

Systematic Review and Meta-Analysis of Behavioral Interventions for Pediatric Insomnia

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Objective To evaluate and quantify the evidence for behavioral interventions for pediatric insomnia. **Methods** Meta-analysis of 16 controlled trials and qualitative analysis of 12 within-subject studies were conducted (total $n = 2,560$). **Results** Meta-analysis found significant effects for four specified sleep outcomes: sleep-onset latency, number of night wakings, and duration of night wakings, and sleep efficiency, with small to large effect sizes across the controlled clinical trials involving typical children. No significant effects were found for the two studies conducted with special needs populations. Finally, within-subjects studies demonstrated significant effects for all sleep outcomes with large effect sizes. Risk of bias assessment and GRADE ratings of the quality of the evidence are described. **Conclusion** Moderate-level evidence supports behavioral interventions for pediatric insomnia in young children. However, low evidence for children, adolescents, and those with special needs (due to a lack of studies that met inclusion criteria) highlights the need for future research.

Key words bedtime problems; behavioral insomnia of childhood; behavioral treatment; insomnia; night wakings; pediatric insomnia; treatment.

Introduction

Sleep problems are common in children across development. Although definitions (in terms of age, frequency, severity, and duration of symptoms) and sample populations (typically developing vs. children with neurologic or psychiatric comorbidities) have varied, the prevalence of pediatric insomnia in children and adolescents ranges from 10% to as high as 80% in children with neurodevelopmental or psychiatric comorbidities (Corkum, Tannock, & Moldofsky, 1998; Dohnt, Gradisar, & Short, 2012; Henderson, France, Owens, & Blampied, 2010; Mindell, Sadeh, Kwon, & Goh, 2013; Mindell, Sadeh, Wiegand, How, & Goh, 2010; Quach, Hiscock, Ukoumunne, & Wake, 2011; Roberts, Roberts, & Chan, 2008; Sadeh, Mindell, Luedtke, & Wiegand, 2009; Souders et al., 2009; Thorndike, 2009). The most common types of sleep problems include difficulties initiating sleep and

maintaining sleep. In young children, this is commonly referred to as “bedtime problems and night wakings,” whereas in older children and adolescents this is typically identified as insomnia.

Longitudinal studies have demonstrated that sleep problems often persist throughout childhood and adolescence (Byars, Yolton, Rausch, Lanphear, & Beebe, 2012; Jenni, Fuhrer, Iglowstein, Molinari, & Largo, 2005; Meltzer, Plaufcan, Thomas, & Mindell, 2014; Roberts, Roberts, & Duong, 2008). Not only does insomnia tend to persist, there is increasing evidence that inadequate sleep quality and quantity in children and adolescents is associated with a number of negative functional outcomes, including sleepiness, inattention, and other cognitive and behavioral deficits (Beebe, 2011), as well as psychiatric and health outcomes, such as obesity and metabolic consequences (Bell & Zimmerman, 2010; Magee &

Hale, 2012). Insomnia and sleep disturbances have also been shown to increase the risk of depression, as well as suicide and self-harm behaviors, in both children and adolescents (Roberts, Roberts, & Chen, 2002; Singareddy et al., 2013; Wong, Brower, & Zucker, 2011). There is also a significant impact on families, with parents and caregivers reporting negative effects on daytime function and well-being, as well as elevated levels of family stress (Hiscock & Wake, 2002; Meltzer & Mindell, 2007; Mindell et al., 2011a; Thome & Skuladottir, 2005).

Definition of Disorder

At this time, there is no absolute definition of pediatric insomnia. Furthermore, differing definitions have been used in clinical settings and in research. Within the clinical realm, the second revision of the *International Classification of Sleep Disorders* (ICSD-II; American Academy of Sleep Medicine, 2005) uses the clinical diagnostic category of Behavioral Insomnia of Childhood, which is further classified into sleep-onset association type, limit-setting type, or combined type. In 2006, a working group developed a consensus definition of pediatric insomnia (Mindell, Emslie, et al., 2006). Pediatric insomnia was defined as “repeated difficulty with sleep initiation, duration, consolidation, or quality that occurs despite age-appropriate time and opportunity for sleep and results in daytime functional impairment for the child and/or family. The phrases “age-appropriate,” “functional,” and “for the child and/or family” were intentionally added given the nuances of sleep disturbances during the developmental period. The latest renditions of both the *Diagnostic and Statistical Manual of Mental Disorders* (5th ed.; DSM-5; American Psychiatric Association, 2013) and the ICSD-3 (American Academy of Sleep Medicine, 2014) subsume pediatric insomnia under one umbrella diagnosis (DSM-5—Insomnia Disorder and ICSD-3—Chronic Insomnia Disorder), with both diagnoses taking developmental issues into consideration. From a clinical standpoint, these definitions also require that the symptoms must be frequent, be present for a specified time, and result in some significant impairment in functioning either in the child, the parent(s), or the family. Thus, mild and transient symptoms should not constitute a sleep disorder. Other than a few studies assessing the prevalence of insomnia in adolescents using diagnostic criteria (Dohnt et al., 2012; Johnson, Roth, Schultz, & Breslau, 2006; Ohayon & Roberts, 2001), no research studies have used these specific clinical definitions. Rather, intervention studies have used a number of different criteria, from parent endorsement of a “sleep problem” to others using more concrete operational definitions based on frequency, severity, and/or chronicity.

For the purposes of this review, we have attempted to be consistent with the current existing literature, using the nosology of “pediatric insomnia” to refer to any difficulties with sleep onset or sleep maintenance.

Behavioral Interventions

The preponderance of treatment studies for pediatric insomnia has used behavioral interventions, that is, interventions that are based on learning principles. Previous reviews of the literature have demonstrated strong empirical evidence for the efficacy of these behavioral interventions. Two older comprehensive reviews focused on empirically supported treatments for bedtime problems and night wakings in young children (Kuhn & Elliott, 2003; Mindell, 1999). At the time, three interventions, unmodified extinction (ignoring all negative behaviors after lights out until a set time in the morning), graduated extinction (brief parental checks after lights out, which may decrease in frequency, again ignoring all negative behavior), and parent education/prevention, were identified as well established and efficacious. Other interventions, including bedtime fading/positive routines (includes a positive bedtime routine, moving the child’s bedtime later to match when he/she is currently falling asleep, and stimulus control techniques) and scheduled awakenings (waking and then consoling a child 15–30 min before the child’s typical spontaneous nocturnal awakening, which is expected to assist in sleep consolidation) were identified as “probably efficacious” or as a “guideline,” because of lack of empirical evidence to label these as “well-established” interventions.

