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ORIGINAL ARTICLE

Behavioral interventions for pediatric insomnia: one treatment may not fit all

Michal Kahn[1,*], Michal Juda-Hanael[1], Efrat Livne-Karp[1], Liat Tikotzky[2], Thomas F. Anders[3] and Avi Sadeh[1]

[1]School of Psychological Sciences, Tel Aviv University, Tel Aviv, Israel, [2]Department of Psychology, Ben-Gurion University of the Negev, Beer-Sheva, Israel and [3]Department of Psychiatry at Brown University, Providence, RI

*Corresponding author. Michal Kahn, School of Psychological Sciences, Tel Aviv University, Ramat Aviv 69978, Israel. Email: michalkahn10@gmail.com.

Abstract

Study Objectives: Behavioral interventions for pediatric insomnia are cost-effective and benefit most families, but there is no evidence indicating which treatments are most suitable for specific patient populations. This randomized controlled trial evaluated the moderating role of infant separation anxiety in two brief interventions for infant sleep problems.

Methods: Ninety-one infants aged 9–18 months (61% boys) with pediatric insomnia were randomized to either Checking-in, a Graduated extinction protocol which involves gradual separation from parents, or to the Camping-out intervention, in which parental presence is maintained. Sleep was measured using actigraphy and parent reports. Infant separation anxiety was observed in the laboratory. Assessments were completed at baseline, post-treatment and 6-month follow-up.

Results: Improvement in sleep was demonstrated following both interventions and maintained at follow-up. Separation anxiety did not change significantly following treatment. Infant separation anxiety moderated treatment efficacy, with greater benefit for infants with high separation anxiety in the Camping-out compared to the Checking-in intervention.

Conclusions: This study provides support for considering infant separation anxiety in the effort to personalize treatment for pediatric insomnia. Pediatricians should incorporate evaluation of infant separation anxiety to assessment processes, and favor more gentle treatment approaches, such as Camping-out, over Graduated extinction for highly anxious infants.

Clinical Trial Registration: NCT01489215.

Statement of Significance

Behavioral interventions for pediatric insomnia, such as Graduated extinction and Camping-out, have a solid base of evidence for improving infant sleep. However, while not all families benefit from treatment, factors that may moderate efficacy have yet to be examined. In this randomized controlled trial infant separation anxiety moderated treatment outcomes, with greater improvement in actigraphic and parent reported wake after sleep onset for infants with high separation anxiety in the Camping-out compared to the Graduated extinction intervention. These findings inform clinicians about the importance of tailoring treatment to specific patient characteristics, as opposed to the one-treatment-fits-all approach. Future research should test whether infant separation anxiety moderates efficacy of other intervention protocols, and identify additional infant and parent moderators of outcome.

Key words: infant sleep; pediatric insomnia; randomized controlled trial; actigraphy; separation anxiety

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Introduction

Pediatric insomnia occurs in 15%–30% of infants, typically presenting as prolonged nocturnal wakefulness and difficulties in initiating and maintaining sleep [1, 2]. It tends to be persistent, and has been associated with a myriad of adverse short- and long-term consequences, including child physiological, emotional, cognitive, and behavioral problems [3–8], as well as parental poor general- and mental-health [9–11]. These substantial costs for both the child and family highlight the need for adequate assessment and effective treatment.

Most evidence-based interventions for pediatric insomnia stem from psychological learning theory, aiming to promote infant self-soothing by reducing parental involvement throughout the sleep process [12]. The intensity of these interventions varies, as some approaches advocate immediate removal of parental presence at night (e.g. Extinction), while others endorse gradually withdrawing parental presence (e.g. Graduated extinction), or specifically reducing parental involvement in soothing to sleep while maintaining parental proximity (e.g. Camping-out) [13–15]. Recent years have shown accumulating evidence to the efficacy of behavioral interventions in improving infant sleep and parental well-being both in the short- and long-term [16–18]. Furthermore, despite concerns raised by some [19], as yet no evidence of harm has been documented as a result of these treatment protocols [20, 21]. Accordingly, they have been recommended for the treatment of bedtime and night waking problems by the Standard of Practice Committee of the American Academy of Sleep Medicine [13, 22].

