Behavioral Treatment of Bedtime Problems and Night Wakings in Infants and Young Children

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Abstract: This paper reviews the evidence regarding the efficacy of behavioral treatments for bedtime problems and night wakings in young children. It is based on a review of 52 treatment studies by a task force appointed by the American Academy of Sleep Medicine to develop practice parameters on behavioral treatments for the clinical management of bedtime problems and night wakings in young children. The findings indicate that behavioral therapies produce reliable and durable changes. Across all studies, 94% report that behavioral interventions were efficacious, with over 80% of children treated demonstrating clinically significant improvement that was maintained for 3 to 6 months. In particular, empirical evidence from controlled group studies utilizing Sackett criteria for evidence-based treatment provides strong support for unmodified ex-

tinction and preventive parent education. In addition, support is provided for graduated extinction, bedtime fading/positive routines, and scheduled awakenings. Additional research is needed to examine delivery methods of treatment, longer-term efficacy, and the role of pharmacological agents. Furthermore, pediatric sleep researchers are strongly encouraged to develop standardized diagnostic criteria and more objective measures, and to come to a consensus on critical outcome variables.

Keywords: Bedtime problems, night wakings, behavioral insomnia of childhood, treatment, behavioral treatment

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1. INTRODUCTION

BEDTIME PROBLEMS AND FREQUENT NIGHT WAKINGS ARE HIGHLY PREVALENT IN YOUNG CHILDREN, OCCURRING IN APPROXIMATELY 20% TO 30% of infants, toddlers, and preschoolers.[1-7] In addition, longitudinal studies have demonstrated that sleep problems first presenting in infancy may persist into the preschool and school-aged years and become chronic.[8-11] Furthermore, the impact of disturbed and inadequate sleep in young children can be both significant and extensive.[12] There is increasing evidence that sleep disruption and/or insufficient sleep has deleterious effects on children's cognitive development (e.g., learning, memory consolidation, executive function), mood regulation (e.g., chronic irritability, poor modulation of affect), attention, and behavior (e.g., aggressiveness, hyperactivity, poor impulse control), as well as health (e.g., metabolic and immune function, accidental injuries) and overall quality of life.[13-16] In addition, studies have documented secondary effects on parents[a] (e.g., maternal depression), as well as on family functioning.[17-19] Finally, the economic burden related to healthcare costs for sleep problems in infants and young children has been

estimated to be considerable.[20,21] A number of treatment strategies for bedtime behavior problems and night wakings in children exist, including behavioral management techniques, parent education, and medication. In contrast to the paucity of data that exists regarding pharmacologic treatment,[22-24] there is now a solid body of literature supporting empirically based behavioral treatments of bedtime problems and night wakings in infants, toddlers, and preschoolers. In addition, studies have also demonstrated that these strategies, compared to pharmacological treatments, are often more effective, may be more acceptable to both parents and practitioners,[25-28] and avoid potential harmful side effects associated with medication use. Behavioral sleep management strategies have the further advantage of potentially generalizing to the management of daytime issues.

Given the impact of sleep disturbances in infants and young children, and the availability of empirically supported treatment strategies, the development of clinical guidelines for the management of bedtime resistance and night wakings in young children is important and necessary. As the basis for developing those clinical guidelines, and building on several previous thorough reviews of empirically-based non-pharmacologic treatments of behavioral insomnias of childhood,[29-31] we present an updated critical summary of the current literature. A brief discussion of the issues pertaining to the definition and diagnosis of behavioral insomnia of childhood is included.

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[a] The term "parents" is used throughout the paper for stylistic reasons to denote any type of guardian or caregiver (e.g., grandparent).

1.1 Definition of Disorder and Prevalence

To clarify the definitions used in this review, it is important to make a distinction between the clinical diagnoses applicable to bedtime problems and night wakings in children, and the research definitions used in studies of children with these sleep problems. First, within the clinical realm, the 1997 International Classification of Sleep Disorders[32] separates bedtime problems

and night wakings into two distinct diagnostic categories: Sleep Onset Association Disorder and Limit Setting Sleep Disorder. The most recent revision of the International Classification of Sleep Disorders[33] uses similar terminology, but subsumes both of these clinical entities under the new clinical diagnostic category of Behavioral Insomnia of Childhood, which is further classified as sleep-onset association type, limit-setting type, or combined type. From a clinical standpoint, it should also be emphasized that the diagnostic criteria for a sleep disorder require a specific constellation of symptoms of a defined severity level to be present for a specified time and to result in some significant impairment in functioning either in the child or in the parent(s) or family. As with all psychiatric disorders, mild and transient symptoms do not necessarily constitute a sleep disorder. Bedtime problems, primarily seen in children 2 years of age and older, include bedtime stalling and bedtime refusal. Bedtime refusal behaviors are typically described as stalling, verbal protests, crying, clinging, refusing to go to bed, getting out of bed, attention-seeking behaviors, and multiple requests for food, drinks, and stories ("curtain calls"). This constellation of sleep behaviors generally falls within the diagnostic category of behavioral insomnia of childhood, limit-setting type, in which parents demonstrate difficulties in adequately enforcing bedtime limits (e.g., inconsistent or inappropriate bedtime for the child's age, conceding to multiple requests for attention after bedtime). In general, night wakings fall within the diagnostic category of behavioral insomnia of childhood, sleep onset association type, with most children relying on sleep onset associations (e.g., rocking, feeding, parental presence) to fall asleep at bedtime. During the course of normal nighttime arousals, these children are then unable to recreate this sleep association, requiring parental assistance to return to sleep.[4] Night wakings are typically viewed as problematic by caregivers only when they involve "signaling" (e.g., accompanied by crying, protesting, or getting out of bed), and are frequent and/or prolonged.

It should be noted, however, that essentially no empirical studies of "sleep problems" in children have utilized these specific clinical definitions. Rather, intervention studies have employed a number of different research criteria (see below) that are closely related to criteria for defining a sleep disorder but do not completely parallel the diagnostic criteria to define "problematic" sleep onset and maintenance-related behaviors. In addition, because bedtime resistance and frequent night wakings commonly coexist, thus are often "lumped" together for the purposes of defining inclusion criteria for studies and assessing treatment outcomes.[7] Furthermore, most studies do not distinguish between bedtime resistance and delayed sleep onset, which although often associated are not always interchangeable in terms of etiology or treatment.

In any discussion of research definitions of sleep problems in children, it should be noted that defining a sleep disorder in children, compared to adults, is more complex and challenging for several reasons. First, virtually all behavioral problems in young children, including bedtime problems and night wakings, are defined primarily by caregivers, and thus the definition is influenced by a host of variables, including parent education level, parental psychopathology, family dynamics, household composition, and parenting styles. Even those studies that have utilized a strict "research definition" of sleep problems have relied largely on parent-report data, which are subject to a number of reporting biases. The definition of these sleep problems may also be developmentally based, namely transient problems that can be understood in the context of normal physical, cognitive, and emotional changes occurring at various developmental stages. Furthermore, parental recognition and reporting of sleep problems in children also varies across childhood, with parents of infants and toddlers more likely to be aware of sleep concerns than those of school-aged children and adolescents. In addition, culturally-based values and beliefs regarding the meaning, importance, and role of sleep in daily life, as well as culturally-based differences in sleep practices (e.g., sleeping space and environment, solitary sleep vs. co-sleeping, use of transitional objects) have a profound effect not only on how a parent defines a sleep "problem" but on the relative acceptability of various treatment strategies. However, although it is clear from the above discussion that bedtime problems and night wakings are defined by a number of subjective complaints arising from parent's perception of behavior as well as the effects of sleep disruption (e.g., irritability and inattention), it should be emphasized that this is also the case for other broadly accepted childhood psychiatric disorders (e.g., oppositional defiant disorder, enuresis, attention-deficit/hyperactivity disorder).