The most recent review of the literature was published in 2006 by the American Academy of Sleep Medicine (Mindell, Kuhn, et al., 2006) in conjunction with a standards of practice document (Morgenthaler et al., 2006). This review of 52 treatment studies for bedtime problems and night wakings in young children found that 94% of studies were efficacious, with >80% of children treated demonstrating clinically significant improvement (Mindell, Kuhn, et al., 2006). These improvements were maintained for 3–6 months. More specifically, empirical evidence from controlled group studies using Sackett criteria for evidence-based treatment provided strong support for unmodified extinction and preventive parent education. In addition, support was provided for graduated extinction, bedtime fading/positive routines, and scheduled awakenings.

For older children and adolescents, interventions for insomnia (e.g., cognitive-behavioral therapy for insomnia or CBT-I) have received significantly less attention in the literature, with none of these previously published reviews

including older youth. Similarly, behavioral interventions for insomnia in youth with autism or attention-deficit/hyperactivity disorder (ADHD) have not been included in previous comprehensive reviews, with published meta-analyses in these populations focusing instead on subjective and objective sleep parameters in those with ADHD (Cortese, Faraone, Konofal, & Lecendreux, 2009) or the use of melatonin as a treatment for insomnia in youth with autism (Guenole & Baleyte, 2011; Rossignol & Frye, 2011). Finally, no meta-analytic reviews have included behavioral interventions for insomnia in children with mood disorders (e.g., depression, anxiety) or chronic/life-threatening illnesses (e.g., asthma, diabetes, cancer).

Rationale for Review

Although behavioral interventions for insomnia have been shown to be effective in pediatric populations, the most recent comprehensive review was published in 2006 (Mindell, Kuhn, et al., 2006). Since then, 14 new studies have been published, including randomized controlled trials with longitudinal outcome data. Notably none of the previous reviews conducted have included meta-analysis techniques. Furthermore, the current review involves much more stringent inclusion criteria, primarily in only including studies with a sample size of at least 12 and standardizing the sleep outcome measures assessed. In addition, this review has a broader focus than previous papers, including older children and adolescents, as well as children with neurodevelopmental disorders, mood disorders, or chronic illnesses. Finally, this review uses the GRADE system to evaluate the quality of the evidence for the use of behavioral interventions for pediatric insomnia.

Purpose

The primary objective of this article is to provide a review of the empirical evidence regarding the efficacy of behavioral interventions for the clinical management of pediatric insomnia.

Review Aims

Aim 1. To evaluate and update the current knowledge about the efficacy of behavioral interventions in the treatment of bedtime problems and night wakings in young children.

Aim 2. To evaluate the efficacy of behavioral interventions for the treatment of pediatric insomnia in older children and adolescents.

Aim 3. To evaluate the efficacy of behavioral interventions for the treatment of pediatric insomnia in children

with neurodevelopmental disorders, mood disorders, or chronic illnesses.

Methods

Identification and Selection of Treatment Studies

This review includes intervention studies using behavioral treatments for sleep problems in children and adolescents. Inclusion criteria included (1) intervention study published in a peer-reviewed journal; (2) primary aim/focus was the use of a behavioral or psychoeducational treatment that involved behavioral principles (defined as an intervention based on learning principles); (3) minimum sample size of 12 participants; and (4) published in English. Exclusion criteria included (1) no behavioral intervention or behaviorally based psychoeducational component; (2) study was not published in a peer-reviewed publication, such as a dissertation; and (3) non-English journal. We considered controlled clinical trials separately from studies that used a within-subjects design (baseline compared with posttreatment).

Type of Participants

This review includes children aged 0–17.9 years (inclusive) who have insomnia, defined as bedtime problems and/or night wakings for younger children, and/or difficulties initiating and maintaining sleep in older children and adolescents. Although parents (including guardians and other legal caregivers) may have been the primary participant in the intervention (in particular for younger children), all studies focused primarily on an intervention to improve the child's sleep problem. Children of special populations, such as children with autism, ADHD, or any other medical/psychiatric condition, were also included in this review.

Type of Interventions

Studies were included if the intervention was primarily behavioral in nature, targeting sleep initiation or sleep maintenance difficulties. The intervention had to aim to treat the child, although the parent was often the person who received the intervention to assist his/her child. We excluded interventions where sleep was not the primary intervention target (e.g., improvement of sleep following CBT for depression or anxiety). We also excluded studies that combined behavioral interventions with pharmacological interventions.

Type of Outcomes

Four sleep outcomes were targeted in this study (1) sleep-onset latency (duration to fall asleep), (2) number of night wakings, (3) duration of night wakings, and (4) sleep

efficiency (number of minutes of sleep divided by the number of minutes in bed). Only studies that included at least one of these four outcomes were included. Posttreatment data (at the completion of the intervention) and follow-up period, categorized as (1) 3–11 months or (2) ≥ 12 months, were included in analyses. If there were multiple outcome sources provided, we prioritized first by the authors' choice of primary outcome. Otherwise, we prioritized by selecting diary data first, questionnaire data second, and then actigraphy, as parental perceptions were considered the primary outcome.

Article Search

Treatment studies selected for review in this article were identified through (1) PsychINFO, (2) Medline, (3) Cochrane databases (CENTRAL, CDSR, CMR, HTA), (4) Embase, and (5) Database of Abstracts of Reviews of Effects (DARE) searches (January 1970–May 2013). See Supplementary Materials for complete search strategy. We also used “pearling,” the process of manually scanning the reference lists of identified articles for additional relevant studies not identified in the electronic database search. In addition, we examined the reference lists of identified meta-analyses and systemic reviews.

For any study published in the past 10 years (2003–2013) that met all other criteria but did not include one of the four designated outcome variables, we directly contacted the authors and requested available data on any of the four outcome variables.

A total of 6,917 articles were considered from the initial search and included all articles published through May 2013 (Figure 1). This list of articles was screened for relevant titles, and abstracts of all marginally relevant titles were examined. The large majority of the articles were excluded because they did not meet inclusion criteria, with 93 articles selected for full review. Following full review, an additional 64 articles were excluded either because they did not include any of the four outcome variables ($n = 43$) or because the sample size was too small ($n = 21$; Supplementary Table 1). Thus, 29 articles were included, capturing 28 studies (one article was a published follow-up study to an earlier included study). Of these studies, 16 studies were controlled trials and 12 were within-subject designs. Thus, the present article is based on evidence from 28 individual studies ($n = 2,582$ participants) that met inclusion criteria.