However, despite their cost-effectiveness and safety, approximately 20% of families do not benefit sufficiently from these treatments [13]. The barriers for successful implementation and achievement of treatment gains may include parental factors, such as low tolerance for infant crying [23, 24], as well as infant factors, and the parent–infant interactive context [25]. Specifically, since many of the behavioral interventions entail a certain degree of separation from the parents, infant separation anxiety may be a critical factor in determining treatment outcomes. Heightened infant distress in the face of separation has been associated with insecure attachment, poor emotion regulation, and disrupted sleep [26–28]. These tendencies might hinder adherence to behavioral interventions, as infants may express increased distress when left to attempt self-soothing, making it more difficult for parents to reduce their nighttime involvement. It is thus plausible that interventions such as Camping-out, in which a smaller ``dose'' of separation is recommended, may be better tolerated and more beneficial for families of infants that exhibit intense separation anxiety.

These postulations correspond with the burgeoning interest in identifying not only which interventions work, but also for whom do they work best [29]. Scientific knowledge regarding moderators of treatment has advanced considerably in the domain of behavioral interventions for various child psychopathologies [30–32]. However, the field of infant sleep research has thus far failed to address these issues in a systematic manner. In their meta-analysis of behavioral interventions for pediatric insomnia Meltzer and Mindell [18] identify the lack of studies investigating factors that predict treatment success as a major gap in the field. This study addresses this gap by being the first to examine the role of infant separation anxiety as a moderator of outcomes in behavioral treatments for infant sleep problems.

In the current randomized controlled trial (RCT) parents of infants with pediatric insomnia were randomly assigned to either a Graduated extinction protocol we named Checking-in, or to the Camping-out protocol. Both interventions have shown evidence for efficacy [13, 33], yet they differ in the extent of separation they entail. Infant sleep and separation anxiety were assessed at baseline, post-treatment, and a 6-month follow-up. This study aimed to evaluate the efficacy of each intervention in improving infant sleep, and to determine whether infant separation anxiety moderates treatment outcomes. We hypothesized that both interventions would lead to a reduction in sleep problems, with no change in separation anxiety following treatment, and that baseline separation anxiety would moderate treatment efficacy, with more benefit for infants with high separation anxiety in the Camping-out compared to the Checking-in intervention.

Methods

Participants

Participation flowchart is illustrated in CONSORT Figure 1. Participants were recruited through web-based media advertisements between February 2012 and February 2015. Inclusion criteria were: (1) infant age range 9–18 months; (2) significant sleep problem lasting at least 3 months, manifested in an average of at least 30 min sleep onset latency (SOL), at least 30 min wake after sleep onset (WASO), and/or at least 3 awakenings per night based on parent reports; and (3) two-parent families with both mother and father willing to participate in study procedures. The latter criterion was employed due to interest in parental gender differences that were part of a larger study. Exclusion criteria were: (1) infant pervasive developmental disorder or significant medical illness and (2) any concurrent treatment for infant sleep problems.

Of the 188 families who approached the study, 97 were excluded at the telephone screening interview. The remaining 91 infants (M_{age} = 12.25 months, SD = 3.11; 56 boys) were randomized to either Checking-in or Camping-out interventions. Groups did not differ in baseline demographic variables (see Table 1), or in any of the baseline sleep variables (all $ps > 0.16$). All participating families were conservative to secular Jewish, and analysis of the demographic characteristics suggests that the sample was mostly representative of middle-upper socioeconomic status in Israel (e.g. 91% of mothers and 76% of fathers reported >15 years of education). Three families (Checking-in = 1, Camping-out = 2) did not engage in treatment, and 26 families (Checking-in = 10, Camping-out = 16) discontinued treatment or failed to complete the post-treatment assessment. Reasons for dropping out were most often due to difficulty complying with the intervention guidelines. Ten additional families were lost to 6-month follow-up (Checking-in = 5, Camping-out = 5). There was no significant difference in drop-out rates between groups ($\chi^2(1) = 1.47$, $p = 0.22$). In addition, no differences were found between families that continued and families that discontinued therapy in parent age, years of education or workload, or in infant age, sex, sleep measures or separation anxiety (all $ps > 0.19$). The study was approved by the local Institutional Review Board and all parents provided written informed consent. Clinicaltrials.gov Identifier: NCT01489215.

