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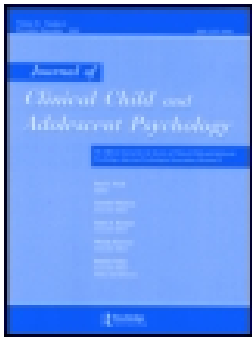
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Anxiety Treatment and Targeted Sleep Enhancement to Address Sleep Disturbance in Pre/Early Adolescents with Anxiety

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Sleep disturbance is prevalent in anxious youth and prospectively predicts poor emotional adjustment in adolescence. Study 1 examined whether anxiety treatment improves subjective and objective sleep disturbance in anxious youth. Study 2 examined whether a sleep intervention called Sleeping TIGERS can further improve sleep following anxiety treatment. Study 1 examined 133 youth (ages 9–14; 56% female; 11% ethnic/racial minority) with generalized, social, or separation anxiety over the course of anxiety treatment (cognitive behavioral treatment or client-centered treatment). Sleep-related problems (parent-, child-report) and subjective (diary) and objective (actigraphy) sleep patterns were assessed across treatment in an open trial design. Study 2 included 50 youth (ages 9–14; 68% female; 10% ethnic/racial minority)

who continued to report sleep-related problems after anxiety treatment and enrolled in an open trial of Sleeping TIGERS. Pre- and postassessments duplicated Study 1 and included the Focal Interview of Sleep to assess sleep disturbance. Study 1 demonstrated small reductions in sleep problems and improvements in subjective sleep patterns (diary) across anxiety treatment, but outcomes were not deemed clinically significant, and 75% of youth stayed above clinical cutoff. Study 2 showed clinically significant, large reductions in sleep problems and small changes in some subjective sleep patterns (diary). Anxiety treatment improves, but does not resolve, sleep disturbance in peri-pubertal youth, which may portend risk for poor emotional adjustment and mental health. The open trial provides preliminary support that Sleeping TIGERS can improve sleep in anxious youth to a clinically significant degree.

INTRODUCTION

The current studies evaluated whether efficacious anxiety treatment improves sleep in peri-pubertal anxious youth (Study 1) and if a targeted sleep intervention further improves residual sleep problems among youth already treated for anxiety (Study 2). There are several reasons for this focus. First, sleep disturbance is pervasive in anxious youth, with up to 90% reporting at least one sleep difficulty and 82% reporting two or more (Chase & Pincus, 2011). Commonly reported sleep disturbances include insomnia, nightmares, difficulty sleeping alone, fatigue, and reduced sleep time (e.g. Alfano, Ginsburg, & Kingery, 2007). Second, sleep disturbance is increasingly prevalent in youth initiating the transition to adolescence (referred to here as peri-pubertal youth), as naturally occurring biological changes, including changes to the circadian system (i.e., delaying of the sleep phase), sleep-wake homeostasis (i.e., slower mounting of homeostatic sleep drive), and sleep architecture (i.e., decreased slow wave sleep) intersect with environmental changes, including increased academic, social, and extracurricular pressures, and growing autonomy (e.g. Carskadon, 2011). Concomitantly, this peri-pubertal developmental window is marked by significant neuromaturational changes in circuitry (e.g., medial prefrontal cortex-amygdala-striatal networks) supporting socioemotional development (Ahmed, Bittencourt-Hewitt, & Sebastian, 2015), leaving youth susceptible to emotion regulation difficulties and internalizing symptoms (Powers & Casey, 2015). Finally, sleep disturbance is well documented as a prospective predictor of poor emotional adjustment and mental health outcomes such as anxiety and depression in mid- to late adolescence, with some evidence for peri-puberty as a uniquely sensitive period for these effects (for a review, see McMakin & Alfano, 2015). Therefore, sleep disturbance in peri-pubertal anxious youth may have negative cascading effects on development and functioning. An intervention to address both anxiety and sleep disturbance early in the developmental symptom trajectory may therefore help to improve short- and long-term mental health outcomes. On the other hand, failing to resolve sleep disturbance in anxious youth at the cusp of puberty may portend risk for poor mental health outcomes.

The Effects of Anxiety Treatment on Sleep in Youth

There is a growing literature on the effects of behavioral interventions for anxiety on sleep. However, research is somewhat limited by methodological constraints. An early study demonstrated an effect of cognitive behavioral therapy (CBT) on somatic symptoms, which included sleep problems as part of the symptom cluster, in a sample of youth with generalized anxiety disorder (GAD; Kendall & Pimentel, 2003). However, the broad focus on somatic symptoms limits the ability to interpret the specificity of treatment-related effects on sleep problems. More recent investigations included more heterogeneous samples of anxious youth (Caporino et al., 2017; Clementi, Alfano, Holly, & Pina, 2016; Peterman et al., 2016) with some studies suggesting that anxiety interventions may be most helpful for targeting specific sleep-related problems associated with bedtime difficulties (i.e., Bedtime Resistance, Sleep Anxiety, Presleep Arousal; Clementi et al., 2016; Peterman et al., 2016), and a separate study finding that anxiety interventions may have greater effects on sleep disturbance relative to waitlist control in children relative to adolescents (Donovan, Spence, & March, 2017). These prior studies have shown mostly small effects with respect to changes in sleep disturbance following anxiety treatment (Caporino et al., 2017; Clementi et al., 2016; Peterman et al., 2016). In addition, only one of the aforementioned studies investigated changes in sleep disturbance as an a priori hypothesis (Peterman et al., 2016). Prior research is limited by a lack of validated sleep scales for assessing sleep-related problems (Caporino et al., 2017; Donovan et al., 2017; Kendall & Pimentel, 2003) and a lack of objective (actigraphy) and subjective (diary report) measures of daily sleep patterns (Caporino et al., 2017; Clementi et al., 2016; Kendall & Pimentel, 2003; Peterman et al., 2016).

Taken together, these studies suggest that anxiety interventions are associated with modest reductions in sleep disturbance, with the most robust findings in the domains of presleep bedtime difficulties (Clementi et al., 2016; Peterman et al., 2016). Small effect sizes suggest that youth may benefit from the addition of targeted sleep interventions to address residual sleep disturbance. Clementi and Alfano (2014) piloted one such intervention—a targeted behavior therapy intervention featuring a two-session sleep

enhancement component. Despite improvements in sleep quality at posttreatment and 3-month follow-up, findings were difficult to interpret due to high variability in weekly sleep ratings. In addition, the authors called for additional research to address the small sample size ($n = 4$; single case study design), included patients with primary GAD only, and utilized self-reports only (Clementi & Alfano, 2014).

Targeted Sleep Interventions for Youth

A number of studies have assessed the benefits of targeted sleep interventions among peri-pubertal and adolescent youth, mostly in classroom settings, with mixed outcomes. An initial randomized-controlled comparison of a sleep intervention with a CBT framework versus class as usual yielded significant increases in sleep knowledge relative to class as usual, but no significant reductions in targeted sleep disturbances or depressive symptoms at posttreatment or 6-month follow-up assessments (Moseley & Gradisar, 2009). A subsequent study expanded on this framework by incorporating motivational interviewing to address poor outcomes (Cain, Gradisar, & Moseley, 2011). Again, despite significant improvements in sleep knowledge and increases in motivation to regularize bedtimes, improvements in targeted sleep disturbances and daytime functioning were not significantly greater than class as usual, leading authors to conclude that increased motivation does not necessarily translate to long-term behavioral changes (Cain et al., 2011). Furthermore, neither of these interventions specifically targeted youth with emotional problems (i.e., anxiety or depressive symptoms), who may be particularly vulnerable to sleep disturbance. A randomized controlled trial of CBT for insomnia including Internet-delivery, group format, and waitlist group showed significantly greater improvements in objective (actigraphy) and subjective (diary) sleep patterns, as well as clinically significant moderate to large reductions in subjective sleep-related problems, in Internet, and in group CBT relative to waitlist at postintervention and at 2-month follow up assessments. However, authors noted that participants were recruited from the general population, and those with severe comorbidity were excluded. In addition, they noted that participants recruited from the general population may have increased motivation to make behavioral changes relative to clinic-referred samples (De Bruin, Bögels, Oort, & Meijer, 2015).

