EFFICACY OF AN INTEGRATED SLEEP AND ANXIETY INTERVENTION FOR ANXIOUS CHILDREN: A PILOT RANDOMIZED CONTROLLED TRIAL

A Dissertation

Presented to

The Faculty of the Department

of Psychology

University of Houston

In Partial Fulfillment of

The Requirements for the Degree of

Doctor of Philosophy

By

Michelle A. Clementi

July, 2017

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Abstract

Less than optimal response rates and long-term outcomes following treatment for child anxiety disorders suggest that interventions may need to target more precise underlying mechanisms that maintain anxiety in order to improve treatment outcomes. Children with anxiety disorders report high rates of sleep-related problems and evidence suggests that sleep may impact exposure-based treatment outcomes given the role of sleep in facilitating extinction learning. Thus, addressing sleep as part of anxiety-focused interventions may produce superior outcomes in terms of both anxiety and sleep. Although three studies have shown purely anxiety-focused interventions improve sleep-related problems, wide developmental ranges, lack of control groups, and a proxy measure for sleep are notable limitations. Preliminary findings support the efficacy of Targeted Behavioral Therapy (TBT), an integrated intervention that targets sleep problems and anxiety in children with generalized anxiety disorder (GAD). The current pilot study used a randomized, controlled design to examine the efficacy of TBT compared to 'gold standard' cognitive-behavioral therapy (CBT) for anxiety among 20 children (ages 6-12) with primary GAD. Assessments were conducted at baseline, post-treatment, and 6-month follow-up, which included diagnostic interviews, multi-informant measures, and objective sleep monitoring (i.e., actigraphy). Sleep-related questions were also collected on a weekly basis, as well as more comprehensive assessment of sleep and anxiety at mid-treatment. Results indicate that sleep, anxiety, and global functioning significantly improved across both groups from baseline to post-treatment, and improvements were maintained at 6-month follow-up based on moderate to very large effect sizes. Objective sleep onset latency also decreased marginally for both groups at post-treatment. The TBT group demonstrated a significant decrease in child-

reported anxiety from mid-treatment to post-treatment (i.e., after the sleep intervention) that was not observed in the CBT group. A linear decrease in weekly bedtime problems was observed for nearly twice as many TBT participants compared to CBT participants, suggesting progressive improvement in bedtime problems across 16-weeks of treatment with TBT. Findings demonstrate the potential utility of anxiety interventions for improving some sleep-related problems, but raise questions about the nature of sleep disturbances in anxious youth and specific aspects of sleep to be targeted during intervention. Future directions and limitations are discussed.

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Introduction

Child anxiety disorder prevalence rates range from 3 to 24% in community samples (Cartwright-Hatton, McNicol, & Doubleday, 2006) and median age of onset most commonly occurs in middle childhood (Kessler et al., 2005). Studies suggest that in the absence of treatment, anxiety disorders in youth do not remit over time (Pine, Cohen, Gurley, Brook, & Ma, 1998) and are predictive of future additional anxiety disorders, depression, and substance abuse (Benjamin, Harrison, Settipani, Brodman, & Kendall, 2013; Costello, Mustillo, Erkanli, Keeler, & Angold, 2003). Cognitive-behavioral therapy (CBT) is an effective treatment of choice for child anxiety as evidenced by highly consistent remission rates across multiple reviews and meta-analyses (Crowe & McKay, 2017; James, Soler, & Weatherall, 2005; James, James, Cowdrey, Soler, & Choke, 2013; Silverman, Pina, & Viswesvaran, 2008). One review of CBT for child anxiety disorders found a remission rate of 59% in the treatment groups versus 16% in the control groups (James et al., 2013). However, over one-third of children still experience clinically significant anxiety symptoms following treatment. Further, few studies have examined long-term outcomes, and of those that have, little evidence exists supporting long-term maintenance of anxiety symptom improvement (Benjamin et al., 2013; James et al., 2013). Specifically, the Child/Adolescent Multimodal Study (CAMS), one of the largest randomized controlled trials examining CBT for child anxiety, revealed that approximately half of all CBT participants met criteria for an anxiety disorder at 6- and 9-month follow-up (Piacentini et al., 2014). Low remission rates and lack of long-term maintenance may be explained by current treatments overlooking potential causal/maintaining factors of anxiety. These limitations call for current research to focus on dissecting causal, maintaining, and mechanistic factors of anxiety disorders and incorporating these factors into novel, targeted interventions.

The Relationship Between Sleep and Anxiety

Inadequate/disrupted sleep is continually found to serve as a causal/maintaining factor of anxiety disorders and thus may be an appropriate treatment target. Experimental studies in healthy adolescents show inadequate sleep to produce adverse daytime consequences such as problems with mood and emotion regulation, in addition to increased anxiety and greater catastrophizing thoughts (Baum et al., 2014; Reddy et al., 2016; Talbot, McGlinchey, Kaplan, Dahl, & Harvey, 2010). Extensive longitudinal studies have also identified early sleep problems as a robust predictor of later anxiety (Gregory & O'Connor, 2002; Gregory et al., 2005; Gregory, Eley, O'Connor, & Plomin, 2004; Leahy & Gradisar, 2012; Shanahan, Copeland, Angold, Bondy, & Costello, 2014). For instance, nearly half of school-aged children with persistent sleep-related problems go on to meet criteria for an anxiety disorder in adulthood (Gregory et al., 2005). More specifically, experiencing difficulty falling asleep, early morning awakening, and exhaustion has been found to predict higher rates of generalized anxiety disorder (GAD) in adolescence (Shanahan et al., 2014).

Evidence also suggests that early anxiety predicts future sleep-related problems, thus depicting a reciprocal relation between sleep and anxiety across development (Goldman-Mellor et al., 2014; Johnson, Roth, & Breslau, 2006; Shanahan et al., 2014). A four-decade longitudinal study found that adolescents with anxiety disorders were nearly twice as likely to experience insomnia in mid-adulthood (Goldman-Mellor et al., 2014). Additionally, children described by parents and teachers as having high rates of internalizing problems (e.g., excessive worry, sadness) were at significantly increased risk for insomnia as adults (Goldman-Mellor et al., 2014). In sum, sleep problems and anxiety symptoms may exacerbate one another on a short-term basis (e.g., poor sleep may result in emotional dysregulation/anxiety during the day, which leads to more difficulty falling asleep at night),

and increase the likelihood of emotional problems later in development. Because sleep-related problems may be both a causal and maintaining factor in child anxiety disorders, it may be important for interventions to address both anxiety symptoms and sleep-related problems in order to prevent chronic problems in either domain and to improve overall recovery rates for child anxiety disorders.

Subjective Sleep-related Problems and Anxiety in Children

Clinically anxious children experience exceedingly high rates of sleep-related problems, ranging from 82-95% based on parent- and self-report (Alfano, Beidel, Turner, & Lewin, 2006; Alfano, Ginsburg, & Kingery, 2007; Alfano, Pina, Zerr, & Villalta, 2010; Chase & Pincus, 2011; Hansen, Skirbekk, Oerbeck, Richter, & Kristensen, 2011; Hudson, Gradisar, Gamble, Schniering, & Rebelo, 2009a). Nearly half (46%) of anxious youth have at least one frequent sleep-related complaint and 83% have intermittent complaints (Alfano et al., 2006). Frequency of sleep-related problems is related to increased anxiety severity (Alfano et al., 2007; Chase & Pincus, 2011) and children with more sleep-related problems have more impaired functioning at home and within the family (Alfano et al., 2007). In the absence of intervention, these problems persist in most children with anxiety disorders (Hansen, Skirbekk, Oerbeck, Wentzel-Larsen, & Kristensen, 2013). Although sleep-related problems occur frequently across all types of child anxiety disorders (e.g., Alfano et al., 2007), growing evidence suggests that sleep-related problems are most prevalent among children with GAD specifically (Alfano et al., 2006; Alfano et al., 2007). In one study, Alfano and colleagues (2010) found that up to 90% of children with GAD reported difficulty sleeping, a significantly higher rate in comparison to children with separation anxiety disorder, social phobia, and obsessive-compulsive disorder.

Sleep-related problems in childhood refer to problems such as difficulty falling/staying asleep, difficulty waking in the morning, bedtime resistance, nighttime fears, and daytime sleepiness. Although the literature commonly refers to "sleep problems" in anxious children, "sleep-related problems" may in fact be a more accurate term to describe the problems experienced in anxious populations due to the fact that most problems refer to difficulties surrounding the bedtime and sleep onset period versus disrupted sleep throughout the night. Specifically, bedtime resistance and nighttime fears have emerged as the most common problems in anxious children (Gregory & Eley, 2005; Hansen et al., 2011; Hansen et al., 2013). Bedtime resistance may include various types of emotional responses and behaviors such as avoidance of getting into bed, requests to delay bedtime (e.g., in order to get a drink of water, go to the bathroom, etc.), arguments with parents, or demands that a caregiver stay at the child's bedside. Nighttime fears can include a broad range of fearful themes including separation from caregivers (resulting in co-sleeping), fear of the dark or imaginary creatures, strange noises, and/or intruders/burglars. These high rates of persistent sleep-related problems in anxious children, in addition to the apparent overlap between daytime anxiety and bedtime anxiety, suggests the need to intervene in both domains (i.e., anxiety and sleep-related problems) to improve overall functioning.

Objective Sleep Problems

Interestingly, although children and parents report higher rates of sleep problems in anxious children compared to non-anxious populations (Alfano et al., 2006), objective data (i.e., actigraphy, polysomnography) indicate minimal differences in the actual sleep of anxious versus non-anxious children (Alfano, Patriquin, & De Los Reyes, 2015; Alfano, Reynolds, Scott, Dahl, & Mellman, 2013; Forbes et al., 2008; Forbes et al., 2006; Patriquin, Mellman, Glaze, & Alfano, 2014). Although some studies have reported differences in sleep

architecture (i.e., less slow-wave sleep and reduced latency to rapid eye movement (REM) sleep) in anxious children compared to controls (Alfano et al., 2013; Forbes et al., 2008; Patriquin et al., 2014), studies have generally failed to find differences in total sleep time, number or duration of nighttime wakings, bedtimes, or morning wake-up times based on either polysomnography (PSG) or actigraphy (Alfano et al., 2015; Forbes et al., 2006; Patriquin et al., 2014). Anxious children do show significantly longer sleep onset latency (i.e., longer time to fall asleep) compared to healthy children (Alfano et al., 2015; Alfano et al., 2013; Cousins et al., 2011; Forbes et al., 2008; Patriquin et al., 2014), though these differences are based on discrepancies of only 5 to 7 minutes on average.

Despite minor differences in objective sleep parameters compared to controls, anxious youth (and their parents) generally report sleep problems to be severe, suggesting that children's *perception* of their sleep as opposed to their actual sleep may be problematic. Among adults with insomnia (i.e., difficulty initiating/maintaining sleep or nonrestorative sleep), at least one half of patients misperceive sleep as wake and show elevated rumination and worry about sleep loss and its impact on daytime functioning (Harvey, 2002; Harvey & Tang, 2012). These cognitions theoretically trigger an anxious state (i.e., autonomic arousal and emotional distress) resulting in heightened levels of nighttime arousal. In other words, many adults with insomnia incorrectly believe that they obtain less sleep than they actually do. Ironically, these distorted beliefs/perceptions about sleep, in addition to an escalating cycle of excessive anxiety and rumination during the pre-sleep period, may ultimately result in actual sleep loss and impairments in daytime functioning over the long-term (Harvey, 2002; Harvey & Tang, 2012).

