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Treatment for behavioral insomnia in young children with neurotypical development under 6 years of age: A systematic review

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ABSTRACT

This literature review examines all treatments for behavioral insomnia in children under 6 years of age to determine which treatments have empirically demonstrated efficacy. Following PRISMA guidelines, three databases were investigated (Pubmed, Cochrane and Psychinfo) to select randomized controlled trials (RCTs) which assess treatments for behavioral insomnia in children under 6 years of age, all with neurotypical development. A total of 908 articles met the search criteria. 21 articles were selected and analyzed in their entirety for a total of 2363 children (ranging from 2 months to 6 years of age). Based on these studies, treatment of behavioral insomnia in young children under 6 years of age is primarily based on behavioral therapy. There is no evidence that pharmacological treatments are effective in the long term for neurotypical children. This review highlights the lack of RCTs in this field: new RCTs should be carried out among young children to refine and optimize the therapeutic approach and to address the risk of therapeutic abuse through the use of non-scientifically validated methods.

1. Introduction

Sleep disorders in young children affect between 30 and 40% of children [1]. Pediatric insomnia in young children is defined as repeated difficulty in initiating and/or maintaining sleep or a complaint about sleep quality that occurs despite the provision of conditions conducive to sleep and is related to the child's developmental stages [2,3]. In research, the inclusion criteria for pediatric insomnia are: 1) more than 3 nighttime awakenings requiring parental presence, 2) a sleep onset latency of more than 30 min, 3) nighttime awakenings lasting more than 20 min and resulting in clinically significant distress or impairment in social, family, school, or any other important areas. These diagnostic criteria must have been present for at least 3 months. Regarding sleep education, autonomy in initiating and maintaining sleep is of central importance for the child.

1.1. Etiologies of insomnia

The development of sleep state organization and sleep-wake cycle is a complex process involving genetic and environmental factors. During the first months of life, while the need for sleep is high, the child's sleep is nevertheless physiologically unstable, fragmented by short waking states, preventing children less than 6 months old from sleeping through the night. The ability to sleep through the night is a process which depends on brain maturation [4,5] and also on the capacity of the infant not needing to be fed during the night and being able to self-soothe. Young children manage to develop autonomy at sleep onset or after a waking period during the night if they are given the opportunity to implement self-soothing behaviors. If caregivers consistently respond too quickly to the child's crying or demands (child being held, being fed at sleep onset and/or during the night awakenings after 6 months of age …), children will be soothed via hetero-soothing. This type of intervention will be increasingly required, thus preventing the child from

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Abbreviations

AASM	the American Academy of Sleep Medicine
CBCL	Child Behavior Checklist
CBT	Cognitive Behavioral Therapy
CSDS	Composite Sleep Disturbance Score
ICSD-III	The International Classification of Sleep Disorders—3*rd* edition
PSQI	Pittsburgh Sleep Quality Index
RCT	Randomized Controlled Trials
SFRMS	Société Française de Recherche et Médecine du Sommeil
SOL	Sleep Onset Latency
WASO	Wake After Sleep Onset
WL	Waiting List

establishing autonomy at sleep onset or after a normal night waking period. Circadian rhythms enable a natural day-night alternation of wake-sleep period.

This regulation is achieved via external environmental factors, commonly called external time cues or zeitgebers (e.g., light-dark cycle rhythmicity, sleep ritual at bedtime, early and regular getting up times, day time interactions and activities, i.e.) [6]. External time cues such as consistent nightly bedtime routines, play an important role in the development of the young child's circadian rhythm [7]. This rhythm has an important impact on sleep stability [8]. The regulation of sleep-wake rhythms and sleep behaviors are not innate: the child learns to differentiate between day and night by observing the regularity of their environment (parents' behavior) and learns to fall asleep on their own according to parental interactions.

Pediatric insomnia is characterized by a complaint or observation made by caregivers regarding at least one of the following elements: Difficulty initiating or maintaining sleep, waking up earlier than the desired time, refusal to go to bed at an appropriate time or difficulty initiating sleep without parental intervention. These symptoms are sometimes accompanied by a daytime complaint by the child, but mainly by the parents who often have to intervene at night at the child's bedside. The etiology of insomnia in children is either linked to medical conditions [9] and/or environmental [10,11], or psychological and/or behavioral conditions. Behavioral insomnia (ICSD-III) represents approximately 70% of cases of insomnia in children [9]. Clinically, there are two types of behavioral insomnia: **sleep onset association type** is characterized by the need for specific conditions for falling asleep (often parental presence) for a period of more than three months, where falling asleep is problematic and difficult. In the absence of these conditions, falling asleep is delayed and/or sleep is disturbed. When the child wakes up at night, the adult must intervene so the child can fall back asleep; **limit setting type** is characterized by the child experiencing difficulty in initiating or maintaining sleep as evidenced by a refusal to go to bed at the appropriate time or after a nighttime awakening. The parent sets insufficient or inappropriate boundaries for the child to engage in sleep-conducive behavior. In both types of insomnia, the sleep disturbances are not better explained by another sleep disorder (medical or neurological condition, substance use or mental disorder) [12].

