

Behavioral Interventions for Infant Sleep Problems: A Randomized Controlled Trial

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abstract

OBJECTIVES: To evaluate the effects of behavioral interventions on the sleep/wakefulness of infants, parent and infant stress, and later child emotional/behavioral problems, and parent-child attachment.

METHODS: A total of 43 infants (6–16 months, 63% girls) were randomized to receive either graduated extinction ($n = 14$), bedtime fading ($n = 15$), or sleep education control ($n = 14$). Sleep measures included parent-reported sleep diaries and infant actigraphy. Infant stress was measured via morning and afternoon salivary cortisol sampling, and mothers' self-reported mood and stress. Twelve months after intervention, mothers completed assessments of children's emotional and behavioral problems, and mother-child dyads underwent the strange situation procedure to evaluate parent-child attachment.

RESULTS: Significant interactions were found for sleep latency ($P < .05$), number of awakenings ($P < .0001$), and wake after sleep onset ($P = .01$), with large decreases in sleep latency for graduated extinction and bedtime fading groups, and large decreases in number of awakenings and wake after sleep onset for the graduated extinction group. Salivary cortisol showed small-to-moderate declines in graduated extinction and bedtime fading groups compared with controls. Mothers' stress showed small-to-moderate decreases for the graduated extinction and bedtime fading conditions over the first month, yet no differences in mood were detected. At the 12-month follow-up, no significant differences were found in emotional and behavioral problems, and no significant differences in secure-insecure attachment styles between groups.

CONCLUSIONS: Both graduated extinction and bedtime fading provide significant sleep benefits above control, yet convey no adverse stress responses or long-term effects on parent-child attachment or child emotions and behavior.



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Dr Gradisar provided co-conception and design of the study, supervision of most of the analyses and conducted the rest of analyses, significant contribution to the interpretation of analyses, and was main contributor to writing of manuscript; Dr Jackson provided co-conception and design of the study, collected most of the data (pretreatment to 3 months), conducted most of the analyses, provided significant input to the literature reviewed, was a minor contributor to writing of the manuscript, and provided critical evaluation of manuscript drafts; Dr Spurrer provided co-conception and design of the study, critical evaluation of manuscript drafts, and interpretation of findings; Ms Gibson provided input into study design, collected most of the 12-month follow-up data, and provided interpretation of findings and critical evaluation of manuscript drafts; Dr Whitham provided input into the study design, conducted data scoring and analyses of 12-month

WHAT'S KNOWN ON THIS SUBJECT: Recommended guidelines exist for the treatment of nocturnal wakefulness for infants, including graduated extinction and bedtime fading. Such interventions have a solid evidence base for improving infant sleep, yet little is known about their contraindications.

WHAT THIS STUDY ADDS: Sustained improvements in sleep latency were found for both treatment groups, but not controls, yet no significant differences occurred in the infant salivary cortisol, parental stress and mood, and attachment profiles between all groups.

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Nocturnal wakefulness is normal during early infant development (ie, first 12 months).¹⁻³ Night wakings allow infants to signal parents' provision of sustenance and comfort.^{1,3,4} At 2 months of age, sleep homeostatic pressure develops, potentially compressing nighttime awakenings.² Large declines in nocturnal wakefulness occur (on average) over the first 6 months of age, and plateau thereafter,^{2,5} occurring after 24-hour circadian rhythm stabilization at ~3 to 6 months of age.^{6,7} Infants' nighttime awakenings typically diminish by the end of the first year of life³; however, from 6 months, 16% to 21% of infants continue experiencing nocturnal wakefulness such that parents report their child has a "sleep problem."^{8,9} Sleep problems may be due to reduced sleep homeostatic pressure² and/or a "coercive behavior trap," whereby parents' nocturnal responses are more reinforcing than sleep.¹ Aside from an array of known daytime impairments that follow from sleep restriction in adults,¹⁰ serious consequences have been reported for families who have an infant with a sleep problem. Mothers of infants with a sleep problem are more likely to use physical punishment,^{11,12} and are at an increased risk of developing depression (eg, >2.0 odds ratio).^{9,13-15} Also worth noting is that mothers with emotional disturbances (ie, stress, depression) are more likely to report intrusive thoughts of harming their infant,^{16,17} and some even commit filicide.¹⁸⁻²⁰ Thus, evidenced-based treatments that rapidly resolve infants' sleeplessness while minimizing family distress are vital.