Anxious children have also been shown to spend more time in bed on weeknights compared to healthy controls, even though these groups do not differ in total sleep time

(Alfano et al., 2015). More time spent awake in bed (particularly on school nights) may contribute to perceptions of poor sleep. Indeed, evidence suggests that children with sleep problems engage in dysfunctional beliefs about sleep, which contribute to increased anxiety, and ultimately increased sleep problems over the long-term (Gregory, Cox, Crawford, Holland, & Haravey, 2009; Gregory, Noone, Eley, & Harvey, 2010; San Ng, Dodd, Gamble, & Hudson, 2013). No studies, however, have examined both subjective and objective indices of sleep when as part of anxiety treatment which could offer insight into relationships among objective sleep disruption, negative sleep perception, and anxiety symptoms.

Sleep in the Context of Anxiety Interventions

Despite sleep playing a key role in child anxiety disorders, only three studies have examined sleep in the context of anxiety interventions (Clementi, Alfano, Holly, & Pina, 2016; Donovan, Spence, & March, 2017; Peterman et al., 2016). Clementi et al. (2016) and Peterman et al. (2016) found that parent-reported bedtime resistance and sleep anxiety (i.e., nighttime fears) significantly improved following cognitive-behavioral therapy for child anxiety disorders. However, most sleep-related problems still remained near clinically significant levels post-treatment (Clementi et al., 2016; Peterman et al., 2016), suggesting that directly targeting sleep-related problems during anxiety interventions may need to occur to enhance outcomes. Additionally, both studies were limited by lack of a control group, absence of follow-up assessment, and a wide developmental range (ages 7-17) (Clementi et al., 2016; Peterman et al., 2016). The importance of examining more restrictive age ranges in this area of study is supported by the findings of Donovan et al. (2017) that children, but not adolescents, demonstrated a significant decrease in sleep-related problems following an online CBT program for anxiety. However, this study was limited by the use of a proxy measure for sleep-related problems (i.e., non-validated composite of sleep-related items from

the Child Behavior Checklist; Achenbach & Rescorla, 2001) (Donovan et al., 2017). This growing body of work suggests that anxiety interventions alone may improve some sleep-related problems in anxious children as a function of the increase in anxiety management skills (e.g., relaxation, modification of anxiety-based cognitions) and subsequent improvements in self-efficacy. Nonetheless, given the strong cyclical association between the two problems, targeting both issues may further augment treatment outcomes and warrants further examination.

Addressing sleep problems early during anxiety-based interventions may also facilitate fear extinction during subsequent exposures. Sleep has a well-established role in emotional memory and learning processes (Walker & van Der Helm, 2009) and several experimental studies demonstrate sleep to play a crucial role in fear extinction (i.e., the goal of exposures for anxiety) (Pace-Schott et al., 2009; Spoormaker et al., 2010; Spoormaker et al., 2012). Specifically, sleep deprivation is associated with impaired extinction learning, in addition to reduced generalization of extinction to novel stimuli (Pace-Schott et al., 2009; Spoormaker et al., 2010; Spoormaker et al., 2012). These findings suggest that poor sleep quality in the context of exposure therapy may hinder generalization of extinction learning to anxiety-provoking stimuli encountered in everyday life (Zalta et al., 2013). Indeed, two experimental studies have demonstrated that participants with spider phobia who slept following exposure sessions demonstrated better outcomes (i.e., increased approach behaviors and better extinction retention and generalization) compared to participants who stayed awake (Kleim et al., 2014; Pace-Schott, Verga, Bennett, & Spencer, 2012). Similarly, recent treatment studies have demonstrated that poor baseline sleep quality predicts poorer CBT treatment outcomes in adults, specifically slower treatment improvements and higher post-treatment anxiety symptoms and severity (Ramsawh, Bomyea, Stein, Cissell, & Lang,

2016; Zalta et al., 2013). Only one study has examined this question in youth and found that greater baseline sleep efficiency (based on parent report) predicted lower anxiety symptoms following anxiety treatment and also marginally predicted treatment responder status (Peterman et al., 2016). Therefore, addressing sleep problems prior to exposure may in fact increase an individual's ability to benefit from anxiety exposures, resulting in better anxiety treatment outcomes. Thus, even though minimal differences exist in objective sleep parameters between anxious and control children (Alfano et al., 2015; Forbes et al., 2006; Patriquin et al., 2014), it is notable that approximately one-third of "healthy" school-age children obtain less than the recommended 9-12 hours of sleep (Buxton et al., 2015; Paruthi et al., 2016).

Integrated Sleep and Anxiety Intervention

As stated above, anxiety interventions may alter anxious children's perception of poor sleep and improve coping skills and self-efficacy for managing both sleep and anxiety. Additionally, sleep interventions may improve sleep quality, which could maximize extinction-based learning during anxiety exposures. Therefore, children with anxiety disorders may benefit from an *integrated* sleep and anxiety intervention to improve overall outcomes in both domains. Targeted Behavioral Therapy (TBT) was developed to address sleep-related problems and anxiety symptoms in school-aged children with primary GAD (Alfano, 2010) due to high rates of sleep problems among this diagnostic group specifically (Alfano et al., 2006; 2007). TBT includes a prescriptive sleep intervention, in addition to weekly check-ins regarding sleep-related problems throughout the program. Preliminary data examining TBT in a small number of school-age children (n = 4) revealed reductions in child-reported anxiety and sleep-related problems at post-treatment and 3-month follow-up (Clementi & Alfano, 2014). None of the children met criteria for a GAD diagnosis at follow-

up, and most were functioning at normal levels and displayed clinically meaningful improvements in child-reported anxiety, worry, and sleep-related problems (Clementi & Alfano, 2014). However, examination of TBT in a randomized controlled treatment trial (RCT) is needed. We also note that the minimal improvement observed for some sleep-related variables (i.e., parent-reported problems and sleep onset latency) in the Clementi & Alfano (2014) study, together with the typical length of effective sleep interventions used in other studies (e.g., Moseley & Gradisar, 2009), suggest that the brief 2-session sleep intervention format used in the original TBT protocol may be inadequate for producing meaningful changes in the sleep of anxious children.

Summary & Specific Aims

In sum, less than optimal remission rates for child anxiety disorders calls for the further development, examination, and refinement of childhood anxiety treatment programs. Specifically, examination of sleep-related problems in the context of anxiety interventions warrants further attention due to high rates of subjective sleep problems, particularly among youth with GAD (Alfano et al., 2006; 2007; 2010). Previous studies suggest that parent-reported sleep-related problems may be improved by targeting anxiety alone (Clementi et al., 2016; Donovan et al., 2017; Peterman et al., 2016), yet these studies were limited in terms of participant characteristics, study design, and measurement of outcomes. Further, incorporating a sleep intervention into anxiety treatment may improve various sleep parameters over time, in turn facilitating generalization of extinction-based learning during treatment to other settings. Thus, targeting both sleep-related problems and anxiety symptoms in treatment may be important for increasing anxiety disorder remission rates and producing durable long-term outcomes.

Preliminary evidence provides support for TBT, an integrated sleep and anxiety intervention program for children with GAD (Clementi & Alfano, 2014), and highlights the need for future efficacy trials. The current study therefore included a randomized controlled trial (RCT) of TBT compared to a well-established CBT program for childhood anxiety ("Coping Cat"; Kendall, 2000). We chose to compare TBT to the Coping Cat program (referred to heretofore as "CBT") rather than a waitlist or non-active control condition for several reasons. Kendall's Coping Cat program (Kendall, 1994; Kendall et al., 1997) is the most empirically-supported and disseminated treatment for children with anxiety disorders to date (Albano & Kendall, 2002; Velting, Setzer, & Albano, 2004) with demonstrated efficacy in several RCTs (Kendall, 1994; Kendall et al., 1997; Kendall, Safford, Flannery-Schroeder, & Webb, 2004; Kendall & Southam-Gerow, 1996). The program has accordingly achieved the rare distinction of "probably efficacious" (Davis, May, & Whiting, 2011; Ollendick & King, 1998).

The current study also extended the number of sleep intervention sessions implemented in an initial study of TBT and examined changes in numerous aspects of sleep (parent-report, child-report, objective measures) and anxiety at post-treatment and 6-month follow-up.

The first aim of the study was to examine whether parent, child, and clinician reports of anxiety, sleep, and global functioning differed between the TBT and CBT at post-treatment and 6-month follow-up. Based on previous findings (Clementi et al., 2016; Donovan et al., 2017; Peterman et al., 2016) and the fact that CBT is an efficacious treatment for childhood anxiety, we hypothesized that both treatments would produce equivalent reductions in anxiety and parent-reported bedtime resistance and sleep anxiety, in addition to increases in global functioning at post treatment (Hypothesis 1a). We also hypothesized that

at post-treatment, TBT would produce superior outcomes compared to CBT in overall child-reported sleep-related problems based on the treatment's explicit focus on sleep (Hypothesis 1b). We further hypothesized that at 6-month follow-up, TBT would produce superior outcomes in all variables (i.e., stronger maintenance of anxiety, global functioning, and parent- and child-reported sleep improvements) compared to CBT (Hypothesis 1c).

The second aim of the study was to examine and compare objective sleep patterns among children treated with TBT and CBT at post-treatment and 6-month follow-up. We hypothesized that at both time points, TBT would produce superior outcomes in reducing sleep onset latency compared CBT (Hypothesis 2).

Finally, the third aim of the study was directed at better understanding the value and timing of adding an explicit sleep intervention to anxiety treatment. We examined symptom trajectories and patterns of change during treatment, expecting that TBT would produce superior outcomes in reducing anxiety symptoms from mid-treatment to post-treatment (i.e., after the sleep intervention) compared to CBT (Hypothesis 3a). We also hypothesized that in the TBT group (only), a linear decrease in weekly bedtime problems (i.e., bedtime resistance, parental involvement at bedtime) would be observed across treatment (Hypothesis 3b).

Method

Participants

The current study compared the efficacy of TBT to a well-established CBT intervention (Coping Cat) for childhood anxiety among a sample of 20 children, ages 6-12 ($M = 9.00$, $SD = 1.97$), with a primary diagnosis of GAD. Children were recruited through advertising in local family magazines, flyers in the community, and mailings to local school counselors and nurses. Inclusion criteria were: (a) primary diagnosis of GAD based on the Anxiety Disorders Interview Schedule for DSM-IV for Children/Parents (ADIS-CP;

Silverman & Albano, 1996); (b) between the ages of 6 and 12 years old—the minimum age was set to ensure children have the cognitive skills to worry (Szabó & Lovibond, 2004) and could complete self-report questionnaires; the maximum age was set to minimize hormonal effects of puberty on sleep and anxiety (McMakin & Alfano, 2015); (c) enrollment in regular education classes (i.e., to rule out IQ < 70); and (d) English as the primary language. Exclusion criteria included: (a) diagnosis of a psychotic disorder, pervasive developmental disorder, bipolar disorder, eating disorder, or substance abuse; (b) suicidal ideation/self-harm; (c) current use of treatment services for anxiety or sleep problems, including behavioral or pharmacological interventions; (d) use of any medications known to impact sleep (e.g., stimulants).

See Table 1 for demographic data of the treatment completers. As stated in the inclusion criteria, all participants met criteria for a primary GAD diagnosis. Fifty-seven percent of participants (n = 12) also met criteria for a comorbid diagnosis (TBT n = 5; CBT n = 7). There were no significant differences in frequency of comorbidity between groups. Multiple participants met diagnostic criteria for more than one comorbid diagnosis. Comorbid diagnoses in the TBT group included social phobia (n = 3), separation anxiety disorder (n = 3), specific phobia (n = 2), panic disorder (n = 1), oppositional defiant disorder (n = 1), and enuresis (n = 1). Comorbid diagnoses in the CBT group included social phobia (n = 6), separation anxiety disorder (n = 1), specific phobia (n = 1), and attention-deficit hyperactivity disorder (n = 1).