1.2. Treatment recommendations

A total of 4 systematic reviews on the treatment of insomnia in neurotypical children have been published [13–16]. 1) In 2006, based on 52 studies, the American Academy of Sleep Medicine (AASM) revealed that behavioral methods are on average 80% effective in treating behavioral insomnia in children aged 0–4 years [13]. This review focused solely on behavioral treatments to propose a guideline on good practice. 2) In 2014, Meltzer & Mindell conducted a systematic review and meta-analysis of Behavioral Interventions for Pediatric Insomnia, including 28 studies, of which 17 randomized controlled trials (RCTs) with a population aged between 0 and 17.9 years old (n = 2560). They showed a significant improvement in four sleep parameters: sleep onset latency, number of nighttime awakenings, duration of nighttime awakenings and sleep efficiency [14]. 3) In 2018, Ma and colleagues conducted a systematic review and meta-analysis of the efficacy of cognitive behavioral therapy (CBT) in children and adolescents. They investigated 10 RCTs with sample populations aged between 5 and 19 years old (n = 464), which demonstrated significant improvements in two sleep parameters: sleep onset latency and sleep efficiency [15]. 4) In 2021, Fangupo and colleagues conducted a systematic review and meta-analysis on the impact of behavioral interventions specifically on sleep duration in a sample population aged between 0 and 5 years. They showed an increase in the duration of nighttime sleep and total sleep. The RCTs included in Fangupo's review some other components (e.g., sleep and obesity prevention) which did not enable an accurate assessment of sleep improvement [16]. In other words, the main objective of the articles selected is not the improvement of sleep.

These literature reviews focused on behavioral treatments for behavioral insomnia in young children. They do not take into account the plethora of treatments proposed to resolve insomnia in children. However, in clinical consultations conducted by two of the present authors (FL and BP), out of 1450 patients aged 0–6 years old seen for child sleep disorders, the parents had tried many treatments to resolve their child's sleep problems: 76.6% of the parents had consulted their pediatricians, 66.7% had tried osteopathy, 34% phytotherapy or plant-based treatments, 33% alternative medicine, 31% homeopathy and 27.2% antihistamine syrups (personal data, not published).

From a clinical point of view, management of sleep disorders in children requires a developmental interpretation of the disorder. Therapeutic methods evolve with age. Depending on the child's development, certain behavioral methods must be adapted, otherwise they will not be effective. As such, from the age of 10 years onwards, methods used with adults are applied (e.g., sleep restriction, stimulus control): these are behavioral and cognitive methods which should not be used with children, and especially not with young children.

The aim of this study, therefore, is to identify which treatments for behavioral insomnia in children under 6 years of age are effective. We conducted a systematic review of studies on treatments for behavioral insomnia that was methodologically robust: namely, we selected only RCTs.

2. Methods

2.1. Identifying and selecting studies on treatments

Studies were included in this review when: 1) the study was published in a peer-reviewed journal; 2) it focused on the assessment of a therapeutic intervention and/or treatment for behavioral insomnia in young children under 6 years of age; 3) it was published in English or French; 4) the methodology of the article had to, to some extent, adhere to the CONSORT methodology [17]; 5) children included in the studies had to be typically developing (children with neurodevelopmental disorders, chronic diseases, non-neurotypical children, children with psychological or psychiatric disorders were excluded from the study); 6) they were original articles.

Studies included in this review had to focus on improving behavioral insomnia in young children through intervention or treatment (without exclusion depending on the type of intervention). We excluded studies in which the primary therapeutic target was not improvement of the child's sleep. For example, a study aimed at improving children's nutrition which observed an improvement in sleep was not included.

2.2. Primary outcomes

In order to assess comparable improvements in young children's sleep across studies, it was necessary to define the outcomes necessarily present in the studies selected. For inclusion in this review, studies had to have at least one primary outcome among the following: 1) sleep onset latency (SOL); 2) wake after sleep onset (WASO); 3) the number of nighttime awakenings; 4) bedtime resistance; 5) the duration of an uninterrupted sleep episode without crying; 6) the total duration of sleep over 24 h; 7) total night and daytime sleep duration; 8) insomnia rate (measured using a sleep scale, which may vary depending on the studies); 9) autonomous falling asleep; 10) perception of the child's sleep as problematic. Sleep efficiency was not selected as a sufficiently reliable and sensitive criterion for assessing improvement in young children's sleep.

2.3. Secondary outcomes

The secondary outcomes were not predefined, they were compiled a posteriori according to the studies selected.

2.4. Article search

Our review followed the PRISMA 2020 guidelines [18]. We searched the following databases: 1) PubMed; 2) Cochrane and 3) Psychinfo. The search criteria were: article type (Randomized Controlled Trial); language (English or French); age (birth – 6 years). The search terms were: 1) (behavioral insomnia or insomnia); 2) (treatment or intervention). Results were dependent on databases (1968–2022 for Pubmed) and RCT publications up to November 10th, 2022. The lists extracted from these databases were combined and duplicates removed. An initial selection was made by reading the titles and abstracts (in case of doubt about the

