] showed that this behavioral sleep intervention was also effective at the 12-month evaluation [33] and in a subsample of children with ADHD and comorbid autism [34]. Another Canadian RCT in children [35] confirmed the superiority of a behavioral sleep distance intervention (Better nights/better days), delivered via written manual with telephone support by a paraprofessional coach, compared to wait list, in reducing Children Sleep Habit Questionnaire (CSHQ) scores. Behavioral sleep parent training was also found more efficacious in reducing bedtime resistance, compared to nonintervention and treatment as usual, respectively, in two other RCTs in children [36,37]. Shokravi et al. reported that an educational program (a sleep hygiene training session, 135 min) coupled with an educational package on sleep was superior to usual care in reducing CSHQ scores for bedtime resistance, sleep onset delay, sleep duration, sleep anxiety, and daytime sleepiness sub-scales [38]. We also found an RCT in children [39] showing that weighted blankets had a significantly more positive effect than light control blankets on total sleep time (Cohen's d = 0.24), sleep efficiency (d = 0.23) and wake after sleep onset (d = −0.27), but not on sleep-onset latency. Finally, Yazdanbakhsh et al. [40] reported that response inhibition cognitive rehabilitation using the Captain's Log MindPower builder was more efficacious, compared to no therapy, in reducing sleep disturbance severity in children with ADHD.

4. Expert opinion

Over the past decade, there has been a gradual increase in the number of RCTs informing the clinical management of sleep disorders in individuals with ADHD. Currently, there is evidence, replicated in at least one additional trial (from a different research group) supporting the use of melatonin for the short-term (within weeks) management of sleep onset delay in children with ADHD; and the use of behavioral therapies for insomnia (difficulties falling asleep, maintaining sleep, and early morning awakenings) in the short and medium term (within months). Additional RCTs testing cognitive-behavioral strategies are ongoing (three RCTs identified on clinicaltrials.gov).

However, the current body of evidence has limitations and, consequently, there is a need for future clinical research addressing several deficits. First, while some RCTs (e.g. [22]) have performed an accurate phenotyping of the sleep disorder, others have included children with ADHD and 'sleep problems' as reported by parents on sleep rating scale (e.g. [2]), or have conflated several types of sleep disorders (e.g. [31]). As highlighted in a seminal paper by Owens [41] (Figure 2), an accurate and precise phenotyping and differential diagnosis are key to stratify the treatment according to the specific type of sleep problems. Thus, future RCTs should recruit participants who have been accurately assessed in terms of specific sleep disorders. Additionally, and on a related vein, in some clinical cases the management of the sleep problem may be addressed by simply modifying the dosing or the timing of the pharmacological treatment of ADHD, rather than implementing a specific treatment. We are therefore looking with interest to the results of an ongoing trial (NCT02638168) testing the effects of an evening dose of methylphenidate. If proven beneficial to reduce hyperactivity at night, and hence favoring

Table 2. Key characteristics of RCTs of non-pharmacological interventions for sleep disorders/disturbance in individuals with ADHD (listed in alphabetical order by study first author).

First author, year	Age	Sleep disorder/disturbance	Active intervention/duration	Control	Sample size	Outcomes (sleep-related)	Key findings
Corkum, 2016 [35]	Mean age in months (SD) Intervention arm: 108.0 (23.65) Waitlist arm: 110.60 (23.72)	Insomnia	Behavioral sleep distance intervention, delivered via written manual with telephone support by a paraprofessional coach (Better nights/better days). Five-session manual and weekly telephone coach support for 2 months (follow-up at 6 months)	Wait list	Total $n = 61$ ($n = 31$: active intervention; $n = 31$ wait list)	*Primary outcomes*: Score on the Children's Sleep Habits Questionnaire, (CSHQ) *Secondary outcomes* Sleep diary Actigraphy variables	Primary outcome: Active intervention significantly better than WL on all the CSHQ subscales (sleep onset, $p = 0.01$; bedtime resistance, $p = 0.01$; sleep duration, $p = 0.04$; total sleep disturbance, $p < 0.01$) Secondary outcomes: improved sleep onset ($p = 0.017$, but not sleep duration ($p = 0.30$), on actigraphy Results on sleep diary measures not provided
Hiscock, 2015 [31]	Mean age (SD) 10.3 (1.8) y active group 9.9 (2.1) y control	Parent reported moderate to severe sleep problems; American Academy of Sleep Medicine diagnostic criteria for at least one sleep disorder or anxiety leading to insomnia	Behavioral sleep intervention (Sleep hygiene practices and standardized behavioral strategies); two fortnightly consultations	Usual clinical care	Total: $n = 244$ ($n = 122$: active intervention; $n = 122$ usual care)	(Primary outcome: (ADHD symptoms) *Secondary outcomes*: Primary caregiver report of child sleep problems over past four weeks (none, mild, moderate, or severe) Children's sleep habits questionnaire Actigraphy	Children in the active treatment group: fewer moderate-severe sleep problems at three months (56% *v* 30%; aOR; 0.30, 95% CI 0.16–0.59; $p < 0.001$) and six months (46% *v* 34%; 0.58, 0.32–1.0; $p = 0.07$). At 3 months: reduction in absolute risk of 25.7%, with an estimated NNT = 3.9. At 6 months: NNT = 7.8. At 3 and 6 months: intervention Children: greater reduction in sleep difficulties on the children's sleep habits questionnaire (ES: −0.8 and − 0.6, respectively) Actigraphy collected in a sample ($n = 54$). At 3 and 6 months sleep duration per night: increased in the intervention group (mean difference: 10.9 minutes, 95% CI: −19.0 to 40.8, ES 0.2 and 9.9 minutes, −16.3 to 36.1, effect size 0.3, respectively