Procedures

Interested families were screened via phone interviews for inclusion/exclusion criteria. Following phone screening, families attended an in-person baseline evaluation in which informed consent and assent were obtained from parents and children, respectively, in

accordance with the University of Houston Institutional Review Board. The baseline evaluation included semi-structured diagnostic interviews, clinician ratings, and parent- and child-reported questionnaires. Eligible children were instructed to wear an actigraph (i.e., objective measure of sleep) for one week before starting treatment. Children were then randomized to TBT or CBT and underwent 16 one-hour weekly treatment sessions. A weekly measure of sleep-related problems was collected at the start of each session and mid-treatment sleep and anxiety questionnaires were administered following the fifth session (i.e., the final sleep-focused session in TBT). Upon treatment completion, families completed the diagnostic interviews and questionnaires during a post-treatment evaluation, followed by one week of actigraphy. The same procedures were completed 6 months later at follow-up. Across both groups, only one child received outside psychotherapy services between the post-treatment and follow-up evaluations (TBT $n = 1$; CBT $n = 0$), and no children began taking psychiatric medications during this time. See Figure 1 for a participant flow chart indicating treatment completers and non-completers. No significant differences were found in terms of rates of non-completers across treatment conditions ($p > .26$). Treatment duration (i.e., number of weeks required to complete all 16 sessions) did not significantly differ between groups ($p > .76$).

Trained doctoral graduate students and post-doctoral fellows conducted all diagnostic interviews and treatment sessions under the supervision of a licensed clinical psychologist. Interviewers were blind to the child's treatment condition at post-treatment and follow-up. Interviews and treatment sessions were videotaped for families that provided consent to be taped. A random sample of 10% of the treatment sessions was used to determine treatment adherence by coding whether the primary goals of each manualized session were addressed and to confirm that the CBT sessions did not address sleep. Of the sampled recordings, 100%

of the TBT session requirements were met and 94% of the CBT session requirements were met. None of the CBT sessions addressed sleep.

Measures

Diagnostic status. The Anxiety Disorders Interview Schedule for DSM-IV—Child/Parent Version (Silverman & Albano, 1996) is a reliable semi-structured interview for youth ages 7-17 (Kendall, Hudson, Gosch, Flannery-Schroeder, & Suveg, 2008). Children and parents are interviewed separately and final diagnoses are based on information from both child and parent interviews. The ADIS-C/P also generates reliable clinician severity ratings (CSR; *r*s .80 –.84) (Silverman, Saavedra, & Pina, 2001) used to identify primary versus secondary disorders. Psychometric properties of the ADIS-C/P include outstanding inter-rater reliability, test–retest reliability, and concurrent validity (Lyneham, Abbott, & Rapee, 2007; Silverman et al., 2001). Excellent interrater reliability was found for the presence or absence of GAD with kappa = 1.0 (based a random sample of 20% of the interviews). Acceptable interrater reliability was also found for primary diagnoses (kappa = .81).

Treatment response. The Clinical Global Impressions Scale (CGI; Guy, 1976) is a clinician-report scale that rates the child's severity of illness and improvement relative to baseline on a 7-point scale. Lower improvement ratings indicate greater improvement (e.g., 1 = very much improved, 2 = much improved). The CGI has been widely used in clinical research, including clinical trials of child anxiety treatments (Piacentini et al., 2014).

Global functioning. The Children's Global Assessment Scale (CGAS; Shaffer et al., 1983) is a unidimensional (global) measure of social and psychiatric functioning for children ages 4–16 years. The clinician-based rating scale ranges from 1 (lowest) to 100 (highest functioning). Scores above 70 are considered to be in the normal range (Shaffer et al., 1983).

Strong inter-rater and test retest reliability, and concurrent and construct validity have been reported (Bird, Canino, Rubio-Stipec, & Ribera, 1987; Bird et al., 1990; Green, Shirk, Hanze, & Wanstrath, 1994).

Anxiety symptoms. The Screen for Child Anxiety-Related Emotional Disorders-Child and Parent Versions (SCARED-C/P; Birmaher et al., 1999; Birmaher et al., 1997) is a 42-item measure of total and different types of anxiety symptoms (i.e., generalized anxiety, separation anxiety, social phobia, panic, and school phobia). Both parent and child-report versions of the measure were administered. The SCARED-C/P has demonstrated good internal consistency, test-retest reliability, and discriminative validity (within anxiety disorders and between anxiety and other disorders) (Birmaher et al., 1997). Reliability in the current sample was excellent (Cronbach's $\alpha = .91$ for child report and $\alpha = .84$ for parent report).

Sleep-related problems. The Children's Sleep Habits Questionnaire (CSHQ; Owens, Spirito, & McGuinn, 2000b) is parent-report questionnaire commonly used to examine sleep behavior in children, including the following sleep-related parameters: bedtime resistance, sleep duration, parasomnias, sleep-disordered breathing, night wakings, daytime sleepiness, sleep anxiety, and sleep onset delay. Items are rated on a 3-point scale corresponding to the frequency of the sleep behavior and parents are asked to recall sleep behaviors occurring during a typical recent week. The CSHQ has been shown to have acceptable internal consistency and reliability in clinic and community samples of children (Owens et al., 2000b). Reliability in the current sample was good (Cronbach's $\alpha = .81$).

The Sleep Self-Report (SSR; Owens, Maxim, Nobile, McGuinn, & Msall, 2000a) is a child-report questionnaire that assesses the same sleep-related domains as the CSHQ. It

yields a total sleep problems score and has shown good internal consistency and reliability (Owens et al., 2000a). Reliability in the current sample was good (Cronbach's $\alpha = .79$).

Actigraphy. An actigraph is a small watch-sized device that is worn on the non-dominant hand 24 hours a day that collects and stores movement data. Each unit was programmed in the laboratory prior to use and worn by the child at night. The unit collected continuous movement data in 1-minute epochs (activity level is sampled at 10-second intervals and summed across 1 minute intervals). The participant provided daily event markers indicating sleep onset and offset by pressing a button when the time-in-bed period begins (i.e., when turn off light to try to fall asleep). Following use, data from the unit were downloaded and scored by a computer-generated algorithm (Sadeh algorithm) that has been shown to be reliable in identifying sleep and wake periods (Sadeh, 2012) and is the most commonly used scoring algorithm in pediatric sleep research (Meltzer, Montgomery-Downs, Insana, & Walsh, 2012). Actigraphy has been validated against polysomnography (PSG) in pediatric samples with high agreement rates in terms of sensitivity to detect sleep periods (Meltzer et al., 2012). Sleep onset latency was the primary actigraphy variable obtained for the current study and was averaged across 4-7 nights of data.

Weekly questions. Sleep-related questions regarding bedtime resistance and parental involvement at bedtime in the past week were administered at the beginning of each treatment session to parents and children. Each question was rated on a scale of 0 (none) to 3 (a lot) to create a sleep problems composite score.

Intervention Content

Targeted Behavioral Therapy (TBT) consisted of 16 weekly 1-hour sessions including a prescriptive sleep intervention and graduated exposures as outlined in the TBT treatment manual (Alfano, 2010). A description of each TBT session is detailed below. The Coping Cat

intervention program was used as the active control condition (CBT) as outlined in the therapist manual (Kendall & Hedtke, 2006a). The *Coping Cat Workbook* (Kendall & Hedtke, 2006b) was also used to encourage child interest and engagement in treatment. Coping Cat has been shown to be an effective intervention program for child anxiety disorders in numerous RCTs (Kendall, 1994; Kendall et al., 1997).

TBT session 1: psychoeducation and treatment rationale. The first session introduced the anxiety treatment model by outlining the relationship between thoughts, feelings, and behaviors. The concepts of avoidance and intolerance of uncertainty ("Fear of the Unknown") were described using personal examples from the child. Sleep was also introduced as a tool to reduce anxiety. Finally, a worry hierarchy was generated with input from the child, parent, and therapist. The therapist described the rationale for exposures and explained that the child would not know beforehand what exposure they would do in order to help the child face the "fear of the unknown". Assigned homework included having the parent and child record situations/events in which the child experienced anxiety in the upcoming week and rating the anxiety severity of these situations/events.

TBT session 2: sleep education and assessment. The second session involved a discussion about the importance of sleep and sleep hygiene. "Sleep Thieves" were introduced as negative activities that disrupt or "steal" sleep from the child. The following "Sleep Thieves" were discussed: caffeine, inconsistent bed and wake times, exposure to bright light at night, energizing activities before bed, sleeping in different beds/places, daytime napping, needing someone else present to fall asleep, and nighttime thoughts and worries. Assigned homework included having the parent and child record the "Sleep Thieves" present over the week, and completing a one-week sleep log.

TBT session 3: develop sleep intervention plan. The third session began with a review of the sleep log and the "Sleep Thieves" noted over the past week. The child was then instructed to draw a picture of his/her bedroom to provide the therapist with information regarding how the sleep environment may be altered. Using the information from the homework and the drawing, a prescriptive sleep intervention was planned. The intervention may have included any of the following approaches, based specifically on the unique sleep problems experienced by the child: *sleep hygiene* (to promote health sleep habits by making changes to the sleep environment and establishing new rules surrounding bedtime); *stimulus control* (to strengthen the association between the bed and sleep by implementing rules such as using the bed for sleep only); *graduated extinction* (to gradually reduce parental involvement at bedtime by implementing a "gradual check" method); and *bedtime passes* (to reduce bedtime refusal and attempts to co-sleep by providing the child with a limited number of passes to get out of bed after lights out). Intervention approaches were used in conjunction with one another when appropriate, but not all approaches needed to be implemented. However, all intervention approaches included positive reinforcements to increase the child's motivation. Assigned homework included implementing the new sleep plan and completing a sleep log, including information about problems implementing the plan.

TBT sessions 4-5: sleep plan implementation. The fourth and fifth sessions began with a review of the sleep log and discussion with the parent and child to assess the family's success in implementing the sleep plan. The therapist conducted a functional analysis of the problem to help identify how the plan might need to be modified, and engaged the parent and child in problem-solving discussions. The therapist could choose to implement a different sleep intervention approach when necessary depending on the problems unique to the family.

Assigned homework included implementing the revised sleep plan and completing a sleep log, including information about problems implementing the plan.

TBT sessions 6-15: systematic desensitization and graduated exposures. The following ten sessions all began with a review of the effectiveness of the child's sleep plan, followed by appropriate modifications to the plan. Next, deep breathing and muscle relaxation exercises were taught and practiced. The child was then told that they would engage in an exposure task and they were asked to focus on the upcoming unknown task while implementing relaxation skills until their anxiety related to the unknown decreased (i.e., implemented systematic desensitization in which relaxation was paired with uncertainty). The child then completed the exposure task until he/she habituated to the task. Difficulty level of exposure tasks increased across sessions (i.e., graduated exposures).

TBT session 16: review and relapse prevention. The final session included a review of the anxiety model, relaxation and breathing skills, and the importance of sleep. The therapist prepared the family for the possibility that anxiety and sleep problems may return. The family was reminded that all skills learned in treatment should be continuously practiced in order to prevent future relapse. This session was audio recorded and the child was given a copy to help them remember what they learned in treatment.