Several interventions exist for infants' sleeplessness. Some with the strongest evidence are based on psychological learning theory (ie, operant conditioning), where the parents' response to their infant's nocturnal cries are totally ignored (extinction), or initially delayed

TABLE 1 Timing of Screening Measures, the Primary Outcome Variable, and Secondary Outcomes

	Pretreatment	1 wk	1 mo	3 mo	12 mo
Edinburgh Postnatal Depression Scale (screen for postnatal depression)	•				
Infant Development Inventory (screen typical development)	•				
Sleep diary (primary outcome [sleep])	•	•	•	•	
Actigraphy (objective measure of sleep)	•	•	•	•	
Salivary cortisol (secondary outcome: infant stress)	•	•		•	•
DASS-21 (secondary outcome: parent stress/mood)	•		•	•	•
Child Behavior Checklist 1.5–5.0 y (secondary outcome: child behavior/emotion)					•
Strange situation procedure (secondary outcome: child-parent attachment)					•

Child Behavior Checklist and DASS-21 were blind scored by JW; strange situation procedure was blind scored by RD; actigraphy data were automatically scored using the ActiWare (v.5, Philips Respironics, Bend, OR) computerized algorithm after manual correction of bedtimes from sleep diaries.²⁸ Sleep diaries were scored by KJ.

(eg, 2 minutes) and then gradually extended up to 6 minutes on the first night (graduated extinction).²¹ Despite a longstanding solid evidence base for improving infant sleep and maternal mood and stress both in the short- and long-term,^{21,22} concerns have nonetheless been raised. The immediate stress experienced by parents while undertaking extinction-based methods can often lead to ceasing such techniques.^{23,24} However, arguably more important (and central to the current article) is that the stress associated with extinction-based treatments might elevate cortisol levels that could have long-term consequences of infant helplessness, and later insecure parent-child attachments and child emotional and behavioral problems.^{3,25} This antithesis to using extinction-based methods has strong support, to the extent that more gentle approaches are sought. Bedtime fading is one such technique.²¹ Based on the physiologic theory of sleep homeostasis,^{26,27} bedtime fading indirectly compresses sleep by gradually limiting time in bed, usually by delaying the infant's bedtime by 15 minutes each night.²¹ The current study's aim is to compare effects from graduated extinction and bedtime fading against a sleep education control on infants' sleep,

stress, attachment, and emotional and behavioral problems, as well as maternal mood and stress, over 3 months of treatment and at a 12-month follow-up. The primary outcome was infants' sleep (sleep latency, number of wakings, wake after sleep onset), and secondary outcomes were infants' cortisol, parents' stress and mood, child-parent attachment, and child behavior. Descriptions and the timing of these measures are presented in Table 1.

METHODS

Participants

A total of 43 infants (mean age 10.8 ± 3.5 months, 6–16 months, 63% girls) and their mothers (mean age 33.3 ± 4.8 years) and fathers (age 35.5 ± 6.4 years) were randomly assigned to receive graduated extinction (*n* = 14), bedtime fading (*n* = 15), or sleep education control (*n* = 14). Inclusion criteria were the following: ≥1 parent identifying their child having a "sleep problem" (parents responded with "yes" to the question "Do you think your child has a sleep problem?")²⁹; doctor/health nurse check ≤1 month where the infant was healthy and attained expected weight gain; and typical infant development (Infant Development

Inventory). Exclusion criteria were the following: significant postnatal depression (Edinburgh Postnatal Depression Scale scores ≥ 15), and indication of suicidality. Most parents were in a marriagelike relationship (92.7%), had higher education qualifications (77.2%), and were middle- to high-income earners ($>AUD\$80\,000$; 48.7%). Mothers were mainly responsible for their infant's sleep (69.3%; 26.9% shared responsibility). Table 2 presents the sample demographics. Parents provided informed consent to participate. The study was approved by the Flinders University Social and Behavioral Research Ethics Committee.

Procedure

Parents contacted researchers in response to advertisements at pediatric outpatient clinics, child care centers, health professional private practices, newspapers, and word-of-mouth. Parents completed a questionnaire and a 90-minute interview (conducted by K.J.) assessing the infant's medical and sleep history. Eligible families were randomly assigned via a predetermined computerized block randomization held by K.J. (random allocation was not concealed from K.J.). Due to ethics committee requirements, parents were allowed to swap conditions. This occurred for 2 families (1 from graduated extinction to sleep education control; 1 from sleep education control to graduated extinction).