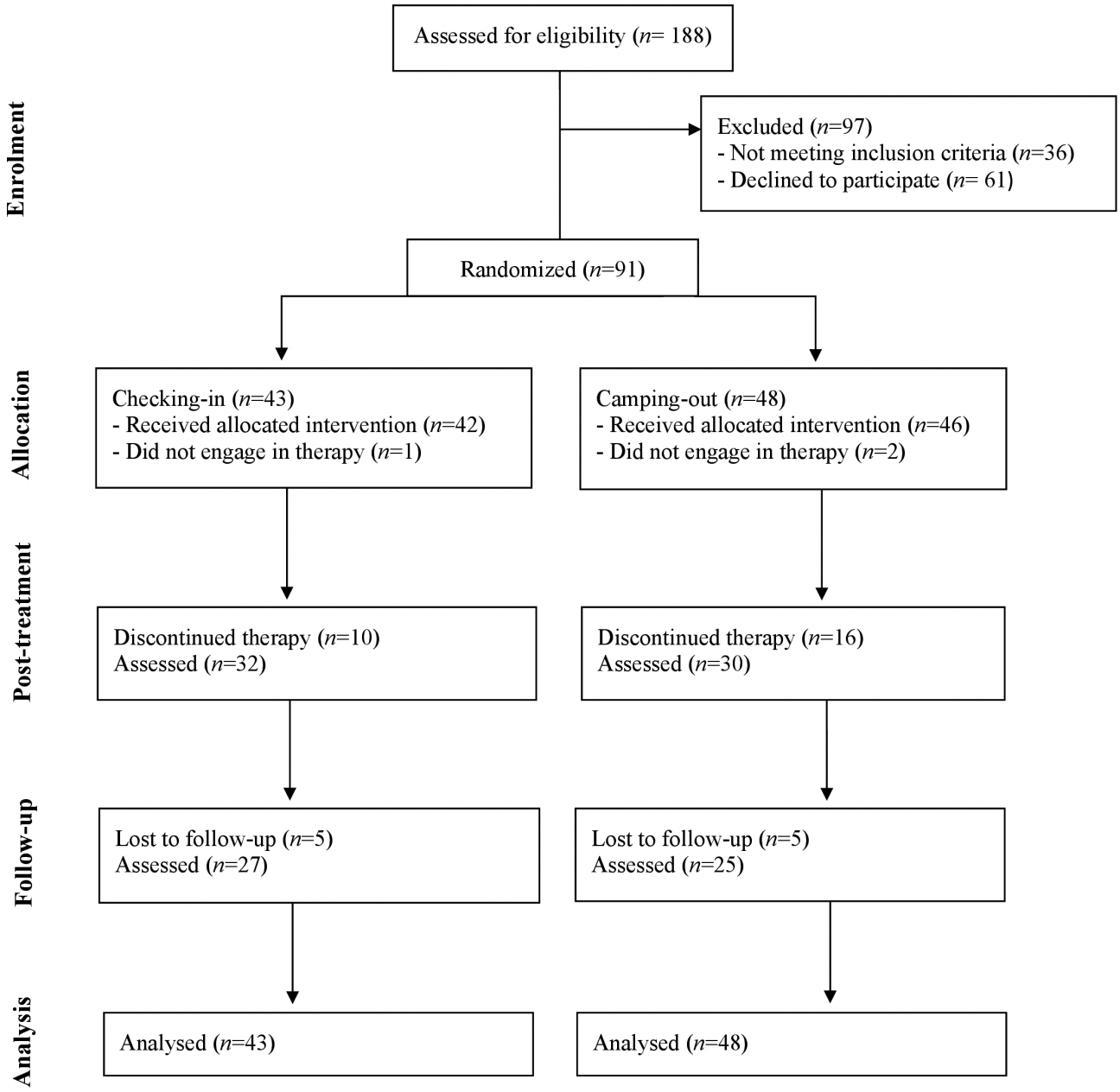

Figure 1. Study flow diagram.

Interventions

Checking-in. We named the Graduated extinction arm of this trial "Checking-in", since we believe this ``softer'' title better represents the intervention's actual essence, and could be better accepted by parents and clinicians. Parents in this group were instructed to facilitate the development of infant self-soothing skills by allowing short periods of time in which their child is left in bed without their presence [13, 20]. The guidelines for this intervention were: (1) Infants should be put in bed awake; (2) Parents should minimize their involvement after putting the infant to bed and leave the room promptly; (3) If the child cries or protests parents should check-in briefly every few minutes to comfort and help the infant resume a sleeping position and/or find sleep aids (e.g. pacifier); (4) This schedule continues until the child falls asleep, and recommences in case of nocturnal awakening. Parents were instructed to continue this protocol throughout the intervention month, gradually increasing the intervals between check-ins every few days. As room sharing was not part of our exclusion criteria, infants allocated to the Checking-in group who were sleeping in their parents' room (n = 4) were instructed to move the cot to a separate room prior to implementation of the intervention.

