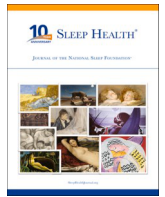


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Should you let your baby cry at night? The "no" rumor persists, despite insufficient scientific evidence with cortisol-stress measures

Despite a wealth of evidence supporting the efficacy and safety of behavioral sleep interventions, there is still widespread confusion regarding whether allowing infants to cry during bedtime is appropriate. This confusion partly stems from the dissemination of informal and formal articles based on misconceptions about cortisol function.

Based on over 30 years of scientific research, the first-line treatment recommended for infant insomnia, supported by data, is *extinction-based methods* (EBMs, e.g., modified extinction, graduated extinction, Ferber method). These methods involve letting one's child cry at night with parental intervention delays, allowing the child to gradually learn to fall asleep independently. Despite the crucial role that these methods play in enabling a developmental learning process, EBMs have been criticized due to false beliefs that temporary stress disrupts cortisol hormone regulation. As a result, rumors surrounding these methods have reduced parent engagement and adherence to these interventions, even though over 30 years of data demonstrate that they are the most effective method for treating behavioral insomnia, with no evidence of harm in the long or short term.¹ Here, we propose to analyze the foundations of these popular beliefs.

The critics of EBMs frequently base their skepticism on the cherry-picking of two studies from the same research team of Middlemiss^{2,7} out of over 30 years of research on EBMs. These studies, with highly questionable methodological credibility, propose that extinction methods disrupt the stress response synchrony between mother and child. The first of these was an uncontrolled open trial with few participants.^{2,7} In light of current scientific standards, generalizing the results from this study with confidence is inappropriate based on current scientific standards (Table 1). First, there was no control group to compare the results. Second, salivary cortisol was the only post-treatment measure calculated. This measurement was conducted 5 days after the start of treatment, which is too soon to know the long-term cortisol results. In addition, no calibration of cortisol measurements was done. These methodological inadequacies have led to major interpretation errors. The authors proceeded to conjecture that the absence of the mother-child cortisol correlation means that the child remained stressed without crying. Despite the wealth of existing evidence that behavioral methods do not have a negative impact on psychopathology³ and attachment over the long term,⁴ these two studies continue to serve as opponents to EBMs despite the lack of reliable empirical methods. When considering that nearly two out of three self-help books do not follow pediatric recommendations,⁵ such dogmatic positions based on one trial's methodology can be

counterproductive in disseminating good practice in the area of children's sleep development.

A "gentler" EBM method, known as the response-based sleep intervention (RBI) was then tested by the aforementioned Middlemiss research team.⁷ This intervention is also based on a behavioral approach but proposes a halfway compromise of parent nonintervention by staying at the child's bedside and accompanying them until they fall asleep. Utilizing pre-post measurement, the RBI resulted in a significant increase in infant total sleep time and a decrease in the average cortisol levels. However, there was no measurement of nighttime awakening, including wake after sleep onset, or sleep onset latency. The authors concluded that this intervention is a better alternative to EBMs, with a decreased likelihood of negative impact on infant well-being. However, this study was again, that of an uncontrolled open trial design, with no comparison to other EBMs and thus this conclusion is likewise speculative. Another concern regarding both studies by Middlemiss is that all treatment was delivered within a residential treatment center, which in and of itself can lead to stress upon admittance and acclimation over time, further raising doubt on the generalizability of their claims. Therefore, from a scientific point of view, these two studies^{2,7} do not allow for conclusions to be drawn about the relationship between stress, behavioral methods, and young children's sleep; and yet these studies are often cited as strong arguments against EBMs.

More recently, two more robust randomized controlled studies were conducted by two other research teams. Blunden et al⁸ compared modified extinction and the responsive method (RBI) in infants. This study, which evaluated the levels of cortisol and sleep outcomes, did not observe any variations in cortisol and concluded that both methods were equally effective, with the latter being better tolerated by parents. Thus, their study, which utilized a more robust scientific method, found no evidence to support the claim that modified extinction elevates cortisol levels in children. Furthermore, Gradisar et al⁶ demonstrated that graduated extinction and bedtime fading interventions lead to significant reductions in nocturnal wakefulness and sleep onset latency in infants, without inducing chronic elevations in cortisol levels or negatively impacting long-term emotions and behaviors. Additionally, no significant differences in attachment styles were observed between groups, suggesting that these interventions do not compromise the quality of parent-child relationships. Consequently, these findings support the efficacy of behavioral sleep treatments in promoting healthy sleep in young children without adverse consequences.