(*Continued*)

Table 2. (Continued).

First author, year	Age	Sleep disorder/disturbance	Active intervention/duration	Control	Sample size	Outcomes (sleep-related)	Key findings
Hiscock, 2019 [32]	Mean age (SD) 9.6 (1.7) y active 9.4 (1.8) y control	Parent report of a moderate/severe sleep problem meeting criteria for American Academy of Sleep Medicine criteria for chronic insomnia disorder, delayed sleep – wake phase disorder, or were experiencing sleep-related anxiety	Behavioral sleep intervention (Sleep hygiene practices and standardized behavioral strategies) Tow face-to-face, 2 weeks	Usual clinical care	Total $n = 361$ n = 183 active intervention n = 178 usual care	*Primary outcome*: sleep problem at 3 and 6 months (good agreement with Children's Sleep Habits Questionnaire) *Secondary outcomes*: at 3 and 6 months: Sleep difficulties (Children's Sleep Habits Questionnaire)	Primary: Proportion of children with moderate to severe sleep problems: lower in the intervention (28.0%, 35.8%) compared with usual care group (55.4%, 60.1%; 3-month: risk ratio (RR): 0.51, 95% CI 0.37, 0.70, $p < .001$; 6-month: RR: 0.58; 95% CI 0.45, 0.76, $p < .001$). Secondary: Intervention children had improvements across multiple Children's Sleep Habits Questionnaire subscales at 3 and 6 months.
Lönn, 2023 [39]	Mean age (SD) 9.5 (2.4) y active 9.4 (2.1) y control	Parent reported sleep problems verified by three selected questions from the CSHQ: sleep initiation (>20 min, 3–7 days per week), sleep maintenance (waking up several times per night, 3–7 days per week), and sleep duration (sleep too little, 3–7 days per week).	Weighted blankets (WBs) 4 + 4 weeks	Lighter control blankets (CBs)	Total; $n = 94$ Active: $n = 46$ Control: $n = 48$	*Primary outcomes*: Actigraph measures Sleep-onset latency (SOL); wake after sleep onset (WASO); total sleep time (TST); sleep efficiency (SE) *Secondary outcomes*: subjectively measured sleep CSHQ -parent-reported Insomnia Severity Index (ISI) child-reported	Weighted blankets: significant effect on total sleep time (mean diff. 7.72 min, p = 0.027, Cohen's d = 0.24), sleep efficiency (mean diff. 0.82%, $p =$ 0.038, Cohen's d = 0.23) and wake after sleep onset (mean diff. −2.79 min, $p = 0.015$, Cohen's d = −0.27), but not on sleep-onset latency ($p = 0.432$)
Mehri, 2020 [36]	7.55 (0.99) intervention 6–9 year 10.87 (0.83) intervention 9–12 year 7.65 (1.11) Control 6–9 year 10.20 (0.44) Control 9–12 year	At least one problem in sleeping, based on parents' reports using the Children's Sleep Habits Questionnaire (CSHQ)	Behavioral parental training (BPT) for 5 weeks	No intervention	Total: $n = 56$ Active: $n = 28$ Control: $n = 28$	Children's sleep habits questionnaire (CSHQ) immediately after the intervention, and two months after the intervention	Immediately after the intervention, bedtime resistance in the intervention group: statistically significantly lower than the control group ($p = 0.03$). Two months after intervention problems in sleep duration ($p =$ 0.01) and total sleep score ($p = 0.03$) in the intervention group was statistically significantly lower than the control group
Papadopoulos, 2019 [34] (subsample of Hiscock, 2015 [31] in children with ADHD and autism)	Total sample Age range: 5 to 13 years old Intervention group Mean age (SD): 9.8 (2.0) years Usual care group Mean age (SD): 10.3 (1.7) years	Sleep onset association disorder, limit setting disorder, delayed sleep phase, insomnia, and/or experiencing significant night time anxiety	Brief Behavioral Sleep intervention, consisting of two face-to-face sleep consultations and a follow-up phone call with a trained clinician, each 2 weeks apart	Usual care	Total: $n = 61$ Active: $n = 28$ Control: $n = 33$	*Primary outcomes* Child sleep problems (mean change in Child Sleep Habits Questionnaire at 3 and 6 months post randomization) Secondary outcomes: No sleep measures	At 3 months post-randomization: compared with families receiving usual care, families in the intervention group reported a greater decrease in child sleep problems (ES =−0.7, $p = 0.02$) No significant difference 6 months post-randomization (ES = −0.5, $p = 0.08$)