Data Extraction

Data extraction from the identified studies included references, demographic information, inclusion/exclusion criteria, characteristics of the treatment, and outcome

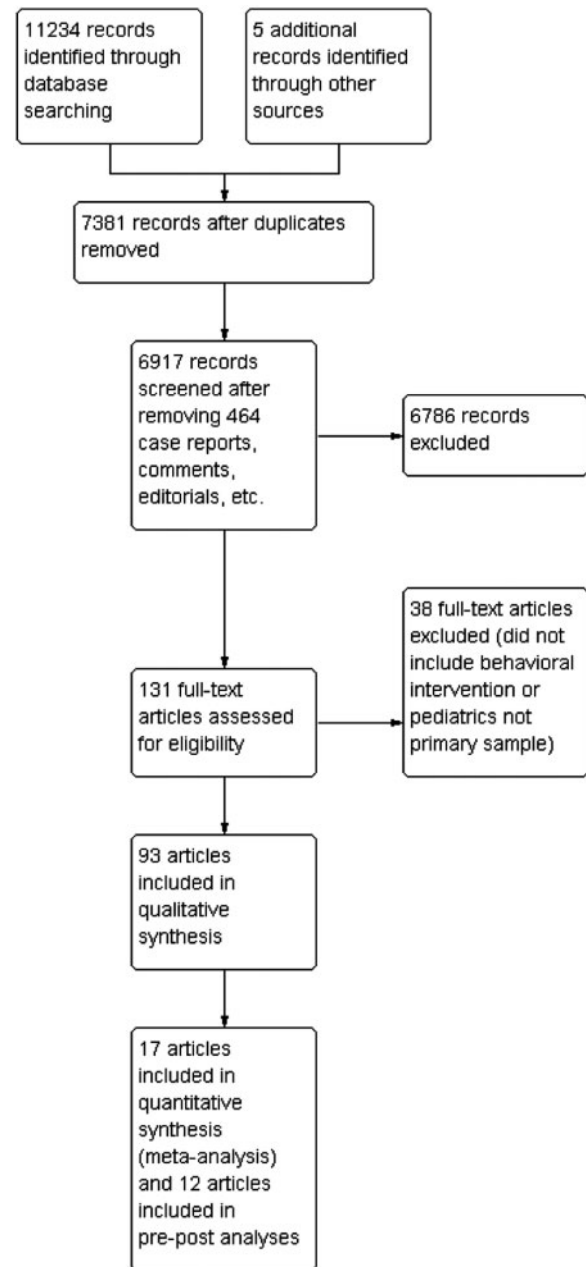


Figure 1. Summary of evidence search and selection.

measures. Data extraction was completed by at least one author and one undergraduate-level psychology student. Any discrepancies were evaluated by the other author, and consensus was reached by the two authors.

Measures of Treatment Effect

We measured studies within four groupings: (1) controlled trials of behavioral interventions with young children, approximately ages birth to 5 years, (2) controlled trials of behavioral interventions with school-aged children and

adolescents, (3) controlled trials of children from special populations, and (4) within-subject studies of behavioral interventions across all age-groups and types of participants. We further classified outcomes as short-term posttreatment (up to 3 months), and if available, data were also extracted for medium follow-up (3–11 months) and long-term follow-up (≥ 12 months). If more than one intervention group was included, we chose the experimental condition hypothesized to have the largest effect to avoid inflating outcomes. Analyses are presented for each of the four sleep outcomes. We pooled data using standardized mean difference and fixed-effect models, as studies did not consistently use the same scales. Effect sizes were based on Cohen's *d* and interpreted with the following: 0.2 = small, 0.5 = medium, 0.8 = large (Cohen, 1992).

Risk of Bias

All studies were reviewed for risk of bias using the recommended Cochrane guidelines (Higgins & Green, 2011), with ratings for randomization, allocation concealment (selection bias), blinding of participants and personnel, blinding of outcome assessment (detection bias), and selective reporting (reporting bias). Because of the nature of psychological interventions, blinding of participants and personnel was excluded for this review.

GRADE Ratings

Quality of evidence was assessed using the GRADE criteria (Guyatt et al., 2011). Studies included in the analysis were assessed based on five categories: risk of allocation bias, indirectness, inconsistency, imprecision, and publication bias. Overall ratings of the outcomes include: "high" (further research is very unlikely to change the confidence in the estimate of the effect); "moderate" (further research is likely to have an important impact on the confidence in the estimate of effect and may change the estimate); "low" (further research is very likely to change our estimate of effect; and "very low" (we are very uncertain about the estimate of effect).

SUMMARY of Results for Controlled Trials

Table I provides a summary of study characteristics for the 16 controlled clinical trials and the 12 within-subjects studies. (Supplementary Table 1 provides information about the excluded studies, and Supplementary Table 2 provides detailed study characteristics for the 16 controlled trial studies). The following section summarizes the findings across the three study aims: (1) behavioral

interventions for young children, (2) behavioral interventions for school-aged children and adolescents, and (3) behavioral interventions for children with special needs. Within each section, efficacy related to the four outcome variables studies are reviewed, as well as the durability of improvements over time.

General Findings

In sum, 2,133 children participated across the 16 selected studies that evaluated behavioral interventions for pediatric insomnia and used the methodologically stronger controlled trial design.

In the 14 studies that identified the gender of the subjects, 1,105 of 2,043 (54%) of the subjects were male. Thirteen studies provided the mean age of the subjects. The majority of the studies primarily included young children (ages birth to 5 years; 12 of 16 studies; mean age = 17.6 months) and four studies focused on school-aged children (7.2 years). No studies included adolescents. One study included children with autism spectrum disorder and another children with Down syndrome. No studies that met our inclusion criteria involved children with ADHD, mood disorders, or chronic medical illnesses.

Six studies were conducted in the United States, two in the U.K., two in Australia, and two in Canada, with the remaining taking place in Italy, Japan, New Zealand, and Sweden.

Across the 16 studies, 8 (50%) studies were clinical trials with a treatment as usual control group, and 5 (31%) studies were clinical trials with a wait-list control. The other three studies involved a clinical trial with two treatment groups, clinical trial with a placebo arm, and a clinical trial with historical controls.

In terms of mode of delivery, in 13 of 16 (81%) studies, the treatment intervention was delivered in person. Two of the studies (15%) provided treatment via an Internet intervention. Three studies (19%) included a booklet or pamphlet as their sole intervention or part of their intervention. Follow-up data were collected in the majority of studies (75%, 12 of 16 studies), with 9 (56%) studies conducting follow-up between 3 and 11 months, and 1 study (6%) conducting an assessment 1 year later.