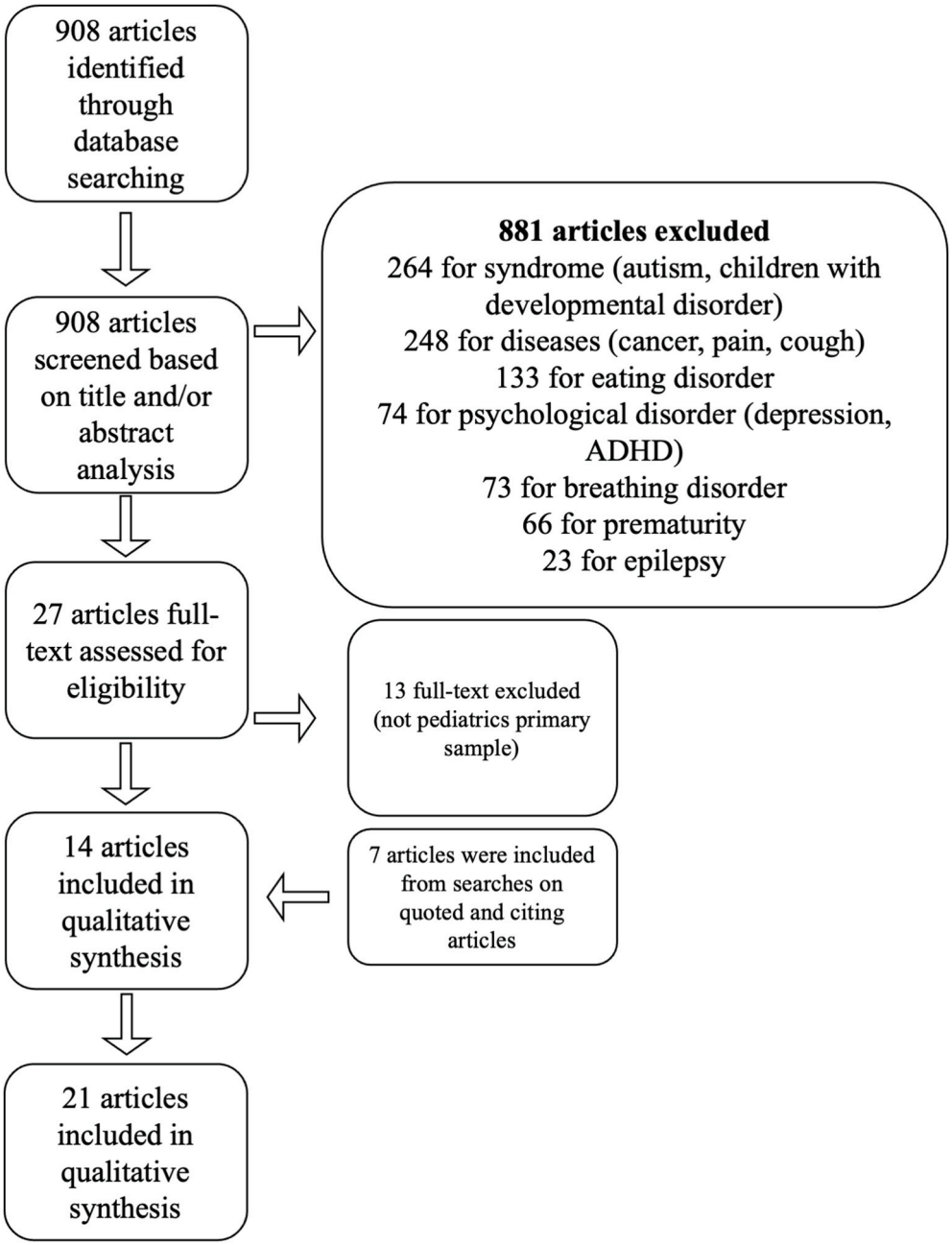

Fig. 1. Flow chart.

main objective of the article). To complete this selection of articles, searches were carried out on the references cited or the references citing reviews of the literature dealing with children's sleep. The selection was conducted in double by two of the present authors (FL and BP).

2.5. Data extraction

Data extraction from the identified studies included references, demographic information (age, gender ratio), inclusion and exclusion criteria, treatment characteristics, and measures performed. Data extraction was performed by two of the present authors (FL and BP). Only significant results ($p < .05$) are presented in this review. All results described in this article correspond to the results of the articles.

3. Results

3.1. General observations

We summarized evidence from the scientific literature via systematic searches of electronic databases of all RCTs published to date using PubMed, the Cochrane library and Psychinfo. This systematic review was conducted according to PRISMA guidelines [18].

A total of 908 RCTs met the search criteria. Following analysis of these articles, 881 were excluded from the study because they did not meet the inclusion criteria (Fig. 1): 264 had autism or a neurodevelopmental disorder; 248 had a chronic disease (cancer, pain); 133 had an eating disorder (obesity, anorexia); 74 had a psychological disorder (depression); 73 had a respiratory disorder; 66 were premature children; and 23 had epilepsy. This initial screening resulted in the selection of 27 full-text articles, which enabled the exclusion of 13 additional articles because they did not meet the age criteria or were not RCTs. Following the first reading of these 14 selected articles, and as a result of searches on quoted and citing articles, 7 additional articles were included [7,19–24]. The characteristics of these articles are described in Table S1.