Table 1
An illustrative methodological comparison of several main token studies comparing the treatment of behavioral insomnia in children measuring cortisol: response-based sleep intervention and extinction-based methods

Protocol	Pre-post design	Randomized controlled trial	Pre-post design	Randomized controlled trial
Methods	5 d extinction of crying responses	Graduated extinction vs Bedtime fading ^a vs Control group (education)	5 d "response-based"	Responsive versus controlled crying
N	25 mother-infant dyads	43 mother-infant dyads: graduated extinction (n = 14); bedtime fading (n = 15); or sleep education control (n = 14)	34 mother-infant dyads	41 mother-infant dyads: responsive (n = 15); controlled crying (n = 18); or controlled (treatment as usual) (n = 8)
N analyzed	12	29	23	29
Drop-out	13	14	11	12
Age	4-10 mo	6-16 mo	4-11 mo	4-12 mo
Cortisol sample	Mother and the child salivary cortisol sampling 1/ At the beginning of the sleep routine 2/ After falling asleep	Only children Morning and afternoon salivary cortisol sampling	Mother and child salivary cortisol sampling (1) Upon waking, (2) At the beginning of the sleep routine (3) 20 min after falling asleep	Mother and the child salivary cortisol sampling (1) After breastfeeding (2) Before the sleep routine (3) 45 min after the start of the intervention
Cortisol measurement	(1) Day 1 (2) Day 3 of protocol	(1) Pretreatment (2) 1 wk after treatment	(1) For the 3 d of the program	(1) Week before treatment (2) Start of the treatment
Follow-up	None	3 mo and 12 mo	Day 9 after treatment	2 and 6 wk after treatment
Outcomes	Not analyzed -Infants' signaling and distress behaviors -Sleep practices -Questionnaire Attachment Q-Sort -Maternal Separation Anxiety	- Sleep diary -Actigraphy -Edinburgh Postnatal Depression Scale -Depression, Anxiety and Stress Scale -Child Behavior Checklist -Strange situation procedure	- Edinburgh Postnatal Depression Scale -Depression, Anxiety and Stress Scale	-Distress -Maternal perception of infant distress -Edinburgh Postnatal Depression Scale -Sleep diary

As this table is illustrative, note that this is a nonexhaustive list: a rich literature exists containing over 30 y of empirical tests on the efficacy of extinction-based methods.

^a The bedtime fading method consists of delaying a child's bedtime in order to improve their falling asleep and then gradually adjusting their bedtimes.

The replicability of results in psychology is crucial and is unfortunately often neglected.⁹ Theories based on too few studies (and especially open trial designs) that have not been reproduced can have adverse consequences, especially when they are used to make decisions about child health. As a result, for the past 10 years, the debate on the effect of stress from EBMs has remained open.¹⁰ It is important to note that stress is recognized as a natural and necessary response that mobilizes adaptation, or learning how to appropriately adapt to new situations, thus serving as a crucial enabler of healthy child development. Furthermore, it is very difficult to measure and represent cortisol holistically, given its production being linked to a circadian rhythm and being highly variable from one child to another.¹¹ Despite the more reliable methodology of these two more recent studies,^{5,8} false beliefs still persist like all rumors,¹² which call for caution in studies' interpretation and scientific integrity.

