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SCIENTIFIC INVESTIGATIONS

A Single Arm Pilot Trial of Brief Cognitive Behavioral Therapy for Insomnia in Adolescents with Physical and Psychiatric Comorbidities

Tonya M. Palermo, PhD[1,2]; Sarah Beals-Erickson, PhD[2]; Maggie Bromberg, PhD[2]; Emily Law, PhD[1,2]; Maida Chen, MD[1,2]

[1]University of Washington, Seattle, WA; [2]Seattle Children's Research Institute, Seattle, WA

Study Objectives: The majority of adolescents with chronic insomnia have physical health or psychiatric comorbidities; insomnia is also associated with greater negative daytime symptoms (e.g., depressive symptoms) and reduced overall health-related quality of life (HRQOL). However, to date, there has been limited attention to treatment of insomnia in this population. The purpose of this study was to determine the preliminary efficacy of a brief cognitive behavioral therapy for insomnia (CBT-I) intervention on sleep, psychological symptoms, and HRQOL outcomes in adolescents with insomnia and co-occurring physical or psychiatric comorbidities.

Methods: We conducted a single arm pilot trial in which 40 youth (mean age = 14.93, standard deviation = 1.89) with insomnia and physical or psychiatric comorbidities (e.g., depression, chronic pain, anxiety, gastrointestinal problems) received CBT-I in four individual treatment sessions over 4 to 6 w. Adolescents completed 7 days of wrist actigraphy and self-report measures of insomnia, sleep quality and behaviors, psychological symptoms, and HRQOL outcomes at pretreatment, immediate posttreatment, and 3-mo follow-up.

Results: CBT-I was associated with improvements in self-reported measures of sleep including insomnia symptoms, sleep quality, sleep hygiene, pre-sleep arousal, and sleep onset latency. Psychological symptoms and HRQOL also improved. Effects were generally sustained at 3-mo follow-up.

Conclusions: CBT-I may be efficacious for adolescents with co-occurring physical and mental health comorbidities; future randomized controlled trials are needed to test the effect of CBT-I on sleep, psychological symptoms, and HRQOL and to evaluate maintenance of treatment effects over longer time periods.

Keywords: adolescents, chronic pain, cognitive behavioral therapy, depression, health-related quality of life, insomnia, intervention, sleep

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INTRODUCTION

Insomnia, characterized by difficulties falling asleep or staying asleep, affects 10% of the adolescent population.[1] Adolescents with insomnia commonly have comorbid medical and psychiatric disorders, such as depression, anxiety, and chronic pain.[2] More recent conceptualizations of insomnia consider it to be a transdiagnostic contributor to the multiple causal factors that underlie medical and psychiatric conditions.[3] Insomnia may contribute to the onset, maintenance, and recurrence of these symptoms. For example, insomnia may precede the onset of major depressive episodes and sleep disruption may lead to physical health disorders such as chronic pain.[4,5] There is a large evidence base supporting the efficacy of cognitive behavioral therapy for insomnia (CBT-I) among adults with a diverse range of comorbid physical and psychiatric conditions.[6] In contrast, CBT-I is still in early stages of development within child and adolescent populations.

There have been a handful of randomized controlled trials of CBT-I in children and adolescents, showing benefit on improving sleep outcomes.[7–9] However, most of these trials and existing pilot studies have excluded youth with comorbid mental and physical health conditions.[9–11] Indeed, to date, only two small trials of CBT-I have included youth with any comorbid mental health condition (i.e., depression[12]; substance use[13]). This is surprising given that the majority of youth presenting for treatment of insomnia symptoms have a comorbid mental and/or physical health condition.[14,15] CBT-I has potential to not only improve sleep patterns for this population but to positively affect emotional and physical symptoms and overall health-related quality of life (HRQOL). To address this gap in knowledge, we recently developed a brief CBT-I intervention for youth with insomnia and comorbid medical and psychiatric conditions, and demonstrated that the intervention is feasible and acceptable to this population.[16]