Risk of Bias

A summary of risk of bias can be found in Figure 2, and a detailed risk of bias for each of the controlled clinical trials can be found in Supplementary Figure 1. Nine studies were scored as low risk of bias for randomization, with six studies scored unclear due to a lack of information about how randomization was determined. One study

Table I. Characteristics of Included Studies

Authors	Total <i>n</i>	Country	Treatment arm(s)	Control arm(s)	Mode of delivery
Young child					
Adachi et al., 2009	194	Japan	Sleep education	Treatment as usual	Booklet and presentation
Adair, Zuckerman, Bauchner, Philipp, & Levenson, 1992	292	USA	Written information, sleep chart, sleep education	Historical controls	Booklet and physician
Eckerberg, 2002	67	Sweden	Advice and support	Written information	Pediatrician
Mindell et al., 2011 ^a	264	USA	Customized sleep profile/	Treatment as usual	Internet
Mindell et al., 2011a ^b			profile + structured bedtime routine		
Mindell et al., 2009	405	USA	Structured bedtime routine	Treatment as usual	Internet
Moore, Friman, Fruzzetti, & MacAleese, 2007	19	USA	Bedtime pass	Wait-list control	In person
Scott & Richards, 1990 ^c	120	U.K.	Education booklet + support group/ education booklet/treatment as usual with booklet	Treatment as usual	Researcher
Seymour, Brock, During, & Poole, 1989 ^d	45	New Zealand	Standardized sleep program/written guide	Wait-list control	In person and written
Stremler et al., 2013	246	Canada	Sleep education	Treatment as usual	Nurse
Stremler et al., 2006	30	Canada	Sleep education + written information	Treatment as usual	Nurse
Wolfson, Lacks, & Futterman, 1992	60	USA	Sleep education	Treatment as usual	Psychologist in person
Children/adolescents					
Cortesi, Giannotti, Sebastiani, Panunzi, & Valente, 2012 ^c	160	Italy	Multicomponent behavioral treatment (MCBT) + melatonin/MCBT/ melatonin	Placebo	Psychologist in person
Paine & Gradisar, 2011	42	Australia	CBT-I	Wait-list control	Psychologist in person
Quach, Hiscock, Ukoumunne, & Wake, 2011	108	Australia	Tailored behavioral intervention	Treatment as usual	Research assistant in school
Special populations					
Adkins et al., 2012	36	USA	Sleep education	Wait-list control	Booklet
Stores & Stores, 2004	45	U.K.	Sleep education	Wait-list control	Psychologist in person
Within-subjects design					
Blunden, 2011	33	Australia	Graduated extinction	Pre-post design	Psychologist in person
Bootzin & Stevens, 2005	17	USA	CBT-I + bright light therapy + mindfulness-based stress reduction	Pre-post design	Psychologist in person
Bramble, 1997	8	U.K.	Extinction	Pre-post design	Psychologist in person
Eckerberg, 2004	95	Sweden	Graduated extinction	Pre-post design	Clinician
Johnson & Lerner, 1985	12	USA	Scheduled awakenings	Pre-post design	Psychologist in person
Leeson, Barbour, Romaniuk, & Warr, 1994	23	Australia	MCBT	Pre-post design	Multidisciplinary team
Pritchard & Appleton, 1988	31	U.K.	Graduated extinction with parental presence	Pre-post design	Therapist
Sadeh, 1994	50	Israel	Graduated extinction	Pre-post design	Psychologist in person
Schlarb, Brandhorst, & Hautzinger, 2011	18	Germany	CBT-I	Pre-post design	Therapist
Schlarb & Brandhorst, 2012	28	Germany	Sleep education + CBT-I	Pre-post design	Internet
Skuladottir & Thome, 2003	33	Iceland	MCBT	Pre-post design	Nurse
Skuladottir, Thome, & Ramel, 2005	79	Iceland	MCBT	Pre-post design	Nurse

Note. ^aThree-arm trial; ^bMindell et al., 2011a is a follow-up study to Mindell et al., 2011b; ^cFour-arm trial; CBT-I = cognitive behavioral therapy for insomnia.

was scored high risk, as the last eight subjects were assigned to active treatment after randomization was terminated due to demand for treatment. There were 4 studies that described adequate allocation and 12 studies that were unclear. Seven studies either used a third person blinded to group allocation for outcome assessment or used an objective measure of sleep (i.e., actigraphy) not influenced by

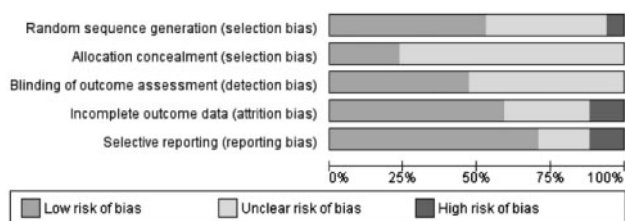


Figure 2. Risk of bias graph: review authors’ judgments about each risk of bias item presented as percentages across all included articles.

blinding, with nine studies judged unclear. Ten studies provided information about attrition demonstrating no differences between completers and noncompleters, four were judged unclear, and two studies rated high risk of bias; one due to missing data not balanced across groups and the other because attrition was likely due to improvements in child sleep leading to early study withdrawal. Eleven studies reported complete data that were extracted, three studies were judged unclear, and two studies did not provide complete that could be extracted and were thus judged high risk of bias for selective reporting.

Effects of Interventions

Tables II–IV present the summary of findings for the three hypotheses examining behavioral interventions for young children (Table II), children/adolescents (Table III), and special populations (Table IV).

Table II. Summary of Findings Table for Young Child Studies

Behavioral interventions for pediatric insomnia for young children						
Patient or population: Young children						
Settings: Multiple (in clinic, in hospital, at home)						
Intervention: Behavioral interventions for pediatric insomnia						
Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	Number of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk Control	Corresponding risk Behavioral interventions for pediatric insomnia				
Sleep-onset latency		The mean sleep-onset latency in the intervention groups was 0.33 standard deviations lower (0.48–0.18 lower)		776 (5)	⊕⊕⊕⊖ moderate^a	SMD –0.34 (–0.46 to –0.21)
Night waking frequency		The mean night waking frequency in the intervention groups was 0.26 standard deviations lower (0.35–0.17 lower)		1,835 (11)	⊕⊕⊕⊖ moderate^a	SMD –0.28 (–0.36 to –0.19)
Night waking duration		The mean night waking duration in the intervention groups was 0.40 standard deviations lower (0.54–0.25 lower)		785 (5)	⊕⊕⊕⊖ moderate^a	SMD –0.34 (–0.46 to –0.22)

Note. *The basis for the **assumed risk** (e.g., the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval.

GRADE Working Group grades of evidence.

High quality ⊕⊕⊕⊕: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality ⊕⊕⊕⊖: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: ⊕⊕⊖⊖ Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: ⊕⊖⊖⊖ We are very uncertain about the estimate.

^aHeterogeneity $I^2 = >45\%$, variation can be explained.