During pretreatment, families completed sleep measures (7-day sleep diary; ankle-worn activity monitor [AW64 Minimitters; Philips Respironics, Bend, OR]), and maternal depressed mood and stress (depression and stress subscales of the Depression Anxiety Stress Scale–Short Form [DASS-21]). Parents collected infant saliva samples in the morning (mean \pm SD time 8:59 AM ± 1.27 hours) and

TABLE 2 Demographic Characteristics of Participating Families, by Treatment Group

	Graduated Extinction	Bedtime Fading	Education Control
Child			
Age, mean \pm SD, mo	10.8 \pm 3.7	11.8 \pm 3.4	9.61 \pm 3.3
Boys, n (%)	5 (39)	5 (31)	5 (42)
Mother			
Age, mean \pm SD, y	31.38 \pm 4.4	34.44 \pm 5.1	33.82 \pm 4.3
Education status, n (%)			
Did not complete high school	—	—	1 (8.3)
Completed high school	2 (15.4)	3 (18.8)	1 (8.3)
Completed higher education	11 (84.6)	13 (81.3)	10 (83.3)
Father			
Age, mean \pm SD, y	33.38 \pm 5.4	35.67 \pm 7.0	37.73 \pm 6.2
Education status, n (%)			
Did not complete high school	—	1 (7.1)	3 (27.3)
Completed high school	2 (15.4)	5 (35.7)	—
Completed higher education	11 (84.6)	8 (57.1)	8 (72.2)
Family			
Parental status, n (%)			
Two parents	13 (100)	14 (87.5)	11 (91.7)
Single parent	—	2 (12.5)	1 (8.3)
Household income per annum, n (%) ^a			
<50 000	—	4 (26.7)	3 (25.0)
50 000–80 000	4 (33.3)	5 (33.3)	4 (33.3)
>80 000	8 (66.7)	6 (40.0)	5 (41.7)

Data missing for $n = 1$ for each of graduated extinction and bedtime fading groups. —, no data.

afternoon (mean \pm SD time 3:38 PM ± 1.24 hours) on 2 consecutive days by using sterile cotton-tipped eye spears.³⁰ Blinded frozen samples (-20°C) were thawed and centrifuged before cortisol analysis in duplicate by enzyme-linked immunosorbent assay (Salimetrics, LCC, State College, PA). The group origin of the samples was blinded to the laboratory, and samples were within acceptable validity criteria (the intra-assay coefficient was $<10\%$, and the interassay coefficients at 3.0 nM and 27.5 nM were 13.5% and 9.3%, respectively).³¹

Parents subsequently underwent their individualized treatment session. Graduated extinction involved a set schedule of gradually delaying parents' response to their infant's cry (see Supplemental Table 4). Parents were instructed to put their infant to bed awake and leave the room within 1 minute. When reentering the room, they comforted their child, but avoided picking the child up and turning the lights on. Bedtime fading involved gradually

limiting the infant's nocturnal sleep opportunity (Supplemental Table 4). For the sleep education control, parents were provided sleep information from a statewide child health service (www.cyh.com; Supplemental Table 4). Families received a booklet describing their intervention, and 24/7 cell phone support (by K.J.). Of calls received, these included clarification of techniques, delaying treatment, and clarifying measurements (saliva, actigraphy), with no perceived differences in the number of calls between groups (unfortunately, no systematic data were recorded for these calls; thus, these data are based on our retrospective recall).

Parents participated with their child in the strange situation procedure to assess child-parent attachment.³² This procedure used 8 standardized interactions (including separations and reunions) between the parent, child, and a stranger (the stranger was blind to children's group allocation), which were videotaped and blind scored (by R.D.) according