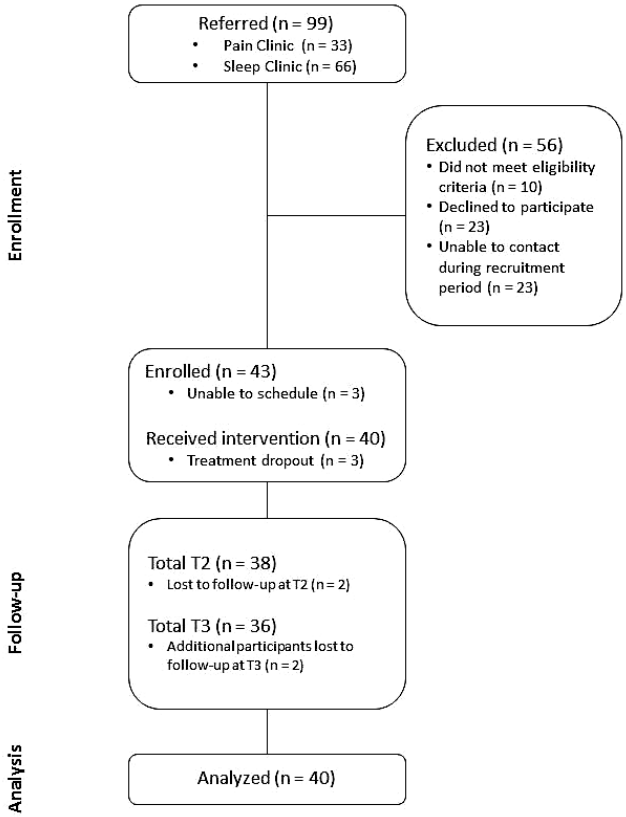
In the current study, we aim to evaluate the preliminary efficacy of brief CBT-I intervention on sleep, psychological

BRIEF SUMMARY

Current Knowledge/Study Rationale: Insomnia is highly prevalent in the adolescent population and frequently occurs in the context of other medical and psychiatric concerns (e.g., chronic pain, depression). Efficacy of cognitive behavioral therapy for insomnia (CBT-I) has been established in adults with comorbid conditions; however, there are limited data on the efficacy of CBT-I in adolescents with co-occurring health or psychiatric conditions, which we aimed to examine in this pilot trial.

Study Impact: CBT-I is feasible to implement with adolescents with co-occurring medical and psychiatric conditions and is associated with improvements in insomnia, sleep quality and habits, psychological symptoms, and health-related quality of life. Our preliminary findings support the need for future randomized controlled trials of CBT-I in this population.

Figure 1—Study flowchart.



symptoms, and HRQOL outcomes at posttreatment and 3-mo follow-up in youth with co-occurring physical and psychiatric conditions. We hypothesize that adolescents will demonstrate significant improvements in self-reported insomnia symptoms, sleep quality, sleep hygiene, and pre-sleep arousal, as well as on actigraphic-measured sleep patterns. We also expect youth to have significant improvements on measures of psychological symptoms and HRQOL. Given the preliminary nature of this pilot trial, a primary goal is to evaluate the size of treatment effects to inform future more definitive trials of CBT-I in this population.

METHODS

Study Design

Adolescents were recruited over a 10-mo period (2014–2015) from two specialty clinics serving youth with insomnia and co-occurring medical and psychiatric conditions, a pediatric pain medicine clinic and a pediatric sleep clinic, at an academic medical center in the Pacific Northwest. The study design was a single-arm pilot trial to evaluate feasibility and preliminary efficacy of brief cognitive behavioral therapy for youth with chronic insomnia and comorbid physical health and psychiatric conditions (CBT-I). All participants received up to four sessions of CBT-I and completed assessments at pretreatment, immediate posttreatment, and 3-mo follow-up. The trial was terminated as planned after all 3-mo follow-up assessments were completed. The Institutional Review Board at the academic medical center approved this study. Parents provided informed consent and adolescents provided informed assent prior to initiating study procedures.