In keeping with our inclusion criteria, only 21 RCTs were selected for this review, including a total of 2363 children. This screening selected all possible treatments for behavioral insomnia. The 21 studies comprised between 34% and 62% of boys, with an average of 51%. Drop-out rates were reported in 17 of the 21 studies, ranging from 0% to 16%. All studies included children between the ages of 2 months and 6 years. Only 16 studies provided the mean age of the children: for six of the studies, the children included had a mean age of less than 12 months; for five studies the mean age was 12–18 months, for three studies a mean age of 18–24 months, and finally, for two studies the children had a mean age of 27–29 months. All children included in these studies were developmentally normal on the day of study inclusion and were not ill. Table S1 describes the characteristics of the studies selected. Eight studies were conducted in the United States, three in Australia, three in New Zealand, and two in the United Kingdom. The remaining studies were conducted in Italy, Canada, Brazil, Israel, and Iran. There have been no RCTs conducted in Africa. Of the 21 studies selected, 17 were carried out in face-to-face consultations, three via an internet-based device, and one study both in person and over the internet. Only four studies used objective measures to assess the children's sleep (actimetry) [24–27]. All selected articles used at least one of the primary outcomes defined during the article selection process. Among the primary outcomes, autonomous sleep onset was not found in any article. The articles selected measured the following secondary outcomes: 1) number of nighttime awakenings with crying; 2) duration of nighttime crying; 3) number of times the child got out of bed; 4) bedtime (the time at which the child lies down in bed, this does not correspond to the time of falling asleep). Three studies compared a treatment versus a placebo (the placebo used was specified only in one single study [20] and was composed of sugar syrup with a tartrate or amaranth coloring depending on the concentration of active ingredient in the treatment group; the other two studies [19,28] did not specify the placebo used). One study compared two pharmacological treatments [22]. One study compared two behavioral methods [24]. One study compared a behavioral technique coupled with a pharmacological treatment and a behavioral technique coupled with a placebo [21]. In only one study was the control group given treatment as usual [29]. In 12 studies, the control group was obtained from a waiting list (WL) during which the parents were asked not to change their child's sleep habits (although compliance with this instruction was not verified in any of the studies). The WL group received information about the child's normal sleep in 3 studies [26,30,31] or information about the child's safety in 2 studies [25,32]. Six studies performed a follow-up of less than 2 months [23,25,28,32–34]; 8 studies performed a follow-up of between 3 and 6 months [19,24,30,31,35–38]. Three studies performed a 1-year follow-up [26,29,39,40], including one study with a follow-up of some patients at 30 months [21]. Three studies did not perform any follow-up [20,22,41]. Of the 21 RCTs selected, 14 studies were published after the publication of the first CONSORT RCT recommendations in 1996 [42]. Only four studies [24,25,31,38] out of the 14 potential studies cited the CONSORT recommendations [17], which were only ruled on in 2001.

3.2. Results of the selected randomized controlled trials

Table S1 provides a summary of the characteristics of the 21 studies selected. Table S2 lists the RCTs which assessed a specific treatment as measured by improved outcomes.

3.3. Behavioral interventions

3.3.1. Complete extinction

The **complete extinction** method consists of ignoring the child's nighttime crying (or requests) between bedtime and their wake-up time in the morning. The safety of the bedroom must be checked beforehand, and the parents must make sure their child is not hungry or thirsty, that they are clean, and that they are not in danger of hurting themselves if remaining in the bedroom alone. Supervision is maintained in case of illness or insufficient safety. Once these aspects have been checked, the parents leave the room and ignore the child's requests until the morning. The goal of this method is to limit parental interventions that act as reinforcers of the child's undesirable behaviors (i.e., crying, screaming). However, this method requires parents to let their child cry, which can be emotionally difficult for them and for the child [43].

The effectiveness of this method is demonstrated in 4 RCTs [33,35–37] involving 64 children with positive results for the number of nighttime awakenings, duration of nighttime awakenings, bedtime resistance, score on a sleep questionnaire, the number of nighttime awakenings with crying, the duration of crying, and bedtime (Table S3). These results have been demonstrated in small studies with numbers of less than 15 participants per group.

3.4. Graduated extinction

The **graduated extinction** method (Ferber, 1985), also called **checking in,** consists of ignoring the child's nighttime cries (or requests) for a predefined period of time (usually 5 min) before intervening. Either the delay is progressively increased (5 min, then 10 min, then 15 min, etc.) over the course of the night, or it remains constant with an intervention every 5 min, a delay which increases from one day to the next (Day 1: every 5 min, Day 2: every 10 min). The waiting time should never exceed 20 min. As with the complete extinction method, the child's environment and needs are checked before the method is implemented. The child then lies awake in bed and the parents leave the room. This is repeated each time the child signals his awakening (at the time of initial sleep or nighttime awakenings). As with the complete extinction method, the aim of this method is to limit the positive reinforcement maintained by the parents' behavior, and to enable the child

to develop self-soothing abilities without unwanted associations (i.e., parental presence).

For both extinction methods, it is made clear to parents that their child's crying and demands will increase initially, known as "burst extinction" [44]. Without this precaution, compliance with the method is low [33].

The efficacy of the graduated extinction method is demonstrated in 7 RCTs [24–26,31,34,36,38] involving 230 children with a positive outcome in sleep duration without parental intervention, number of nighttime awakenings, duration of nighttime awakenings, sleep onset latency, bedtime resistance, sleep questionnaire score, sleep as a problem, number of nighttime awakenings with crying, and bedtime (Table S4). These results were demonstrated by comparing intervention and control groups (waiting list) in 6 studies. One study compared two treatment methods [24] (graduated extinction vs camping out). The graduated extinction method showed very good efficacy but remains sensitive to the parents' tolerance of their child's crying [45], as this method requires leaving the child to cry for several minutes.