To address these issues, researchers have begun to develop and test multicomponent behavioral sleep interventions including CBT plus mindfulness-based approaches that may simultaneously improve anxiety symptoms. Results of pilot open trials of group sleep treatments for adolescents including CBT components plus mindfulness-based cognitive exercises to address bedtime ruminative anxiety (Bei et al., 2013; Schlarb, Liddle, & Hautzinger, 2011) were positive, with the first study, targeting primary insomnia, showing high treatment attendance and satisfaction and significant improvements in subjective sleep and emotional functioning (Schlarb et al., 2011). The second—a school-based program—showed small

to moderate improvements in objective (i.e., actigraphy) sleep patterns and moderate to large improvements in child-reported sleep problems but nonsignificant reductions in child-reported anxiety (Bei et al., 2013). As a follow-up to the Bei et al. (2013) pilot study, the SENSE study (Blake et al., 2016) used a multimethod approach (e.g. actigraphy, diary, self-report) to compare a multicomponent sleep intervention, including CBT and mindfulness (e.g., body scan, deep breathing, etc.) with an active control intervention in a randomized controlled trial targeting 12- to 17-year-old high school students at risk for anxiety and sleeping difficulties. The sleep intervention was associated with small to moderate effects for subjective (diary) and objective (actigraphy) sleep patterns, subjective sleep-related problems (child-report), and anxiety (Blake et al., 2016), highlighting the importance of utilizing strong methodology to evaluate the efficacy of targeted sleep interventions. However, mixed findings for impacts on anxiety suggest that there is not yet clear evidence that these multicomponent approaches sufficiently resolve both anxiety and sleep problems. Moreover, the extent to which these findings may be replicated in a treatment-seeking sample is unclear, nor is it clear if these approaches would prove efficacious in a slightly younger age range to allow for a stronger preventative approach at the cusp of the pubertal transition.

The Current Studies

Building on recent work in this area, the present two-study project aimed to determine if efficacious anxiety treatment improves sleep (Study 1), and if targeted sleep enhancement further improves sleep in clinic-referred peri-pubertal youth who have been treated with a full course of anxiety treatment (Study 2). The present study builds upon the prior body of work by including a sizeable sample (133 youth) of youth at the cusp of the pubertal transition, an a priori focus on sleep, a clinical population of active treatment-seeking youth and families, and a multimodal assessment of sleep problems (including parent- and child-report of sleep problems, sleep diary and actigraphy assessments of sleep patterns, and independent evaluator-administered sleep interview).

STUDY 1

Method

Participants

Participants were 133 youth, ages 9–14, with a primary diagnosis of GAD, social phobia (SP), and/or separation anxiety disorder (SAD) who participated in the Child Anxiety Treatment Study (CATS; Silk et al., 2016). CATS included a large randomized-controlled trial for anxiety that assessed clinical course, treatment outcomes, and neuro-behavioral correlates of treatment response. For the present study, youth receiving either CBT or client-centered therapy

(CCT) were combined into one group to address the question of how anxiety treatment impacts sleep in an open trial design. Sample demographics included 74 (55.6%) females, 14 (10.5%) racial/ethnic minorities with the majority of this group identifying as African American, a mean age of 10.96 ($SD = 1.47$), and mean family income of \$88,034 ($SD = \$68,174$). Primary anxiety diagnoses included 73 with GAD only; 22 with SAD only; 16 with SP only; 11 with GAD and SP; 9 with GAD and SAD; 1 with SAD and SP; and 1 with GAD, SAD, and SP. See Silk et al. (2016) for the CONSORT diagram for the CATS anxiety clinical trial.

Measures

Parent-Report of Sleep Problems. Children's Sleep Habits Questionnaire (CSHQ; Owens, Spirito, & McGuinn, 2000a) is a 35-item parent-report measure of child sleep-related problems in the past week. The total score includes 33 items, which comprise eight subscales that assess Bedtime Resistance, Sleep Onset Delay, Sleep Duration, Sleep Anxiety, Nighttime Waking, Parasomnias, Sleep Disordered Breathing, and Daytime Sleepiness. Higher scores reflect greater sleep disturbance, and a total score of greater than or equal to 41 is recommended as a clinical cutoff. The CSHQ has satisfactory internal consistency, test-retest reliability, and discriminant validity (Owens et al., 2000a). Internal consistency in the current sample was strong for total score (Cronbach's $\alpha = .89$) and acceptable to strong for subscales (Cronbach's α s = .60–.83).

Child-report of Sleep Problems. Sleep Self-Report (SSR; Owens, Spirito, McGuinn, & Nobile, 2000b) is a 26-item child-report measure of sleep disturbance in the past week, aligning with items assessed in the parent CSHQ, and yielding a total sleep disturbance score (Owens et al., 2000b). Internal consistency in the current sample was strong (Cronbach's $\alpha = .84$).

Actigraphy Estimates of Sleep Patterns. The Ambulatory Monitoring Octagonal Basic Motionlogger actigraph captured objective estimates of sleep patterns. Actigraphy has acceptable agreement with polysomnography and high agreement with subjective measures of sleep schedule (e.g., total sleep time; Sadeh, 2011). Participants were asked to wear the actigraph from Thursday evening to Tuesday morning. Data collected during the school year and summer were included. Each night of sleep was coded dichotomously for whether it was a school night based on child-report of school attendance via cell phone on the day following the sleep period as part of ecological momentary assessment (see Silk et al., 2016). The majority (66%) of actigraphic sampling included five nights, 18% included four nights, 7% included three nights, 5% included two nights, and 4% had one night ($M = 4.36$, $SD = 1.10$). Actigraphy variables were identified a priori based on

prior literature that delineates key indices for assessing sleep health (Buysse, 2014), including sleep onset latency (minutes it takes to fall asleep after "lights out"), sleep efficiency (total sleep time divided by time in bed), wake after sleep onset (minutes awake between initial sleep onset and waking), and total sleep time (minutes of sleep between sleep onset and waking). In addition, change in the midpoint of the sleep period from school nights to non-school nights captured the use of non-school nights to "catch up" on sleep—often referred to as social jetlag.

Diary Estimates of Sleep Patterns. Participants tracked subjective sleep patterns using a sleep diary (Bertocci et al., 2005) on nights when they wore the actigraph. Each entry was coded for whether it was a school night. Diaries included subjective report of sleep (same variables as actigraphy data) in addition to ratings along a 100-cm line that was measured to provide a score of 0–100 for subjective sleep quality (100 = best quality sleep) and difficulty waking (100 = least difficulty waking). Across both studies, the majority (8%) of diary sampling included five nights, 14% included four nights, 1% included three nights, and 1% included one night ($M = 4.82$, $SD = 0.49$).

Procedure

Participants were recruited via community ads (bus ads, radio, newspapers), and in pediatric offices distributed throughout a northeastern metropolitan area in the United States. Potential participants contacted the study by email or phone and were screened by phone and then in person according to procedures approved by the Institutional Review Board. Following a discussion and signing of Institutional Review Board-approved consent and assent, participants were screened by trained bachelor's- and master's-level independent evaluators (IEs) masked to treatment assignment (CBT, CCT). Participants were compensated according to completion of assessments throughout the study, at a rate of approximately the minimum wage per hour. Inclusion criteria for anxiety was a primary diagnosis of GAD, SP, and/or SAD based on the *Diagnostic and Statistical Manual of Mental Disorders* (4th ed.; American Psychiatric Association, 1994). The IEs assessed psychiatric diagnosis through administration of the Kiddie Schedule for Affective Disorders and Schizophrenia (Kaufman et al., 1997) to parent and child separately, followed by integration of findings into preliminary diagnoses. All preliminary ratings were reviewed by a child psychiatrist (N. Ryan), who established the final diagnosis. Sixteen percent of interviews were co-rated with high interrater reliability ($\kappa = .97$). Exclusion criteria were (a) having a current primary diagnosis of major depressive disorder, obsessive-compulsive disorder, posttraumatic stress disorder, conduct disorder, substance abuse or dependence, or attention deficit hyperactivity disorder combined or hyperactive-impulsive types

(to decrease the likelihood of movement artifact during the functional magnetic resonance imaging for the parent project) or (b) lifetime diagnoses of autism spectrum disorder, bipolar disorder, psychotic depression, schizophrenia, or schizoaffective disorder present per CATS inclusion/exclusion criteria. In addition, those on psychotropic medication were excluded. Following assessment, participants were randomized to receive CBT or CCT for anxiety. Treatment was delivered by seven master's- and doctoral-level therapists. There were no group differences in treatment response between the treatment conditions, though a full recovery was more likely for youth enrolled in CBT. For a full description of CATS procedures, interventions and outcomes, see Silk et al. (2016).