We have published data from this trial in one previous manuscript, which focused on the development, feasibility, and acceptability of our CBT-I intervention.[16] In the current study, we report for the first time on the preliminary efficacy of our CBT-I intervention on sleep, emotional functioning, and HRQOL outcomes. These data have not been published previously.

Participants

Participants included 40 adolescents and one of their parent caregivers. Eligible participants were: (1) between 11–18 y old; (2) had seen a medical provider in the pediatric pain or sleep specialty clinics; (3) qualified as having insomnia based on a phone-administered screening of insomnia using research diagnostic criteria (difficulty initiating or maintaining sleep 3 or more nights during the past month and significant daytime impairment in at least one domain); and (4) the adolescent had a comorbid physical or psychological condition by provider referral information and parent report. Adolescents were excluded if: (1) they or their parent were not fluent in reading or speaking English; (2) they were actively psychotic or suicidal; or (3) they had received cognitive behavioral sleep treatment within the previous 6 months.

Many youth (42.5%) were receiving outside treatment during their study participation including psychological treatment for anxiety, depression, or chronic pain, and psychiatric visits for medication management. This additional treatment was stable and had been occurring prior to study enrollment and no new treatments were started during the intervention period.

As shown in the study flow diagram (**Figure 1**), a total of 99 referrals were received (33 from pain clinic, 66 from sleep clinic). Of these referrals, 76 were screened for eligibility via telephone, and the remaining 23 were unable to be reached. Of the families contacted, 10 were excluded because inclusion criteria were not met and 23 declined to participate because of lack of interest or time constraints. The remaining 43 families were enrolled in the study. Three families were unable to be reached to complete pretreatment assessments. This yielded a final sample of 40 families who were offered the intervention and were included in analyses. Two families chose to discontinue study participation after one to two sessions and an additional family chose to discontinue treatment after two sessions, but remained enrolled for follow-up assessments. Of the remaining 37 families who completed active treatment, the majority (92%) completed all four treatment sessions. Retention was high for follow-up; 95% of participants completed posttreatment assessment questionnaires (n = 38) and 90% of participants completed 3-mo follow-up assessments (n = 36). Families who did not complete treatment were not significantly different from completers on demographics, including age, sex, Child Behavior Checklist, School-Age version (CBCL) scores, or the number or type of comorbidities.

Procedures

Providers in the pediatric pain and sleep medicine specialty clinics at an academic children's hospital identified potential participants during clinic visits. Providers gave potential participants a study flyer and requested permission to share their contact information with study staff. All potentially eligible families completed a telephone screening interview to determine whether they met study eligibility criteria. The presence of insomnia was determined via a developmentally modified version of the Research Diagnostic Criteria for Insomnia.[17]

After completing informed consent and prior to initiating the intervention, adolescents completed online questionnaire measures of sleep habits and behaviors, psychological symptoms, and HRQOL via research electronic data capture.[18] Adolescents also wore an Actiwatch and completed an online sleep diary for 7 days at each assessment. Immediate posttreatment assessments were completed at 4 to 6 w, and follow-up assessments were completed at 3 mo. Self-report and actigraphy assessments were repeated at these data waves. Pretreatment sample characteristics were obtained from the parents. The parents completed a demographic questionnaire, a screening measure of adolescent emotional and behavioral functioning (the Child Behavior Checklist), and the Pediatric Sleep Questionnaire to screen for sleep-disordered breathing via research electronic data capture. Study staff not involved in treatment delivery conducted all assessment procedures. Study participants were compensated with gift cards for completion of assessments ($80/family) and parking was reimbursed ($10/visit) for participation in intervention study visits.

Cognitive Behavioral Therapy for Insomnia and Comorbid Conditions

Development of our manualized CBT-I protocol has been described in detail elsewhere.[16] The primary goal of treatment is to develop a consistent sleep-wake schedule by limiting time awake in bed. The core intervention strategies delivered to adolescents are: (1) sleep education, (2) sleep hygiene training, (3) sleep restriction, and (4) stimulus control. The primary focus of parent treatment strategies is operant training to support their adolescent's sleep changes. The protocol also includes the following optional treatment modules to be delivered at any point during the four treatment sessions based on the therapist's clinical judgment: (1) cognitive reframing/positive thinking, (2) anxiety coping, (3) relaxation training, (4) fatigue management, and (5) parent operant training to address bedtime resistance and co-sleeping. A brief description of each of the four sessions is provided in **Table 1**.