Camping-out. The Camping-out intervention is based on the same principles of Checking-in, with the additional element of parental passive presence throughout the night. Thus, rather than leaving the infant's room, parents spend the night sleeping next to his/her crib in a separate bed or mattress. This variation

Table 1. Demographic characteristics by group at baseline

	Checking-in, N = 43	Camping-out, N = 48	Between-group statistics t(p)
Child			
Age	12.32 (3.26)	12.11 (2.88)	0.32 (0.75)
Gender (% boys)	23 (53)	33 (69)	χ^2 = 2.23 (0.14)
Number of children in the family	1.5 (0.64)	1.54 (0.66)	−0.31 (0.76)
Mother			
Age	32.00 (3.16)	33.12 (4.05)	−1.42 (0.16)
Years of education	16.37 (1.95)	16.40 (1.99)	−0.08 (0.94)
Workload (h per week)	31.86 (17.45)	25.78 (16.79)	1.55 (0.13)
Father			
Age	34.59 (3.97)	35.33 (4.89)	−0.77 (0.44)
Years of education	16.05 (2.57)	15.71 (2.56)	0.59 (0.56)
Workload (h per week)	41.20 (14.79)	43.43 (16.25)	−0.59 (0.56)

is based on the assumption that parental presence provides reassurance that facilitates gradual development of self-soothing capacities [33, 34]. Parents were instructed to provide brief reassurance to the child every few minutes (as in the Checking-in intervention) in case he/she cries or protests, and then return to their recumbent position on the adjacent bed or mattress. After seven nights of sleeping next to the child, parents were to gradually remove their presence over the course of a few days; first during the night, and then also at bedtime. At this stage parents were asked to continue the brief comforting schedule throughout the remainder of the intervention month as in the Checking-in protocol (i.e. upon crying or protest, enter the room to briefly reassure the child, and promptly leave afterwards), with gradually increasing intervals.

Procedures

The study design was a parallel group RCT with two groups (Checking-in and Camping-out) and 3 assessment points. Sleep was assessed actigraphically during the week before commencing treatment, 3 weeks after commencing treatment, and 6 months after commencing treatment. Other measures were collected during a laboratory visit scheduled at the end of each of the 3 assessment weeks.

An initial screening interview was conducted over the telephone, and eligible families were invited to the university clinic. Consenting families underwent the baseline assessment, including lab assessment of infant separation anxiety, completion of parent questionnaires, and home-monitoring of infant sleep for seven consecutive nights. Families were randomly assigned to either Checking-in or Camping-out and met with a clinical psychologist for an individualized treatment session explaining the intervention guidelines. Parents were contacted by phone 3 and 7 days following the treatment session to discuss progress and potential concerns. Lab and home assessments were repeated using the same procedures 1-month (post-treatment) and 6-month (follow-up) after the initial treatment session.

Measures

Actigraphy. Sleep–wake patterns were measured using actigraphy, which has been established as a valid method to objectively assess sleep in the infant's natural setting [35, 36]. Parents were asked to attach a micro-mini actigraph (Mini Motionlogger, Ambulatory Monitoring, Inc., Ardsley, NY), to their child's ankle for seven nights at each assessment period. Data were scored using the Sadeh algorithm, which is the most commonly used analysis method in pediatric populations [35, 37]. Sleep diaries were completed by parents and used to identify and amend any irregularities in actigraphic data. The following actigraphic sleep metrics were used, based on the inclusion criteria defining the presence and severity of infant sleep problem: (1) WASO and (2) number of awakenings (NW) lasting 5 min or longer. Actigraphic SOL was not used as an outcome measure, due to our inability to ascertain lights-out timing.

Brief infant sleep questionnaire. The Brief Infant Sleep Questionnaire (BISQ) is a well-validated sleep questionnaire aimed at assessing parent-reported infant sleep patterns [38]. Parents completed the BISQ at each assessment point. The derived measures used in this study were: (1) SOL (2) WASO; and (3) NW.