3.5. Structured bedtime routines

A **structured bedtime routine** entails carrying out the same series of activities just before and during the child's bedtime. The child should be put to bed no more than 30 min after the routine begins. The sleep routine corresponds to behaviors performed often in the same order leading to bedtime (taking a bath, putting on pajamas, brushing teeth, reading a story to the child, etc.). This routine represents an external time-giver and promotes the establishment of a sequence of behaviors leading to sleep [39,46].

The effectiveness of the structured bedtime routine method is demonstrated in 4 RCTs [29,34,39,41] involving 829 children with positive results for: duration of nighttime sleep, duration of sleep without parental intervention, number of nighttime awakenings, duration of nighttime awakenings, sleep latency, bedtime resistance, score on the sleep questionnaire, sleep considered as a problem, number of nighttime awakenings with crying, and number of times the child gets out of bed (Table S5). These results demonstrate the effectiveness of this method, which is easy for all parents to implement.

3.6. Sleep education

This method involves educating parents about normal and pathological child sleep. Among other things, this sleep education consists of a course on child sleep. The content of this educational course is adapted from a developmental perspective to match the actual development of the child as closely as possible. The different phases of sleep, the child's current sleep cycle, the duration of each cycle and its interest for the child's development are discussed. Normal physiological awakenings are also addressed, i.e., phases of sleep during which the sleeper ends a cycle and awakens. Regarding infants, the active sleep stage should be discussed, as during active sleep the newborn may move, groan, open its eyes, cry out, or breathe noisily or irregularly. This statement applies only to newborns and maybe often confused with wakefulness. This confusion leads parents to interact with the child and this interaction fragments his sleep, which in turn causes the child to wake up and promotes behavioral insomnia from the youngest age. For older children, explaining this state of sleep may provide a better understanding of behavioral insomnia.

The efficacy of the sleep education method is demonstrated in 3 RCTs [23,29,32] involving 217 children with positive results for: duration of nighttime sleep, duration of sleep without parental intervention, number of nighttime awakenings, duration of nighttime awakenings, sleep latency, bedtime resistance, score on the sleep questionnaire, sleep considered as a problem, number of nighttime awakenings with crying, number of times the child gets out of bed and bedtime (Table S6). These results demonstrate the efficacy of this parental education approach.

3.7. Bedtime fading

Bedtime Fading involves temporarily delaying bedtime to coincide with the usual sleep onset time. This improves sleep latency by increasing sleep pressure. When sleep onset is rapid, bedtime can be progressively advanced so that the child goes to bed earlier. The same bedtime should be maintained for a few days in a row to ensure that the child still falls asleep quickly (i.e., advance bedtime by 15 min every 2/3 days). This method is appropriate for sleep initiation difficulties.

The efficacy of the bedtime fading method is demonstrated in one single RCT [26] involving 15 children aged between 6 and 16 months with positive results for: the number of nighttime awakenings, the duration of nighttime awakenings and sleep onset latency (Table S7). These results were demonstrated in a single small study.

3.8. Scheduled awakenings

Scheduled awakenings [33]. This method asks parents to awaken their child before a typical spontaneous awakening by providing the usual responses (breastfeeding, bottle, affection) as if the child had woken up spontaneously. This method is used for children who present very regular arousals. Often used in a population of children with non-Rapid Eye Movement sleep parasomnias (confusional arousals, night terrors, sleepwalking), the hypothesis of this method is that by anticipating the occurrence of these arousals, they can be avoided. After determining the average number of arousals during the night and the regularity thereof, parents should awaken their child between 15 and 60 min before the arousal and as many times as the usual arousals tend to occur [33]. It is then easier to control the parents' behavior and gradually reduce scheduled awakenings.

The effectiveness of the scheduled awakening method was demonstrated in one RCT [33] involving 11 children aged between 6 and 54 months old with a positive result for the number of nighttime parasomnias (Table S8). These results were demonstrated in a single small study with a very large age range, making it difficult to interpret these results.

3.9. Camping out

The **camping out** method consists of a technique of gradually reducing parental presence, asking parents to be present with the child until they fall asleep. The parents' presence should be as neutral as possible, and they should not interact with or respond to the child's requests. The parent sleeps in the child's room for several days on a separate bed. If the child cries, the parent intervenes briefly and without taking the child out of bed. Once this interaction is over, the parent returns to their bed. Afterwards, the parent can leave the room once the child is asleep. At each awakening, the parent repeats the same behavior to get the child to fall asleep. The distance between the child and the parent gradually increases to reduce parental presence and reinforce the development of the child's self-soothing techniques.

Concerning the studies by Hiscock et al. [30,31], given that the participants had the choice between a graduated extinction method and a camping out method, and without indication of the percentage of participants involved in one or the other method, these two studies provide additional power to behavioral methods but were not used to provide weight in justifying the effectiveness of one or the other method.

The effectiveness of this method was demonstrated in one RCT [24] involving 48 children with positive results for: the number of nighttime awakenings, duration of nighttime awakenings and sleep latency (Table S9). These results were demonstrated by comparison with two intervention groups (camping out and graduated extinction). This method provides the option of not leaving the child to cry and of accompanying them to sleep. Parents who cannot bear to hear their children crying may prefer this effective method for behavioral insomnia.