(*Continued*)

Table 2. (Continued).

First author, year	Age	Sleep disorder/disturbance	Active intervention/duration	Control	Sample size	Outcomes (sleep-related)	Key findings
Sciberras, 2020 [33] (12-month outcome analyses of Hiscock, 2015)	Age range: 5–12 y	Sleep onset association disorder, limit setting disorder, delayed sleep phase, insomnia, night time anxiety	Two face-to-face sessions intervention (covering sleep hygiene and standardized behavioral strategies)	Usual care	Total: $n = 144$ Active: $n = 122$ Control: $n = 122$	CSHQ Question" Has your child's sleep been a problem for you over the past 4 weeks?'"	Intervention children had lower total scores on the CSHQ compared to the usual care children (Adjusted mean difference, MD − 1.9; 95% CI − 3.5 to −0.4; $p = 0.02$; Cohen's d: −0.2) at 12 months. Intervention children had fewer sleep onset delay (AMD −0.3; 95% CI − 0.5 to − 0.1; $p = 0.002$; d: −0.4), and night waking difficulties (AMD −0.4; 95% CI −0.8 to − 0.01; $p = 0.04$; d: −0.2) on the CSHQ
Shah, 2023 [37]	Mean = 10.66 y, range 8 − 12 y	Score on CSHQ > 41	Behavioral Sleep Intervention Module (Three techniques: sleep hygiene, faded bedtime with response cost, and graduated extinction) for 12 weeks (+Methylphenidate (10 − 30 mg))	Treatment as usual (Methylphenidate (10 − 30 mg) for at least three months)	Total: $n = 100$ Active: $n = 50$ Control: $n = 50$	CHSQ: Bedtime Resistance, Sleep Onset Delay, Sleep Duration, Sleep Anxiety, Night Waking, Parasomnias, Sleep-Disordered Breathing, and Daytime Sleepiness	Significant improvement in interventional group in "duration of sleep ($p = 0.006$), daytime sleepiness ($p = 0.012$), total score ($p = 0.000$), parasomnias ($p = 0.005$), and sleep disordered breathing ($p = 0.010$)." No significant difference on "night awakenings ($p = 0.027$)
Shokravi, 2016 [38]	Age range: 7 to 13 years Mean age (SD): 8.62 (1.57) years	Bedtime resistance, Sleep onset latency, sleep duration, Sleep anxiety, sleep waking, parasomnias, Sleep breathing disorder, Daytime sleepiness	Educational program (a sleep hygiene training session, 135 min) + Educational package (booklet about sleep health, visual schedules or to-do-lists and stickers, Incentive awards for the children) + two follow-up telephone calls	Usual care	Total: $n = 62$ Active: $n = 28$ Control: $n = 28$	Child sleep problems (mean change in Child Sleep Habits Questionnaire) two months after intervention	Compared with control children, experimental children had a significant- reduction in mean scores of Bedtime resistance ($p < 0.05$), Sleep onset delay ($p < 0.05$), Sleep duration ($p < 0.05$), Sleep anxiety ($p < 0.05$), Daytime sleepiness ($p < 0.05$) and total score of CSHQ ($p < 0.05$)
Yazdanbakhsh, 2018 [40]	Total sample Age range: 7 to 12 years old Cognitive rehabilitation group Mean age (SD): 9.0 (1.70) y Control group Mean age (SD): 9.0(1.56) y	Sleep problems	Response inhibition cognitive rehabilitation using the Captain's Log MindPower builder (2014 version) individually for 12 sessions (two 1-hour sessions per week)	No therapy	Total: $n = 20$ Active: $n = 10$ Control: $n = 10$	Improvement in quality of sleep (measured using Pittsburgh Sleep Quality)	Mean score of the experimental group was reduced from 6.20 to 2.40 for sleep disorders. Cognitive rehabilitation of response inhibition was effective in Improving the quality of sleep (P < 0.001)

CSHQ: Children Sleep Habit Questionnaire; NNT: number needed to treat.