TBT parental involvement. The parent and child were both active participants in the first five sessions (psychoeducation and sleep intervention) and the final session (review and relapse prevention). All other sessions involved the child only, with the exception of a brief check-in with the parent at the beginning of the session to review sleep-related issues, and at the end of session to communicate homework assignments.

Coping Cat Program (Active Control Condition). The Coping Cat program is an evidence-based child anxiety treatment program developed at the Child and Adolescent

Anxiety Disorders Clinic at Temple University (Kendall & Hedtke, 2006a). Several RCTs provide support for the efficacy of this program (Kendall, 1994; Kendall et al., 1997; Kendall et al., 2008). The Coping Cat program included two sections: psychoeducation and cognitive strategies (sessions 1-8) and exposure to anxiety-provoking situations (sessions 9-16). The first section, psychoeducation and cognitive strategies, focused on anxiety management strategies, such as identifying physiological reactions to anxiety, engaging in relaxation, recognizing anxious thoughts, identifying coping thoughts, and problem-solving. The second section, exposure to anxiety-provoking situations, utilized modeling and graduated exposure tasks. (Kendall & Hedtke, 2006a; Podell, Mychailyszyn, Edmunds, Puleo, & Kendall, 2010).

Data Analytic Plan

Power Analysis. To detect treatment effects (i.e., within-subject main effects), we anticipated large effect sizes based on previous child anxiety treatment research (e.g., Hudson et al., 2009b). With a Type I error of .05, a total sample of at least 8 participants would yield excellent power (95%) to detect within-subject main effects. To detect time x treatment group interaction effects, we anticipated a small-to-medium effect size (e.g., d = 0.39; Reynolds, Wilson, Austin, & Hooper, 2012) based on a recent meta-analysis examining CBT for child anxiety versus an active control condition (i.e., supportive counseling, psychoeducation) (Reynolds et al., 2012). With a Type I error of .05, a total sample of 38 participants was needed to yield acceptable power (80%) to detect a time x group interaction effect. Because the current pilot study (n = 20) was underpowered to detect interaction effects, reported outcomes focus on effect sizes and confidence intervals.

Intent-to-Treat Analyses. RCTs often suffer from issues related to protocol noncompliance and missing outcomes (e.g., due to dropout). Removal of participants that withdrew from treatment or were noncompliant with the protocol from study analyses can

result in an overoptimistic estimate of the efficacy of an intervention (Gupta, 2011). This issue can be addressed with the statistical concept of intent-to-treat (ITT), an approach that provides an unbiased estimate of intervention effects using the last observation carried forward (LOCF) method in which the last available data point prior to withdrawal is retained in the analyses (Streiner & Geddes, 2001). The ITT approach reflects a practical clinical scenario because it includes all randomized participants regardless of adherence or subsequent withdrawal.

However, the ITT approach has also been criticized because end-point data will differ among noncompliant, dropout, and compliant participants. Further, including participants who did not receive treatment (e.g., dropped out after one session) in overall analyses provides little information about treatment efficacy (Gupta, 2011). ITT analysis has also been criticized for being susceptible to type II error due to an overly cautious approach. Because of these criticisms and the fact that the current study represented a pilot investigation of TBT, we analyzed and reported findings based on the subset of participants with complete data. However, additional ITT analyses using all randomized participants were also examined and reported in the results section below.

Analysis of Treatment Response & GAD Remission. Based on previous CBT treatment studies for child anxiety (e.g., Walkup et al., 2008), treatment response was determined based on the percentage of children rated as 1 (very much improved) or 2 (much improved) on the Clinical Global Impression—Improvement scale. Fisher's exact tests were used to compare treatment response rates between groups. Remission of GAD was indicated by the absence of the diagnosis at post-treatment or follow-up. Fisher's exact tests were used to compare the percentage of participants in remission between groups.

Analyses of Specific Aims. To examine Aim 1, equivalence testing and repeated-measures analysis of variance (ANOVA) were used. To examine whether the TBT and CBT groups produced equivalent reductions in anxiety and parent-reported bedtime resistance and sleep anxiety, and increases in global functioning (Hypothesis 1a), a confidence interval (CI) approach to equivalence testing was used. Because non-significance in traditional hypothesis testing does not allow for the conclusion that the groups are equivalent, equivalence testing must be used to determine whether two interventions are equivalent in producing an outcome. Two-sided 95% confidence intervals for the mean change from baseline were used to compare the TBT and CBT groups to assess for equivalence in sleep and anxiety outcomes. The lower confidence limit (LCL) estimated the maximum amount by which TBT was inferior to the CBT, and the upper confidence limit (UCL) estimated the maximum about by which TBT was superior to CBT. If the mean change from baseline for the TBT group was less than one LCL unit below or one UCL above the mean change from baseline for the CBT group, the outcomes were deemed to be equivalent.

To examine if the TBT group produced superior outcomes compared to the CBT group in reducing child-reported sleep-related problems at post-treatment (Hypothesis 1b) and if TBT produced superior outcomes compared to CBT regarding anxiety, sleep-related problems, and global functioning at follow-up (Hypothesis 1c), a 2x3 ANOVA design was carried out. The independent variables were group (TBT versus CBT) and time (baseline, post-treatment, follow-up) and the dependent variables were global functioning (CGAS), anxiety (SCARED-C, SCARED-P), parent-reported sleep-related problems (CSHQ total score, bedtime resistance subscale, sleep anxiety subscale), and child-reported sleep-related problems (SSR). We predicted that there would be an interaction effect for group x time such that the TBT group would demonstrate greater reductions in child-reported sleep-related

problems from baseline to post-treatment in comparison to CBT. We also predicted that there would be an interaction effect for group x time such that the TBT group would demonstrate greater reductions in anxiety and sleep-related problems (parent and child report), and greater improvements in global functioning from baseline to follow-up compared to CBT. Effect sizes and confidence intervals were calculated for all treatment outcomes due to the preliminary nature of this study.

To examine Aim 2, a 2x3 repeated-measures ANOVA was used to examine whether TBT produced superior outcomes in sleep onset latency compared to CBT at post-treatment and 6-month follow-up (Hypothesis 2). The independent variables were group (TBT versus CBT) and time (baseline, post-treatment, follow-up) and the dependent variable was sleep onset latency (based on actigraphy). We predicted that there would be an interaction effect for group x time such that the TBT group would experience greater improvements in sleep onset latency from baseline to post-treatment and baseline to follow-up compared to the CBT group.

To examine Aim 3, patterns of symptom change and treatment outcome were examined with a repeated-measures ANOVA and Simulation Modeling Analysis (SMA; Borckardt et al., 2008). To examine whether targeting sleep-related problems early in treatment improved subsequent response to anxiety exposure sessions (Hypothesis 3a), a 2x3 repeated measures ANOVA was carried out in which the independent variables were group (TBT versus CBT) and time (baseline, mid-treatment, post-treatment) and the dependent variables were parent and child-reported anxiety (SCARED-C, SCARED-P). We predicted that there would be an interaction effect for group x time such that TBT would produce superior outcomes in anxiety from mid-treatment to post-treatment compared to the CBT group (Hypothesis 3a).

To test whether a meaningful reduction and linear change in weekly bedtime problems (i.e., bedtime resistance and parental involvement at bedtime) occurred from the sleep intervention phase to the anxiety treatment phase in the TBT group (Hypothesis 3b), Simulation Modeling Analysis (SMA; Borckardt et al., 2008) was used. SMA is a program designed to analyze short streams ($n < 30$) of autocorrelated time-series data. Conventional statistics assume that observations are independent, which is not the case in time-series data; time-series data is autocorrelated or series dependent. SMA accounts for autocorrelation, which reduces the risk of Type I error, and uses simulation methods (i.e., randomly generated data streams that are similar to the original data stream in terms of number of data points and degree of autocorrelation) (Borckardt et al., 2008). SMA can also be used to examine slope change via Pearson's correlation across multiple data points. Slope Vector 4 from SMA was selected to examine whether a significant linear change occurred in the slope of weekly data points across both phases of the intervention—in other words, cumulative change from the sleep intervention phase (Sessions 1-5) through the anxiety exposure phase (Sessions 6-16). We predicted that there would be a significant linear reduction in bedtime problems (i.e., bedtime resistance and parental involvement at bedtime) across the 16 treatment sessions for TBT, but not for CBT.

Results

Preliminary Analyses

Frequency distributions for all variables were examined to detect potential outliers and deviations from normality. All outcome variables were determined to be distributed normally according to the Kolmogorov-Smirnov statistic. Comparison of the mean and 5% trimmed mean indicated that no outliers had a strong influence on the mean and therefore were not deleted. Independent and chi-square comparisons revealed no significant

differences on any demographic or outcome variables between treatment completers and noncompleters. Among treatment completers only, independent t-tests and chi-square comparisons indicated no significant group differences on any demographic or outcome variables. See Table 1 for group comparisons on demographic and diagnostic variables.

Treatment Response & GAD Remission

At post-treatment, 81% (n = 9) of participants in the TBT group and 70% (n = 7) of participants in the CBT group were considered treatment responders. The same number of participants were considered treatment responders at 6-month follow-up (TBT n = 9, CBT n = 7), indicating that both groups maintained gains over time. Fisher's exact tests indicated that response to treatment was not associated with treatment group at post-treatment, p = .64, or at follow-up, p = .46.

Additionally, at post-treatment, 54% (n = 6) of participants in the TBT group and 70% (n = 7) of participants in the CBT group met criteria for remission (i.e., no longer met criteria for GAD as their primary diagnosis). At 6-month follow-up, 70% (n = 7) of participants in the TBT group and 78% (n = 7) of participants in the CBT group were in remission. Fisher's exact tests revealed that remission status was not associated with group at post-treatment, p = .66, or at follow-up, p = .56. These response and remission rates were comparable to rates from previous child anxiety treatment studies (Kendall et al., 1997; Kendall & Southam-Gerow, 1996; Hirshfeld-Becker et al., 2010; Walkup et al., 2008).

Aim 1: To examine whether anxiety and subjective sleep outcomes differed between TBT and CBT at post-treatment and 6-month follow-up.

Equivalence testing using a confidence interval approach was used to examine group outcomes at post-treatment (Aim 1a). Two-sided 95% confidence intervals were obtained through independent t-tests comparing change from baseline on sleep and anxiety measures

between TBT and CBT. Results revealed that changes from baseline to post-treatment were equivalent across both treatment groups for all subjective measures (CGAS, SCARED-P, SCARED-C, CSHQ, SSR). For example, the mean change of parent-reported anxiety from baseline to post-treatment for the TBT group was estimated with 95% confidence to be no more than 11.71 units (LCL) inferior or 12.12 (UCL) units superior to the CBT group. See Table 2 for change scores and confidence intervals utilized for equivalence testing. Intent-to-treat analyses revealed the same findings as the completer analyses.

A series of 2 (treatment group: TBT, CBT) x 3 (time: baseline, post-treatment, follow-up) repeated measures ANOVAs were performed to examine treatment effects for all subjective measures (Aim 1b). Because Type I errors are likely given multiple statistical tests among a small sample size, a Bonferroni correction (Holm, 1979) was used. The critical value for each ANOVA was set at $p = .007$ based on seven a priori hypotheses (.05/7). See Table 3 for means and standard deviations of all treatment outcome measures at baseline, post-treatment, and follow-up. Effect sizes for *F*-tests are reported as partial eta squared (see below). Effect sizes for follow-up t-tests are reported as Cohen's *d* (see Table 4).