Interventions. CBT was provided using the Coping Cat therapist manual (Kendall & Hedtke, 2006a) and workbook (Kendall & Hedtke, 2006b). Treatment involved 16 sessions with 14 sessions spent working directly with the child and two sessions (session numbers four and nine) targeting parent behavior. The first eight sessions focused on anxiety management skills (i.e., identifying somatic symptoms and anxious self-talk, problem solving, using self-evaluation and reward) and relaxation training. The second set of eight sessions included graduated exposure to anxiety-provoking stimuli and situations.

CCT (Cohen, Deblinger, Mannarino, & Steer, 2004) is a nondirective, supportive psychotherapy incorporating the principles of humanism. This manualized intervention includes active listening, reflection, empathy, and fostering of discussion of feelings. CCT was used to reflect the standard supportive psychotherapy that youth with anxiety may receive in community settings. The treatment was delivered in 16 sessions, with parents playing a primary role in Sessions 4 and 9 to mirror the CBT intervention.

CBT and CCT treatment teams were advised to manage any sleep complaints as they typically would within the treatment approach (e.g., CBT via coping thoughts at bedtime; CCT via supportive listening about stressors that may be interfering with sleep).

Treatment Integrity. Therapists were trained by master clinicians in each treatment. To guard against treatment drift, 16% of video recorded sessions were watched and rated for fidelity by the teams that originally developed the manuals, using standardized checklists for each treatment. Fidelity ratings were 99% and 98% for CBT and CCT, respectively.

Analytic Plan

Statistical analyses were performed using SPSS 24.0. To assess change across treatment within the anxious group (baseline, 5 week, and posttreatment for parent- and child-

report; and baseline, 4 week, 8 week, 12 week, and post-treatment for actigraphy and diary), we used mixed linear models (MLM) with maximum likelihood estimation to maximize power by allowing us to use noncomplete cases in our analyses and to account for intercorrelations among repeated measurements. Relevant sleep variables were nested within individuals in order to assess changes in sleep using an autoregressive covariance structure of order 1, which controls for autocorrelation between data collected across different time points for a given individual. Analyses were conducted categorically, whereby the latter assessment time points were analyzed in reference to baseline scores, as we anticipated possible nonlinear change across treatment and this approach would allow us to identify when changes occurred. Variance in random intercept was examined.

All analyses included age and gender as covariates given known sleep differences. Also, sleep diary and actigraphy analyses included the number of school nights during which data were collected as a covariate to account for differences in sleep patterns on school nights versus non-school nights. Although we considered conducting analyses for school nights and non-school nights separately, this would have risked significant sample size loss given that data were collected year-round (in support of broader study goals) and therefore not all youth had school night data at all time points. Sleep indices were aggregated to capture average sleep patterns across each 5-day assessment period. For significant findings, anxiety treatment condition (CBT, CCT) was added to the model as a covariate to examine possible effects of treatment type on results.

MLM can be biased if missing data patterns are informative (e.g., participants missing data later in the study may be more likely to have dropped out of treatment and thus may represent a unique distribution); thus, we also pursued mixed pattern analysis following steps outlined by Son, Friedmann, and Thomas (2012) summarized as (a) identify patterns of missing data in actigraphy, diary, and self-report data sets; (b) create dummy variables to represent each of the identified patterns; (c) conduct mixed linear models where intercept, pattern of missingness, time, and Time \times Pattern of Missingness were used as fixed variables to predict each treatment outcome. Patterns that evidenced effects on outcomes could then be used as covariates in primary analyses as needed.

RESULTS

Based on plots of normality and descriptive statistics, several adjustments to the analytic plan were made. First, sleep efficiency was dropped from analyses, as it was found to be too highly correlated with wake after sleep onset (e.g., diary $r = -.99$, $p < .001$). In addition, as is highly common in actigraphy and sleep diary analyses, variables were logarithmically transformed to correct for violations of normality (i.e., skewness), except for the

estimates of total sleep time (actigraphy and diary), sleep quality (diary only), and difficulty waking (diary only), which were normally distributed. All analyses were conducted with outlier-corrected data (outliers moved to within 1.5 interquartile range), and there were no changes to outcomes; thus, these analyses are not presented in text (available from the author). There were no effects of anxiety treatment condition (CBT, CCT) on sleep outcomes; thus, these analyses are not presented in text (available from the authors). With regard to mixed pattern analysis, as outlined in the analytic plan, we found nine patterns of missing data for actigraphy, four for diary data, and three for each of the self-reports. *T* tests indicated that several patterns were associated with treatment disposition and time, suggesting they were missing not at random. Therefore, we conducted MLM with each pattern predicting outcomes to examine possible effects, resulting in 19 MLM models. Of these 19 models, only one pattern of missing data evidenced a significant effect on outcome, but it did not interact with time and was therefore unrelated to treatment effects. Therefore, patterns of missingness did not inform primary analyses for the current study and were not included as covariates.

Primary Analyses

Change in Parent- and Child-reported Sleep-related Problems During Anxiety Treatment

There were small effects on child- and parent-reported sleep (Cohen's $d < .5$; see Table 2). Child-reported sleep-related problems (SSR Total) were significantly lower at both midtreatment ($t = -3.17, p = .002$) and posttreatment ($t = -3.26, p = .001$) relative to baseline. Estimated marginal means for SSR Total were 40.70 (baseline), 38.19 (midtreatment), and 38.13 (posttreatment; see Table 2). Parent-reported sleep-related problems (CSHQ Total) were significantly lower at posttreatment ($t = -3.34, p = .001$) but not at midtreatment ($t = 0.11, p = .91$), relative to baseline. Estimated marginal means for CSHQ Total were 51.16 (baseline), 51.25 (midtreatment), and 48.67 (posttreatment).

As a post hoc follow-up to effects on parent-reported CSHQ total scores, we explored changes in subscales. There was a significant reduction in Bedtime Resistance at midtreatment ($t = -2.20, p = .03$) and posttreatment ($t = -3.63, p < .001$), Sleep Onset Delay at midtreatment ($t = -3.02, p = .003$) and posttreatment ($t = -3.21, p = .002$), Sleep Anxiety at posttreatment ($t = -4.58, p < .001$), Parasomnias at posttreatment ($t = -3.52, p = .001$), and Daytime Sleepiness at midtreatment only ($t = 2.06, p = .04$). No significant reductions were found for Sleep Duration, Night Wakings, or Sleep Disordered Breathing. See Table 2.

Analysis of Clinical Impact

We used Cochran's Q test to assess change in the proportion of youth greater than or equal to the clinical cutoff of 41 on parent-reported CSHQ Total over the course of anxiety treatment. Results indicated that there was no significant decrease in the proportion of youth with total scores greater than or equal to the cutoff of 41 from baseline ($M = 83.54\%$) through midtreatment ($M = 84.81\%$) and posttreatment ($M = 77.22\%$; Cochran's $Q = 3.88, p = .14$).