Table III. Summary of Findings Table for Child/Adolescent Studies

Behavioral interventions for pediatric insomnia for children and adolescents						
Patient or population: Children and adolescents						
Settings: Multiple (in clinic, in person, in school)						
Intervention: Behavioral interventions for pediatric insomnia						
Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	Number of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Children and adolescents	Behavioral interventions for pediatric insomnia				
Night waking duration		The mean night waking duration in the intervention groups was 0.33 standard deviations lower (0.56–0.09 lower)		308 (3)	⊕⊕⊕⊕ very low ^{a,b,c}	SMD –0.33 (–0.56 to –0.09)
Sleep efficiency		The mean sleep efficiency in the intervention groups was 2.24 standard deviations higher (1.74–2.73 higher)		107 (2)	⊕⊕⊕⊕ very low ^{a,b,d}	SMD 2.24 (1.74 to 2.73)

Note. *The basis for the **assumed risk** (e.g., the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval.

GRADE Working Group grades of evidence.

High quality ⊕╕╕╕: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality ⊕╕╕⊕: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: ⊕⊕⊕⊕ Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: ⊕⊕⊕⊕ We are very uncertain about the estimate.

^aHeterogeneity $I^2 = >45\%$, variation can be explained.

^bLimited number of studies.

^cSmall sample size.

^dWait-list control.

Table IV. Summary of Findings Table for Special Population Studies

Behavioral interventions for pediatric insomnia for special populations of children						
Patient or population: Special populations of children						
Settings: Multiple (community center and in home)						
Intervention: Behavioral interventions for pediatric insomnia						
Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	Number of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Behavioral interventions for pediatric insomnia				
Night waking duration		The mean night waking duration in the intervention groups was 0.25 standard deviations higher (0.15 lower to 0.64 higher)		98 (2)	⊕⊕⊕⊕ very low ^{a,b}	SMD 0.25 (–0.15 to 0.64)
Sleep efficiency		The mean sleep efficiency in the intervention groups was 0.06 standard deviations higher (0.34 lower to 0.46 higher)		98 (2)	⊕⊕⊕⊕ very low ^b	SMD 0.06 (–0.34 to 0.46)

Note. *The basis for the **assumed risk** (e.g., the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval.

GRADE Working Group grades of evidence.

High quality ⊕╕╕╕: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality ⊕╕╕⊕: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: ⊕⊕⊕⊕ Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: ⊕⊕⊕⊕ We are very uncertain about the estimate.

^aWait-list control.

^bLimited number of studies and small sample size.

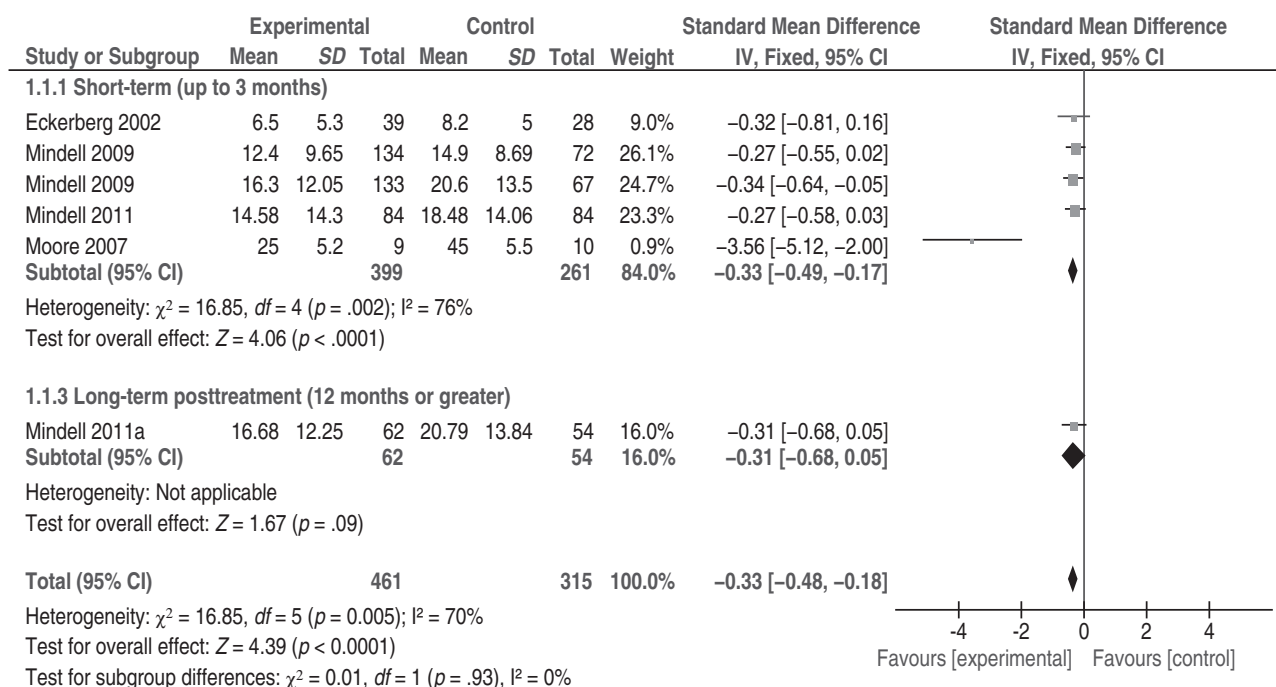


Figure 3. Forest plot of comparison: 1 Young Children, outcome: 1.1 Sleep-onset latency.

Efficacy in Young Children

Overall, there were 12 controlled trial studies (plus one separately published follow-up study) involving young typical children, for 1,874 participants. Four studies assessed sleep-onset latency, with a significant overall effect and small to medium effect size [$Z = 4.06$, $p < .001$; standard mean deviation (SMD) = 0.33] at posttreatment (Figure 3). Frequency of night wakings was included in seven studies, resulting in a significant overall effect and small to medium effect size ($Z = 5.99$, $p < .001$; SMD = 0.40; Figure 4). A nonsignificant overall effect was found at 3–12 month follow-up across five studies ($Z = 1.40$, $p = .16$; SMD = 0.10). Finally, night waking duration was included in four studies for a significant overall effect and small to medium effect size ($Z = 5.50$, $p < .001$; SMD = 0.44, Figure 5). Only one study (Mindell et al., 2011b) conducted long-term follow-up, thus no conclusions can be drawn for any of the outcomes. In addition, no studies included sleep efficiency as an outcome.

Efficacy in School-Aged Children and Adolescents

There were three controlled trials that studied the efficacy of behavioral interventions for school-aged children and adolescents, with 214 participants. All participants were school aged, ranging from 4 to 13 years. No controlled trials included adolescents. Only one study included sleep-onset latency as a measure (Supplementary

Figure 2); therefore, no conclusions can be drawn. All three studies included night waking duration (Supplementary Figure 3), which was significant at posttreatment ($Z = 2.67$, $p = .008$; SMD = 0.39). Only one study included 3–12 month follow-up, thus no conclusions can be drawn. Finally, sleep efficiency was included in two studies (Supplementary Figure 4) and was found to have an overall significant effect at posttreatment with a large effect size ($Z = 8.88$, $p < .001$; SMD = 2.24).