While the research criteria used in the literature to define bedtime problems and night wakings are not consistent across studies, a number of researchers have attempted to operationalize and standardize the definition of sleep problems in infants and young children. These definitions generally include parameters related to some combination of frequency (e.g., number of wakings per night, nights per week with bedtime resistance), severity (e.g., duration of night wakings), and chronicity (e.g., weeks to months) of behaviors. For the purposes of this review, we have attempted to be consistent with the current existing literature, using the nosology of bedtime problems/resistance and night wakings to refer to "sleep problems" in infants and young children.

1.2 Prevalence

The identified prevalence of "problematic" bedtime resistance and frequent night wakings is remarkably similar across studies, even when comparing studies across cultures. It is estimated that overall 20% to 30% of young children in cross-sectional studies are reported to have significant bedtime problems and/or night wakings.[1-5] For infants and toddlers, night wakings are one of the most common sleep problems, with 25% to 50% of children over the age of 6 months continuing to awaken during the night.[30] However, because these 2 sleep complaints frequently co-exist and similar treatments strategies may be used for both, many studies do not approach them as separate concerns and thus individual prevalence rates are difficult to estimate.[7,34]

1.3 Etiology

The etiology of bedtime resistance and night wakings in childhood involves a multifactorial pathophysiologic mechanism and represents a complex combination of biological, circadian, and neurodevelopmental factors that are influenced by, but not solely attributable to, environmental and behavioral variables (such as sleeping arrangements and parenting styles).[22,35] Thus, bedtime resistance and night wakings in childhood may be viewed as arising within a similar paradigm as psychophysiological insomnia in adults, and involve predisposing, precipitating, and perpetuating factors. The predisposing factors for these problems are grounded in circadian and homeostatic perturbations that form the neurobiological substrate upon which these sleep problems are super-

imposed. The inability to "sleep through the night" and "settling" problems at bedtime/failure to "self-soothe" after night wakings essentially represent a delay in the emergence or a regression of behaviors associated with the neurodevelopmental processes of sleep consolidation and sleep regulation, respectively, that occur over the first few years of life.[3,4,36-38] Although the evolution of sleep consolidation and sleep regulation in childhood is governed principally by maturation of neural and circadian mechanisms, like many other neurodevelopmental processes (e.g., emergence of language, bowel and bladder control), it is also influenced by the context and environment in which they occur.[37,39,40] Thus, these sleep problems by definition involve some elements of learned behavior that are then amenable to modification by behavioral strategies.

The precipitating and perpetuating factors associated with bedtime resistance and night wakings are myriad, and include both extrinsic (e.g., environmental situations, parental issues) and intrinsic (e.g., temperament, medical issues) factors and often represent a combination of these issues. Bedtime problems are often associated with child temperament or challenges related to calming a child.[41-45] For example, "fussy" children may insist on a particular type of soothing/sleep-inducing technique, resisting any alternative that is less dependent on the caregiver. Some caregivers may have problems of their own (e.g., depression, alcoholism, long work hours) that interfere with their ability to set clear limits both during the day and at bedtime. Caregivers of children with current medical issues, or a history of a serious illness, may also have difficulty setting limits, due to guilt, a sense that the child is "vulnerable," or concerns about doing psychological harm to the child. Furthermore, other sleep disorders such as obstructive sleep apnea have been shown to be associated with increased bedtime behavior problems.[46,47] In other cases, there is a "mismatch" between parental expectations regarding sleep behaviors and the normal developmental trajectory. Finally, environmental factors, such as living accommodations that require a child to share a bedroom with a sibling, parent, or additional family members (e.g., grandparents) residing in the home, may also contribute to poor limit setting or negative sleep onset associations. Caution, though, must be exercised in the interpretation of some of these factors. For example, sleep proximity within the home and parent expectations may be determined by cultural, ethnic, and socio-economic differences.

1.4 Impact

The clinical impact of bedtime resistance and night wakings usually involves identifiable alterations in an infant or child's behavior. However, any discussion of the significance of pediatric sleep problems must also underscore the importance of the relationships between sleep problems and mood, development, learning, performance, and health. A wealth of empirical evidence clearly indicates that significant performance impairments and mood dysfunction are associated with daytime sleepiness resulting from insufficient or interrupted sleep.[16,48,49] Higher-level cognitive functions regulated by the prefrontal cortex, such as cognitive flexibility and the ability to reason and think abstractly, appear to be particularly sensitive to the effects of disturbed, insufficient, and/or irregular sleep.[16,50-52] Furthermore, these sleep problems appear to be an important precursor and potential early indicator of future anxiety, depression, and substance use disor-

ders.[49,53-55] Sleep problems also place a significant burden on parents and the parent-child relationship. Finally, health outcomes of inadequate sleep include potential deleterious effects on the cardiovascular, immune, and various metabolic systems, including glucose metabolism and endocrine function.

2.0 PURPOSE

The primary objective of this paper is to provide a review of the empirical evidence regarding the efficacy of behavioral interventions for the clinical management of bedtime problems and night wakings in infants and children. Secondary objectives include an evaluation of the impact of behavioral interventions on the child and parent and the durability of outcomes (short-term and long-term). The primary interventions reviewed here are standard behavioral treatment techniques that include: 1) extinction (unmodified extinction, Graduated Extinction, extinction with parental presence); 2) positive bedtime routines/faded bedtime with response cost; 3) scheduled awakenings; and 4) parent education/prevention.

3.0 METHODS

3.1 Identification and Selection of Treatment Studies

Treatment studies selected for review in this paper were identified through PsycLIT and MEDLINE searches (1970-2005) using the following keywords: (1) sleep problem-disorder-disturbance-disruption-patterns-sleeplessness; (2) bedtime problems-resistance-struggles-refusal-tantrums; (3) dyssomnias-insomnia; (4) limit setting sleep disorder-settling problems; (5) night waking-nighttime awakenings-sleep onset association disorder; (6) treatment-intervention-management-nonpharmacological-cognitive behavioral-parent training- parenting- mother-infant interaction-anticipatory-guidance-prevention-primary-care intervention; (7) children-infant-toddler-infancy-pediatric-babies-newborn-pre-school.

The criteria for inclusion of a study were as follows: (a) study included any child between the ages of 0 - 4 years 11 months (older children included in any study were excluded from the analyses; most studies including older children were case reports and single-case designs); (b) intervention study of any behavioral or psychoeducational treatment that involved behavioral principles; and (c) focus was on bedtime problems, night wakings, or a behaviorally-based sleep problem (all other sleep disorders were excluded, including parasomnias and nightmares). Exclusion criteria included: (a) no behavioral intervention or behaviorally-based psychoeducational component, (b) sleep problem associated with a primary medical or psychiatric condition (including known developmental disabilities), and (c) study was not published in a peer-reviewed publication, such as a dissertation. All types of studies, including case studies and single-subject designs, were included in the analyses.