Infant separation anxiety. Infant distress in response to brief parental separation was assessed using a standardized validated laboratory separation episode [39–41]. After engaging in free play with the parent in the laboratory setting, an experimenter joined and engaged in 1 min of play with the infant. The parent was then instructed to say goodbye to the infant, leave the room and return after 2 min. While separated, parents could observe their infant through a one-way mirror until re-entering the room. This procedure was repeated twice, once with each parent (order counterbalanced across participants), with 10 min of play between episodes. Infant reactions were videotaped throughout the episodes, and anxiety was rated by two trained coders, blind to group allocation, using a 7-point scale from 1 (low anxiety, indicated by calmness or minimal protest) to 7 (high anxiety, indicated by intense and inconsolable crying, whining, or clinging). To increase scoring sensitivity, each episode was divided into three separately scored segments: (1) time from parent's announcement of separation until departure; (2) first 15 s after separation; and (3) the remaining time until parent's return. A randomly chosen subsample consisting of 20% of videos was double-coded, and interrater reliability for each segment was found to be excellent (absolute agreement intraclass correlation coefficients range: 0.81–0.90). Additionally, consistency was high between segments (α Cronbach coefficients range: 0.89–0.95), and between mother and father episodes (α Cronbach coefficients range: 0.52–0.71). Thus, a general separation anxiety score was calculated for each infant in each assessment point by averaging scores of all segments across both separation episodes.

Data analysis plan

Using the MCAR test, it was confirmed that data was missing completely at random (χ^2(1,274) = 1,209.18, p = 0.91). Generalized estimating equations (GEE) [42, 43] were used to test for treatment effects, as recommended for clinical trials [44]. GEE accounts for repeated within-subject measurements, and accommodates missing data, allowing for analyses of the intent-to-treat sample. The full information maximum likelihood approach is used in GEE to replace missing values with correlated data, based on which estimated marginal means are computed. Unstructured covariance matrices were specified in all

models to represent uncorrelated or inconsistent dependencies between measures. All randomized participants were included in analyses. Overall effects of the interventions on objective and subjective (reported by parents on the BISQ) sleep measures, as well as separation anxiety were estimated using models containing main effects of group (Checking-in and Camping-out) and time (baseline, post-treatment, and 6-month follow-up), and their interaction terms.

Treatment moderation effects by separation anxiety were tested using GEE modeling of the interaction between treatment group, time, and baseline separation anxiety. Significant three-way interaction terms indicated differential intervention effects as a function of infant separation anxiety. Significant interaction effects were interpreted using post hoc marginal means pairwise comparisons [45]. Finally, to evaluate effect sizes, the standardized mean difference between groups (i.e. Cohen's *d*) was calculated based on the estimated means and standard errors generated from GEE analyses.

The sample size was determined based on prior studies, which have reported medium to large effect sizes for sleep outcomes (subjective measures usually yielding larger effect sizes compared to actigraphy) [13, 20], suggesting that with a probability level of 0.05, $N = 90$ participants would yield 80% power.

Results

Sleep

GEE models for actigraphic and parent reported sleep measures yielded main effects of time for actigraphic WASO (Wald = 34.860, $b = 42.779$, SE = 7.28, $p < 0.001$), as well as for parent reported SOL (Wald = 39.36, $b = 12.57$, SE = 3.15, $p < 0.001$), WASO (Wald = 51.24, $b = 47.89$, SE = 6.89, $p < 0.001$), and NW (Wald = 144.97, $b = 3.25$, SE = .28, $p < 0.001$). No other main or interaction effects were found, indicating that improvement in sleep occurred regardless of intervention group. Descriptive statistics of all sleep measures at all assessments are presented in Table 2. From baseline to post-treatment, analyses revealed substantial reductions across groups in actigraphic WASO (mean difference = 17.19 min, Cohen's $d = 0.55$), and in parent reported SOL (mean difference = 16.63 min, Cohen's $d = 1.36$), WASO (mean difference = 34.67 min, Cohen's $d = 0.74$), and NW (mean difference = 2.94, Cohen's $d = 2.03$). These improvements were maintained at follow-up, as indexed by the absence of change in parent reported sleep measures, and an additional reduction in actigraphic WASO (mean difference = 5.70 min, Cohen's $d = 0.69$) from post-treatment to the 6-month assessment.

Separation anxiety

The GEE model testing for changes in separation anxiety over time in both groups revealed no significant main or interaction effects, suggesting that there were no meaningful changes in infant separation anxiety in either intervention groups or across groups following treatment (see Table 2).