Furthermore, a comprehensive understanding of the multifaceted role of cortisol in human physiology can be crucial to avoid misunderstandings and guide appropriate clinical interventions. The research on cortisol, from fetal life to adulthood, demonstrates the vital importance of this hormone in human developmental processes.¹³ At the end of pregnancy, an elevation in cortisol is crucial for preparing the newborn to effectively adapt to postnatal environmental stimuli.^{14,15} At birth, cortisol continues to play a central role in regulating numerous physiological processes, including stress response and metabolism modulation.¹⁶ Adequate cortisol release in response to stressful stimuli is essential for ensuring effective adaptation and maintaining optimal homeostasis in the face of environmental changes.^{17,18} Additionally, appropriate cortisol levels during childhood are closely associated with healthy neurological and psychosocial development, thereby enhancing resilience to the challenges of daily life.¹³

The temporary elevation of cortisol levels is a normal physiological response to change in general. Thus, the neurodevelopmental, emotional, and cognitive consequences are very different when said stress is transient (acute), as is the case with EBMs, or chronic, which may be more deleterious. The elevation of cortisol also depends on sleep quality: young children who have fragmented sleep with multiple waking have higher cortisol levels upon waking than those who have good quality sleep.¹⁹ Finally, it appears that the relationship between cortisol release and its consequences also depends on individual and environmental factors (maternal stress, quality of mother-child relationships).¹³ Therefore, a transient elevation in cortisol can be considered a covariate of healthy development, so it is necessary to differentiate between transient and long-term elevations.

The safety of any method proposed for teaching a child independent sleeping habits is not to assess whether it provokes (initial) stress and thus elevation of the cortisol level, but whether it influences a child's sense of secure vs. insecure attachment.¹³ Secure attachment develops when parents respond appropriately to a child's needs and has an impact on the development of mental health. Several longitudinal studies have shown no effect of leaving babies to "cry it out" on attachment quality.^{4,6,20,1} If the mother-child asynchrony observed by Middlemiss et al,² indicates a disturbance in their communication, oxytocin would be a more relevant marker than cortisol because it is involved in prosocial behavior and the regulation of stress.²¹ We also propose that oxytocin should be included in studies as an objective marker of attachment,²² rather than focusing on cortisol as a measure of stress.

As an important reminder, in the first months of life, infants need their caregivers' involvement at night for external regulation and feeding. However, for older infants, the aforementioned results of the previously discussed scientific literature^{23,24} demonstrate that a

reduction in parent nighttime soothing (or intervention) may lead to important developmental steps that overall, result in promoting sleep autonomy in their children. Therefore, while reducing parental soothing behaviors may generate temporary stress within the child-parent dyad, this stress appears necessary. Nonetheless, it is important to adopt a flexible approach that considers cultural values, norms, and the specific needs of each family, while best supporting healthy development of a child's sleep practices and expectations; especially their capacity to self-soothe.

For behavioral childhood insomnia, EBMs are considered the reference and empirically-validated treatment method treatment method^{23,24} for sleep professionals that are solicited by exhausted parents seeking remediation of this issue. In reality, these professionals aim to support exhausted families by providing practical, effective, and tailored tools to provide a solution to this issue, as per their request. The long waiting lists for pediatric sleep clinicians and services reflect a growing demand for interventions designed to help families overcome this exhausting cycle. Therefore, it is often necessary to clarify misunderstandings about EBMs, to ensure that parents may consider applying this method which is often an appropriate solution for the treatment of their child's insomnia.

Moreover, no study has actually shown a negative impact of behavioral methods on the psychology of the caregiver or child, rather an advantage: reduced stress over the first month of the intervention⁶ and depression in mothers,¹ with no change in children's level of separation anxiety.^{20(p20)} EBMs are not likely harmful, but studies with robust methodology continue to be necessary to evaluate the short-term and long-term effects of Behavioral Sleep Interventions.^{23,24} This research area has significant societal implications and therefore continued research needs to be conducted, with less of a focus on continuing this debate but instead assessing which interventions work best for which families. Small-sample studies conducted by Blunden et al⁸ and Gradisar et al⁶ are very important and should be replicated on a larger scale. The current seeming ambiguity makes many parents feel guilty and stigmatizes the more empirically-founded clinical practices while the consequences of child insomnia lasting for months or even years are well recognized.²⁵ Finally, it should be emphasized that EBMs must be prescribed by pediatricians or practiced by psychologists or neuropsychiatrists with caution. They must be adapted in the event of specific clinical cases (e.g., neurodevelopmental disorders, premature infants, chronic organic conditions, maternal psychopathology, cases of neglect, etc.), and should not be considered a dogmatic approach either to be applied systematically. The RBI method can be considered as a potential transitional form of the fuller EBM, and is often used as a first step in treatment.

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