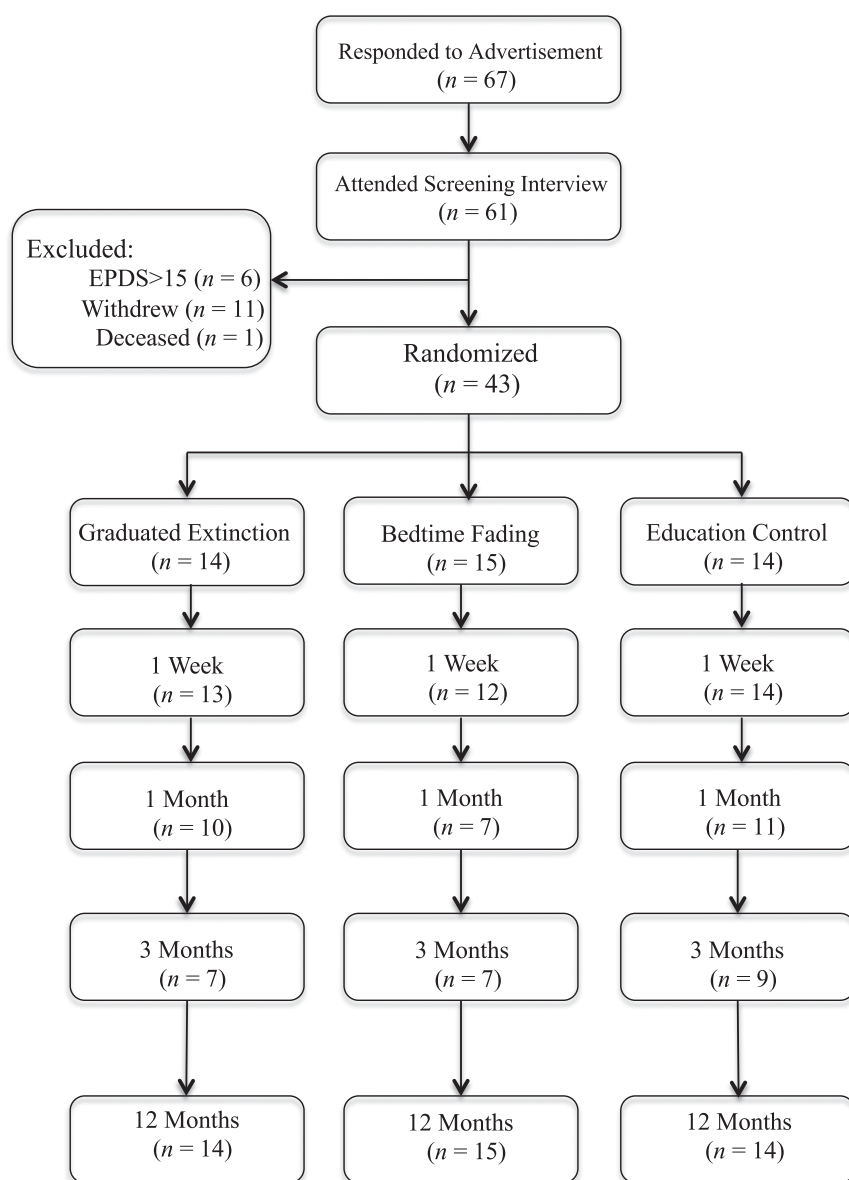


FIGURE 1
Participant flow through the randomized controlled trial.

to gold standard criteria. Recordings of each child-parent dyad were coded as either secure, insecure (avoidant), insecure (resistant), and insecure (disorganized).

Analysis

Linear mixed-model regressions were used to test for significant interactions on primary (sleep diary) and secondary (infant cortisol; maternal stress/mood) outcome variables. Within-group Cohen's *d* effect sizes were calculated to

demonstrate changes within each intervention. A time-of-day effect was found between morning and afternoon cortisol values (pretreatment, $P < .01$), thus morning and afternoon cortisol values are analyzed separately. Fisher's exact test was used to assess differences in attachment styles between groups. A series of 1-way analyses of variance assessed between-group differences on the Child Behavior Checklist. No effect sizes were available for using bedtime fading on typically

developing infants, nor some of the important secondary outcomes tested in the current trial (eg, salivary cortisol). Large effect sizes (Cohen's $d > 0.80$) for graduated extinction (compared with controls) have been reported for sleep.²¹ Based on a power of 0.80, and a probability level of .05, at least 21 participants per group would be needed to detect a large effect size.

RESULTS

Figure 1 presents the flow of participants through each stage of the study.

Infant Sleep

Figure 2 presents descriptive statistics for infants' sleep over the 3-month treatment and follow-up period. Linear mixed model regression analyses of sleep diaries showed significant interactions for sleep latency, $P < .05$, wake after sleep onset, $P < .0001$, number of awakenings, $P = .01$, and total night sleep time, $P < .01$. From pretreatment to the 3-month follow-up, sleep latency showed large declines for infants in both the graduated extinction (-12.7 minutes; $d = 0.87$) and bedtime fading (-10 minutes; $d = 1.04$) groups, but no change for the control group ($+2.0$ minutes; $d = -0.11$). There was a very large decline in the number of awakenings for infants in the graduated extinction group ($d = 1.98$), yet no changes for infants in both the bedtime fading ($d = 0.10$) and control ($d = 0.13$) groups. Large improvements in wake after sleep onset were found for infants in the control (-31.7 minutes; $d = 0.93$) and bedtime fading (-24.6 minutes; $d = 0.99$) groups, with a very large improvement found for the graduated extinction group (-44.4 minutes; $d = 2.02$). Finally, total sleep time showed a moderate increase in the graduated extinction condition ($+0.32$ hour), little change in the bedtime fading condition ($+0.09$ hour), and