A total of 3,008 abstracts were considered from the initial search that included all articles published through January 2005. The large majority of these were excluded because they did not meet inclusion criteria, with 92 articles selected for full review. Following full review, 35 articles were excluded primarily because the study population included children with developmental disabilities or the treatment was exclusively pharmacological. "Pearling," the process of manually scanning the captured arti-

cles' bibliography for additional relevant references not detected by Medline, netted an additional 5 citations.

The present paper is based on evidence from 52 individual studies (n > 2,500 subjects) that met inclusion criteria; these studies are denoted by an asterisk in the reference list. Each article was reviewed and rated by 2 task force members. Any disagreements were resolved by discussion and consensus among task force members.

3.2 Treatment Procedures: Description and rationale

Interventions for bedtime problems and night wakings consist primarily of time-limited parent training strategies that incorporate behaviorally-based interventions, founded on principles of learning and behavior (e.g., reinforcement, extinction, shaping). Parent training typically involves a therapist "coaching" the parents to become the active agents of change to address their child's problematic sleep patterns, habits, or sleep-related behaviors. Among the many forms of behavioral health services for young children, no other treatment has been more thoroughly investigated or widely applied as parent management training.[56]

Extinction

The first studies that were conducted on the treatment of early childhood sleep problems focused on the use of extinction [57]. Unmodified extinction procedures for sleep problems involve having the parents put the child to bed at a designated bedtime and then ignoring the child until a set time the next morning (although parents continue to monitor for illness, injury, etc). Behaviors that are ignored include crying, tantrums, and calling for the parents. Exceptions to ignoring the child include any concerns that the child is hurt, ill, or in danger. The biggest obstacle associated with extinction is lack of parental consistency. Parents must ignore their child's cries every night, no matter how long it lasts. If parents respond after a certain amount of time, the child will only learn to cry longer the next time. Parents are also instructed that post-extinction response bursts may occur. That is, often at some later date there is a return of the original problematic behavior. Parents are instructed to avoid inadvertently reinforcing this inappropriate behavior following such an extinction burst. The common term used in the media and self-help books to describe unmodified extinction techniques is the "cry it out" approach.[58]

The major drawback of unmodified extinction procedures is that it is stressful for parents. Many parents are unable to ignore crying long enough for the procedure to be effective. As a variant to unmodified extinction, some studies have utilized extinction with parental presence. This procedure involves the parents staying in the child's room at bedtime but ignoring the child and his/her behavior. Some parents find this approach more acceptable and are able to be more consistent.

Graduated Extinction

Rather than having the child cry for extended periods, Graduated Extinction procedures have been developed. The term "Graduated Extinction" refers to a variety of techniques. Typically, parents are instructed to ignore bedtime crying and tantrums for specified periods. The duration or interval between check-ins with the child is often tailored to the child's age and temperament, as well as the parents' judgment of how long they can tolerate the

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Table 1— Diagnostic Criteria of Behavioral Insomnia of Childhood

A. A child's symptoms meet the criteria for insomnia based upon reports of parents or other adult caregivers.

B. The child shows a pattern consistent with either the sleep-onset association type or limit-setting type of insomnia described below:

   i. Sleep-onset association type includes each of the following:

     1. Falling asleep is an extended process that requires special conditions.

     2. Sleep-onset associations are highly problematic or demanding.

     3. In the absence of the associated conditions, sleep onset is significantly delayed or sleep is otherwise disrupted.

     4. Nighttime awakenings require caregiver intervention for the child to return to sleep.

   ii. Limit-setting type includes each of the following:

     1. The individual has difficulty initiating or maintaining sleep.

     2. The individual stalls or refuses to go to bed at an appropriate time or refuses to return to bed following a nighttime awakening.

     3. The caregiver demonstrates insufficient or inappropriate limit setting to establish appropriate sleeping behavior in the child.

C. The sleep disturbance is not better explained by another sleep disorder, medical or neurological disorder, mental disorder, or medication use.

American Academy of Sleep Medicine. The International Classification of Sleep Disorders, 2nd ed.: Diagnostic and Coding Manual. Westchester, IL: 2005.[33]

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child's crying. Either parents can employ a fixed schedule (e.g., every 5 minutes) or they can wait progressively longer intervals (e.g., 5 minutes, 10 minutes, then 15 minutes) before checking on their child. With incremental Graduated Extinction, the intervals increase across successive checks within the same night or across successive nights. The checking procedure itself involves the parents comforting their child for a brief period, usually 15 seconds to a minute. The parents are instructed to minimize interactions during check-ins that may reinforce their child's attention-seeking behavior.

The goal of Graduated Extinction is to enable a child to develop "self-soothing" skills in order for the child to fall asleep independently without undesirable sleep associations (e.g., nursing, drinking from a bottle, rocking by parent). Once these skills are established, the child should be able to independently fall asleep at bedtime and return to sleep following normal nighttime arousals. In the popular literature, this type of intervention is often referred to as "sleep training."[59]

Positive Routines/Faded Bedtime with Response Cost

Positive routines involve the parents developing a set bedtime routine characterized by quiet activities that the child enjoys. Faded bedtime with response cost involves taking the child out of bed for prescribed periods of time when the child does not fall asleep. Bedtime is also delayed to ensure rapid sleep initiation and that appropriate cues for sleep onset are paired with positive parent-child interactions. Once the behavioral chain is well established and the child is falling asleep quickly, the bedtime is moved earlier by 15 to 30 minutes over successive nights until a pre-established bedtime goal is achieved. A scheduled wake time

is established and daytime sleep is not allowed, with the exception of age-appropriate naps.

These two strategies are similar in that they match the child's bedtime with his/her natural sleep onset time and rely heavily on stimulus control techniques as the primary agent of behavior change. Both treatments aim to increase appropriate behaviors and control of affective and physiological arousal, rather than focusing on reducing inappropriate behaviors, as is done with the previously described extinction strategies.

Scheduled Awakenings

Scheduled awakenings involve parents awakening and consoling their child approximately 15 to 30 minutes before a typical spontaneous awakening. This strategy begins with establishing a baseline of the number and time of spontaneous nighttime awakenings. Preemptive awakenings are then scheduled. Parent-induced scheduled awakenings are typically followed by the parents' usual response to a spontaneous awakening, such as rocking or nursing the child back to sleep. Scheduled awakenings are then faded out, by systematically increasing the time span between awakenings. These scheduled awakenings appear to increase the duration of consolidated sleep.

Parent Education/Prevention

One approach to treatment of sleep disturbances is to prevent their occurrence. A number of behavioral interventions have been incorporated into these parent education programs, with a focus on early establishment of positive sleep habits. Strategies typically target bedtime routines, developing a consistent sleep schedule, parental handling during sleep initiation, and parental response to nighttime awakenings. Almost all programs have incorporated the recommendation that babies should be put to bed "drowsy but awake" to help them develop independent sleep initiation skills at bedtime, and enabling them to return to sleep without intervention following naturally occurring nighttime arousals.