Results indicated that for all subjective outcome variables, there were no significant between-group effects ($ps > .60$) or interactions between treatment group and time ($ps > .26$). However, results revealed a significant effect of time for the following subjective measures: clinician-rated functioning (CGAS), $F(2, 15) = 25.88$, $p < .001$, partial eta squared = .78; parent-reported anxiety (SCARED-P), $F(2, 15) = 14.86$, $p = < .001$, partial eta squared = .67; parent-reported sleep problems (CSHQ total), $F(2, 15) = 15.63$, $p < .001$, partial eta squared = .68; parent-reported bedtime resistance (CSHQ Bedtime Resistance subscale), $F(2, 15) = 11.74$, $p = .001$, partial eta squared = .61; parent-reported sleep anxiety (CSHQ Sleep Anxiety subscale), $F(2, 15) = 11.33$, $p = .001$, partial eta squared = .60; and child-reported

sleep problems (SSR), $F(2, 16) = 6.05$, $p = .01$, partial eta squared = .43. Considering the adjusted alpha, the main effect of time was not significant for child-reported anxiety (SCARED-C), $F(2, 15) = 4.51$, $p = .03$, partial eta squared = .38. ITT analyses revealed equivalent findings to the completer analyses for all variables with the exception of child-reported anxiety; for this variable, ITT analyses revealed a significant main effect of time, $F(2, 27) = 5.38$, $p = .01$, partial eta squared = .29, with a significant reduction in both groups from baseline ($M = 35.83$, $SD = 13.41$) to post-treatment ($M = 27.00$, $SD = 14.38$), $t(29) = 3.49$, $p < .01$ and from baseline to follow-up ($M = 27.80$, $SD = 14.92$), $t(29) = 3.02$, $p < .01$.

Significant main effects were followed-up with dependent t-tests with a Bonferroni correction to examine whether significant changes occurred for both treatment groups. See Table 4 for effect sizes (Cohen's *d*) and confidence intervals for all outcome variables. Results indicated significant improvement in clinician-rated functioning from baseline ($M = 55.05$, $SD = 5.32$) to post-treatment ($M = 69.19$, $SD = 7.03$), $t(20) = -7.62$, $p < .001$ and from baseline to follow-up ($M = 70.39$, $SD = 8.47$), $t(17) = -6.91$, $p < 001$. Regarding anxiety outcomes, there was a significant reduction in parent-reported anxiety from baseline ($M = 34.00$, $SD = 11.71$) to post-treatment ($M = 20.20$, $SD = 11.28$), $t(19) = 5.00$, $p < .001$ and from baseline to follow-up ($M = 17.78$, $SD = 12.85$), $t(18) = 6.13$, $p < .001$.

Regarding sleep outcomes, results revealed a significant reduction in total parent-reported sleep problems from baseline ($M = 57.10$, $SD = 9.28$) to post-treatment ($M = 44.3$, $SD = 7.06$), $t(19) = 6.18$, $p < .001$ and from baseline to follow-up ($M = 43.61$, $SD = 8.35$), $t(18) = 6.27$, $p < .001$. For parent-reported bedtime resistance, there was a significant reduction from baseline ($M = 11.00$, $SD = 3.21$) to post-treatment ($M = 7.30$, $SD = 1.89$), $t(19) = 5.31$, $p < .001$ and from baseline to follow-up ($M = 7.72$, $SD = 2.44$), $t(18) = 4.40$, $p < .001$. For parent-reported sleep anxiety, there was a significant reduction from baseline ($M =$

8.25, *SD* = 1.86) to post-treatment (*M* =5.70, *SD* = 2.03), $t(19) = 5.00$, $p < .001$ and from baseline to follow-up (*M* = 6.00, *SD* = 2.03), $t(18) = 5.14$, $p < .001$.

Results also revealed a significant reduction in child-reported sleep problems, from baseline (*M* = 43.38, *SD* = 8.00) to post-treatment (*M* = 38.48, *SD* = 5.45), $t(20) = 3.17$, $p < .01$ and from baseline to follow-up (*M* = 38.32, *SD* = 7.22), $t(18) = 3.39$, $p < .01$.

Aim 2: To examine whether objective sleep outcomes differed between TBT and CBT at post-treatment and 6-month follow-up.

Of the 20 treatment completers, 1 participant had no actigraphy data at baseline, 3 had no data at post-treatment, and 4 had no data at follow-up (due to discomfort and/or noncompliance with wearing the equipment or because the family moved out of the area). Of the participants with actigraphy data, 3 participants at baseline, 4 participants at post-treatment, and 3 participants at follow-up had unusable sleep onset latency data due to noncompliance with event marker instructions (i.e., did not press marker indicating start of bedtime period or clearly pressed the marker too early). Thus, a total of 11 participants (TBT *n* = 6, CBT *n* = 5) had usable sleep onset latency data at all three time points and 12 participants (TBT *n* = 7, CBT *n* = 5) had usable sleep onset latency data at the first two time points (baseline and post-treatment).

Chi-square analyses and independent t-tests revealed that participants with incomplete actigraphy data (i.e., did not have usable data at all three time points) were more likely to be male, $\chi^2 = 4.07$, $p = .04$, and from a family with a lower household income ($20-60,000/year), $\chi^2 = 7.79$, $p = .05$. Participants with incomplete actigraphy data also had marginally higher parent-reported anxiety at baseline (*M* = 39.70, *SD* = 11.81) compared to those with complete actigraphy data (*M* = 30.00, *SD* = 10.08), $t(19)=2.03$, $p = .06$.

Of participants included in the following analyses, treatment groups did not differ at any time point in terms of whether or not actigraphy data was collected during the summer/holiday break or the school year (*p*s > .55).

Due to the extent of missing sleep-onset latency data for all three time points, we utilized 2x2 ANOVAs in order to maximize sample sizes included in each analysis. The first 2 (treatment group: TBT, CBT) x 2 (time: baseline, post-treatment) repeated measures ANOVA examined treatment effects for sleep onset latency (as measured by actigraphy) from pre to post treatment. No significant interaction was observed between treatment group and time, $F(1, 10) = .40$, $p = .54$, partial eta squared = .04. However, results revealed a marginally significant main effect of time, $F(1, 10) = 4.10$, $p = .07$, partial eta squared = .29 indicating an overall decrease in sleep onset latency from baseline ($M = 22.97$, $SD = 14.79$) to post-treatment ($M = 17.06$, $SD = 7.19$). On average, sleep onset latency was reduced by 4.36 minutes in the TBT group and 8.09 minutes in the CBT group at post-treatment. A medium effect size (Cohen's $d = .51$) was detected for change in sleep onset latency from baseline to post-treatment.

The 2x2 repeated-measures ANOVA examining changes in sleep onset latency from post treatment to follow-up revealed no significant findings in terms of the interaction between treatment group and time, $F(1, 10) = 2.15$, $p = .17$, partial eta squared = .04, or the main effect of time, $F(1, 10) = .41$, $p = .54$, partial eta squared = .18. Intent to treat analyses were not conducted for actigraphy data as there was no mid-treatment actigraphy assessment, therefore rendering the last observation carried forward (LOCF) method less meaningful.

Aim 3: To examine symptom trajectories and patterns of change during treatment.

A series of 2 (treatment group: TBT, CBT) x 3 (time: baseline, mid-treatment, post-treatment) repeated measures ANOVAs were performed to examine change in parent- and

child-reported anxiety symptoms across the course of treatment (Aim 3a). No significant interaction was observed between treatment group and time for parent-reported anxiety, $F(2, 17) = .77$, $p = .48$, partial eta squared = .08. However, results revealed a significant main effect of time, $F(2, 17) = 15.08$, $p < .001$, partial eta squared = .64. Follow-up t-tests indicated a reduction in both treatment groups for parent-reported anxiety from baseline ($M = 34.62$, $SD = 11.76$) to post-treatment ($M = 20.20$, $SD = 11.28$), $t(19) = 5.00$, $p < .001$ and from mid-treatment ($M = 34.60$, $SD = 11.76$) to post-treatment, $t(19) = 5.45$, $p < .001$. Large effect sizes were detected for baseline to post-treatment parent-reported anxiety ($d = 1.25$) and mid-treatment to post-treatment parent-reported anxiety ($d = 1.25$). The between group main effect was not significant, $F(1, 18) = .03$, $p = .87$, partial eta squared = .01, suggesting no difference in the effectiveness of the two treatments on parent-reported anxiety.

In the second 2x3 ANOVA, results indicated a marginally significant interaction between treatment group and time for child-reported anxiety, $F(2, 17) = 3.39$, $p = .06$, partial eta squared = .29. Follow-up t-tests revealed that in the TBT group, child-reported anxiety significantly decreased from baseline SCARED-C ($M = 36.50$, $SD = 12.20$) to post-treatment ($M = 20.80$, $SD = 11.08$), $t(9) = 4.27$, $p < .01$ and from mid-treatment ($M = 31.80$, $SD = 12.28$) to post-treatment, $t(9) = 4.37$, $p < .01$. Large effect sizes were detected in the TBT group for baseline to post-treatment child-reported anxiety ($d = 1.35$) and mid-treatment to post-treatment child-reported anxiety ($d = .94$). In the CBT group, no significant changes were revealed in child-reported anxiety across baseline, mid-treatment, or post-treatment, all ps > .21. See Figure 2.

ITT analyses revealed equivalent findings to the completer analyses in terms of parent-reported anxiety, but not child-reported anxiety. For child-reported anxiety, ITT analyses revealed no significant interaction between treatment group and time for child-

reported anxiety, $F(2, 27) = 5.88$, $p = .20$, partial eta squared = .11. However, ITT results revealed a significant main effect of time, $F(2, 27) = 5.88$, $p < .01$, partial eta squared = .30. Follow-up ITT t-tests showed a reduction in child-reported anxiety in both treatment groups from baseline ($M = 35.83$, $SD = 13.41$) to post-treatment ($M = 27.00$, $SD = 14.37$), $t(29) = 3.49$, $p < .01$ and from mid-treatment ($M = 31.17$, $SD = 13.17$) to post-treatment, $t(29) = 2.86$, $p < .01$. For ITT analyses examining child-reported anxiety, small-to-medium effect sizes was detected for baseline to post-treatment ($d = .64$) and for mid-treatment to post-treatment ($d = .30$).

Finally, SMA was conducted using Version 11.10.16 for Windows to examine change in bedtime problems across each intervention session separately for both treatment groups (Aim 3b). SMA tests for slope change revealed a significant slope change indicating a linear decrease in bedtime problems straight through from the sleep intervention to the exposure phases for 5 (42%) TBT participants and a marginal slope change for 2 (17%) TBT participants. In the CBT group, a significant slope change indicating a linear decrease in bedtime problems (from the cognitive and somatic-focused phase to the exposure-focused phase) was observed for 2 (20%) participants and a marginal slope change for 1 (10%) participant. Fisher's exact test indicated that the treatment groups were not significantly different in terms of how many participants demonstrated a significant slope change, $p = .27$. See Table 5 for slope changes (Pearson's correlations) in bedtime problems across treatment.

Discussion

Despite the well-established prevalence of sleep problems among clinically-anxious youth, and those with GAD in particular, few studies have examined whether sleep-related improvements occur following CBT for anxiety or whether sleep may need to be targeted directly during treatment. The current study addressed this gap by comparing the efficacy of

a newly-developed, integrated sleep and anxiety intervention to a 'gold standard' CBT intervention for anxious youth. Rather than a waitlist or non-established active treatment, we chose to compare TBT to Coping Cat (Kendall, 1994) to examine the added utility of a sleep intervention over and above the effectiveness of established treatment for child anxiety disorders. Multi-informant, multi-method sleep and anxiety outcomes were examined in both groups at post-treatment and 6-month follow-up.