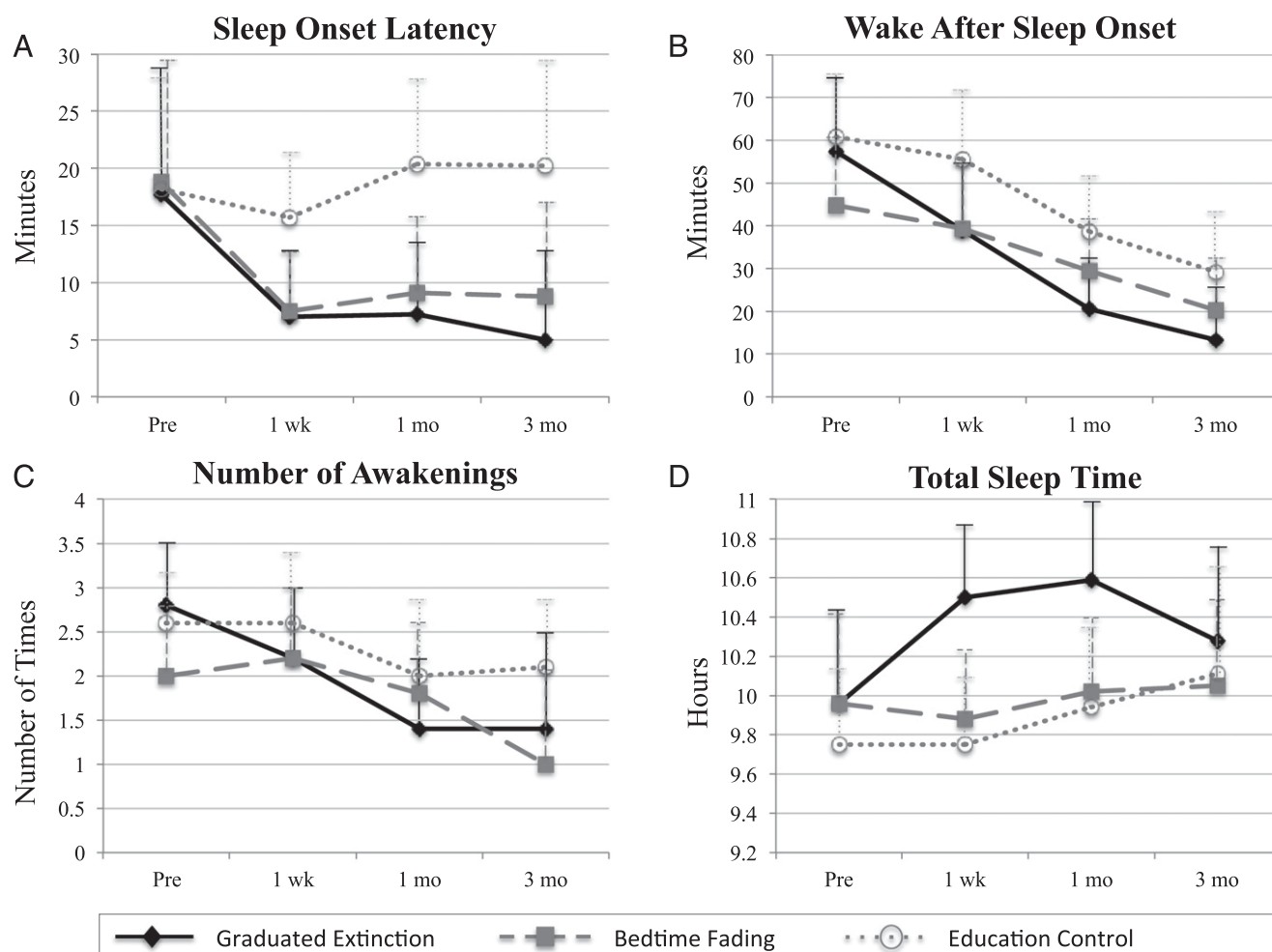


FIGURE 2 Means (95% confidence interval [CI]) during and after treatment of infants in graduated extinction, bedtime fading, and sleep education control for (A) sleep onset latency, (B) wake after sleep onset, (C) number of awakenings, and (D) total nocturnal sleep time.

a moderate increase in the control condition (+0.36 hour). Actigraphy showed no significant interactions for wake after sleep onset, $P > .05$, and total sleep time, $P > .05$.

Infant and Parental Stress

Morning and afternoon infant cortisol values for each group over time are presented in Fig 3. No significant interactions occurred for morning cortisol, $P > .05$, yet there was for afternoon cortisol values, $P < .01$. From pretreatment to the 12-month follow-up, morning cortisol showed a small decline in the graduated extinction group ($d = 0.23$), a moderate drop in the bedtime fading group ($d = 0.62$), yet no change for the control group ($d = 0.17$).