The intervention was delivered in four sessions over 4 to 6 w. Session duration was a maximum of 75 min. All sessions were completed in-person at our research center. Therapists followed a therapist manual developed for the study. Teens and parents received treatment manuals that included handouts and homework assignments for each session, as well as booklets with vignettes of other families who received CBT-I. Study materials (therapist, adolescent, and parent manuals) are available from the first author upon request. Adolescents completed daily sleep diaries during the intervention period, which study therapists entered into a spreadsheet to calculate average sleep and wake times and sleep efficiency. These data were used to titrate sleep restriction schedules each week. Parents participated in at least part of all sessions; the involvement of parents varied based on the developmental needs of the adolescent and judgment of the therapist.

Table 1—Description of cognitive behavioral therapy for insomnia (CBT-I) for adolescents with physical and psychiatric comorbidities.

Sessions	Description
1	**Orientation** Establish rapport, conduct sleep interview, review treatment protocol including importance of sleep diary completion **Sleep education** Psychoeducation about adolescent sleep needs and problems **Sleep hygiene** Review healthy sleep habits, select two for homework
2	**Sleep diary review** Explain sleep diary data, review success/barriers in sleep hygiene homework **Stimulus control** Education and planning for "nesting place" for use, create bedtime "wind down" routine **Sleep restriction** Education and planning for new bedtime based on sleep diary data, safety plan regarding driving
3	**Sleep diary review** Explain sleep diary data, review success/barriers in stimulus control and sleep restriction homework **Stimulus control** Review "nesting place" and bedtime routine adherence, create wake up plan **Sleep restriction** Review adherence, set new bedtime based on sleep diary data
4	**Sleep diary review** Explain sleep diary data, review success/barriers in stimulus control and sleep restriction homework **Maintenance planning** Education and planning for continued titration of sleep schedule **Relapse prevention** Review of skills, planning for potential challenges
Optional	**Relaxation (with teen)** Deep breathing, imagery, mindfulness **Cognitive strategies (with teen)** Positive self-talk, scheduled worry time **Fatigue management (with teen)** Planning how to cope without napping **Eliminating bedtime resistance/co-sleeping (with parent)** Planned parental ignoring, operant training/behavioral reinforcement

Therapist Qualifications, Training, and Treatment Fidelity

The intervention was delivered by trained study therapists (three postdoctoral pediatric psychology fellows, one licensed

pediatric psychologist); all had prior experience in cognitive behavioral therapy for youth with chronic medical or psychiatric conditions. Study therapists were trained via a 2-day in-person workshop that included didactic instruction in pediatric sleep problems, training in the intervention protocol, and discussion of case examples. During the trial, study therapists were supervised in weekly sessions by the first author (a licensed pediatric psychologist experienced in providing CBT-I to youth with comorbid conditions) to ensure treatment fidelity.

Measures

Pretreatment sample characteristics

Parents reported on their relationship to the adolescent, household income, marital status, racial/ethnic background, parent and adolescent age, parent occupation and education, and their adolescent's current prescription and over-the-counter (OTC) medication use.

To screen for sleep-related breathing disorders present at baseline, parents completed the Sleep-Related Breathing Disorders Scale of the Pediatric Sleep Questionnaire.[19] This 22-item scale assesses symptoms of sleep-related breathing disorders (e.g., snoring, apneas, mouth breathing). Higher mean scores indicate greater risk of having a sleep-related breathing problem; mean scores higher than 0.33 are considered clinically significant.

Parents also completed the CBCL to screen for adolescent emotional and behavioral concerns.[20] The CBCL is a 120-item broadband parent-report measure that provides norm-referenced scores on a variety of psychological, emotional, and behavioral symptoms in youth, with higher scores indicative of greater problematic emotional and behavioral symptoms. Problem scores of T > 63 are in the clinical range.