Efficacy in Children With Special Needs

There were only two studies that met criteria and had a control group that involved behavioral interventions for sleep problems for children with special needs, with $n = 67$. One study included children with autism spectrum disorders, whereas the other focused on children with Down syndrome. There were no significant effects for any of the four sleep outcome measures, $p > .05$ (Supplementary Figures 5–8).

Quality of Evidence Summary

The GRADE system was used to assess the quality of evidence across studies. All three outcomes for young children (sleep-onset latency, night waking frequency, and night waking duration) were scored moderate quality (Tables II–IV). This means that further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. The

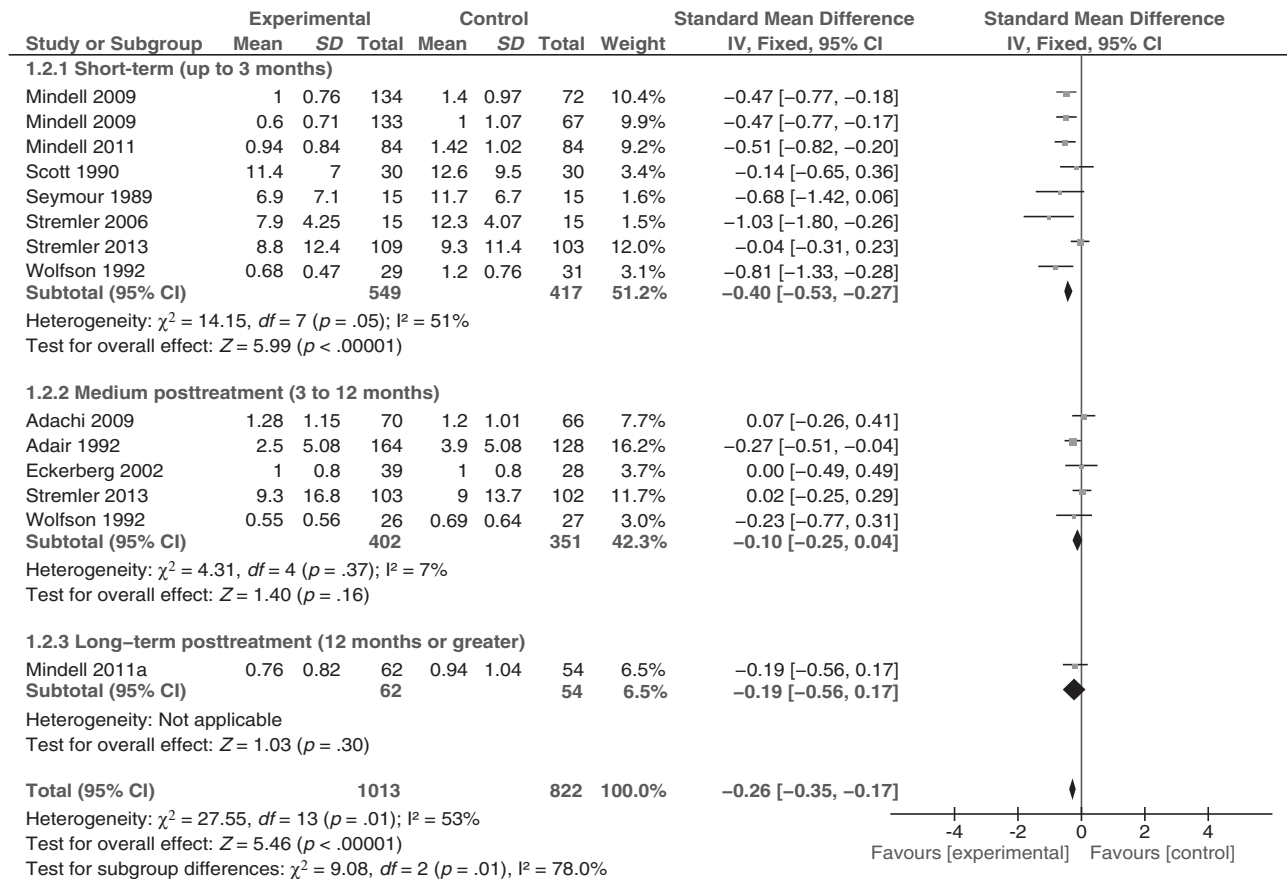


Figure 4. Forest plot of comparison: 1 Young Children, outcome: 1.2 Night waking frequency.

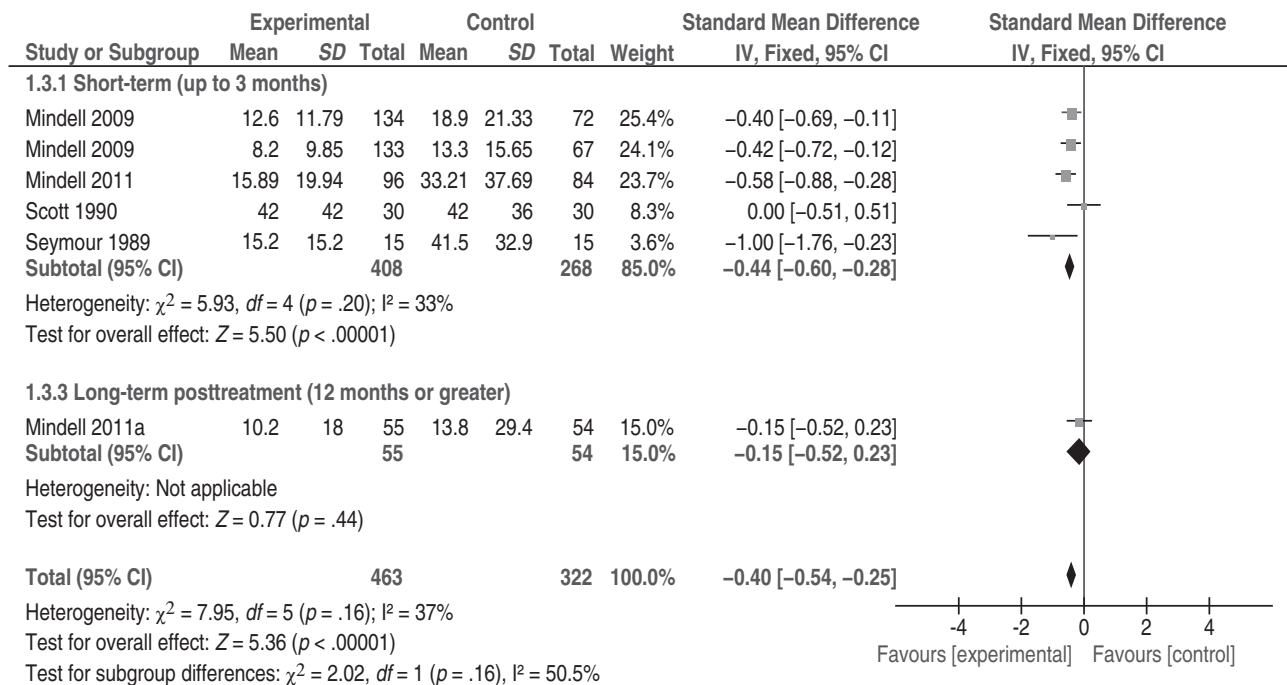


Figure 5. Forest plot of comparison: 1 Young Children, outcome: 1.3 Night waking duration.

remaining four ratings (both child/adolescent and special population: night waking duration and sleep efficiency) were all scored as very low quality (Tables III and IV), suggesting that we are uncertain about the estimate. A quality of evidence table could not be created for the other outcomes (both child/adolescent and special population: sleep-onset latency and night waking frequency) because of a lack of identified studies assessing these outcomes.