The first aim of the study was to examine whether parent, child, and clinician reports of anxiety, sleep, and global functioning differed between the TBT and CBT groups at post-treatment and 6-month follow-up. Based on previous studies demonstrating the efficacy of CBT for improving anxiety (Crowe & McKay, 2017) and parent-reported sleep problems (Clementi et al., 2016; Donovan et al., 2017; Peterman et al., 2016), we hypothesized that at post-treatment, the TBT and CBT groups would produce equivalent improvements in anxiety, parent-reported sleep problems, and global functioning. We also hypothesized that at post-treatment, TBT would produce superior outcomes compared to CBT in reducing child-reported sleep-related problems based on preliminary findings (Clementi & Alfano, 2014) and theorized increases in children's self-efficacy in improving their sleep. Results supported the former hypothesis, but not the latter. Equivalency testing revealed equivalent changes in all outcome variables, including child-reported sleep problems, between groups at post-treatment. Findings at 6-month follow-up indicated improvements in all outcome variables were maintained for both groups (i.e., no group differences were detected) with medium to very large effect sizes. This result was contrary to our hypothesis that TBT would produce superior outcomes in all outcome variables compared to CBT 6 months after treatment.

Similar outcomes across groups may be explained by the reciprocal nature of sleep and anxiety. First, regarding subjective sleep improvements, a decrease in subjective sleep-

related problems in both groups may represent a secondary result (i.e., epiphenomenon) of improvements in anxiety symptoms, including improved self-regulatory strategies and increased self-efficacy. In the context of anxiety, self-efficacy refers to the perceived ability to successfully manage anxiety-provoking situations, and consequently determines whether and to what extent regulatory/coping behavior are necessary (Bandura, 1977). Suveg and colleagues (2009) demonstrated that following CBT for anxiety, children exhibited increased anxiety self-efficacy, worry regulation, and emotion understanding (which can serve as a prerequisite for adaptively modifying/regulating one's emotional reactions). As such, improvements in anxiety self-efficacy may enhance children's "sleep self-efficacy", or perceived ability to self-soothe and cope with worry/fears at nighttime.

Additionally, CBT for childhood anxiety might impact sleep-related problems more directly vis-à-vis reductions in overall levels of arousal following treatment. That is, improvements in anxiety symptoms may extend beyond the daytime period to include reductions in nighttime-fears and bedtime arousal as well. Indeed, recent treatment studies have found a decrease in pre-sleep arousal following CBT for anxious children in the absence of strategies directly targeting this period (Clementi et al., 2016; Peterman et al., 2016). Along these lines, Blake and colleagues (2017) demonstrated anxiety reductions and improvements in sleep following a CBT and mindfulness intervention were specifically mediated by reductions in pre-sleep arousal.

Overall, our findings suggest that traditional CBT for childhood anxiety disorders produces improvements in parent and child-reported sleep-related problems even in the absence of direct intervention. We also found these improvements to be maintained six months later. However, examination over longer-term follow-up periods is warranted. Given that persistent sleep problems in childhood can be associated with anxiety disorders more

than a decade later (Gregory et al., 2005), it is possible that knowledge/skills regarding healthy sleep that are gained during an integrated intervention may translate to improvements at more distal follow-up periods. On the other hand, it should also be considered that certain GAD symptoms (e.g., perfectionism, rigidity) might mask subjective reports of sleep-related improvements among those receiving sleep treatment. That is, since individuals with GAD often place great value and importance on performance, and perceive others to hold them to similarly high standards (Frost et al., 1990), TBT's focus on sleep being a skill that can be improved may have led to critical self-evaluations of sleep during and after the sleep intervention.

It is also critical to note that sleep-based outcomes may depend on children's developmental level. While school-aged children often demonstrate behaviorally-based and anxiety-driven sleep-related problems (e.g., bedtime resistance, nighttime fears), sleep problems during adolescence are generally marked by delayed bedtimes and reduced sleep duration, driven by physiological, social, and environmental changes that occur during this developmental period (Colrain & Baker, 2011). Findings from Donavan et al. (2017) demonstrating that school-aged children, but not adolescents, experienced secondary sleep improvements following CBT for anxiety support the notion that improvements in anxiety may not translate to improvements in sleep problems in older youth.

In terms of anxiety symptoms, our hypothesis that post-treatment decreases in anxiety would be equivalent between treatment groups was supported. This hypothesis was based on the fact that both treatment conditions utilized a well-established anxiety treatment approach (i.e., exposure therapy). However, we also hypothesized that anxiety symptom improvement would be maintained to a greater degree in the TBT group at 6-months follow-up based on the presumed long-term benefits of healthy sleep on anxiety. Contrary to our expectations,

anxiety-related improvements did not differ by treatment condition at follow-up nor were differences in subjective sleep problems apparent. Across both treatment conditions, improvements in parent-reported anxiety symptoms were maintained at follow-up with medium to very large effect sizes. Despite some suggestion in the data that child-reported anxiety symptoms improved to a greater extent in the TBT group at post-treatment, this difference failed to reach statistical significance with correction for multiple tests ($p = .03$) and inclusion of drop-outs in the analyses. Thus, larger treatment outcomes trials may be better able to address this question.

As mentioned, longer follow-up periods (i.e., greater than 6 months) may also be needed to more definitively examine the question of whether anxiety reduction is enhanced over time when sleep is directly targeted. Rationale for longer-term follow-up stems from models of allostasis and allostatic load. Allostasis refers to the maintenance of stability/homeostasis during periods of stress and is mediated by a number of physiological functions, including metabolic, hormonal, immune, and neural responses (McEwen, 1998). When these systems are exposed to chronic or repeated periods of stress (e.g., due to sleep disturbance), allostatic load, or the cumulative wear and tear on the brain and body increases (McEwen, 1998). Allostatic load has been shown to impact the amygdala, a brain region involved in fear/anxiety (McEwen & Chattarji, 2004) and produces cumulative negative changes in various systems associated with mood and anxiety disorders (McEwen, 2003). McEwen (2006) specifically posit chronic sleep loss to contribute to allostatic load, which may in turn increase risk for anxiety disorders. Therefore, it is possible that follow-up at more distal time points may better reveal the impact of improvements in sleep on anxiety outcomes.

The second aim of the study was to examine and compare objective sleep across

treatment groups at post-treatment and 6-month follow-up. We hypothesized that at both time points, TBT would produce superior outcomes (i.e., decreased sleep onset latency) compared to CBT. Results revealed a marginally significant decrease in sleep onset latency for both groups from baseline to post-treatment, with an average decrease of approximately 6 minutes. This finding aligns with previous work indicating a 5-7 minute difference in sleep onset latency between untreated anxious children compared to healthy children (Alfano et al., 2015; Cousins et al., 2011). Interestingly, although sleep duration might be expected to increase as a function of decreased sleep onset latency, this was not the case for the TBT group as follow-up analysis indicated that in the TBT group only, sleep duration decreased by nearly 25 minutes from baseline to follow-up, $F[2,13] = 2.28$, $p = .05$.

Together, these sleep findings underscore the importance of viewing sleep broadly rather than according to separate independent indicators. Although sleep medicine as a field tends to focus on the ways separate sleep parameters differ between populations and contribute to sleep disorders, the concept of global "sleep health" needs to be considered (Buysee, 2014). *Sleep health* may be defined as a multidimensional concept existing on a continuum (i.e., rather than deficiency/sufficiency states), and composed of measures of sleep duration, sleep efficiency (ease of falling/staying asleep), timing of sleep within the 24-hour day, alertness/sleepiness, and subjective sleep quality (Buysee, 2014). Thus, it considers the aggregate role of multiple dimensions of sleep in determining one's sleep health. Although changes in sleep onset latency and sleep duration together were of specific interest in the current study, a broader framework of sleep health is surely needed.

With regard to the two sleep dimensions of interest in the current study (i.e., sleep onset latency and sleep duration), consistency across time may be as important to consider as average duration. Although regularity (versus variability) of sleep is not included in the

formal definition of sleep health for adult populations, this dimension is important for anxious populations because it is a key treatment target (Buysee, 2014) and has been linked to cognitive and behavioral outcomes in youth populations specifically (Biggs et al., 2011; Kelly, Kelly, & Sacker, 2013).

More variable day-to-day sleep patterns may be especially relevant for anxious children given its association with co-sleeping/bed-sharing (Palmer, Clementi, Meers & Alfano, under review). Co-sleeping is highly common among anxious school-age children, likely due to heightened fear/arousal surrounding sleep (Palmer, Clementi, Meers & Alfano, under review), and has been linked with more variable nightly sleep duration and problematic sleep patterns including delay in sleep timing (Palmer et al., under review). Given that 1 in 3 children with GAD have been found to co-sleep at least sometimes (Palmer et al., under review), similar rates may have been present in the current sample and have produced high intra-individual variability in sleep in this group. A recent study examining moderators of treatment outcome for anxious children demonstrated that CBT produced greater anxiety improvements in children with more variable sleep patterns (i.e., more day-to-day sleep problems related to sleep quality, efficiency, and waking) compared to supportive therapy (Wallace et al., 2017). Thus, this specific sleep dimension warrants consideration in future studies in order to enhance and personalize treatment.

The third and final aim of the present study was to examine symptom trajectories and patterns of change during treatment by separately examining changes in anxiety symptoms and changes in bedtime problems across the 16-week treatments. First, we hypothesized that TBT would produce superior outcomes in anxiety symptoms from mid-treatment (i.e., after the sleep intervention for TBT and after the cognitive and somatic sessions in CBT) to post-treatment compared to the CBT group. This hypothesis was rooted in extant research

demonstrating sleep to enhance memory consolidation and extinction learning (Pace-Schott et al., 2012). Accordingly, results indicated a significant decrease in anxiety during the second half of treatment for the TBT group only. Thus, addressing sleep-related problems prior to implementing exposures may have indeed maximized the potency of extinction learning in one of two ways. First, based on findings that chronically disrupted sleep results in greater amygdala activation to threatening stimuli (Motomura et al., 2013), improved sleep over the weeks preceding exposures may have contributed to reduced negative emotional reaction to anxiety-provoking stimuli in exposure tasks (and in turn potentially increased approach behaviors). Second, experimental studies have suggested that consolidation of extinction learning can be enhanced through increased sleep following exposures (Kleim et al., 2014; Pace-Schott et al., 2012). Addressing sleep problems early in treatment may have contributed to improved sleep during the exposure phase of treatment, though this was not directly measured in the current study. Future work should specifically examine nightly sleep *during* exposure therapy (rather than an average at post-treatment) following an initial sleep intervention to elucidate this hypothesis.

Although not a direct aim of the current study, another interesting finding regarding anxiety symptom change is the fact that despite the overwhelming support for CBT as an efficacious treatment for child anxiety (James et al., 2013), the absence of the cognitive and somatic component in the TBT condition (replaced with the sleep intervention) did not diminish anxiety-based improvements. This finding is in line with a burgeoning literature on the relative contribution of "anxiety management strategies" to CBT outcomes for child anxiety (Ale et al., 2015; Chu et al., 2015; Whiteside et al., 2015). Anxiety improvements in TBT were maintained at follow-up to the same degree as in CBT, and treatment response and remission rates (in terms of clinician-rated improvement and primary GAD diagnosis) were

similar to other studies examining CBT for child anxiety. Further, for child-reported anxiety, large effect sizes were detected for the TBT group, while small-to-moderate effect sizes were detected for the CBT group (from baseline to post-treatment and baseline to follow-up). These findings reinforce the salience of exposures in treating anxious school-aged children. Indeed, a recent meta-analysis demonstrated that the addition of anxiety management strategies (e.g., cognitive coping strategies) before introducing exposure tasks did not increase the efficacy of exposure-based treatment for childhood anxiety (Ale et al., 2015). In sum, exposures appear to be the driving force in anxiety symptom reduction following CBT.