3.10. Pharmacological treatments for child insomnia

The efficacy of antihistamines (trimeprazine 15–90 mg and niaprazine) was assessed in 3 RCTs comparing antihistamine treatment versus placebo [19,20,28] and in one RCT comparing antihistamine treatment versus another benzodiazepine-based treatment [22]. Involving a total of 67 children with positive results for: total sleep time, number and duration of nighttime awakenings and sleep being considered less of a problem (Table S10). Improvement in symptoms was observed during treatment. However, upon discontinuation of treatment, improvements were not sustained. One study was stopped before the end of the original study because only 2 children showed improvement in symptoms [20].

The efficacy of benzodiazepine (diazepam) treatments was assessed in one single RCT comparing benzodiazepine treatment versus antihistamine treatment [22] involving 30 children with positive results for the number and duration of nighttime awakenings (Table S11). As with the antihistamine treatments, improvement of symptoms was observed during treatment. When the treatment was stopped however, the improvement in sleep was not maintained. In the end, this study showed no difference in efficacy between treatment with a benzodiazepine or an antihistamine [22].

The efficacy of a combined treatment approach (pharmacological and behavioral) was assessed in one single RCT [21] involving 15 children with positive results for: the number of nighttime awakenings and the number of awakenings with crying (Table S12). This study shows good efficacy of this method of extinction coupled with an antihistamine over 10 days. The improvement of sleep was faster for the experimental group compared to the placebo group. Four weeks after treatment, no difference was observed between the extinction and extinction plus antihistamine groups, which thus demonstrates an equivalent effect without pharmacological treatment. In this case, antihistamines accelerated the initiation of extinction by the parents, probably due to the drowsiness induced by the substance at the beginning of the night.

3.11. Alternative treatment for child insomnia

No RCTs have been conducted to assess the efficacy of an alternative method for treating behavioral insomnia in young children. Although the effectiveness of these alternative treatments has never been demonstrated, they are nevertheless very commonly used.

Melatonin: no study has investigated the efficacy of melatonin (in any form and/or dose) on behavioral insomnia in young neurotypical children (0–6 years).

Herbal medicine or homeopathy: No study has investigated the efficacy of any plant-based preparation on behavioral insomnia in young children, whether neurotypical or neuro-atypical.

Manipulation therapy (chiropractic and physiotherapy), **mind and body therapy** (hypnosis, relaxation): no study has investigated the link between these different therapies and sleep disorders in young children.

4. Discussion

The purpose of this literature review was to identify which treatments for behavioral insomnia in children under 6 years of age have demonstrated efficacy. This systematic review provides an update on all treatments for behavioral insomnia in young children. Treatments for behavioral insomnia in young children without any comorbidities have not been widely studied in RCTs, and the existing studies are not all of good scientific quality (small sample sizes, lacking follow-up, lacking monitoring of treatment compliance, or lacking monitoring of the behavior of the waiting list group). Despite cultural differences, there have been no RCTs conducted in Africa. Europe has not conducted a new study in 30 years and all existing studies have focused solely on pharmacological interventions [19,22,28].

All behavioral methods have been shown to reduce the number and duration of nighttime awakenings and sleep onset latency in young children. Short-term efficacy is demonstrated in 11 studies with a follow-up between 1 and 4 months, for a total of 1020 children [23,25,26,30–37]. Maintenance of these improvements over time is demonstrated in two studies with a 6-month follow-up for a total of 153 children [24,38]; and three studies with a 12-month follow-up for a total of 712 children [26,29,39,47].

All methods show positive effects on young children's sleep. We can conclude with a good level of certainty that the methods of complete extinction, gradual extinction, positive rituals and sleep education can be recommended. However, more caution should be taken regarding camping out, scheduled awakenings and bedtime fading, as the evidence is less convincing, mainly due to both the small number of RCTs including these treatments and the small number of children included. It should be noted that positive rituals and sleep education are particularly appropriate for preventing insomnia and in children under 12 months of age. At one year or older, complete or graduated extinction is often necessary. In current clinical practice, positive rituals and sleep education are generally carried out prior to extinction in order to regulate the child's rhythms in relation to their age-related needs. This step may seem evident to practitioners, but these aspects of chronotherapy are not sufficiently emphasized in studies.

The **complete extinction** method reduces the number and duration of nighttime awakenings as well as bedtime resistance in a sample population of children aged between 6 months and 6 years old. Demonstrated in 4 RCTs [33,35–37], the complete extinction method can therefore be recommended for children from 6 months of age who present behavioral insomnia without comorbidity. This method promotes rapid improvement of sleep among young children in the short and medium term since the improvements were shown to be maintained at 3-month follow-up. The number of RCTs validating the efficacy of the complete extinction method is low, only 4 valid studies demonstrate this. The drop-out rate for these studies was between 2% and 13% (m = 9.25%) and is explained by the parents' refusal to leave their child to cry.

The **graduated extinction** method leads to an improvement of sleep among young children aged 6 months to 5 years old, with an increase in total sleep time and nighttime sleep time due to a decrease in the number and duration of nighttime awakenings, a decrease in sleep onset latency and a reduction in bedtime resistance. Demonstrated in 7 RCTs [24,26,30,31,34,36,48], this method is recommended for children from 6 months of age who present difficulties in initiating and maintaining sleep independently, requiring parental presence or intervention. A rapid and durable improvement of sleep disorders is observed, along with maintenance of the improvements at a 1-year follow-up. The number of RCTs demonstrating the efficacy of graduated extinction remains relatively low compared to the extent of its use in practice. The drop-out rate is between 3% and 16% (m = 6%), which is equivalent to that for the complete extinction method and is explained by the parents' refusal to leave their child to cry.