Many parent education programs have targeted soon-to-be-parents, as well as parents of newborns. For this review, preventive education was designated for parent education that was conducted during the prenatal period or during the first 6 months. This strategy focuses on a prevention model rather than an intervention model, as denoted by the above behavioral treatments. In contrast, general parent education was defined as occurring after 6 months of age and involved provision of information about normal sleep.

4.0 SUMMARY OF RESULTS

Table 2 (which can be accessed on the web at http://www.aasmnet.org/), summarizes the 11 studies included in the present review that meet Sackett evidence Levels I and II, based on criteria described in the method section. The following section summarizes the magnitude of changes obtained on infant/toddler behavior (e.g., bedtime crying) and sleep parameters, the clinical significance of those changes, the durability of improvements over time, and the comparative efficacy of single and combined treatments.

4.1 General findings

More than 2,500 infants and toddlers participated across the 52 selected studies that evaluated behavioral interventions for bed-

time struggles and frequent night waking. Nearly half of the subject pool (n=1,135) participated in the methodologically strongest studies employing a randomized controlled trial (RCT) design.

In the 40 studies that identified the gender of the subjects, 760 out of 1359 subjects were male (56%). Thirty-six studies provided the mean age of the subjects. The average age of the subjects in these studies was 20 months. The age range of the total pool of participants spanned from 1 week to 10 years (although only participants under 5 years of age were considered in this paper).

Seven studies indicated race; 67% of the 858 of subjects in these 7 studies were Caucasian. The remaining 33% of subjects, in those studies in which race was identified, were African-American, Asian, or the study did not provide this information. Nineteen studies were conducted in the United States, 10 in England, 7 in Australia, and 4 in New Zealand, with the remaining taking place in Canada, Iceland, Israel, Scotland, Sweden, Switzerland, or other European countries.

Of the total participant pool, 731 subjects (29%) across 28 studies were clinically referred by a professional (n=579) or self-referred (n=152) for sleep problems. A significant percentage of children (52%) across 14 studies were recruited specifically to participate in the research study, often during routine medical appointments or by posting community advertisements. It should be noted that 7 of the 9 studies in Evidence Level I recruited their research participants, whereas studies using small "n" multiple baseline designs were more likely to involve participants who were clinically referred.

Table 3 summarizes the guidelines by which the classification of evidence was evaluated, as adapted from Sackett.[60] Of the 52 selected studies, 8 (15%) represented RCTs that were classified as Level I.[17,18,20,61-65] Three studies (6%) were classified as Level II.[66-68] Twenty-six (50%) met criteria as a Level III study,[7,19,21,69-91] many of which used a multiple-baseline research design. The remaining 15 (29%) fell into Levels IV[92-94] or V.[57,95-103]

These 52 studies assessed the efficacy of a number of behavioral interventions that varied greatly in procedural delivery. Despite these differences, most of the interventions can be placed into the following categories: extinction and its variants (i.e., unmodified extinction, extinction with parental presence, Graduated Extinction), positive bedtime routines, scheduled awakenings, bedtime fading with response-cost, Positive Reinforcement, and parent education/prevention.

This empirical literature includes a wide range of outcome variables. Many researchers collected data on sleep-related variables (e.g., sleep onset latency, frequency and duration of awakenings, total sleep time), whereas others focused more on child behavior outcomes (e.g., duration of crying, frequency of leaving the bedroom, and callouts to parents). Behavioral and sleep related variables were both measured in only a few studies; some major studies included no child outcome variables, choosing instead to focus on parent sleep or emotional adjustment.

Among the studies summarized, 11% identified bedtime resistance as the primary dependent variable,[17,57,76,86,88,103] whereas frequent awakenings were the main focus in 27% of the studies.[19,21,63,64,66,72,75,78,79,82,89,92,97,104] Exactly 50% of the studies targeted the "clinical dyad" of bedtime resistance and night waking.[7,20,61,62,65,67-71,73,77,80,81,85,87,90,91,93-96,98,101,102,105] One study was unique in that it targeted bedtime fears,[83] whereas 5 studies addressed nonspecific "sleep problems."[17,18,84,99,100] Consistent with previous reviews (e.g.,[5,29,31]), as discussed above, we chose to consider bedtime disturbance and frequent night waking together. The 2 sleep disturbances frequently coexist,[34] and treatments that

Table 3—AASM Classification of Evidence

Recommendation Grades	Evidence Levels	Study Design	Studies
A	I	Large, well-designed, randomized, and blinded controlled study with statistically significant conclusions on relevant variables	9 studies:[17,18,20,61-65,104]
B	II	Smaller, well-designed, randomized and blinded, controlled study with statistically significant conclusions on relevant variables	4 studies:[66-68,105]
C	III	Well-designed, non-randomized prospective study with control group	26 studies:[7,19,21,69-88,90,91,101]
C	IV	Well-designed, large prospective study with historical controls or careful attention to confounding effects or small prospective study with control group	3 studies:[23,92,94]
C	V	Small prospective study or case series without control groups	10 studies:[57,95-103]
Adapted from Sackett[60]			**Total: 52 studies**

target 1 often generalize to the other.[7]

4.2 Specific behavioral interventions

In his 1959 study, Williams[57] appears to have been the first to formally apply Unmodified Extinction to problematic bedtime behavior. Extinction has a strong record of accomplishment, now having been evaluated in 19 separate research studies involving 552 participants.[b] With the exception of 2 studies[68,85], in 17 studies the procedure has proven highly effective in eliminating bedtime problems and night wakings, and improving sleep continuity.[57,62,63,67,71,74-76,87-89,96,97,99-101,103]

Graduated Extinction was first devised by Rolider and Van-Houten[86] as a more parent-friendly alternative to Unmodified Extinction. The protocol was modified slightly and popularized by Ferber in his 1985 self-help book[58], as well as by Douglas in 1989[106]. This variation on the extinction theme has now been evaluated in 14 studies and 748 participants. All 14 reported positive treatment outcomes as indicated by a reduction in bedtime problems and/or night wakings.[7,16-19,21,62,72,73,81,84,86,99,105] An additional 5 studies relied on the same underlying behavioral principle (i.e., gradual removal of parental attention or physical proximity) without using the formal checking procedure outlined in the original protocol.[23,68,90,96,100] It appears safe to conclude that Graduated Extinction, as applied to bedtime problems and night waking, now stands on equal empirical footing as its predecessor.

Extinction with Parental Presence is a more recent variant of extinction. The procedure is more popular in England but appears to be making its way to the U.S. Four research studies involving 290 children found the procedure to be effective.[18,84,98,104]

Positive Routines were first used by Milan in 1981[107] to address bedtime tantrums of three children with severe handicaps. Two studies[17,77] have since evaluated the protocol with 81 typically developing children, and both concluded that the procedure is rapid and effective. Positive Routines provides a positive, albeit less tested, alternative to extinction that may reduce the undesirable

post-extinction response burst that many parents have difficulty tolerating.