Moderation effects

The GEE model testing moderation of baseline separation anxiety on reduction in actigraphic WASO yielded a significant Time-by-Treatment-by-separation anxiety interaction, Wald = 18.764, $p = 0.001$, indicating differential treatment effects for Checking-in versus Camping-out as a function of infant separation anxiety (Figure 2). Post hoc analyses revealed a reduction in WASO from baseline to post-treatment for infants with lower separation anxiety in the Camping-out group (mean difference = 26.18 min, $p = 0.02$, Cohen's $d = 0.42$), whereas no significant post-treatment improvement was found for infants with higher separation anxiety in the Camping-out group (mean difference = 18.30 min, $p = 0.14$, Cohen's $d = 0.31$) or for lower or higher separation anxiety in the Checking-in group (mean difference = 21.01 min, $p = 0.13$, Cohen's $d = 0.35$; mean difference = –12.97 min, $p = 0.37$, Cohen's $d = –0.012$ respectively). Marginal means comparisons from post-treatment to follow-up revealed additional declines in actigraphic WASO for infants with both high and low separation anxiety in the Checking-in group (mean difference = 27.84, $p = 0.004$, Cohen's $d = 0.48$; mean difference=27.31, $p = 0.005$, Cohen's $d = 0.47$ respectively). Additional improvement was not significant in the Camping-out groups from post-treatment to follow-up. To control for potential age-related differences in separation anxiety, this model was also tested with infant age as a covariate, and the moderation effect remained significant (Wald = 12.313, $p = 0.002$), ruling out the possibility that this effect was only due to differences in infant age.

A moderation effect was additionally found for parent reported WASO, as reflected by a significant Time-by-Treatment-by-separation anxiety interaction, Wald = 9.60, $p = 0.02$ (Figure 2). Follow-up analyses revealed meaningful reductions in WASO from baseline to post-treatment in the Camping-out

Table 2. Primary and secondary outcome measures by group at baseline, post-treatment and 6-month follow-up assessments

	Baseline		Post-treatment		Follow-up	
	Checking-in	Camping-out	Checking-in	Camping-out	Checking-in	Camping-out
Actigraphic sleep measures						
Wake after sleep onset (min)	109.58 (6.10)	120.49 (5.74)	99.19 (9.16)	96.99 (7.38)	71.93 (8.24)	73.03 (9.56)
Number of awakenings	5.85 (0.29)	6.54 (0.35)	5.95 (0.52)	5.28 (0.43)	5.61 (0.58)	5.39 (0.69)
Parent reported sleep measures						
Sleep onset latency (min)	30.33 (3.09)	32.80 (2.85)	13.44 (2.79)	15.89 (3.06)	16.84 (3.39)	21.21 (3.15)
Wake after sleep onset (min)	63.73 (7.36)	73.08 (9.24)	47.60 (17.22)	17.80 (5.81)	21.79 (6.97)	17.32 (6.92)
Number of awakenings	4.99 (0.36)	4.46 (0.36)	1.51 (0.41)	2.07 (0.27)	1.44 (0.25)	1.52 (0.28)
Infant separation anxiety	2.59 (0.25)	2.63 (0.23)	3.25 (0.38)	2.63 (0.35)	3.03 (0.37)	2.07 (0.33)

Data are given as mean (standard error).