Change in Subjective Sleep Patterns During Anxiety Treatment

Results for sleep diary analyses indicated a significant effect for total sleep time, such that it was greater at posttreatment relative to baseline ($t = 3.28, p < .001$). Wake after sleep onset significantly changed across anxiety treatment, such that it was not significantly lower relative to baseline at Week 4 ($t = -0.99, p = .32$) or Week 8 ($t = -1.92, p = .06$) but was significantly lower at Week 12 ($t = -3.20, p = .001$) and posttreatment ($t = -3.43, p = .001$) relative to baseline. Sleep quality changed across treatment such that ratings were significantly higher (indicating better sleep quality) at posttreatment ($t = 3.81, p < .001$) relative to baseline but were not significantly different at Week 4 ($t = 1.52, p = .13$), Week 8 ($t = 0.97, p = .33$), or Week 12 ($t = 2.74, p = .01$) compared to baseline. Results also indicated significant change in sleep onset latency, such that it was significantly lower at Week 4 ($t = -2.88, p = .004$) and Week 8 ($t = -2.33, p = .02$) but not at Week 12 ($t = -1.97, p = .05$) or at posttreatment ($t = -1.59, p = .11$), relative to baseline. No significant changes were found for difficulty waking or midpoint of sleep period across anxiety treatment. See Tables 1 and 2 for details.

Change in Objective Sleep Patterns (actigraphy) During Anxiety Treatment

There were no effects on actigraphy over the course of anxiety treatment. See Tables 1 and 2 for details.

STUDY 2

Method

Participants

As shown in the participant flow diagram (Figure 1), participants in the Study 2 open trial sleep enhancement intervention (Sleeping TIGERS) were 50 anxious youth who completed treatment in the randomized controlled comparison of CBT and CCT and met criteria for clinically significant sleep complaints based on sleep screener (i.e., CSHQ) at the conclusion of anxiety treatment ($n = 85$). The 35 families who declined participation most frequently stated as reasons for not participating: fatigue from study

TABLE 1
Descriptive Statistics for Sleep-Related Problems Sleep Patterns at Baseline

| <i>Measures</i> | <i>Study 1 M (SD)</i> | <i>Study 2 M (SD)</i> |
|---------------------------------------|-----------------------|-----------------------|
| CSHQ Total | 51.18 (9.32) | 51.41 (8.08) |
| SSR Total | 40.68 (7.56) | 39.24 (5.52) |
| Sleep Diary | | |
| Sleep Onset Latency (Minutes) | 20.61 (16.29) | 18.45 (10.87) |
| Wake After Sleep Onset (Minutes) | 5.44 (7.13) | 5.78 (8.12) |
| Midpoint of Sleep Period (Clock Time) | 03:15 a.m. (00:47) | 02:57 a.m. (00:36) |
| Total Sleep Time (Minutes) | 528.45 (57.47) | 544.55 (55.28) |
| Sleep Quality (0–100) | 66.32 (18.69) | 73.46 (20.26) |
| Difficulty Waking (0–100) | 62.58 (21.35) | 66.46 (23.04) |
| Sleep Actigraphy | | |
| Sleep Onset Latency (Minutes) | 19.95 (13.38) | 21.88 (16.78) |
| Wake After Sleep Onset (Minutes) | 45.07 (36.77) | 46.48 (38.06) |
| Midpoint of Sleep Period (Clock Time) | 03:15 a.m. (00:49) | 03:34 a.m. (01:17) |
| Total Sleep Time (Minutes) | 475.61 (53.41) | 482.17 (53.93) |

Note: Raw means and standard deviations. Midpoint of sleep period is formatted in hours and minutes. CSHQ = Children's Sleep Habits Questionnaire; SSR = Sleep Self-Report.

participation (i.e. 16 sessions of anxiety treatment and related assessments), busy schedules, and/or child or parent not perceiving sleep as a problem (despite positive sleep screener). Participants were 68% female, were 10% ethnic minority, had a mean age of 11.55 ($SD = 1.64$), and had a mean household income of \$94,681.86 ($SD = \$47,627.84$).

Measures

Subjective Sleep-related Problems (Parent- and Child-report), Objective Sleep Patterns (Actigraphy), and Subjective Sleep Patterns (Diary). Measures were identical to those administered in Study 1. With regard to the number of nights of actigraphy included in sampling for Study 2, 70.4% had five nights of recordings, 22% had four, 4% had three, and 4% had one ($M = 4.56$, $SD = 0.88$). With respect to number of sleep diaries, 83.3% had five nights, 12.5% had four, 2% had three, and 2% had one ($M = 4.75$, $SD = 0.70$).

Clinical Assessment of Sleep. The Focal Interview of Sleep (FIOS) is a clinician-rated semistructured interview developed as part of this trial to assess sleep disturbance in children and adolescents. The evaluator seeks an initial qualitative description of the most concerning parent-reported sleep problem in an open-ended format. This is followed by a series of yes-or-no questions regarding common sleep concerns (i.e., difficulty going to bed, difficulty falling asleep, nighttime waking, difficulty waking, daytime sleepiness, irregular sleep schedules [> 2 hr difference in sleep or wake times across a 1-week period], sleep walking, bedwetting, and nightmares, or *other* concerns). For each sleep concern endorsed by either parent or child, the evaluator asks more

detailed questions (i.e., operational definition, level of concern about sleep problem, onset, frequency, duration, intensity, triggers, and protective factors). Parent and child are interviewed separately, and all sleep concerns endorsed by either party are pursued in detail with both parties. The interviewer provides a final rating based on information from both parent and child. Thirty-six percent of the videotapes were viewed and rated by an independent rater; interrater reliability was strong, with intraclass correlations ranging from .79 to .98, with the exception of concern about wake after sleep onset, which had an intraclass correlation of .57. Means and standard deviations for FIOS outcome variables at Study 2 baseline are as follows: IE sleep problems = 3.12 (1.20), concern = 2.85 (0.62), intensity = 2.75 (0.59), frequency = 6.76 (2.53), functional impairment = 2.43 (0.81), and duration = 26.71 (18.44).

Procedure

Those who joined Study 2 received a pretreatment assessment by an IE. Sleeping TIGERS (described next) began within 2 weeks of preassessment, with delivery by a different therapist than in Study 1, with the exception of one participant who refused a new therapist and was in need of services, so an exception was made. Following the intervention, participants received a posttreatment assessment.

Intervention. Sleeping TIGERS (Dahl et al., 2009) is a six- to eight-session sleep enhancement program using a motivational framework to target sleep-wake regulation and related behaviors. The range of sessions is to accommodate varying needs where the last two sessions are used to practice and reinforce material as needed (clinicians made this decision at Session 4 supervision based on progress and symptoms). The range was particularly important in the current trial to provide flexibility given that these youth had already completed 16 sessions of anxiety treatment and were sometimes doing quite well by Session 6. Forty-seven of 50 intent-to-treat participants (94%) completed six or more sessions of Sleeping TIGERS (13 completed six, 15 completed seven, and 19 completed eight). The majority of the sample (84.2%) completed treatment during the school year. The three noncompleters reported family stress or busy schedules as reasons for withdrawing from treatment.