The **structured sleep routine** method improves many sleep parameters. Often used in prevention, from 3 months to 3 years of age, it promotes an increase in total sleep time and nighttime sleep time due to a decrease in the number and duration of nighttime awakenings, a decrease in sleep onset latency and a reduction in bedtime resistance. Demonstrated in 4 RCTs [29,32,39,41], this method makes it possible to reduce the likelihood of sleep disorders by encouraging the child to self-soothe from an early age. The maintained efficacy of the structured routine method is observed at 1-year follow-up. This method is recommended for children from 3 months of age and even from birth so as to respond to or anticipate difficulties related to the child's lack of autonomy during sleep initiation. Only one study cites a drop-out rate of 12% for various reasons (mother's refusal to participate, illness of the child or the mother), the other studies do not report any drop-out rate.

The **sleep education** method proved effective in 3 RCTs [23,32,47], in a sample population of children aged between 2 months and 3 years of age. This method promotes an increase in total sleep duration over 24 h

as well as duration of continuous sleep without crying. Sleep education is generally practiced with the parents to anticipate or respond to the child's sleep difficulties. This method is recommended from 2 months of age with no upper age limit to reduce the risk of the child developing behavioral insomnia. The drop-out rate was between 0% and 12% for various reasons (mother's refusal to participate, illness of the child or mother).

The **bedtime fading** method proved effective in one single RCT [26], in a sample population of children aged between 6 and 16 months. In particular, it reduces sleep latency, the number and duration of nighttime awakenings and increases the duration of nighttime sleep. This method could be successful for children from 6 months of age with difficulties initiating sleep and with late bedtimes. However, only one study has been conducted on this method, so it cannot be recommended at this time. The drop-out rate was zero, with sleep improvement maintained in the long term as evidenced at follow-up after 1 year.

The **scheduled awakening** method shows efficacy in one single RCT [33], in a sample population of children aged between 6 and 54 months. In particular, it reduced the duration of nighttime awakenings as well as the number of nighttime awakenings with crying. This method could be recommended for children from 6 months of age with difficulties in initiating and maintaining sleep, particularly with very regular nighttime awakenings. However, due to the small number of studies validating its effectiveness, this method cannot currently be recommended. The drop-out rate was 12% for this method with a maintenance of sleep improvement at 6 weeks. In routine care, this method is mainly used to treat parasomnias in slow-wave sleep (sleepwalking, sleep terrors and confusional arousals) [49].

The **camping out** method demonstrated efficacy in one single RCT [24], in a sample population of children aged between 9 and 18 months. In particular, it reduced sleep onset latency and the number and duration of nighttime awakenings. This method could be recommended for children from 9 months of age who have difficulty initiating sleep autonomously. However, due to the small number of studies validating its efficacy, it is not currently possible to recommend this method. The drop-out rate was 3% for this method with the improvement of sleep in the long term observed at follow-up at 6 months.

Pharmacological treatments, whether antihistamines [19,20,22,28] or benzodiazepines [22], have shown only very short-term efficacy, depending on the intake of the drug, without the efficacy being maintained once the treatment is stopped. Only one RCT [21] demonstrated a short-term interest in the use of a pharmacological treatment coupled with behavioral therapy (in this case, complete extinction). The simultaneous use of an extinction method and a pharmacological treatment based on antihistamines resulted in faster improvement of the child participants' sleep compared to participants treated with an extinction method and a placebo. The extinction method alone showed the same efficacy as that coupled with a pharmacological treatment. The only difference with an antihistamine treatment is the rapidity of the effect of the extinction method, likely due to the drowsiness effect of the treatment. No difference is noted between the groups after 10 days of treatment, however. To date, pharmacological treatments cannot be recommended for insomnia in children with no comorbidity.

Melatonin: There are no studies on the effect of melatonin on sleep in neurotypical children. In children under 5 years of age, the efficacy of melatonin in treating insomnia has only been assessed in 28 children with autism spectrum disorders (2–7 years old). The use of extended-release melatonin showed clinically significant improvements by increasing total sleep time, reducing sleep latency and the number of nighttime awakenings, with a positive effect maintained after 1 year of treatment [50]. The use of sustained-release melatonin did not negatively impact the staturo-ponderal development and puberty of these patients at a 2-year follow-up [51]. However, the diagnosis and management of sleep disorders in a population of children with autism spectrum disorder is complex and is not comparable to that of neurotypical children.

Herbal medicine or homeopathy: There are no published RCTs on the effect of herbal treatments for pediatric insomnia. Moreover, in adults, studies show no significant difference between the herbal preparation and a placebo [52].

This literature review shows that extinction methods are the most frequently recommended and the most effective [14,16,25,53–55]. However, these methods have been the subject of controversy for several years [56]. Implementation of extinction method is often met with parental resistance, as parents find extinction too stressful and too difficult to put in place in connection with Bowlby's attachment theory, which stipulated that an insecure attachment can lead to psychiatric illnesses. These criticisms stem from the "cry it out" debate in the scientific literature [56–60] and in society [61,62]. Nevertheless, the long-term impact of these methods on child attachment has not been demonstrated [63]. Since the article by Blunden et al. (2011) questioning extinction methods, eight RCTs have been published and all show reliable therapeutic efficacy. Only one study has investigated an alternative (camping out) that notably gives parents the option, among others, not to leave the child crying alone in their room and thus offers methods more adapted to the parents' profile [24]. However, studies on alternative methods adapted to the psychological profiles of the parents are lacking. A single pilot study has investigated the stress felt subjectively and the objective stress via cortisol secretions between an extinction method and a more reactive method. This study shows no difference between the different groups. Children in the reactive group simply woke up less [64].