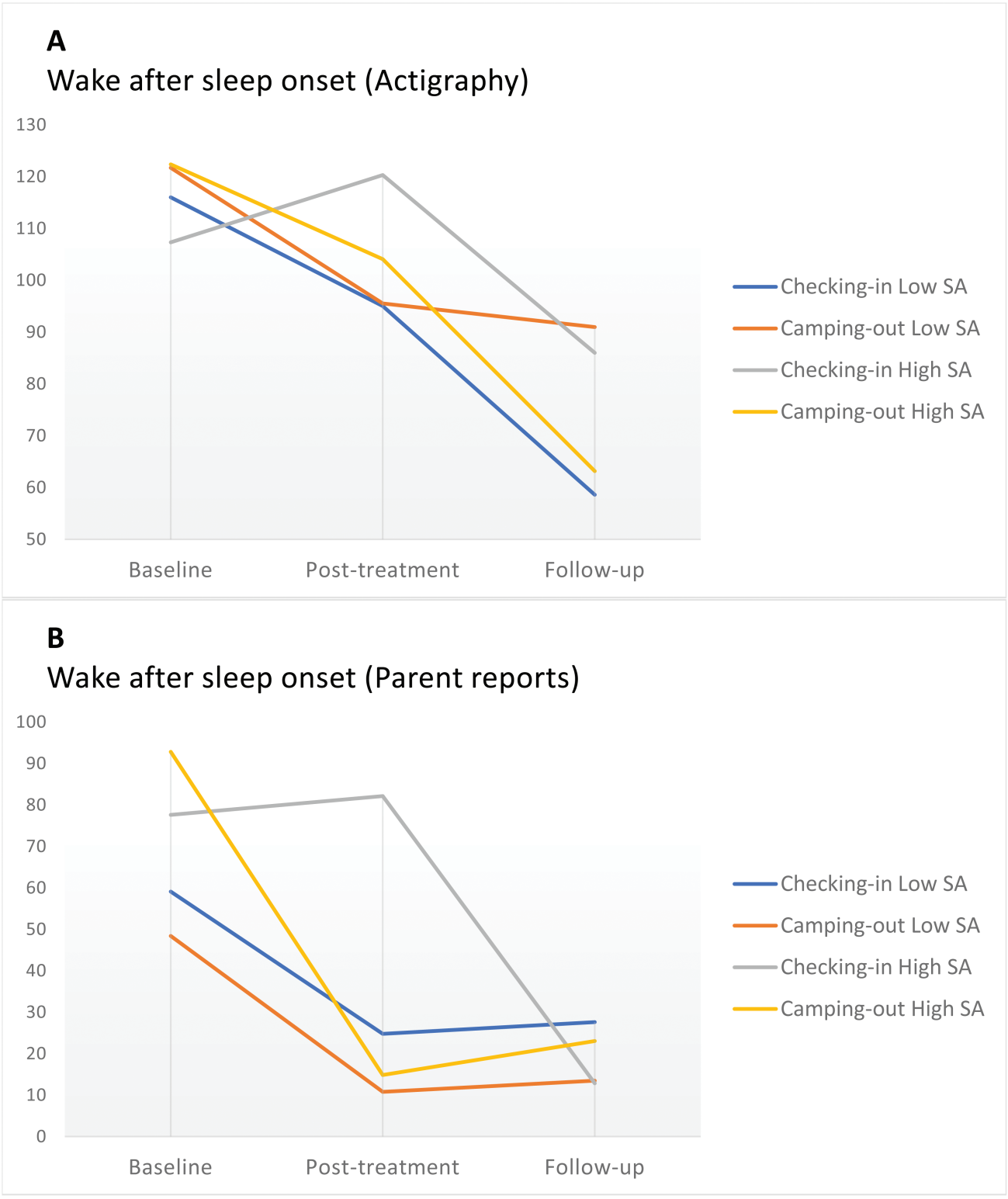

Figure 2. Wake after sleep onset (min) measured using actigraphy (A) and parent reports (B) at baseline, post-treatment, and follow-up as a function of the interaction between separation anxiety and treatment group (Checking-in or Camping-out).

intervention for both infants with initial low and high separation anxiety (mean difference = 37.61 min, p = 0.01, Cohen's d = 0.93; mean difference = 77.96 min, p < 0.001, Cohen's d = 1.36 respectively). In the Checking-in group improvements were significant for infants with low separation anxiety (mean difference = 34.31 min, p = 0.03, Cohen's d = .62), whereas no significant change in WASO was observed among infants with high separation anxiety (mean difference = –4.52 min, p = 0.92,

Cohen's d = –.02). Post hoc analyses of changes from post-treatment to follow-up revealed a significant reduction in parent-reported WASO for infants with high separation anxiety in the Checking-in group (mean difference = 69.30, $p < 0.001$, Cohen's d = 1.23), but not for other infant groups. This moderation effect also remained significant when controlling for infant age (Wald = 7.119, $p = 0.03$).

GEE models testing separation anxiety moderation of other actigraphic and parent-report outcome measures were nonsignificant.

Discussion

To the best of our knowledge, this RCT was the first to investigate outcome moderators of behavioral interventions for infant sleep problems. As expected, treatment efficacy was moderated by baseline infant separation anxiety. Whereas significant reductions in parent reported WASO were found for low anxiety infants in both intervention groups, and for high anxiety infants in the Camping-out group, no significant reductions were detected for infants with high separation anxiety in the Checking-in group, either using actigraphy or parent reports. These results suggest that interventions involving lower degrees of separation from parents may be more beneficial for infants who exhibit heightened separation anxiety. Such infants may be prone to exhibit higher levels of distress upon parents' attempts to reduce their involvement, which may both increase arousal and deter parents from following through with the protocol [19, 46]. Our results correspond with previous findings demonstrating the role of separation anxiety in the treatment of anxiety disorders. Higher separation anxiety has been shown to predict poorer outcomes, and to moderate treatment effects, requiring multi-modal treatment to produce significant gains [47, 48]. The present study extends these principles to the field of infant sleep interventions, suggesting that anxious infants may not benefit from typical Graduated extinction, but require a specifically tailored, gentler approach.