The intervention targets thoughts, feelings, and behaviors at bedtime (e.g., stimulus control, reducing negative affective stimuli from scary movies, family conflict, social media, etc.), personal motivation, development and maintenance of good habits (e.g., stimulus control, reducing caffeine, increasing physical activity), sleep regularity (e.g., maintaining consistent wake time, using light-dark cues to entrain rhythms), media use at night (e.g., establishing media curfew, dimming light emitted from media), and presleep anxiety and rumination (e.g., savoring positive moments at bedtime on a "mental television," learning to "switch" the channel when youth find they are "stuck" on a worry or rumination channel when it is

TABLE 2
Linear Mixed-Model Summary for Study 1: Effects of Anxiety Treatment on Sleep

| Measures | Intercept | | | | Posttreatment | | | Estimated Marginal Mean (SE) | <i>d</i> |
|--|-------------------|----------|------------------|------------------|---------------|----------------|---------------|------------------------------|----------|
| | Coefficient (SE) | <i>t</i> | CI | Coefficient (SE) | <i>t</i> | CI | | | |
| CSHQ Total | 61.62 (5.40)*** | 11.42 | [50.94, 72.31] | -2.50 (0.75)** | -3.34 | [-3.97, -1.02] | 48.67 (0.85) | 0.27 | |
| a. Bedtime resistance | 13.89 (1.88)*** | 7.39 | [10.17, 17.61] | -0.83 (0.23)*** | -3.63 | [-1.28, -0.38] | 8.91 (0.29) | 0.27 | |
| b. Sleep Onset Delay | 3.00 (0.41)*** | 7.26 | [2.18, 3.82] | -0.25 (0.08)** | -3.21 | [-0.40, -0.10] | 1.82 (0.07) | 0.33 | |
| c. Sleep Duration | 3.92 (0.97)*** | 4.05 | [2.01, 5.84] | 0.18 (0.17) | 1.05 | [-0.16, 0.51] | 4.80 (0.17) | -0.10 | |
| d. Sleep Anxiety | 12.45 (1.29)*** | 9.65 | [9.89, 15.00] | -0.74 (0.16)*** | -4.58 | [-1.06, -0.42] | 6.15 (0.20) | 0.35 | |
| e. Night Waking | 5.26 (0.90)*** | 5.83 | [3.47, 7.04] | -0.11 (0.13) | -0.80 | [-0.37, 0.16] | 4.32 (0.15) | 0.07 | |
| f. Parasomnias | 10.97 (1.15)*** | 9.51 | [8.69, 13.26] | -0.69 (0.20)*** | -3.52 | [-1.07, -0.30] | 8.78 (0.20) | 0.34 | |
| g. Sleep-disordered Breathing | 3.46 (0.45)*** | 7.64 | [2.56, 4.36] | -0.07 (0.09) | -0.75 | [-0.24, 0.11] | 3.37 (0.08) | 0.08 | |
| h. Daytime Sleepiness | 14.62 (2.26)*** | 6.48 | [10.16, 19.09] | -0.33 (0.33) | -1.00 | [-0.98, 0.32] | 13.87 (0.34) | 0.09 | |
| SSR Total | 54.70 (4.06)*** | 13.49 | [46.68, 62.72] | -2.58 (0.79)*** | -3.26 | [-4.14, -1.02] | 38.13 (0.73) | 0.37 | |
| Sleep Diary | | | | | | | | | |
| a. Sleep Onset Latency ^a | 3.19 (0.43)*** | 7.38 | [2.34, 4.05] | -0.11 (0.07) | -1.59 | [-0.26, 0.03] | 2.69 (0.08) | 0.16 | |
| b. Wake After Sleep Onset ^a | 1.14 (0.54)* | 2.10 | [.07, 2.22] | -0.36 (0.10)*** | -3.43 | [-0.56, -0.15] | 0.98 (0.10) | 0.34 | |
| c. Midpoint Sleep Period ^a | 4.99 (0.12)*** | 39.99 | [4.74, 5.23] | 0.02 (0.01) | 1.16 | [-0.01, 0.06] | 5.28 (0.02) | -0.10 | |
| d. Total Sleep Time | 702.68 (27.06)*** | 26.00 | [649.20, 756.17] | 18.94 (5.68)*** | 3.33 | [7.78, 30.10] | 548.93 (5.29) | -0.35 | |
| e. Sleep Quality | 74.40 (11.19)*** | 6.65 | [52.27, 96.53] | 6.68 (1.75)*** | 3.81 | [3.23, 10.13] | 73.20 (1.92) | -0.33 | |
| f. Difficulty Waking | 84.33 (11.38)*** | 7.41 | [61.81, 106.84] | 0.65 (2.15) | 0.30 | [-3.59, 4.88] | 63.42 (2.12) | -0.03 | |
| Actigraphy | | | | | | | | | |
| a. Sleep Onset Latency ^a | 3.22 (0.25)*** | 12.75 | [2.72, 3.71] | 0.05 (0.06) | 0.93 | [-0.06, 0.17] | 2.95 (0.05) | -0.11 | |
| b. Wake After Sleep Onset ^a | 4.48 (0.40)*** | 11.12 | [3.68, 5.27] | -0.08 (0.09) | -0.96 | [-0.25, 0.09] | 3.48 (0.08) | 0.10 | |
| c. Midpoint Sleep Period ^a | 7.38 (0.02)*** | 446.20 | [7.35, 7.41] | 0.00 (0.00) | 0.65 | [-0.00, 0.01] | 7.41 (0.00) | -0.07 | |
| d. Total Sleep Time | 603.32 (25.44)*** | 23.71 | [553.00, 653.63] | 3.40 (5.52) | 0.62 | [-7.45, 14.25] | 478.60 (5.02) | -0.1 | |

Note. Results for covariates (gender, age, and number of school nights) are not reported in the table. Random effects, including variance of intercept and autoregressive model of order 1 residual covariance parameters (to correct for autocorrelation between time points), were included in the model but are not reported in the table. Estimated marginal means and standard errors are reported to guide interpretation of direction of effects relative to baseline. SE = Standard Error; CI = Confidence Interval; CSHQ = Children's Sleep Habits Questionnaire; SSR = Sleep Self-Report.

^aSleep diary and actigraphy variables were logarithmically transformed.

p* < .05. *p* < .01. ****p* < .001.

time to go to sleep). The majority of the behavioral strategies were drawn from established behavioral treatments (e.g., CBT for insomnia), whereas others were developed as part of this trial and tailored to specific needs of this population (e.g., presleep savoring, "media curfew," reducing high social and affective stimulation at bedtime).

Treatment Integrity. Treatment integrity was managed via three strategies. First, multiday therapist training workshops were conducted at the start of the study and approximately 1 year after study start. Both workshops involved a specific focus on promoting adherence and on delivering treatment with a high level of fidelity. Second, fidelity was a topic covered within the weekly supervision sessions which were led by three sleep experts who developed the manual (Dahl, Harvey, and McMakin). In addition, via a random numbers generator (with nonreplacement), 10% of sessions were rated for treatment integrity and fidelity by expert therapists using standardized checklists to indicate whether

appropriate content was covered. Approximately 7% of these ratings were conducted during the study to reduce drift, and the remaining 3% were conducted following the trial. All sessions were included in this random review. Ratings indicated that 96% of session minutes and 97% of overall sessions reflected high fidelity.

Analytic Plan

MLM was performed as described in Study 1. Measures and time points for Study 2 included parent and child self-report, sleep diary, actigraphy, and clinician-rated sleep disturbance at baseline and posttreatment. Study 2 included only two time points, thus ruling out the use of pattern mixture models. Instead, missing data were coded dichotomously, and *t* tests were conducted to examine if missingness was associated with baseline characteristics such as symptom severity or treatment disposition.