Scheduled Awakenings was first described by McGarr and Hovell in 1980[82], then more formally evaluated by a series of three studies by Johnson and colleagues.[63,78,79] Forty-four children have participated across 4 studies. The outcome data indicate that Scheduled Awakenings afford another treatment option for frequent nighttime awakenings. Compared with extinction, the procedure is slightly more complicated to carry out, and studies suggest that results may take several weeks rather than several days. Furthermore, scheduled awakenings are not an appropriate treatment for young children with bedtime struggles.

Having an infant or young child participate in a nightly Standardized Bedtime Routine has become a universal, "common sense" recommendation. This intervention component was included in no fewer than 14 of the selected studies.[28,62,67,68,70,75,84,88,89,96,97,99,101,105] However, it was always included as part of a multi-component treatment package, and has yet to be systematically evaluated as a stand-alone intervention. The same can be said for Positive Reinforcement, which was included as part of the treatment package in 15 studies[28,62,67,68,70,83,87-89,95-97,99-101] yet was never evaluated as the sole intervention.

Finally, outcomes from 5 large-scale studies provide evidence that Parent Education/Prevention may set the standard as the most economical and time efficient approach to behaviorally-based pediatric sleep problems. More than 1,000 parents across 5 studies[20,61,65,66,92] have received sleep education and prevention strategies during their prenatal period or the first 6 months of infancy. Results have proven to be not only statistically significant, but also clinically meaningful to parents who want to teach their newborn essential sleep skills, although given that no studies have done follow-up longer than six months the durability of effects is not yet established. For example, Pinilla[66] was able to teach 100% of infants to "sleep through the night" by 8 weeks of age, whereas only 23% of control infants accomplished this goal. Wolfson[20] used only 4 sessions to help 72% of infants to "sleep through the night" by 3 weeks post-birth, compared to 48% of control infants. Prevention strategies afford the ability to impact large numbers of infants and young children without a great deal

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[b] *The number of subjects represent the total number participating in a given study, not necessarily the number of subjects who received that particular intervention component.*

	< 6 months	6-12 months	>12 months	No follow-up
Table 4—Frequency and Percent of Studies Reporting Durability of Sleep Improvements				
Extinction Methods (n=34)	20 (59%)	8 (23%)	3 (9%)	3 (9%)
Standardized Bedtime Routine (n=14)	11 (79%)	1 (7%)	1 (7%)	1 (7%)
Positive Routines (n=2)	1 (50%)	1 (50%)		
Scheduled Awakenings (n=4)	3 (75%)			1 (25%)
Bedtime Fading/ Response Cost (n=1)				1 (100%)
Positive Reinforcement (n=15)	10 (66.7%)	3 (20%)		2 (13.3%)
Education (n=15)	9 (60%)	1 (7%)	1 (7%)	4 (26%)
General Behavioral Treatment (n=4)	2 (50%)	1 (25%)		1 (25%)
Other (n=12)	5 (41.6%)	5 (41.6%)		2 (16.7%)
Total (n=101)	61 (60%)	20 (20%)	5 (5%)	15 (15%)

of monetary or time investment. Adair[92] was able to reduce frequent night waking by half simply by incorporating written information regarding sleep habits and behavior management into 2 routine well-child medical visits. One potential disadvantage of large scale, less personalized interventions is that parents may not implement the treatment as intended, or at all. St. James-Roberts[65] incorporated Pinilla's successful treatment package into an educational brochure, and attained only a modest increase (10%) in the number of infants who slept through the night at 12 weeks of age. Group comparison data indicated that the intervention group did not implement the essential treatment components.

4.3 Overall Efficacy

Based on authors' conclusions from their own data, 94% (49 of 52) reported that behavioral interventions produced clinically significant reductions in bedtime resistance and night wakings. Three studies reported equivocal findings,[64,68,85] and no study reported detrimental effects. The percentage of participants who improved on relevant outcome measures was reported in a few studies. The average percentage of subjects who improved was 82% (range 10% - 100%), however, the timing of this determination varied considerably.

The 11 studies with the strongest research methodologies (Levels I and II) evaluated the outcomes of 9 different behavioral interventions, either alone, comparatively, or in combination. The interventions most commonly evaluated in the strongest studies included Unmodified Extinction (4 studies), Parent Education/ Prevention (4 studies), and Graduated Extinction (3 studies). Standard Bedtime Routines (2 studies) and Positive Reinforcement (2 studies) were also evaluated, but were always included as part of a larger treatment package. Nine[17,18,20,61-63,65-67] of the 11 studies found positive intervention effects and 2[64,68] were equivocal. Overall, the weight of the evidence from controlled group studies supports two behavioral interventions: Extinction and Parent Education/Prevention, with clear support for Graduated Extinction.

We conclude that infants and toddlers who exhibit bedtime resistance and nighttime awakenings respond favorably to behavioral interventions. Unmodified extinction and Parent Education/Prevention are the two treatment modalities that have the strongest empirical support. Graduated Extinction, bedtime fading/positive routines, and scheduled awakenings were also supported.

4.4 Comparative Efficacy of Treatment Modalities

The studies selected for this review varied greatly in methodologies, therefore it may be difficult to compare "apples to oranges" in selecting among available treatments. Studies used different outcome variables and methods of assessment. Most involved multi-component treatment packages, therefore few data are available directly comparing one pure treatment to another. For example, Reid[62] published an excellent study comparing Extinction to Graduated Extinction. Each intervention, however, also included 2 other treatment components (door closing if the child came out of the bedroom more than once and praise/rewards for a successful night), making it more difficult to directly compare interventions.

Despite the methodological differences, there are a few conclusions that can be drawn based on the handful of studies that conducted head-to-head comparisons of 2 or more treatments. In drawing these conclusions, only the impact on sleep-related variables were considered. One clear finding in these studies is that children participating in an active behavioral sleep intervention demonstrated more rapid and significant resolution to their sleep disturbance than those who did not receive treatment.[17,62,63] These findings support previous work suggesting that pediatric sleep disturbances often become chronic, with few children outgrowing the problem.[9,11]

The direct comparison studies provide little evidence to suggest that any 1 behavioral protocol is vastly superior to another. Positive Routines, Unmodified Extinction, Graduated Extinction, Extinction with Parental Presence, and Scheduled Awakenings were all included in 1 or more comparison studies. All 5 studies that directly compared behavioral treatments found no appreciable differences in long-term efficacy.[17,62,63,74,104] There is evidence that Unmodified Extinction may produce faster improvement than Scheduled Awakenings[63], and that combining sedative medication (antihistamine) with Extinction may produce a more immediate response with reduced infant distress.[74]

Unmodified Extinction and its recent variants (Graduated; with Parental Presence) appear to be on level playing ground, along with Positive Routines. One study concluded that compared to Graduated Extinction, "positive routines produced the fastest improvement in decreasing the tantrum behavior."[17] The data, however, appeared equivalent until approximately week 4 of treatment when Positive Routines continued to produce additional improvement as Extinction reached a plateau. Positive Routines and a variant, Faded Bedtime, appear to provide promising alternatives to more traditional extinction-based protocols. Although the 2 protocols were evaluated in only 3 of the selected studies,[17,69,77] Faded Bedtime with/without response-cost has been studied more extensively in children with developmental disabilities. Notably, Positive Routines and Faded Bedtime closely resemble a combination of 2 behavioral interventions (sleep restriction and stimulus control instructions) that have received the strongest research support in the treatment of adult insomnia.[108]