In light of the findings of this review, new and broader RCTs should be conducted to improve the evidence-based therapeutic proposal. All methods available in the literature should be subjected to RCTs to confirm their efficacy. These studies should be carried out on all continents: studies demonstrating the efficacy of a behavioral method have not yet been conducted in Africa or Europe. RCTs should be conducted for all alternative medicines, treatments or behavioral methods that are regularly proposed without any proof of their efficacy. Each new RCT should be limited to specific ages when validated to ultimately determine which methods are effective based on the type of insomnia and the age of the child. It is also important to compare behavioral and cognitive therapy methods according to the psychological profile of the parents, in order to take into account the psychological sensitivity and cognitions of the parents of the child suffering from insomnia [65]. The systematic integration of a psychological assessment of the parents during studies on children's sleep would provide information with which to improve the choice of therapeutic methods adapted to the parent profiles, to the type of insomnia and to the age of the child.

4.1. The strengths of this review are

Our analysis is the first to research all potential treatments for behavioral insomnia, enabling us to take into account the array of therapeutic treatments available to date, and which are scientifically validated. We can see that there remains a substantial gap between the small number of RCTs on the treatment of insomnia in young children and the wide range of treatments available on the market.

This review is strengthened by its methodology based on the PRISMA protocol [17], which requires a high degree of rigor and completeness in selection processes. Moreover, this review focuses on all the outcomes of the articles included, resulting in a global methodological reflection. For example, the criterion of sleep autonomy is not sufficiently described in the studies. Sleep autonomy is a key diagnostic criterion present since the ICSD-II (2005) [66], yet none of the 11 articles published after this date mention bedtime sleep onset autonomy. This is a fundamental criterion for insomnia in young children and is central to the problem, as well as to the treatment of behavioral insomnia. The RCTs described here focus on the effectiveness of treatment and therapy on sleep parameters, even though some studies show an absence of significant change in sleep via actimetric measurements [25,26]. None have taken

into account the total remission of insomnia which must involve good autonomy in young children. Indeed, improvement in a factor such as a reduction in the number of awakenings, or in latency of falling asleep is not sufficient alone to conclude that sleep is healthy or autonomous.

4.2. Weak points

This systematic review has several limitations: 1) this review focused only on neurotypical children. 2) Some studies had a relatively small number of subjects per group (e.g., n = 11). 3) Very different sleep outcomes were observed across RCTs using a wide range of methods, making a metanalysis impossible. In particular, diagnostic criteria differed for insomnia between studies.

5. Conclusion

Currently, for the treatment of behavioral insomnia in young children under 6 years of age, the only empirically supported treatments are the complete extinction method and the graduated extinction method for nighttime awakenings and bedtime resistance. These show rapid and long-lasting efficacy for children over 6 months of age, all with neurotypical development. Structured sleep routine and sleep education methods are also recommended to prevent and regulate sleep difficulties from birth without age limit. Bedtime fading, scheduled awakening and camping out methods cannot be recommended at present due to the lack of RCTs. No evidence of efficacy has been demonstrated in the short and long term by pharmacological treatments alone or any alternative treatments.

The conclusions of this literature review highlight the contrast between the high prevalence of sleep disorders in young children, and more specifically of behavioral insomnia, and the lack of resources invested in this scientific field. The high prevalence of sleep disorders in children and the lack of professionals trained in the area of sleep in young children create a tension in the treatment of sleep disorders, which often leads families to spend a lot of time looking for therapeutic solutions. This context can give rise to non-professional and non-scientific therapeutic abuses going beyond the deontological framework of care. To address this, it would be advisable to carry out more regular RCTs on new therapeutic methods to improve the solutions proposed to professionals and families.

Practice points.

- Behavioral methods are the only empirically validated treatments for behavioral insomnia in young children with neurotypical development. (0–6 years).
- Pharmacological treatments have never shown long-term effectiveness in the treatment of behavioral insomnia in young children with neurotypical development (0–6 years).
- Alternative treatments such as alternative medicine, herbal medicine or even the use of melatonin have not been studied by Randomized controlled trials for treating behavioral insomnia in young children with neurotypical development (0–6 years).
- Randomized controlled trials are lacking in the field.

Research agenda.

This review has demonstrated the need for further research investigating behavioral insomnia in young children with neurotypical development.

- Melatonin, herbal medicine, homeopathy versus placebo (12 months old and over)
- Room sharing (same room but different sleeping surface) versus bedsharing (same sleeping surface) versus graduated extinction (12 months old and over)
- Token reward method (children older than 36 months)
- Camping out versus graduated extinction
- Assessment of adherence to the different methods according to the parents' and children's profiles (intolerance to the child's crying)
- Assessment of therapeutic components (habituation to child's crying, cognitive restructuring)
- Emotional and humoral (cortisol) repercussions (for parents and children) of complete or graduated extinction treatments and camping out

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Declaration of competing interest

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.smrv.2024.101909.

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