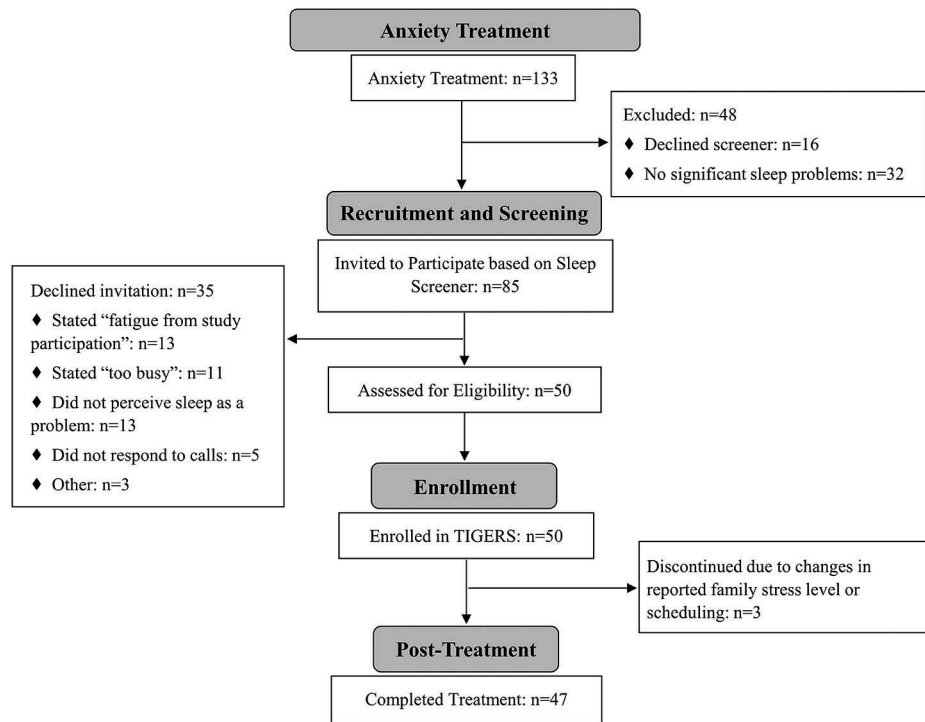


FIGURE 1 Diagram of participant flow through Sleeping TIGERS.

RESULTS

Preliminary Analyses

Descriptive statistics and plots of normality resulted in the same changes described in Study 1. All analyses were conducted with outlier-corrected data (outliers moved to within 1.5 interquartile range), and there were no changes to outcomes; thus, these analyses are not presented in text (available from the author). There were no significant t tests for missingness predicting symptom severity or treatment disposition.

Primary Analyses

Change in Parent- and Child-reported Sleep-related Problems During Sleeping TIGERS

There were large effects on parent and child-reported sleep (Cohen's $d = 1.15$ and 0.83 , respectively; see [Tables 1](#) and [3](#) for descriptives and statistics). Specifically, results showed a significant reduction in child-reported sleep disturbance from baseline to post-treatment ($t = -5.77$, $p < .001$). Estimated marginal means were 38.76 (baseline) and 34.43 (posttreatment). There was a significant change in parent-reported sleep-related problems during the Sleeping TIGERS intervention, such that scores at posttreatment were significantly lower than at baseline ($t = -8.61$, $p < .001$). Estimated

marginal means were 51.14 (baseline) and 42.70 (posttreatment).

As a post hoc follow-up to effects on parent-reported CSHQ total scores, we explored changes in subscales. There was a significant pre-post reduction in Bedtime Resistance ($z = -4.57$, $p < .001$), Sleep Onset Delay ($t = -5.46$, $p < .001$), Sleep Duration ($t = -7.92$, $p < .001$), Sleep Anxiety ($t = -4.36$, $p < .001$), Night Wakings ($t = -3.33$, $p = .001$), Parasomnias ($t = -3.73$, $p < .001$), and Daytime Sleepiness ($t = -4.07$, $p < .001$). No significant reduction was found for Sleep Disordered Breathing ($t = -1.23$, $p = .23$). See [Table 3](#) for details.

Analysis of Clinical Impact

McNemar's test was used to assess change in the proportion of youth greater than or equal to the clinical cutoff of 41 on the CSHQ from baseline to posttreatment. Results indicated that this proportion significantly decreased from 90.0% at baseline to 67.5% at posttreatment ($p = .01$; see [Figure 2](#)). [Figure 2](#) also provides a trajectory of parent-reported sleep for the Study 2 sample that indicates an acceleration of sleep improvement upon the introduction of sleep intervention, relative to anxiety treatment.

Change in Subjective Sleep Patterns (Diary) through Sleeping TIGERS

Significant reductions from baseline to posttreatment were found for sleep quality ($t = 2.09, p < .05$). No other sleep diary indices significantly changed over the course of treatment (see Table 3).

Change in Objective Sleep Patterns (Actigraphy) Indices through Sleeping TIGERS

There were no significant changes observed for actigraphy indices (see Table 3).

Change in Independent Evaluator Ratings of Sleep

FIOS variables showed significant reductions from pre- to post-Sleeping TIGERS: clinician-rated number of sleep problems ($t = -6.27, p < .001$), concern ($t = -10.20, p < .001$), intensity ($t = -5.34, p < .001$), frequency ($t = -6.90, p < .001$), impairment, ($t = -5.31, p < .001$), and duration ($t = -2.83, p = .01$). See Table 3.

DISCUSSION

The current studies examined whether sleep improves among anxious peri-pubertal youth in response to anxiety treatment (Study 1) and if a developmentally informed sleep intervention can further improve sleep among youth with residual sleep disturbance following treatment for anxiety (Study 2). These questions are critical to address during the peri-pubertal period due to (a) the confluence of developmental changes around the onset of puberty that lead to increases in both sleep disturbance and affective problems, and (b) the established prospective links between sleep disturbance and increasing internalizing symptoms (anxiety, depression) in adolescence.

Overall Summary of Findings

Study 1 demonstrated improvements in child- and parent-reported sleep disturbance over the course of anxiety treatment; however, the effect sizes were small and a post hoc test of clinical impact was not significant. In fact, 75% of youth remained above the clinical cutoff on the parent-report of sleep problems at the end of anxiety treatment. In Study 2, an open trial of a sleep enhancement intervention (Sleeping TIGERS, $n = 50$) that followed anxiety treatment, we demonstrated large within-subject effects on multiple indices of sleep disturbance (e.g., parent- and child-report of sleep-related problems, subjective sleep patterns [sleep diary], and a semistructured interview of sleep disturbance), and our post hoc test of clinical impact was significant. Notably, the sleep intervention had a 94% completion rate, supporting acceptability and feasibility of the intervention.

Study 1 Discussion of Key Findings

Similar to prior reports indicating high prevalence of sleep-related problems among youth with anxiety (Alfano et al., 2007; Chase & Pincus, 2011), 80% of anxious youth were above the clinical cutoff on the parent-report of sleep problems (CSHQ). Over the course of anxiety treatment, there was a significant reduction in parent- and child-reported sleep-related problems, with parent reports showing a reduction from baseline to posttreatment (but not midtreatment) and child reports showing a reduction from baseline to midpoint and posttreatment. An exploration of subscales on the parent-report indicated small effects on Bedtime Resistance, Sleep Onset Latency, Sleep Anxiety, and Parasomnias, whereas there were no observed effects on Sleep Duration, Wake After Sleep Onset, Sleep Disordered Breathing, or Daytime Sleepiness. This pattern of results is consistent with prior research indicating that anxiety treatment imparts strongest impacts on Bedtime Resistance, Sleep Anxiety, and Presleep Arousal (Clementi et al., 2016; Peterman et al., 2016).

There were also small improvements in subjective sleep patterns (diary). Specifically, sleep quality showed improvements relative to baseline at posttreatment (but not Weeks 4, 8, or 12). There were also improvements in subjective sleep transitions and maintenance. Average wake after sleep onset was reduced from baseline to Week 12 and posttreatment. Sleep latency onset was significantly reduced at Weeks 4, 8, and 12, though effects were no longer significantly different from baseline at posttreatment. This could be due to relatively small effect sizes making significance unreliable and/or a slight uptick in difficulty falling asleep due to the end of anxiety treatment.

Overall, these changes in sleep over the course of anxiety treatment are noteworthy given that sleep was not explicitly targeted, thus reducing associated demand characteristics. However, enthusiasm for these outcomes is tempered by the fact that this was an open trial, within-subject effect sizes were mostly small, similar to several recent studies (Caporino et al., 2017; Clementi et al., 2016; Peterman et al., 2016), and our test of clinical impact was not significant. This is salient given that response and full remission from anxiety was achieved in 65% and 57% of the sample, respectively (Silk et al., 2016), yet sleep problems above a clinical cutoff persisted for 75% of youth at post anxiety treatment (relative to 80% at baseline and 84% at midtreatment).