Afternoon cortisol showed a large decline in the graduated extinction group ($d = 0.89$), a moderate decline in the bedtime fading group ($d = 0.61$) and a small decline in the control group ($d = 0.39$).

A significant interaction was found for maternal stress, $P < .01$ (Fig 3). There were moderate improvements in all groups from pretreatment to 12-month follow-up (graduated extinction: $d = 0.51$; bedtime fading: $d = 0.62$; control: $d = 0.64$). However, over the initial month of treatment, mothers' stress in the control group remained somewhat unchanged ($d = 0.16$), whereas there was a moderate stress reduction for mothers in the graduated extinction group ($d = 0.67$)

and a large reduction in mothers' stress in the bedtime fading group ($d = 0.86$). Analysis of maternal mood demonstrated no significant interaction, $P > .05$. Mothers' mood improved from pretreatment to the 12-month follow-up in all conditions, with small effects found for those in the graduated extinction ($d = 0.34$) and control ($d = 0.39$) conditions, yet a large effect for mothers in the bedtime fading group ($d = 0.83$).

Twelve-Month Follow-up: Child Attachment and Emotional-Behavioral Problems

Table 3 presents the percentage of parent-child attachment classifications in each group. No significant differences were found

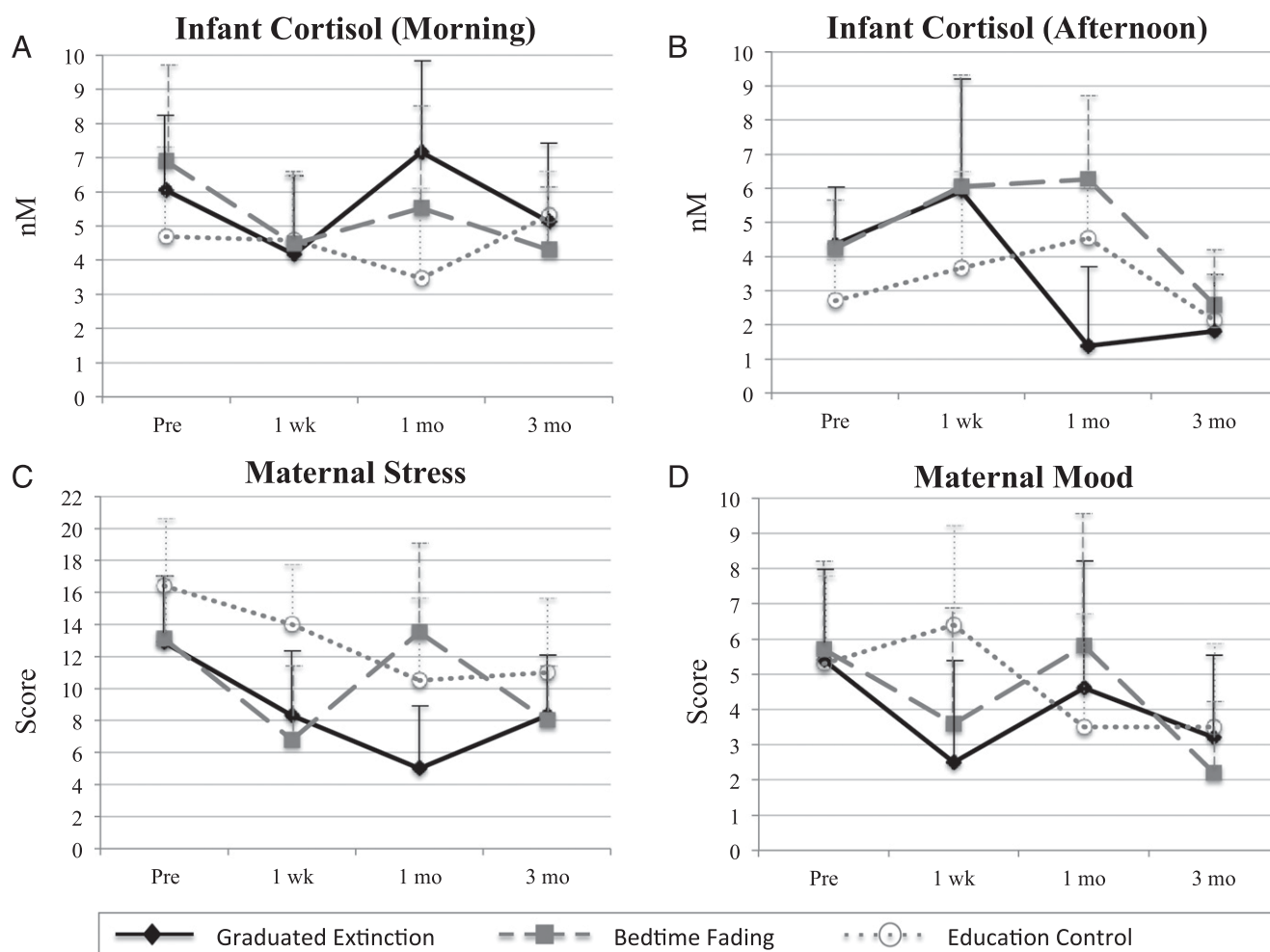


FIGURE 3 Means (95% CI) during and after treatment of infants in graduated extinction, bedtime fading, and sleep education control for (A) infant salivary cortisol morning samples, (B) infant salivary cortisol afternoon samples, (C) self-reported maternal stress, and (D) self-reported maternal mood.

between secure and insecure attachment styles between groups, $P > .05$. There were no significant differences between groups for any emotional or behavioral problems on the Child Behavior Checklist (all $P > .05$; Table 3).

DISCUSSION

Compared with controls, graduated extinction produced large decreases in nocturnal wakefulness (time taken to fall asleep, number of awakenings, minutes awake after sleep onset), yet a novel aspect of this trial was evaluating bedtime fading, about which there has been relatively little research,²² especially in typically developing infants.^{33,34} Bedtime