The second part of our final aim focused on patterns of change across treatment in weekly sleep-related problems. Specifically, we hypothesized that in the TBT group only, there would be a linear decrease in weekly bedtime problems (i.e., bedtime resistance and parental involvement at bedtime) across treatment (rather than differing patterns across the sleep intervention phase and the anxiety exposure phase). Our hypothesis was supported through examination of patterns within individual participants. We found a linear decrease in weekly bedtime problems for nearly twice as many participants in TBT compared to those in CBT. A more observable pattern of change in bedtime problems may have been apparent due to "check-ins" regarding sleep at the beginning of all treatment sessions for the TBT group (even after the sleep intervention phase). Although the proportion of participants in each group showing significant linear reduction in bedtime problems was not statistically different, the sample size was notably underpowered. Findings nonetheless suggest a cumulative improvement in bedtime problems across treatment sessions for the TBT group, while the pattern of change for the CBT group was less linear. In sum, the current study demonstrated that although improvements in sleep-related problems were equivalent at post-treatment and follow-up for both groups, the manner and mechanisms in which these gains

were achieved differed.

The current study has a number of limitations. First, the sample size was inadequate to detect significant differences between treatment groups. Comparing two interventions with a highly efficacious shared treatment component (i.e., exposures for anxiety) requires a large sample to detect an added effect of a sleep intervention. Indeed, meta-analyses of CBT for child anxiety have indicated that CBT compared to non-active control conditions (e.g., waitlist control group) demonstrated moderate to large effect size, but only small-to-moderate effect sizes were observed in trials using active control conditions (e.g., supportive therapy, psychoeducation) (Crowe & McKay, 2017; Reynolds et al., 2012). Still, the scientific value of comparing TBT to an established treatment is greater than comparison to a waitlist where differences would likely have been detectable.

Additionally, conclusions drawn from objective sleep data in the current study were limited by participant noncompliance with actigraphy data collection. The most notable problem included the use of event markers indicating the beginning of the time-in-bed period (which required the child to press a button at “lights out”). Without accurate event markers, sleep onset latency could not be assessed. Further, validity studies have demonstrated that actigraphy consistently underestimates sleep onset latency and overestimates total sleep duration in individuals with insomnia (i.e., extended sleep onset latency) because time lying in bed motionless while trying to fall asleep may be scored as sleep (Sadeh, 2011). Actigraphy also fails to capture parent-child interactions at bedtime (e.g., co-sleeping), which may be key to understanding sleep variability in actual nighttime sleep. It is likely that the current study sample had high co-sleeping rates and greater intra-individual variability in sleep, yet we did not specifically measure these variables or examine how they may have contributed to subjective and objective sleep indicators. Further, in considering the relevance

of variable day-to-day sleep patterns in anxious populations, we were also limited by the "snapshot" of objective sleep due to averaging across 3-7 nights of actigraphy. Although we can hypothesize that high variability in daily sleep was present in this sample—due to inconsistency in average sleep parameters across time in the current study, potential co-sleeping, and documented high variability in sleep onset latency in previous studies (Buysse et al., 2010)—this was not specifically measured.

Finally, threats to internal validity are problematic in all intervention studies, including the current study. Extraneous variables may have contaminated the delivery and implementation of the sleep intervention. For example, shared bedrooms and other siblings in the home, particularly those that had sleep problems, may pose greater challenge in some families' ability to implement a behavioral sleep intervention at home. Similarly, multiple caregivers in the home and parents' work schedules may have impacted the extent to which the intervention was delivered (e.g., variability across caregivers, inability to consistently be present for bedtime routines).

Future studies should seek to expand upon findings from the current pilot study in a larger RCT with additional comparison arms. For example, comparison of TBT to an exposure-only intervention, and a purely sleep-based intervention could provide additional information regarding the impact of each intervention component. In addition to RCT designs, single subject design studies would allow for more specific analysis of change and mediating factors of treatment outcomes. Similarly, objective measures of sleep on nights following exposure sessions will help elucidate the role of sleep in fear extinction, and inform the potential therapeutic role of timed sleep opportunities in treatment, such as planned naps following exposure sessions. While actigraphy is a non-intrusive cost-effective way to estimate sleep-wake patterns in the child's natural environment, future studies may

also consider utilizing PSG given its higher specificity in detecting wake after sleep onset (Meltzer et al., 2012) and to examine specific sleep stages. Sleep assessment must also include parent and child reports since objective sleep measures cannot provide information about co-sleeping or bedtime interactions.

Finally, the feasibility of a 16-session treatment protocol should be considered based on the observed drop out rate of approximately 25% in the current study. This is considerably higher than other CBT trials for child anxiety, which have demonstrated drop-out rates of approximately 10% during a 12-week treatment protocol (Piacentini, Bennett, & Compton, 2014). Decreasing the number of sessions focused on cognitive and/or somatic components of anxiety appear to be one way of achieving more efficient treatment packages without compromising anxiety-based outcomes.

In conclusion, this is the first study to use multi-methods and informants to demonstrate that some sleep-related improvements following CBT for anxiety are maintained even when sleep is not targeted directly. A modest decrease in sleep onset latency was observed at post-treatment in both groups, but more thorough investigation of parent-child interactions (e.g., co-sleeping) during the bedtime period and the subsequent impact on sleep-wake variability should be examined when considering objective changes in nighttime sleep. At the same time, our preliminary findings suggest that an integrated sleep and anxiety treatment may produce an alternate pattern of symptom change across treatment in terms of both anxiety and bedtime problems. Dismantling treatment studies are needed to more comprehensively examine the role of sleep in treatment for child anxiety disorders.

Table 1. Demographics for treatment completers.

Variable	TBT (*n*=11)	Control (*n*=10)	χ^2/t
Age (*M/SD*)	8.91 (2.34)	9.10 (1.60)	-0.22
Sex: Female (*n*/%)	5 (46%)	4 (40%)	0.06
Race/Ethnicity (*n*/%)			2.25
Caucasian	5 (46%)	6 (60%)	
Hispanic/Latino	3 (27%)	1 (10%)	
African American	1 (9%)	0 (0%)	
Biracial/Mixed Race	2 (18%)	3 (30%)	
Marital Status (*n*/%)			0.51
Married	10 (91%)	8 (80%)	
Single/Divorced/Separated	1 (9%)	2 (20%)	
Income (*n*/%)			2.25
$20,000-$60,000	3 (27%)	2 (20%)	
$60,000-$100,000	1 (9%)	3 (30%)	
>$100,000	6 (55%)	5 (50%)	
Maternal Education (*n*/%)			2.98
High school degree	1 (9%)	0 (0%)	
Some college or less	1 (9%)	3 (30%)	
College degree	7 (64%)	4 (40%)	
Advanced degree	2 (18%)	3 (30%)	

Note. No significant group differences (all *p*s > .05)

Table 2. Equivalence testing between treatment groups.

	Post-treatment change from baseline				6-month follow-up change from baseline			
	TBT Mean (SD)	CBT Mean (SD)	*p*	95% CI	TBT Mean (SD)	CBT Mean (SD)	*p*	95% CI
CGAS	13.45 (8.65)	14.9 (8.74)	.71	(-9.39, 6.50)†	16.44 (10.25)	15.56 (9.99)	.85	(-9.22, 11.00)†
Anxiety								
SCARED-P	-13.70 (10.45)	-13.90 (14.57)	.97	(-11.71, 12.12)†	-17.60 (12.19)	-15.44 (11.94)	.70	(-13.86, 9.54)†
SCARED-C	-15.70 (11.63)	-6.00 (16.64)	.15	(-23.19, 3.79)	-16.20 (15.05)	-2.78 (15.63)	.07	(-28.28, 1.43)
Sleep								
CSHQ Total	-12.80 (9.07)	-12.80 (9.07)	1.0	(-8.93, 8.93)†	-15.20 (8.83)	-11.89 (10.37)	.46	(-12.74, 6.12)†
CSHQ-BR	-3.90 (3.07)	-3.50 (3.31)	.78	(-3.40, 2.60)†	-4.20 (3.68)	-2.33 (2.65)	.23	(-5.00, 1.27)
CSHQ-SA	-2.30 (2.21)	-2.80 (2.44)	.64	(-1.69, 2.69)†	-2.40 (1.90)	-2.00 (1.94)	.66	(-2.26, 1.46)†
SSR	-4.18 (7.03)	-5.70 (7.44)	.64	(-5.09, 8.13)†	-4.20 (6.78)	-5.56 (5.85)	.65	(-4.81, 7.52)†
SOL	-4.36 (7.97)	-8.09 (12.67)	.54	(-9.47, 16.92)†	-1.81 (6.98)	-9.84(14.88)	.27	(-7.31, 23.38)†

Note: †95% confidence that the change score for the TBT group is equivalent to change score for the CBT group.
CGAS = Children's Global Assessment Scale; SCARED-P = Screen for Child Anxiety-Related Emotional Disorders- Parent Version; SCARED-C = Screen for Child Anxiety-Related Emotional Disorders- Child Version; CSHQ-BR = Children's Sleep Habits Questionnaire- Bedtime Resistance; CSHQ-SA = Children's Sleep Habits Questionnaire- Sleep Anxiety; SSR = Sleep Self-Report; SOL = sleep onset latency based on actigraphy.

Table 3. Clinical outcomes for treatment completers.

	Baseline		Post-treatment		6-month follow-up	
	TBT Mean (SD)	CBT Mean (SD)	TBT Mean (SD)	CBT Mean (SD)	TBT Mean (SD)	CBT Mean (SD)
CGAS[ab]	55.56 (6.24)	54.62 (4.33)	68.64 (7.80)	69.80 (6.43)	70.33 (9.17)	70.44 (8.26)
Anxiety						
SCARED-P[ab]	33.88 (12.06)	35.69 (9.53)	19.8 (11.27)	20.60 (11.88)	16.30 (15.48)	19.11 (8.84)
SCARED-C[b]	38.94 (12.52)	30.69 (13.38)	20.80 (11.08)	24.10 (11.94)	21.89 (13.72)	25.44 (13.80)
Sleep						
CSHQ Total[ab]	56.00 (8.37)	56.54 (11.40)	44.80 (7.18)	43.80 (7.28)	44.60 (9.30)	44.00 (8.47)
CSHQ-BR[ab]	11.12 (3.81)	10.46 (3.45)	7.40 (2.22)	7.20 (1.62)	7.70 (2.71)	7.78 (2.11)
CSHQ-SA[ab]	8.00 (2.06)	7.92 (2.29)	6.00 (2.26)	5.40 (1.84)	6.30 (2.16)	5.78 (1.86)
SSR[ab]	43.72 (7.14)	43.92 (8.07)	38.55 (6.95)	38.40 (3.50)	39.30 (8.96)	37.22 (4.94)
SOL[ac]	16.53 (9.93)	24.86 (16.52)	14.29 (5.44)	19.60 (9.44)	16.49 (6.94)	20.46 (9.75)

Note: [a]significant main effect of time, [b]significant main effect of time using intent-to-treat analyses. [c]SOL follow-up not included in analyses. Higher CGAS value indicates better functioning. CGAS = Children's Global Assessment Scale; SCARED-P = Screen for Child Anxiety-Related Emotional Disorders- Parent Version; SCARED-C = Screen for Child Anxiety-Related Emotional Disorders- Child Version; CSHQ-BR = Children's Sleep Habits Questionnaire- Bedtime Resistance; CSHQ-SA = Children's Sleep Habits Questionnaire- Sleep Anxiety; SSR = Sleep Self-Report; SOL = sleep onset latency based on actigraphy.