Summary of Results for Within-Subject Designs

Supplementary Table 3 provides the complete summary of study characteristics for the 12 studies conducted that used a within-subjects design and did not include a comparison control group. Similar to above, efficacy related to the four outcome variables studies is reviewed, as well as the durability of improvements over time. Because of design limitations, risk of bias and strength of evidence are not provided for these studies.

General Findings

In sum, 427 children participated across the 12 selected studies that used a within-subjects pre-post design. In the 8 studies that identified the gender of the subjects, 162 of 295 (55%) of the subjects were male. All 12 studies provided the mean age of the subjects. Similar to above, the majority of the studies primarily included young children (<5 years; 9 of 12 studies; mean age = 16.1 months), only one study focused on school-aged children (mean age = 7.2 years), and two studies included adolescents (mean age = 14.9 years). Only one study included children with a variety of developmental delays. No studies that met our inclusion criteria and used a within-subject design involved children with neurodevelopmental disorders, mood disorders, or chronic medical illnesses.

Two studies were conducted in each of the following countries: Australia, Germany, Iceland, U.K., and United States. The two remaining studies were conducted in Israel and Sweden.

In terms of mode of delivery, the intervention was delivered in person in 10 of the 10 (100%) studies that provided this information. Follow-up data, between 3 and 12 months, were collected in four of the studies (33%). No studies included longer-term follow-up.

Efficacy of Within-Subject Studies

There were significant effects for all four sleep outcomes, all with large effect sizes. Five studies included sleep-onset

latency (Supplementary Figure 9), which had a significant overall effect at posttreatment ($Z = 5.09$, $p < .001$; $SMD = 0.75$) with only one study including 3–12 month follow-up. Night waking frequency was included in 9 of the 12 studies and had a significant overall effect with a large effect size at posttreatment ($Z = 15.50$, $p < .001$; $SMD = 1.36$) and at 3–11 months follow-up (three studies; $Z = 10.35$, $p < .001$; $SMD = 1.59$; Supplementary Figure 10). Similar results were found for night waking duration at posttreatment ($Z = 8.93$, $p < .001$; $SMD = 1.08$) and at 3–11 month follow-up (two studies; $Z = 9.10$, $p < .001$; $SMD = 1.63$; Supplementary Figure 11). Finally, sleep efficiency was included as a measure in four studies, with similar significant results and a large effect size ($Z = 5.07$, $p < .001$; $SMD = -0.71$; Supplementary Figure 12).

Discussion

Summary of Findings

The purpose of this meta-analysis and review was to examine the effects of behavioral interventions on pediatric insomnia. We examined treatments separately for young children, children/adolescents, and special populations. Based on controlled clinical trials, we can conclude that behavioral treatments for young children result in significant improvements for sleep-onset latency, night waking frequency, and night waking duration. However, this review highlights that there is currently very low-quality evidence for the treatment of insomnia in older children and adolescents, as well as for children with neurodevelopmental disorders, mood disorders, and/or chronic illnesses.

Using the GRADE criteria, the quality of evidence was assessed. For young children, there is a moderate level of evidence to support behavioral treatments for insomnia in young children. In contrast, there were very low levels of evidence across all variables for the efficacy of behavioral interventions in older children and adolescents, as well as special needs populations. It is important to clarify that this low level of evidence is due to the small number of studies that met inclusion criteria, small sample sizes, and the use of a wait-list control group, rather than due to a lack of findings. However, until additional controlled clinical trials for the treatment of pediatric insomnia in children, adolescents, and special populations are conducted and published, it is not possible to draw conclusions about the efficacy of these interventions.

In addition to the meta-analysis, we reported a systematic review of studies that used a within-subjects design. Although we cannot comment on the quality of the evidence for these studies, the results provide additional

support for the efficacy of behavioral interventions for pediatric insomnia for young children, with 10 of the 12 studies focusing on this population. The other two studies focused on adolescents, providing preliminary information about potential treatment options for insomnia in this population. Notably, not only were we unable to comment on the quality of evidence for two studies that included children with developmental disorders but there were also no within-subjects design studies in our review that included special populations of children, including those with mood disorders or chronic illnesses.

The methodology and inclusion criteria of this meta-analysis significantly differ from previous reviews (Kuhn & Elliott, 2003; Mindell, 1999; Mindell, Kuhn, et al., 2006) that used previously established criteria to evaluate the empirical support for interventions (Chambless, et al., 1996; Sackett, 1993). Because of the strict inclusion criteria (e.g., randomized controlled trials with a minimum of 12 subjects), a number of relevant studies were not included in the review. Although this is a common issue with many meta-analyses, the benefit of using the GRADE approach is the ability to more objectively rate the quality of evidence and strength of recommendations based on the study design, risk of bias, and other factors. Rather than a simple count of studies that showed positive outcomes, this review provides a more transparent summary of findings with detailed reasoning for the quality of evidence ratings (Guyatt et al., 2011).

Despite the strict inclusion criteria, this review strengthens what we know about behavioral interventions for pediatric insomnia and assesses additional factors that were previously not included in reviews. First, earlier reviews evaluated the evidence for specific interventions, whereas this review looked more broadly across behavioral interventions. Second, rather than focusing on only young children, the current review included treatment studies in children, adolescents, and special populations. Third, previous reports included a variety of outcomes, whereas this review focused on four quantifiable outcomes (sleep-onset latency, night waking frequency, night waking duration, and sleep efficiency). Finally, previous reviews lumped all study designs together, whereas this review looked separately at randomized/controlled trials and within-subjects designs.

Issues for Consideration and Limitations

Although there is a moderate level of evidence to support that behavioral interventions are efficacious for treatment of infant and toddler sleep disturbances, questions about these treatments still remain, including what are the essential components of these interventions and what are the

possible short-term and long-term negative effects of these treatments. Compared with previous reviews in which a lack of studies that included long-term efficacy was a concern (Mindell, Kuhn, et al., 2006), the majority of studies in this review included long-term follow-up.