Three of the five direct comparison studies provided sufficient original data that Kuhn and Elliott[29] were able to calculate treatment effect sizes. Unmodified Extinction produced a larger effect size (d = 2.31) than Scheduled Awakenings (d = 1.11) on number of awakenings at 6 weeks post-treatment.[63] Effect sizes for frequency and the duration of bedtime tantrums were comparable for Graduated Extinction (d =0.75; duration= 1.50) and Positive Routines (d =0.88; duration=1.83).[17] At 3 weeks post-treatment, Unmodified Extinction produced a slightly larger effect size (d = 2.63) than Graduated Extinction (d = 1.93) on "good bedtimes" (settled alone in less than 10 minutes), but the results were reversed for "good nighttimes" (slept through night without sleeping with or waking parents) with Graduated Extinction (d = 2.03) slightly outperforming Unmodified Extinction (d = 1.29).[62] Most importantly, the effect sizes for all four interventions surpassed d = 0.80, which reflects a large treatment effect.[109] Overall, these effect sizes indicate that Positive Routines, Unmodified Extinction, Graduated Extinction, and to a lesser degree Scheduled Awakenings, all represent effective treatment options for the treatment of pediatric bedtime problems and frequent night waking.

4.5 Source of Outcome Assessment

Nine studies (17%) employed at least 1 objective outcome measure such as direct observations, videotapes, audiotapes, or actigraphy data.[7,21,69,84,85,88,97,103,104] Seven studies (13%) used a standardized rating scale to assess outcomes related to child behavior or infant security.[62,66,70,74,83,84,88] However, the overwhelming majority of intervention studies (77%) relied on parent completed daily diaries as the primary outcome measure. These diaries most frequently assessed child sleep (56%), however a few (8%) tracked bedtime behavior such as crying, tantrums, or leaving the bedroom. Seven studies (13%) used diaries to collect data on both child sleep and bedtime behavior.[21,65,70,71,83,86,103]

Parent completed sleep diaries typically include daily recordings for nightly bedtime, time asleep, the number, timing, and duration of any night wakings, the time of morning waking, and the duration of any daytime sleep. Although there are some limitations to parent-report measures, they are the most widely used measure of sleep in clinical settings and therefore tend to have high content and face validity. For infants and toddlers, sleep related complaints come from the parents rather than from the child[110]; therefore parents are the most obvious source of information for their child's sleep behavior.[111] Parent completed sleep diaries possess reasonable validity, high internal consistency, and good agreement (> 90%) with video or voice activated recordings, and actigraphic measures of children's sleep-wake patterns.[7,42,75,82,112-115] Parents of sleep disturbed infants have been shown to be good reporters on sleep schedule measures, but do more poorly on sleep quality measures.[116]

4.6 Secondary Outcomes

A number of studies assessed the effects of sleep interventions on secondary outcome variables, such as daytime behavior. These studies addressed possible adverse effects of behavioral interventions, as well as the potential beneficial effects on daytime behavior. A total of 13 studies selected for this review reported results pertaining to child daytime functioning such as crying, irritability, detachment, self esteem, or emotional well-being.[17,28,62,66,70,73,74,83,84,88-90,101] Five studies[17,88-90,101] based their conclusions solely on subjective retrospective parental report, whereas 8 studies.[28,62,66,70,73,74,83,84] collected formal data such as standardized rating scales or observations of parent-child interactions.

Adverse secondary effects as the result of participating in behaviorally based sleep programs were not identified in any of the studies. On the contrary, infants who participated in sleep interventions were found to be more secure[74,117,118c] predictable,[66] less irritable,[90] and to cry and fuss less following treatment.[73] Mothers indicated that behaviorally-based sleep interventions had no effect on maintaining the practice of breast feeding or on infant's total daily fluid intake.[66,92] In a number of studies, parents of older children reported improvements in their children's daytime behavior after participation.[28,70,83,84,89,101] For example, Seymour[89] reported that 73% of parents reported positive changes in their child's daytime behavior. There are several potential mechanisms to account for these findings, but 1 likely factor is the increased total sleep time and improved sleep quality that children and their parents experience following effective treatment.

It is important to indicate that sleep related behavioral intervention also led to improvement in the well-being of the parents beyond the specific benefits in sleep patterns in the children. Twelve studies collected outcome measures on parent mood, stress, or marital satisfaction.[7,17-21,28,62,64,73,74,105] A few studies collected data on fathers, however the majority focused on mothers who tended to demonstrate elevated levels of depressed mood and more disturbed sleep at pre-treatment, probably because they assumed the most responsibility in caring for a sleep disturbed infant or toddler. The results were remarkably consistent across studies. Following intervention for their child's sleep disturbance, parents exhibited rapid and dramatic improvements in their overall mental health status,[64,105] reporting fewer symptoms of depression.[7,18,19,21] They reported an increased sense of parenting efficacy,[20] enhanced marital satisfaction,[7,17,21] and reduced parenting stress.[62,117] For instance, Eckerberg[117] reported that following successful implementation of a behavioral intervention that led to significant improvement of their infant sleep, the parents reported improvements of their own mood, stress level, and fatigue. Similarly, Hiscock[18] reported a 45% decrease in depression scores at 2 and 4 months post-treatment in depressed mothers after participating in a behavioral infant sleep program. The only factor that predicted an increase in maternal depression scores was persistent infant sleep problems[18]. Another study reported that 70% of participating mothers fell above the cutoff score for clinical depression at baseline, but only 10% were still depressed following intervention for their sleep disturbed infant.[19] Finally, in a prevention study, Wolfson[20] provided sleep education to parents before and after the birth of their infant. Parents who received the sleep education reported feeling an increased sense of competence, whereas parents in the control group reported higher stress levels.

Given the strong association between chronic sleep disturbance and risk for depression,[119,120] it is possible that the observed reduction in parental depression is mediated by the improved parental sleep patterns once infant and toddler sleep problems are ameliorated. Three of the selected studies[7,21,95] collected secondary outcome data on parent sleep variables following child

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c *France, 1992 and Eckerberg, 2004 were not selected to be included in this review, however the outcome data from these studies were based on previous studies that were selected.*

participation in a behavioral sleep intervention. One found only minor improvement in parental sleep variables.[21] Mindell,[7] however, reported an 80% reduction in the frequency of parental night waking and less time awake at 1 month post-treatment.

4.7 Durability of Sleep Improvements

As seen in Table 4, 85% of the studies reviewed in this paper examined the maintenance of treatment effects over time. These studies demonstrated that treatment related changes across most types of interventions were maintained at short (< 6 months), intermediate (6 - 12 months) and long range follow-up (> 12 months). Of the studies that reported improvements in either bedtime behaviors or a decrease in night wakings, 89% reported success in all of the participants at follow-up; the other 11% reported continued treatment gains for over two-thirds of their participants.

In the majority of the studies (60%) the follow-up assessment occurred less than 6 months after treatment ended. In fact, only 5% of the studies reviewed reported the maintenance of treatment effects more than 1 year after the intervention ended. The durability of treatment effects should thus be interpreted with caution.