Interestingly, objective and parent-reported WASO significantly decreased between post-treatment and the 6-month follow-up in infants with high separation anxiety in the Checking-in group, rendering all groups equivalent at the follow-up assessment. This additional decline may reflect a maturation effect, given the dramatic changes in the development of sleep during the beginning of life [49, 50]. Alternatively, it may reflect a delayed treatment effect, as documented in previous early childhood sleep intervention studies [51, 52], or possibly a combination of the two. In addition, whereas separation anxiety moderated declines in WASO, moderations were not found for other sleep variables. This suggests that WASO may be particularly responsive to the effects of heightened separation anxiety during Graduated extinction. Self-soothing during repeated parental arrivals and departures may be especially challenging for anxious infants later in the night, since sleep homeostatic pressure and melatonin levels progressively decrease compared to their bedtime levels, setting the stage for heightened arousal without the balancing of physiological processes that promote sleep [53, 54].

More generally, infant sleep problems decreased significantly in this trial following both Checking-in and Camping-out interventions. Reductions in actigraphic and parent-reported WASO, as well as parent reported SOL and NW were documented at post-treatment and maintained at the 6-month follow-up. These results dovetail with previous findings that attest the effectiveness of behavioral interventions for pediatric insomnia [13, 18]. As in previous investigations [34, 55], parent reported sleep showed greater and more robust improvement compared to actigraphic sleep, demonstrated by the larger effect sizes and significant effects in all reported sleep metrics. This discrepancy between objective and subjective sleep measures suggests that during the intervention, infants gradually acquired self-soothing capacities, and thus tended to signal less to parents upon awakening at night [20]. Importantly, no significant changes in infant separation anxiety were found from baseline to post-treatment or follow-up. This finding adds to the accumulating base of evidence demonstrating the safety and lack of adverse ``side effects'' of behavioral treatments for infant sleep problems [20, 21].

Despite its strengths, including the randomized controlled design, repeated objective measurement of sleep and separation anxiety, and 6-month follow-up, the present study has several limitations. First, this trial included two intervention arms, without a waitlist or no-treatment control group. The absence of such control limits our ability to rule out the potential influences of non-specific effects and external factors. Nevertheless, previous studies that have included waiting-list control groups for the treatment of infant sleep problems have demonstrated that they do not tend to decline over the duration of 1 month when untreated [13, 20]. Thus, it seems less likely that significant changes in sleep would have occurred due to the passage of time and external factors alone. Furthermore, the moderation effects by separation anxiety differentiated the Checking-in and Camping-out interventions, suggesting that improvement was due to specific intervention influences. The relatively high proportion of dropout, although demonstrated to be equivalent across groups and unrelated to baseline characteristics, limits the generalizability of our findings, as does the limited size and relative homeogeity of the sample. Future studies should examine the efficacy of these interventions with larger, more diverse samples. Additionally, the type of pediatric insomnia (i.e. sleep onset, limit setting, or mixed type) was not assessed in this trial. Testing whether this feature moderates treatment outcomes could be informative for treatment recommendations, and should thus be an aim of future investigations. Finally, this trial examined the moderating role of infant separation anxiety in only two interventions, both of which were extinction-based. Interventions that entail a smaller extent of infant distress, such as bedtime fading [13], could be even more suitable for highly anxious children. Future studies should investigate the moderating effects of infant separation anxiety in other intervention protocols, and attempt to identify additional infant and parent factors that moderate efficacy.

To conclude, sleep problems constitute one of the most common concerns presented to pediatricians, but a recent review [2] concluded that substantial knowledge gaps preclude primary care providers from adequately addressing these problems. Our results inform the clinician community in showing that brief behavioral interventions for pediatric insomnia are effective, with no detrimental effects on infant separation anxiety. Our findings also demonstrate for the first time that in terms of these interventions, ``one treatment may not fit all'', representing an important initial attempt to understand how separation anxiety may be used to personalize treatment to meet

the needs of specific patient populations. Assessment of infant sleep problems should thus include evaluation of separation anxiety, using questioning or observation of a brief separation, and gentler treatment approaches such as Camping-out may be preferred over Graduated extinction for highly anxious infants.

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Conflict of interest statement. None declared.

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