fading produced large decreases in sleep latency compared with the control group. The control group's sleep did show improvements in nocturnal wakefulness and total sleep, suggesting developmental maturity and/or improvements from sleep education.³⁵ No significant sleep changes were found by using objective actigraphy, suggesting sleep diaries and actigraphy measure different phenomena (eg, infants' absence of crying by parents vs infants' movements, respectively), further suggesting infants may still experience wakefulness but do not signal to parents.³⁶ We do not interpret these data as the infant "giving up,"^{25,37} but instead self-soothing.³⁶ However,

a central research question in the current study was: Do extinction-based techniques produce psychophysiological stress that leads to later problematic emotions and behavior, and thus insecure parent-child attachment?

Child-Parent Stress, Emotions, Behaviors, and Attachment

Relatively minor stressors (eg, brief parental separation) elevate cortisol levels in newborn infants³⁸; however, the cortisol stress response diminishes from 4 months of age.^{30,38,39} This may explain the lack of significant cortisol elevation in the graduated extinction condition in the current study, especially as our sample was older than 4 months of

TABLE 3 Child Behavior Checklist Scores (Mean [95% CI] and Between-Group Effect Sizes [*d*]) at 12-Month Follow-up, by Treatment Group; Attachment Classifications (*n* [%]) by Group

	Graduated Extinction, <i>n</i> = 13	Bedtime Fading, <i>n</i> = 15	Education Control, <i>n</i> = 12	<i>P</i>	<i>d</i> (Graduated Extinction versus Bedtime Fading)	<i>d</i> (Graduated Extinction versus Education Control)	<i>d</i> (Bedtime Fading versus Education Control)
Problem scale scores							
Internalizing problems							
Raw scores	5.00 (2.7–7.3)	6.06 (3.9–8.2)	5.08 (1.8–8.4)	.77	–0.27	–0.02	0.21
T score ^a ≥60, <i>n</i> (%)	—	1 (6.3)	1 (8.3)	.59	—	—	—
Externalizing problems							
Raw scores	10.6 (6.4–14.8)	10.6 (7.7–13.5)	10.2 (5.5–14.9)	.98	0.01	0.06	0.06
T score ≥60, <i>n</i> (%)	1 (7.7)	1 (6.3)	2 (16.6)	.67	—	—	—
Total problems							
Raw scores	10.8 (6.8–14.7)	10.9 (8.2–13.6)	12.1 (7.6–16.6)	.84	–0.02	–0.19	–0.20
T score ≥60, <i>n</i> (%)	—	—	—	—	—	—	—
Attachment classifications							
Secure	7 (54)	9 (60)	5 (62)	—	—	—	—
Insecure (avoidant)	1 (8)	1 (7)	1 (13)	—	—	—	—
Insecure (resistant)	2 (15)	3 (20)	1 (13)	—	—	—	—
Insecure (disorganized)	3 (23)	2 (13)	1 (13)	—	—	—	—

—, not applicable.