Table 4. Treatment effect sizes (Cohen's *d*) and confidence intervals.

	TBT		CBT	
	Baseline to Post	Baseline to F/U	Baseline to Post	Baseline to F/U
CGAS	-1.91 (-2.83, .84)	-1.97 (-2.95, -.83)	-2.70 (-3.77, -1.4)	-2.38 (-3.43, -1.12)
Anxiety				
SCARED-P	1.17 (.20, 2.04)	1.25 (.27, 2.13)	1.30 (.29, 2.20)	1.69 (.58, 2.65)
SCARED-C	1.44 (.43, 2.34)	1.14 (.18, 2.02)	.46 (-.45, 1.32)	.33 (-.59, 1.22)
Sleep				
CSHQ	1.95 (.85, 2.90)	1.73 (.67, 2.66)	1.27 (.26, 2.17)	1.19 (.16, 2.10)
SSR	0.59 (-.28, 1.42)	.43 (-.46, 1.28)	.82 (-.13, 1.69)	.91 (-.07, 1.82)
SOL	.27 (-.70, 1.22)	0 (-.98, .99)	.37 (-.78, 1.47)	.31 (-.77, 1.35)

Note: Effect size magnitude: .20 = small, .50 moderate, .80 = large. F/U = 6-month follow-up; CGAS = Children's Global Assessment Scale; SCARED-P = Screen for Child Anxiety-Related Emotional Disorders- Parent Version; SCARED-C = Screen for Child Anxiety-Related Emotional Disorders-Child Version; SSR = Sleep Self-Report; SOL = sleep onset latency based on actigraphy.

Table 5. Linear slope changes in bedtime problems across treatment.

TBT	Slope change	Control	Slope change
Participant 1	-0.55**	Participant 1	-0.16
Participant 2	-0.67	Participant 2	-0.57
Participant 3	-0.89**	Participant 3	0.29
Participant 4	-0.70	Participant 4	-0.30
Participant 5	-0.94**	Participant 5	0.00
Participant 6	-0.32*	Participant 6	0.06
Participant 7	-0.34	Participant 7	-0.72*
Participant 8	-0.55**	Participant 8	-0.48**
Participant 9	-0.54	Participant 9	.03
Participant 10	-0.65	Participant 10	-.79*
Participant 11	-0.44*		
Participant 12[†]	-0.43**		

Note: Data are Pearson's correlations conducted with SMA. ** $p < .05$ * $p < .10$
[†]TBT participant 12 treated as noncompleter in post and follow-up analyses because all treatment data complete, but did not complete post-treatment assessment.

Figure 1. CONSORT flow diagram.

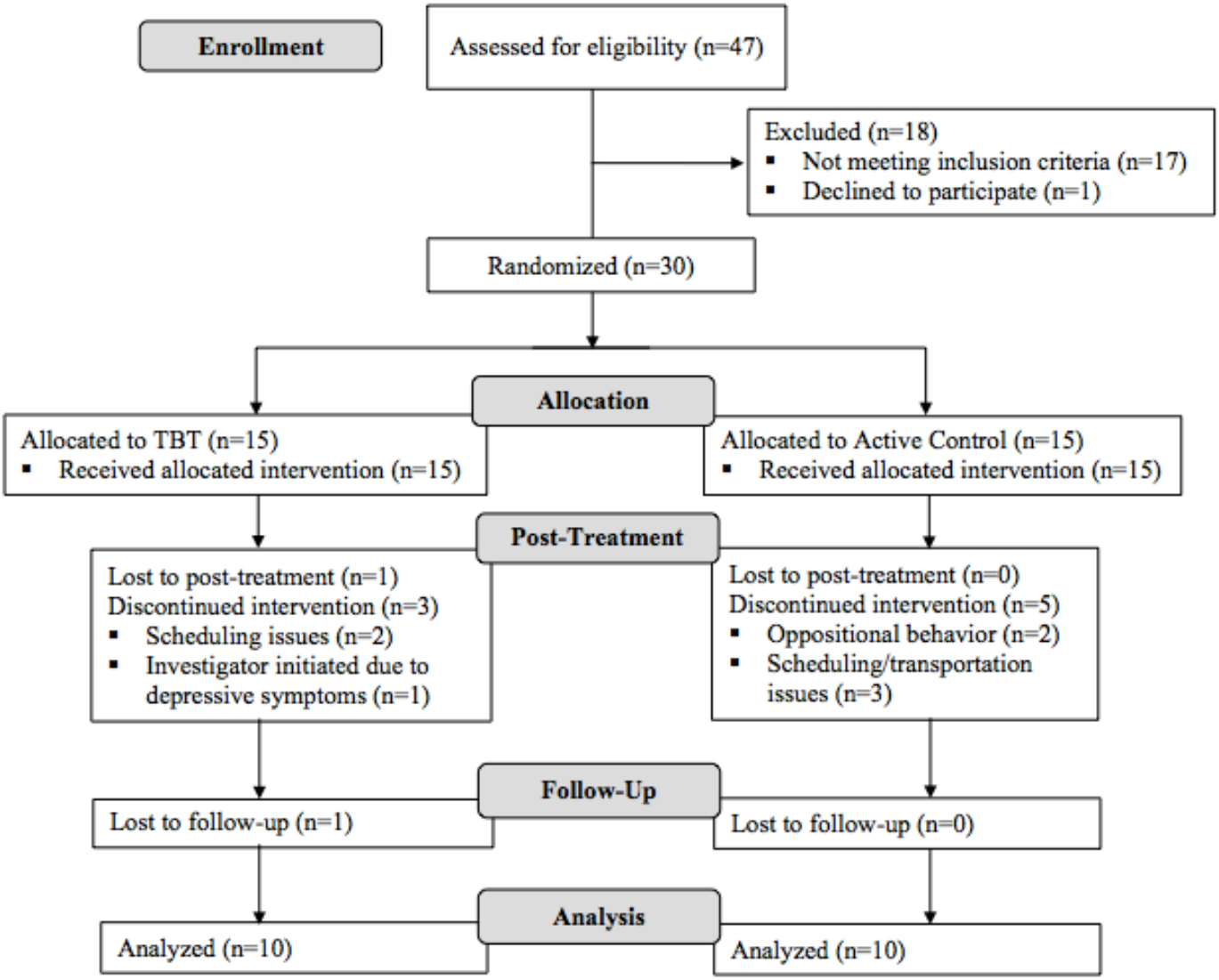
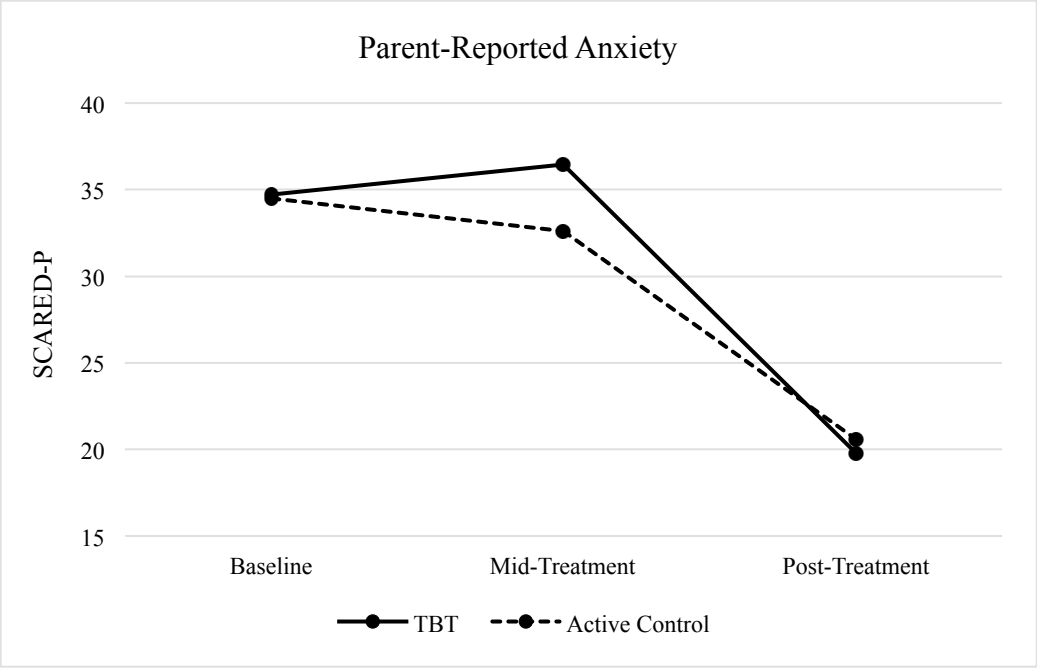
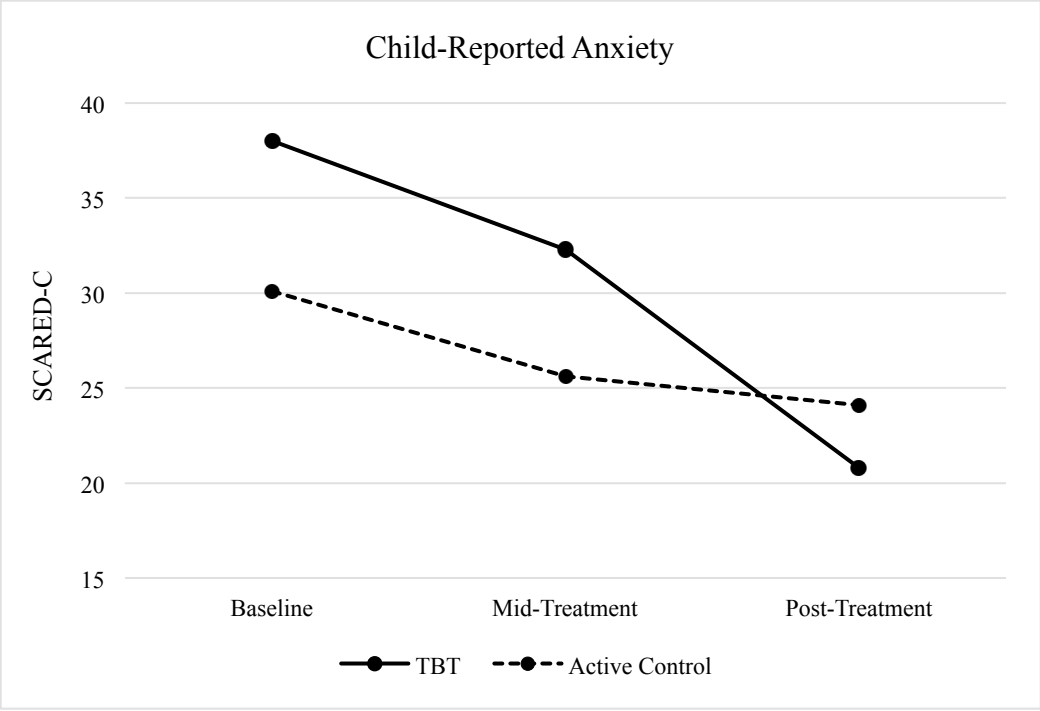


Figure 2. Anxiety symptoms across treatment.





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