Study 2 Discussion of Key Findings

In light of ongoing sleep-related problems following anxiety treatment in Study 1 and the known prospective risk associated with sleep-related problems in adolescence, the focus of Study 2 is contextualized as a critical question. That is, can a developmentally informed sleep intervention improve sleep? In the open trial, Sleeping TIGERS demonstrated large within-subject effects on parent- and child-report of sleep-related problems. Moreover, the effects on the

TABLE 3
Study 2 Linear Mixed-Model Summary for Effects of Sleeping TIGERS on Sleep-Related Problems and Patterns

| Measures | Intercept | | | Posttreatment | | | Post-Tx Estimated Marginal Mean (SE) | d |
|--|-------------------|-------|------------------|------------------|--------|-----------------|---|-------|
| | Coefficient (SE) | t | CI | Coefficient (SE) | t | CI | | |
| CSHQ Total | 47.28 (7.69)*** | 6.15 | [31.76, 62.79] | -8.45 (0.98)*** | -8.61 | [-10.43, -6.46] | 42.70 (1.27) | 1.15 |
| a. Bedtime Resistance | 11.99 (2.03)*** | 5.91 | [7.88, 16.09] | -1.93 (0.42)*** | -4.57 | [-2.79, -1.07] | 6.62 (0.38) | 0.89 |
| b. Sleep Onset Delay | 1.24 (0.66) | 1.89 | [-0.09, 2.57] | -0.70 (0.13)*** | -5.46 | [-0.96, -0.44] | 1.35 (0.12) | 1.02 |
| c. Sleep Duration | 1.38 (1.29) | 1.07 | [-1.23, 3.99] | -1.68 (0.21)*** | -7.92 | [-2.11, -1.25] | 4.47 (0.22) | 1.30 |
| d. Sleep Anxiety | 11.08 (1.96)*** | 5.65 | [7.12, 15.05] | -1.04 (0.24)*** | -4.36 | [-1.53, -0.56] | 5.11 (0.32) | 0.56 |
| e. Night Waking | 5.08 (1.61)** | 3.15 | [1.82, 8.34] | -0.60 (0.18)*** | -3.33 | [-0.97, -0.23] | 3.98 (0.26) | 0.40 |
| f. Parasomnias | 9.83 (1.27)*** | 7.74 | [6.75, 11.89] | -0.79 (0.21)*** | -3.73 | [-1.23, -0.36] | 8.03 (0.22) | 0.62 |
| g. Sleep-Disordered Breathing | 3.19 (0.33)*** | 9.73 | [2.52, 3.85] | -0.08 (0.06) | -1.23 | [-0.21, 0.05] | 3.05 (0.06) | 0.23 |
| h. Daytime Sleepiness | 7.55 (3.53) | 2.14 | [0.43, 14.67] | -2.31 (0.57)*** | -4.07 | [-3.46, -1.16] | 12.27 (0.61) | 0.66 |
| SSR Total | 38.89 (5.44)*** | 7.15 | [27.92, 49.86] | -4.33 (0.75)*** | -5.77 | [-5.86, -2.81] | 34.43 (0.91) | 0.83 |
| Sleep Diary | | | | | | | | |
| a. Sleep Onset Latency ^a | 2.89 (0.62)*** | 4.69 | [1.64, 4.14] | -0.14 (0.11) | -1.29 | [-0.36, 0.08] | 2.67 (0.11) | 0.24 |
| b. Wake After Sleep ^a Onset | 0.62 (1.58) | 0.39 | [-2.60, 3.83] | 0.19 (0.22) | 0.85 | [-0.27, 0.64] | 1.38 (0.26) | -0.14 |
| c. Sleep Quality | 81.50 (21.01)*** | 3.88 | [38.93, 124.06] | 4.85 (2.32)* | 2.09 | [0.12, 9.57] | 77.27 (3.40) | -0.26 |
| d. Difficulty Waking | 97.14 (20.60)*** | 4.72 | [55.72, 138.75] | 5.30 (3.57) | 1.49 | [-1.94, 12.53] | 70.99 (3.58) | -0.27 |
| e. Midpoint Period ^a | 5.26 (0.17)*** | 31.03 | [4.92, 5.60] | -0.01 (0.04) | -0.22 | [-0.09, 0.07] | 5.14 (0.03) | 0.05 |
| f. Total Sleep Time | 798.84 (43.21)*** | 18.49 | [711.42, 886.26] | -5.51 (8.29) | -0.66 | [-22.36, 11.33] | 534.80 (7.71) | 0.13 |
| Actigraphy | | | | | | | | |
| a. Sleep Onset ^a Latency | 3.11 (0.63)*** | 4.93 | [1.83, 4.39] | 0.03 (0.11) | 0.31 | [-0.19, 0.26] | 2.89 (0.11) | -0.06 |
| b. Wake After Sleep ^a Onset | 4.56 (0.73)*** | 6.17 | [3.06, 6.06] | -0.11 (0.15) | -0.77 | [-0.41, 0.19] | 3.44 (0.14) | 0.13 |
| c. Midpoint of Sleep ^a Period | 5.03 (0.28)*** | 18.17 | [-4.47, 5.60] | 0.03 (0.04) | 0.62 | [-0.06, 0.11] | 5.37 (0.05) | -0.10 |
| d. Total Sleep Time | 650.06 (41.94)*** | 15.50 | [565.11, 735.02] | -1.93 (7.95) | -0.24 | [-18.15, 14.30] | 475.71 (7.55) | 0.05 |
| IE FIOS | | | | | | | | |
| a. No. of Problems | 2.03 (0.89)* | 2.28 | [0.28, 3.79] | -1.72 (0.27)*** | -6.27 | [-2.26, -1.18] | 1.56 (0.19) | 1.53 |
| b. Concern | 2.10 (0.59)*** | 3.56 | [0.94, 3.25] | -1.20 (0.12)*** | -10.20 | [-1.43, 0.96] | 1.67 (0.10) | 2.04 |
| c. Intensity | 2.64 (0.55)*** | 4.85 | [1.58, 3.71] | -0.83 (0.15)*** | -5.34 | [-1.13, -0.52] | 1.92 (0.11) | 1.32 |
| d. Frequency | 1.45 (2.58) | 0.56 | [-3.60, 6.50] | -3.01 (0.44)*** | -6.90 | [-3.86, -2.15] | 3.65 (0.42) | 1.23 |
| e. Impairment | 1.28 (0.68) | 1.89 | [-0.05, 2.61] | -0.86 (0.16)*** | -5.31 | [-1.17, -0.54] | 1.58 (0.12) | 1.21 |
| f. Duration | 14.00 (16.93) | 0.83 | [-19.19, 47.18] | -7.28 (2.57)** | -2.83 | [-12.32, -2.23] | 19.60 (2.70) | 0.46 |

Note: Results for covariates (gender, age, and number of school nights) are not reported in the table. Random effects, including variance of intercept and autoregressive model of order 1 (AR1) residual covariance parameters (to correct for autocorrelation between time points) were included in the model but are not reported in the table. Estimated marginal means and standard errors are reported to guide interpretation of direction of effects relative to baseline. Tx = Treatment; CSHQ = Children's Sleep Habits Questionnaire; SSR = Sleep Self Report; IE = Independent Evaluator; FIOS = Focal Interview of Sleep; SE = Standard Error.

^aSleep diary and actigraphy variables were logarithmically transformed.

* $p < .05$. ** $p < .01$. *** $p < .001$.

subscales of the parent-report of sleep problems (CSHQ) were moderate to large and were significant for all subscales except for Disordered Breathing. Finally, post hoc tests supported a significant clinical impact on parent-reported sleep-related problems, with a reduction in the percentage of youth greater than or equal to clinical cutoff on CSHQ (parent-report) from 90% at pre-sleep intervention to 68% at post-sleep intervention.

It is notable that despite a substantial and clinically significant reduction in parent-reported sleep problems, 68% of the sample remained above clinical cutoff on CSHQ. As noted by past research, this cut-point may not be optimized for a clinical population (Langberg et al., 2017) and/or the high rates of insufficient sleep in adolescent populations may suggest that being above a clinical cutoff has become somewhat normative.