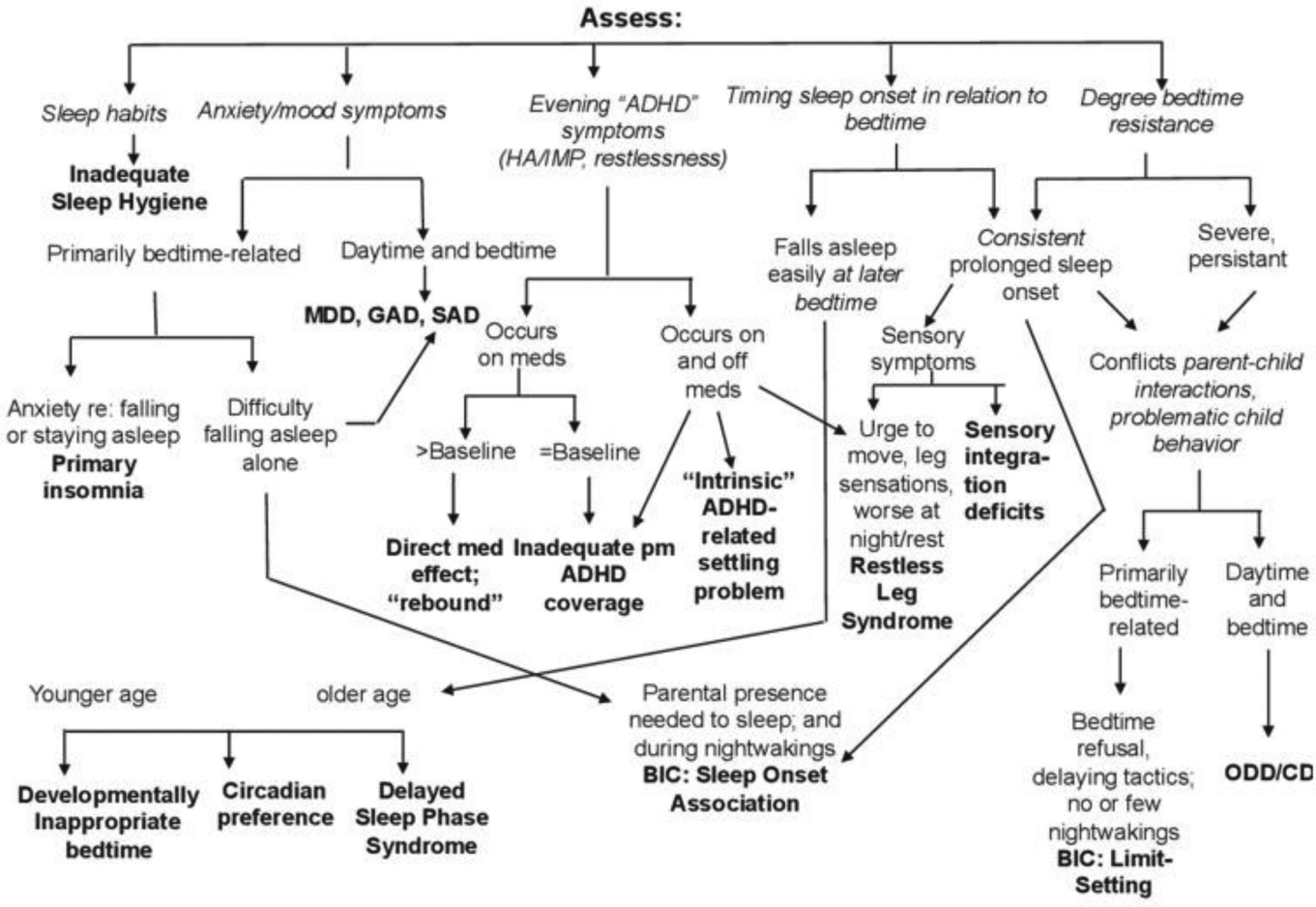


Figure 2. Management of sleep disturbance in individuals with ADHD. * reproduced from [41] with permission of the journal of the Canadian Academy of child & adolescent psychiatry published by the Canadian Academy of child and adolescent psychiatry (CACAP).