It was beyond the scope of this review to assess secondary outcomes beyond sleep outcomes. However, it is important to note that in one study of 6-year-old children (excluded from this review due to outcomes), secondary outcomes were evaluated 5 years after receiving a behavioral intervention for infant sleep problems (Price, Wake, Ukoumunne, & Hiscock, 2012a, b). Although earlier follow-up in this study found significant improvements in sleep compared with controls, long-term follow-up showed no significant differences in sleep. Most importantly, however, there were no differences in any outcome, including child mental health, parent mental health, and parent-child relationships, indicating no negative secondary outcomes to implementing a behavioral intervention during infancy.

What became abundantly clear from this review is the lack of studies that include populations other than typically developing children. Thus, it is critical that studies be conducted in children with special needs. Only one study for children with autism spectrum disorder met inclusion criteria, reporting shorter sleep-onset latency and higher sleep efficiency compared with controls (Adkins et al., 2012). Again, it is important to note that although excluded from this review, additional studies have been conducted with this population. Yet, the majority of these include few participants (e.g., Thackeray & Richdale, 2002), or examine a heterogeneous group of children with developmental disorders (e.g., Weiskop, Richdale, & Matthews, 2005). Other larger-scale studies have been conducted with children with developmental disorders, and have found behavioral interventions to be efficacious, but were not able to be included due to lack of data specific to the outcomes specified here (e.g., O'Connell & Vannan, 2008; Reed et al., 2009).

Surprisingly, no studies were included in this review that included children with ADHD, although sleep problems are highly prevalent in this group. Not only have few studies been conducted on the efficacy of behavioral interventions for sleep problems in these children, none met the designated criteria for this review. It is important to note that those studies that have been conducted (e.g., Sciberras, Fulton, Efron, Oberklaid, & Hiscock, 2011; Vetrayan, Othman, & Victor Paulraj, 2013; Weiss, Wasdell, Bomben, Rea, & Freeman, 2006) have generally reported positive findings. Notably, no treatment studies for sleep disturbances in children with chronic illnesses

(e.g., asthma, diabetes) were identified for this review. To our knowledge, no studies have examined a sleep intervention for children with chronic health conditions, although a small number of studies have included sleep quality as an outcome for behavioral interventions targeting the child's illness (e.g., Degotardi et al., 2006).

In addition to a lack of research in children with special needs, there is also limited research in school-aged children and a dearth of studies with adolescents. Only three studies in this review included school-aged children. All three studies found decreases in night wakings, with one study reporting decreased sleep-onset latency, and two studies showing improved sleep efficiency. Only two studies in our review investigated the efficacy of behavioral interventions for insomnia in adolescents, and in one of those studies, all the participants also had substance abuse issues (Bootzin & Stevens, 2005). Given that ~10% of adolescents meet the DSM-5 criteria for insomnia disorder, it is astonishing that almost no studies have been conducted to date. The reason for the lack of studies is unclear but may reflect a number of different factors, including the general lack of attention adolescent insomnia receives in primary care, the belief that adolescent sleep issues are due primarily to other factors (e.g., delayed circadian rhythms) and/or environmental constraints (e.g., early school start times), or simply the fact that pediatric behavioral sleep medicine is still a young field, whose roots are in treatment for enuresis and sleep problems in young children. Despite the reason, it is essential that over the next decade, additional studies are needed to evaluate behavioral interventions for adolescent insomnia.

Implications for Pediatric Psychology Practice

While it is important for pediatric psychologists to be aware of the significant number of children who experience a sleep problem, this review demonstrates that behavioral interventions are effective for the treatment of pediatric insomnia. For providers working with healthy typically developing young children, there should be no hesitation to implement these methods in clinical practice. Although more evidence is needed, behavioral interventions for school-aged children, adolescents, and youth with neurodevelopmental disorders (e.g., autism, ADHD) should also be used to address insomnia in these populations. Finally, although few studies have examined treatments for sleep problems in children with chronic health conditions, many studies have demonstrated that sleep issues are common in these populations (Lewandowski, Ward, & Palermo, 2011). While there are unavoidable sleep-related issues due to illness factors (e.g., pain, medications), there are a number of behavioral factors that may

develop (e.g., spending extended periods of time in bed not sleeping, inconsistent bedtimes and wake times) that may contribute to the development of insomnia, and could be reversed using behavioral interventions. Likewise, insomnia is common in conjunction with mood disorders, including depression and anxiety, especially during adolescence and should be a focus of future intervention studies.

Implications for Future Research

There are a number of areas that should be addressed with future research studies. First, although evidence is strong for behavioral interventions for insomnia in young children, more studies are needed to help identify factors that may predict treatment success. This will further support current clinical practice, which tailors behavioral interventions for young children based on child (e.g., temperament, age), parent (e.g., age, marital support), and environmental factors (Meltzer, 2010).

Second, more longitudinal studies are needed to demonstrate whether treatment benefits for insomnia are maintained over time. In addition, these longer-term studies also need to examine other functional outcomes, including child mood, behavior, and health, as well as parental mood, marital satisfaction, and family functioning. Third, future studies need to consider some of the methodological limitations of this review, including the need for standardized outcome measures and objective measures of sleep (e.g., actigraphy). Although parental report has been shown to be valid and reliable in younger children (Sadeh, 2004; Werner, Molinari, Guyer, & Jenni, 2008), as youth reach middle childhood (i.e., 8–10 years) and early adolescence, parental report has been shown to be less accurate (Amschler & McKenzie, 2005; Meltzer et al., 2013; Owens, Spirito, McGuinn, & Nobile, 2000; Paavonen et al., 2000). In addition, for randomized clinical trials, the use of objective sleep measures such as actigraphy or videosomnography reduces bias that may result from parental report of outcome data. The use of multi-method, multi-reporter data is needed for clinical trials examining the efficacy of behavioral interventions for pediatric insomnia.

Finally, as previously discussed, there is clearly a need for additional studies that include school-aged children and adolescents, as well as children with neurodevelopmental disorders, mood disorders, and chronic illnesses.

Conclusion

Behavioral interventions are effective at reducing sleep-onset latency, night waking frequency, and night waking

duration in young children. However, insufficient long-term evidence for these changes means limited conclusions can be drawn on the durability of these treatments over time. For typically developing children and adolescents, as well as youth with neurodevelopmental disorders, mood disorders, or chronic illnesses, the lack of controlled clinical trials precludes conclusions about the efficacy of behavioral interventions for these populations. Within-subjects studies provide promising support for behavioral interventions across all populations, yet clearly there is a need for additional controlled clinical trials to identify effective behavioral interventions for the treatment of pediatric insomnia for all youth.

Supplementary Data

Supplementary data can be found at: <http://www.jpepsy.oxfordjournals.org/>

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