Nevertheless, it is clear that insufficient sleep portends a number of risk factors for anxious youth (McMakin & Alfano, 2015) and therefore remains a critical intervention target.

There were also large effects from pre- to post-sleep intervention on subjective diary reports for sleep quality. There were no changes in total sleep time or midpoint of sleep. There were also no changes in actigraphy indices. Finally, the FIOS semi-structured interview indicated large within-subject effects on the total number of sleep problems reported, as well as reductions in concern related to sleep problems and reductions in frequency, duration, and intensity of sleep problems.

It is noteworthy that Study 1 and Study 2 failed to detect impacts on actigraphy estimates of sleep patterns. The discordance in subjective and objective indices is consistent with prior literature and has been discussed in

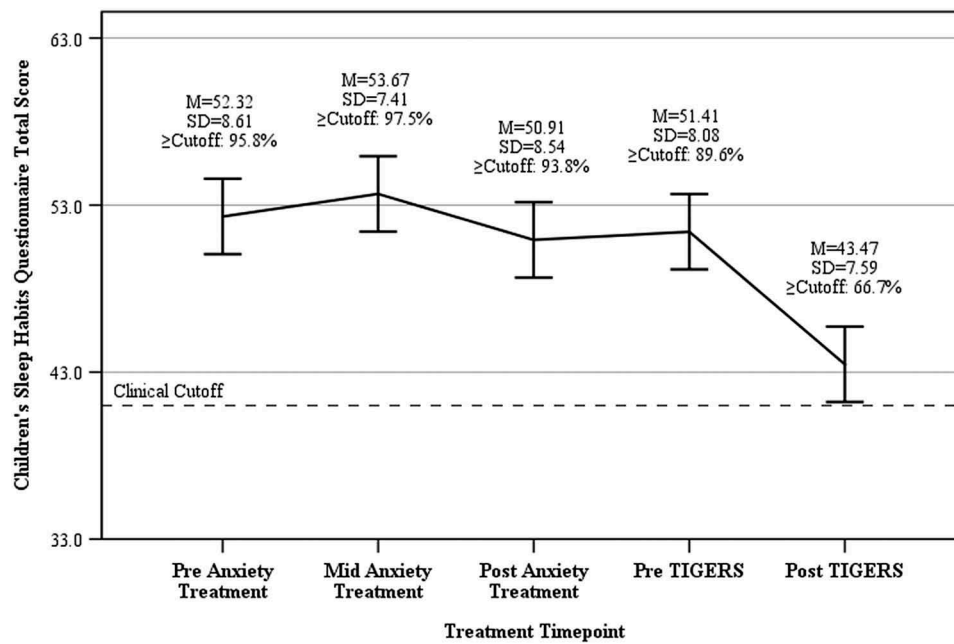


FIGURE 2 Change in parent-reported sleep for the Study 2 sample across anxiety treatment and Sleeping TIGERS intervention.

detail in a recent review (McMakin & Alfano, 2015). In short, discordance may be due to methodological challenges (e.g., it is difficult to measure sleep transitions using actigraphy), differences in perception (anxious youth may hold perceptual biases), or demand characteristics (e.g., social desirability) driving subjective differences in the absence of objective change. Finally, it is possible that the 5-night assessment period was not long enough to reliably detect effects (see Study 1 and 2 Limitations and Contributions section). These will be important issues to unpack in future research. Regardless of the underlying cause of discordance, subjective sleep problems and patterns such as those described here are prospective predictors of emotional adjustment (El-Sheikh, Bub, Kelly, & Buckhalt, 2013) and mental health outcomes (e.g., depression; Gregory, Rijsdijk, Lau, Dahl, & Eley, 2009) such that changes in these dimensions may be important with or without convergence with actigraphy.

Study 1 and 2 Limitations and Contributions

There were several limitations to the current studies. First, our diary and actigraphy estimates were based on 5-day assessment periods, with a notable proportion of the samples (34% in Study 1 and 30% in Study 2) having fewer than 5 nights. Monitoring periods included weekends and could have been obtained during the school year or during periods of holiday. As such, this introduces noise into the

diary and actigraphy sleep estimates. We included the number of school nights (vs. non-school nights) in each assessment period as a covariate in order to account for relevant variance in sleep estimates. These design decisions regarding assessment periods were due to practical constraints that included (a) a need to recruit year-round to maintain flow and address clinical concerns, and (b) a need to minimize burden of data collection for families in this multimethod study. Future work could benefit from a longer assessment period and careful timing of intervention during the school year. Second, our sample is comprised of less than 80% White and mostly middle-class youth. This is a significant limitation and is particularly notable in light of research demonstrating how challenging it is to disseminate empirically supported treatments that are developed in academic centers with narrow demographic sampling. More work will need to be done to test the potential generalizability and dissemination of this treatment into more diverse community settings. Third, although Study 1 and Study 2 drew from the same initial sample of anxious youth, it was not possible to compare youth who did or did not participate in sleep intervention, because the sleep intervention was not randomly assigned. Rather, eligible participants were invited to participate and then self-selected into the intervention—those who chose not to participate often cited fatigue from study participation or busy schedules. This necessarily tempers our conclusions regarding the high completion rate of 94%. Furthermore, there was no active control condition for either study, making it impossible to conclude that the

effects on sleep were related to the intervention rather than the passage of time or other factors. This limitation is somewhat assisted by data in Figure 2 that show the change in sleep among Study 2 participants accelerated upon the introduction of sleep intervention, though demand characteristics (i.e. social desirability) may still be a factor. These design decisions were necessary to manage multiple priorities in this multiple project center grant.

Despite these limitations, our questions regarding whether anxiety treatment resolves sleep disturbance, and whether it is possible to modify sleep following anxiety treatment, garner preliminary support by the design and data presented here. These studies contribute to the literature by overcoming multiple past research limitations. Specifically, the studies address limitations of prior work by including a large sample of treatment seeking anxious peri-pubertal youth early in the transition to the high-risk period of adolescence (Study 1, $n = 133$; Study 2, $n = 50$), an a priori focus on sleep with a multimodal assessment of subjective and objectively sleep-related problems and patterns (retrospective parent- and child-report, actigraphy, diary, semistructured interview) across multiple informants (parent, child, independent evaluator) at multiple time-points across treatment. In addition, a targeted sleep intervention (Sleeping TIGERS) was examined in youth already treated for anxiety, allowing for an evaluation of the impact of a targeted sleep intervention on sleep disturbance that was resistant to efficacious anxiety treatment—to our knowledge, this type of study has not been done previously and therefore provides novel insights regarding the potential for targeted sleep intervention to resolve residual symptoms.

Overall Clinical Implications and Future Directions

If these findings continue to garner support in RCT design, they will carry important clinical implications. That is, although anxiety treatment does improve aspects of sleep, the effects are small and not clinically significant. Addressing residual sleep disturbance in anxious youth is therefore a clinical issue of paramount importance with potential to meaningfully reduce risk for increasing emotional problems (e.g., depression) in adolescence. Our preliminary support for Sleeping TIGERS suggests feasibility and clinical potential to successfully modify sleep in this population via behavioral intervention. A randomized controlled trial is an essential next step to establish efficacy.

Future work may examine whether modifying sleep during this sensitive peri-pubertal period improves developmental trajectories of emotional adjustment and mental health. The current studies were embedded in a larger center grant that includes multimethod assessment of affective functioning (functional magnetic resonance imaging, ecological momentary assessment, parent-child interactions), as well as long-term follow-up of symptoms and functional outcomes (5 years), such that the current studies set the stage for deeper

investigations of the impact of sleep on long-term emotional adjustment and mental health. Also, future work may identify a specific developmental window during the adolescent transition when behavioral sleep intervention can impart greatest impacts on development and therefore be prioritized in clinical decision making. Finally, future work could examine whether delivering a sleep-targeted intervention in parallel to anxiety treatment, versus serially, would yield highest clinical impact.

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