*Epilepsy should also be considered as possible differential diagnosis or comorbidity that may underpin sleep problems.

sleep onset, the results of this trial – when replicated in other studies with similar design – would have important implications for clinical practice. In fact, many clinicians systematically refrain from prescribing evening doses of stimulant, due to concerns that sleep onset may be negatively impacted.

Second, while the present review has focused on RCTs of individuals with ADHD only, arguably clinical services are seeing an increase in children diagnosed with multiple neurodevelopmental conditions, such as ADHD co-occurring with autism and/or intellectual disability. Of note, we found only one sub-analysis [34] of an RCT [31] focusing on participants with comorbid ADHD and autism. Future pragmatic RCTs enrolling more representative populations of children with neurodevelopmental conditions are therefore needed.

Third, while a quite broad range of interventions have been assessed, there is certainly scope for exploring other treatments. In terms of pharmacological interventions, to our knowledge (based on our additional search in clinicaltrials.gov), suvorexant, a dual orexin receptor antagonist approved by the FDA for the treatment of insomnia in adults [42], has not been tested yet in children with ADHD. As non-pharmacological option, we found only one study on bright light therapy (combined with melatonin) in adults with ADHD [26], and we look forward to RCTs of light therapy specifically in children.

Fourth, there is also a need to assess alternative ways of designing and delivering existing interventions. In particular, given practical and financial constraints of implementing face-to-face behavioral interventions for parents of children with ADHD and sleep disorders, there is a need to test the effectiveness and cost-effectiveness of online interventions. Furthermore, among the included studies, we could not find evidence of involvement of people with lived experience in designing the intervention strategies (pharmacological and non-pharmacological). In this regard, an example of a relevant development is represented by the Digital Sleep Support for Children with Attention Deficit Hyperactivity Disorder (DISCA) study [43]. This is an ongoing multicenter RCT across the UK that aims to develop and test the clinical and cost-effectiveness of a digital behavioral intervention, co-designed with expert parents and carers with lived experience, to address chronic insomnia in children with ADHD. Other promising developments in the field are represented by the use of Sleep Tracking Devices, or Virtual Reality (VR) and Augmented Reality (AR) Based Therapies.

Fifth, while the present review focused on sleep outcomes, several trials also assessed the impact of sleep interventions on ADHD core symptoms or other relevant outcomes, such as quality of life, with mixed findings. For instance, some RCTs (e.g. [31]) reported that behavioral interventions also improved non-sleep-

related outcomes, while an RCT of melatonin [20] failed to find effects beyond sleep onset delay. Future studies should consistently assess the impact of treatment type and duration on non-sleep-related outcomes. Furthermore, given the proven causal role of sleep disturbance in contributing to ADHD symptoms [44], it would be important to test whether treatment of sleep disorders in early childhood could reduce the chances of developing ADHD in preschoolers with ADHD traits.

Sixth, currently available RCTs have tested interventions in isolation, except for one RCT testing melatonin after failure of sleep hygiene-based strategies [21]. Testing sequential interventions (first pharmacological and then non-pharmacological treatments, or vice versa) will be crucial to inform future clinical guidelines.

Seventh, whereas current RCTs, in particular those of pharmacological treatments, focus on the short term (few weeks), evidence on the efficacy/effectiveness, cost-effectiveness and safety/tolerability in the longer term is needed. While long-term placebo-controlled trials are ethically and parametrically challenging, withdrawal RCTs (where participants who have been treated for months/years with an active treatment are randomized to continue active treatment or to placebo) may be an alternative option and should be encouraged in the field.

Once a larger body of RCTs becomes available, it will be possible to pool studies in large meta-analyses. Until now, only one meta-analysis [45] focused exclusively on RCTs of interventions for ADHD but it could only include the two RCTs of melatonin mentioned above. A larger number of studies also allow the field to compare the efficacy and tolerability of various interventions by means of network meta-analyses (NMA). Under certain assumptions that can be statistically tested, these allow the comparison of two or more treatments, even when they have not been compared head-to-head. Notably, the only currently available NMA related to the treatment of sleep disorders was limited to melatonin and non-pharmacological approaches in children who had sleep problems but were otherwise healthy [46]. It is also hoped that progress in precision medicine approaches, which are now starting to be tested in the field of ADHD [47], will inform individualized care of those with ADHD and sleep disorders.

In conclusion, even though in the past decade there has been an increased number of RCTs, we look forward to a further expansion of this body of research to be able to inform future clinical guidelines on the management of sleep disorders in children with ADHD.

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