5.0 TREATMENT INTEGRATION

5.1 Multi-Faceted Interventions

Two or more types of interventions, or multi-faceted interventions (MFI), were used in 58% (n=30) of the reviewed studies. Concurrent implementation of multiple interventions was used in the majority of these studies whereas multiple baseline designs, or serial implementation of interventions, were reported in 30% (n = 9) of the 30 MFI studies. Only 4 of these articles were graded as evidence levels I or II,[20,62,65,68] and 16 were graded as evidence level III. The remaining 10 were graded as evidence Levels IV or V.

The types of intervention strategies varied a great deal across studies. The most common MFI interventions paired either Positive Reinforcement (n = 14) and/or Standard Bedtimes Routines (n = 17) with either Extinction or Graduated Extinction. In 3 MFI studies, there was reference to a behavioral intervention, but the type of intervention was not specified. Other behavioral techniques, such as somatic relaxation and deep breathing, time out, punishment, response cost, and a children's bedtime story, were used in 1 or 2 studies each in combination with 1 or more of the more common interventions.

Some form of parent education, either regarding sleep training (behavioral techniques, limit setting, elimination of nocturnal feeding) or general information about sleep (developmental changes in sleep across the first several years of life) was used in 11 of the MFI studies. Although these 11 studies explicitly stated that parent education was a component of the intervention, it is highly likely that a much larger percentage of studies used some form of written or verbal education. Several studies were considered MFI[20,65,72,91,92] because they explicitly stated that parents were instructed in written materials to implement multiple techniques. Finally, in 4 of these studies[20,65,72,92] written material alone was compared to therapist-guided interventions, and as discussed below, head-to-head comparisons tended to favor therapist interventions.

Eight of the MFI studies reported tailoring treatments for the individual child and family. In each of these studies, the types of interventions were discussed, but the specific approach to individualizing the treatments was not specified. Tailoring a treatment to a specific patient's needs is the norm in clinical settings, but this approach establishes several confounds that can limit the ability to generalize study findings, as well as the claims that the treatment is efficacious.

In a similar vein, the strength of the MFI studies lies in their high ecological validity, namely, most clinicians are likely to combine intervention strategies with their patients rather than rely on a single approach. The obvious weakness of the studies using MFI is that the efficacy of individual interventions cannot be analyzed. Multiple baseline or ABAB designs pose even more complexity in testing efficacy as there are carry over effects of the initial intervention strategy. While counter-balancing different interventions helps to control for carry over effects, only 1 study reported the sequence of the intervention and counterbalancing was not reported.[88]

The reported efficacy of the MFI interventions was high, between 50% and 100% of subjects had improved partially or completely, with all but 4 studies reporting between 75% and 100% improvement in bedtime behavior problems and nighttime awakenings. Thus, while there are several weaknesses and confounds inherent in this subgroup of studies that used MFI and tailored interventions, taken as a whole there was generally a large magnitude of positive change in all but 2 studies.[65,68] The strength of these studies lies in the high ecological validity of both tailored and MFI treatment approaches.

5.2 Combining Behavioral and Pharmacological Therapies

Only 1 of the articles[74] reviewed here combined behavioral intervention with pharmacotherapy. Although there are numerous studies of combined behavioral and pharmacologic treatments of adult insomnia, this is the only identified publication in the English language literature on children. The study involved a double blind, placebo controlled trial of trimeprazine (a sedating antihistamine). Thirty-five children aged 7 - 27 months were assigned to groups receiving training in extinction and were administered trimeprazine or placebo. The group receiving active medication improved more quickly, but relapsed slightly upon withdrawal, resulting in no group differences at follow-up. This finding is consistent with studies in adults[121] showing a faster response when pharmacologic agents are combined with behavioral treatments. While the focus of this paper is on behavioral interventions and not pharmacotherapy it is important to address the issue of medications because of their widespread use in clinical practice[26] and there may be specific cases in which it is justifiable to initiate a combined behavioral and pharmacological therapy.[122]

6.0 TREATMENT RESPONSE AND MODERATING VARIABLES

The role of key factors such as the length of the therapy and patient and parent characteristics has not been systematically assessed. However, a number of studies have assessed differences in therapist discipline (e.g., psychologist versus nurse practitioner) and the manner in which the interventions were delivered (written materials versus direct patient therapist contact).

6.1 Child and parent characteristics

There are no systematic reports on patient and parent charac-

teristics vis-à-vis the outcomes of the interventions. Carpenter[96] in a study of group intervention found that 73% of the parents reported improvement and suggested that marital problems, parental depression, and similar problems accounted for the failure of the intervention in the other parents. Similarly, Jones and Verduyn[98] reported 84% success in resolving sleep problems using a behavioral management program, and indicated that the sleep problems were less likely to resolve if marital discord was involved or if only 1 parent attended therapy. In another study,[62] positive outcome of 1 of the interventions (standard ignoring) was associated with maternal characteristics, namely, mothers who were less depressed, less distressed about parenting, and made less disciplinary mistakes were more likely to achieve better outcomes.

6.2 Treatment format

The format of the interventions for sleep problems in early childhood has varied considerably across studies. Although most studies have been based on therapist-parent sessions as the main mode of delivery, studies have explored other more economic modes of delivery, such as interventions by para-professionals or interventions based on an information booklet only.

Eckerberg[72] compared the effects of interventions based on advice and support to interventions based on written information only. The therapeutic approach in both interventions was based on Graduated Extinction. Both interventions reduced protesting and sleep latency, reduced the number of night wakings, and extended sleep duration. The results failed to support differential effects of the treatment format. Scott and Richards[64] compared 3 types of interventions: advice, advice and support, and a booklet group. All 3 groups gradually improved with time.

St. James-Roberts[65] assessed the effects of 3 intervention formats: (1) a behavioral group that received written material and discussed the topic with a clinician; (2) an educational group that received written guide with general guidelines but no specific behavioral instructions; (3) and a control group that received normal health services that were available to the other 2 groups. The behavioral intervention led to a modest (10%) increase in the number of infants who met the criteria for sleeping through the night (5 hours or more) at 12 weeks of age. The educational intervention produced no noticeable differences compared to the control group. It is impossible to determine if the contact with the clinicians or the specific behavioral instructions led to the limited outcome differences between the groups.

Seymour[67] compared the effects of written information with and without therapist contact. A waiting list group served as an additional comparison group. Both treatments (written information with or without therapist contact) led to a significant improvement after 4 weeks of treatment. The results were achieved faster in the group with therapist contact. However, after 4 weeks of treatment there were no significant differences between the 2 interventions. The positive outcomes were maintained at a 3-month post treatment follow-up.

Finally, Weymouth[94] performed 3 studies with different modes of delivery. In study 1, the intervention included a booklet, clinical support, and clinical support with therapists. In study 2, the intervention included a booklet and reduced contacts with the therapist, and in study 3 the intervention included only the booklet. The author concluded that some parents could succeed with a booklet alone, whereas others require additional clinical support.