^a If T score in the borderline or clinical range; *d* > 0.50 = moderate effect; *d* > 0.20 = small effect; data missing for graduated extinction group (*n* = 1) and sleep education control group (*n* = 1).

age (range 6–16 months; mean 10.8 months). We cannot conclude no cortisol response occurred, as we did not collect real-time cortisol data (ie, plasma) during nocturnal treatment implementation. Our diurnal cortisol data indicate the active treatments did not result in chronically elevated levels over time (ie, values were within normative limits),⁴⁰ which is necessary for hypothalamic-pituitary-adrenocortical dysregulation.³⁸

This is a crucial point when considering the chain of arguments forming the hypothesis that graduated extinction may lead to problematic emotions and behaviors in later child development.²⁵ This hypothesis requires a significant and chronic cortisol elevation resulting from graduated extinction, yet is further disconfirmed by examining our long-term emotional and behavioral findings. No significant difference in children's emotions and behaviors could be found between groups 12 months after intervention, with internalizing and externalizing

behaviors comparable across groups. This lack of findings concur with a recent 6-year follow-up assessment of a large randomized controlled trial, where no differences in problematic behaviors and mental health were found between children who received behavioral sleep interventions and those in the control group.⁴¹

The final argument against using extinction-based methods for infant sleep problems is the potential for insecure child-parent attachment.²⁵ No significant differences were found in attachment styles between groups, which suggests a lack of evidence between infants' sleep and attachment.⁵ For parental stress, mothers in both intervention groups reported less stress than mothers in the control group. The lack of support for dysfunctional child-parent relationships (ie, disinhibited attachment, child-parent closeness and conflict, global relationship) after behavioral sleep interventions has also been found in a recent 6-year follow-up study.⁴¹ Altogether, our findings and

those of Price et al.⁴¹ are the only studies that now form a preliminary evidence base that suggests brief behavioral sleep treatments may help young children sleep, yet do not lead to later emotional and behavioral problems, or later parent-child insecure attachment.²⁵

Limitations and Future Research Directions

Although the generalizability of our findings to the population is reduced with a small sample size, they nevertheless support those of a larger follow-up study of behavioral sleep interventions for infants (*n* = 326).⁴¹ Although stress was measured at different time points across interventions, we did not measure acute stress during interventions. Changes in attachment across the study would also have been interesting, yet we note that 12 months of age is the prime age for the strange situation procedure.³² The current study contrasted only 2 behavioral sleep interventions. Future trials are needed

to compare other interventions (eg, extinction with parental presence, cosleeping via room-sharing). Due to ethical obligations and a coroner's inquiry in our home state,⁴² bed-sharing was not an option to evaluate because of infant mortality risks, and we have seen similar warnings internationally.^{43,44} Worth noting is that, to our knowledge, we have been unable to find a similar coronial finding of an infant death due to graduated extinction. Thus, we wish to highlight to researchers the crucial need to build the evidence base for establishing safe and effective treatments for those families who perceive their infant to have a sleep problem.

Clinical Implications

Although graduated extinction is based on learning theory,¹ sleep homeostatic pressure would increase over successive nights of less sleep.^{26,27} Likewise, bedtime fading would increase sleep homeostatic pressure, quickening sleep latency, reducing the time between stimuli (eg, cot) and the response (ie, sleep), and thus infants "re-learn" to initiate sleep. This theoretical overlap allows these treatments to combine in

clinical practice (eg, bedtime fading followed by graduated extinction). Our data suggest introducing bedtime fading will provide quick results for improving sleep-onset latency. Graduated extinction may then be introduced to reduce nocturnal wakefulness during the night (if needed). Our data suggest sleep education alone may not be enough to help most families with an infant who has a sleep problem.

CONCLUSIONS

This randomized controlled trial of behavioral interventions for infant sleep problems found meaningful effects for both graduated extinction and bedtime fading. Compared with the control group, large reductions in nocturnal wakefulness resulted from each treatment. Despite assertions that extinction-based methods may result in elevated cortisol, emotional and behavioral problems, and insecure parent-infant attachment, our data did not support this hypothesis. Coupled with the findings from Price and colleagues,⁴¹ behavioral interventions appear to improve sleep without detrimental

effects on the child or family. Further replication studies by independent groups are needed to confirm and raise confidence in these findings.

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ABBREVIATION

DASS-21: Depression Anxiety Stress Scale–Short Form

follow-up data and the minority of analyses under supervision, provided some input to the literature reviewed and was a minor contributor to writing of manuscript, and provided critical evaluation of manuscript drafts; Dr Sved Williams provided assistance with design of the study, interpretation of findings, and critical evaluation of manuscript drafts; Dr Powell-Davies provided input into the study design, scored the infant-parent attachment, and provided interpretation of findings and critical evaluation of manuscript drafts; Dr Kennaway provided input into study design, expert input into salivary cortisol data collection, scoring of salivary cortisol, interpretation of findings, and critical evaluation of manuscript drafts; and all authors approved the final manuscript as submitted.

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