The results of these studies provide limited support for the cost-effectiveness of using clinical sessions as part of the intervention model for sleep problems in early childhood. In a telephone survey of parents of 12 to 35 month old children[123] it was reported that many parents have used interventions methods based on information provided by the media (e.g., books, parenting magazines, TV) with high rates of success (above 70% for some popular interventions). These results also suggest that many parents can successfully utilize information on sleep related behavioral interventions with no need for professional help.

Another consideration of cost-effectiveness is the potential use of group rather than individual sessions. Only 3 studies assessed the use of parent group sessions and none of them compared group versus individual session format. Reid,[62] Carpenter,[96] and Szyndler[91] reported positive outcomes for group interventions. Research comparing the outcomes of individual versus group session format is needed to assess the possible advantage over more costly individual sessions.

In summary, the mode of delivery varied across studies, with some studies finding little increased benefit for face-to-face interventions. Several factors, such as symptom chronicity and severity, parental mental health and coping skills, are likely moderating factors. The quality and content of the interventions is also a key consideration that requires further assessment.

6.3 Treatment duration

The duration of the interventions varied considerably among published studies. However, there are no published studies comparing structured treatment programs of different durations. Most interventions ranged between 2 weeks and 2 months. The findings suggest that even relatively short interventions (1 - 3 sessions) can be very effective in improving sleep in early childhood. More research is needed to assess the value of more extended treatment programs in terms of short- versus long-term effects on the child's evolving sleep patterns.

7.0 CONCLUSIONS

7.1 General conclusions

This review of 52 treatment studies indicates that several well-defined behavioral approaches produce reliable and durable changes in bedtime problems and night wakings in infants and young children. Across all studies, 94% report that behavioral interventions produced clinically significant improvements in bedtime problems and/or night wakings. Approximately 82% of children benefit from treatment and the majority maintain these results for 3 to 6 months. Empirical evidence from controlled group studies strongly supports unmodified extinction, Graduated Extinction, and preventive parent education about sleep. In addition, the majority of studies also included a consistent bedtime routine, Positive Reinforcement, and general parent education about sleep.

These findings are consistent with the conclusions of 2 previous reviews[5,29] that used previously established criteria in the field of clinical psychology[124] to evaluate the empirical support for behavioral interventions. Mindell,[5] in 1999, found that extinction and parent education on the prevention of sleep problems to be well-established treatments. Furthermore, Graduated Extinction and scheduled awakenings were probably efficacious, with

positive routines a promising intervention. An updated review by Kuhn and Elliott[29] in 2003 found extinction, Graduated Extinction, and early intervention/parent education to be well-established interventions. Scheduled awakenings were considered probably efficacious, whereas extinction with parental presence and positive routines/faded bedtime with response cost were promising interventions.

7.2 Methodological issues

The outcomes of the research on the efficacy of clinical interventions for early childhood sleep problems have been very positive. However, clearly some notable methodological limitations need to be considered. The lack of standard definitions and criteria for sleep problems in early childhood limits the possibility of comparisons between studies and sometimes even for different interventions within studies. A similar problem is the lack of standardized outcome measures that would enable comparisons between studies.

Another potential concern in this area is the inclusion of single-case design studies, rather than sole reliance on RCTs as empirical evidence for these behavioral interventions. The primary limitation in studying a single-case is that the results from that particular case may not be relevant to other cases (external validity). However, larger samples producing statistically significant findings do not necessarily mean that such effects are more powerful or clinically significant.[125] Experimental single-case research designs (e.g., ABAB, multiple baseline) are stronger than large group designs at isolating mechanisms of change (internal validity), and are therefore used more commonly in applied behavioral research, thus highly applicable to the question at hand.

Advances in technology have led to new objective methods to assess sleep in young children. These relatively non-intrusive techniques (e.g., time-lapse video, actigraphy, see Thoman and Acebo[126] for review) may provide clinicians an opportunity to objectively assess target symptoms or problems in addition to parental subjective reports. It has been suggested that inflated improvement effects could result from parental fatigue when parents are asked to document each night-waking on a daily basis for extended periods.[104] However, there are clear benefits to parental report and the combination of subjective and objective measures. Parental subjective experience of the sleep problem is clearly valuable. Furthermore, objective measures may capture nighttime awakenings that are not indicative of sleep disruption, providing a better understanding of children's sleep in general. A combination of these measures is necessary to identify those children with clinically significant sleep problems.

The scarcity of studies comparing different delivery methods (e.g., clinical session versus booklet information) and their conflicting results makes it difficult to assess the essential components needed for an effective intervention. Some of these questions could be answered by traditional outcome research (comparisons between groups). Another approach is the use of process research to assess the contributions of specific elements of interventions (e.g., discussing parental fears and anxieties prior to the behavioral coaching). The complementary role of process research has not been well recognized and implemented in the study of behavioral interventions for sleep problems (see Shirk and Russell[127] for a review of these methodological issues).

Another crucial issue is the assessment of the long-term effi-cacy of the interventions. Most studies reviewed here had a follow-up period of 6 months or shorter. Recently, the long-term maintenance of positive outcomes of cognitive-behavioral interventions has been questioned in different areas of psychopathology in adults.[128] Future research should include longer follow-up periods than those that have been traditionally used.

7.3 Future research

It is clear that there are many crucial questions that remain to be answered regarding the treatment of bedtime problems and night wakings in young children. For instance, in light of the wide-range efficacy demonstrated by different intervention methods, what are the actual curative factors or the essential ingredients of these interventions? Other intriguing questions include: What are the outcome changes in actual sleep patterns as opposed to those reported sleep patterns? How long are these positive outcomes maintained? What are the negative side effects, if any?

Additional research is also needed on the impact of interventions on mood, behavior, and development. Specific child and parent characteristics need further study, such as child (e.g., temperament, age) and parent (e.g., depression, parenting style) variables related to treatment success.

In addition to the above methodological concerns, future research should move toward the use of standardized research diagnostic criteria, as well as standardized assessment measures. The use of standardized diaries and questionnaires would allow comparison across studies and their outcomes, enabling meta-analytic studies in this area. Furthermore, the addition of objective assessment tools, such as actigraphy, would be highly beneficial.

Another primary area in need of further research is the role of pharmacological agents, either alone or in combination with behavioral interventions, in the treatment of sleep issues in young children. These agents are frequently prescribed by pediatricians and child psychiatrists[26,129], however, there is limited research on their efficacy, risks, benefits, and limitations. With the advent of many new hypnotics and the potential risks associated with medications in young children, this research becomes even more crucial. Finally, research is needed to evaluate the efficacy of alternative treatment modalities such as infant massage and nutritional therapy/supplements.

7.4 Summary

After an extensive review of the pediatric sleep literature, we found that two behavioral interventions for bedtime problems and night wakings in young children, specifically Unmodified Extinction (including Extinction with Parental Presence) and Preventive Parent Education, have received strong empirical support across the highest-level of studies. In addition, support is provided for graduated extinction, bedtime fading/positive routines, and scheduled awakenings. An overwhelming majority of children respond favorably to these behavioral techniques, resulting in not only better sleep, but also improvements in child and family well-being. Although significant advances have been made in the behavioral management of these common sleep problems, clearly additional research is necessary and there are more questions to be answered. It is essential that future studies use standardized research diagnostic criteria, include more objective measures, and that pediatric sleep researchers develop a consensus on critical outcome variables

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