Sleep outcome measures

Adolescents completed the Insomnia Severity Index (ISI) to report on their insomnia symptoms.[21] Seven items are summed to create a total score, with scores greater than or equal to 22 indicating severe insomnia; scores of 15 to 21 indicating moderate insomnia; scores of 8 to 14 indicating subthreshold insomnia; and scores of 7 or less indicating the absence of insomnia.[21]

The Adolescent Sleep Wake Scale-Revised was used to assess overall sleep quality.[22] For analyses we utilized a revised, short-form version (10 items) which provides a total sleep quality score with higher scores indicating better sleep quality (ASWS-R).[23]

Adolescents completed the Adolescent Sleep Hygiene Scale to report on sleep habits. This 28-item measure yields a total summary score, with higher scores indicative of better sleep hygiene.[22]

The Pre-Sleep Arousal Scale was administered to assess cognitive and somatic arousal at bedtime. Higher scores indicate greater levels of arousal at bedtime.[24]

A daily sleep diary and actigraphy were used for 7 days at each data collection period. Adolescents completed the sleep diary each morning to record sleep patterns for the previous night. Adolescents reported on the time they got into bed, the time they fell asleep, number and duration of night wakings, the time they woke up to start the day, and the number and duration of daytime naps. Daily sleep diaries have been shown to be a low-cost, accurate method of recording sleep in adolescents.[25] Across each 7-day assessment period, average total sleep time (TST), time awake after sleep onset (WASO), sleep efficiency (SE), and sleep onset latency (SOL) were extracted for analyses.

Adolescents wore an actigraph (Actiwatch 2; Phillips Respironics, Bend, OR) for 7 days on their nondominant wrist at each assessment time point to obtain average TST, WASO, and SE for analysis.

Psychological symptoms and HRQOL outcomes

Adolescents completed two Patient Reported Outcomes Measurement Information System (PROMIS) measures (Pediatric Anxiety Short Form and Pediatric Depressive Symptoms Short Form).[26] Each measure uses eight items to evaluate anxiety or depressive symptoms, respectively. Higher scores signify greater level of worry/fear or depressive symptoms.

The Pediatric Quality of Life Inventory was administered to assess the effect of health on child physical and psychosocial functioning, with higher scores indicating better HRQOL.[27] Items are summed to create a total HRQOL score, as well as summary scores of psychosocial health (emotional, social, and school functioning) and physical health.

Data Analysis Plan

All analyses were completed in SPSS Version 19 (Chicago, IL). Changes in sleep, psychological symptoms, and HRQOL from pretreatment to posttreatment and from pretreatment to 3-mo follow-up were examined using multilevel modeling, which detects change over time and accounts for the nested data structure, retains all available data, and accommodates missing data.

Missing data

As shown in **Figure 1**, retention across repeated assessments was high, of the 40 dyads who completed baseline measures and received treatment, 38 dyads (95%) completed posttreatment assessment, and 36 (90%) completed follow-up assessment. Individual missing items were handled according to instrument guidelines, or were scored using mean imputation in cases where at least 80% of items were completed on the scale. Most participants also completed 7-day sleep diaries and actigraphy assessments. On average, participants completed 5 to 7 days of diaries and 7 nights of actigraphy at each assessment. Specifically, at T1 actigraphy was completed by 38 youth and sleep diaries were completed by 39 youth (mean = 6.4 days); T2 actigraphy was completed by 35 youth and sleep diaries were completed by 32 youth (mean = 5.8 days), and T3 actigraphy was completed by 35 youth and sleep diaries were completed by 33 youth (mean = 5.6 days). All available data were included in analysis.

Prior to model testing, Pearson correlations and independent sample *t*-tests were used to assess whether treatment outcomes varied by pretreatment variables, in order to identify possible covariates to include in outcome analyses. Several significant

positive correlations were found between the pretreatment CBCL Total Problems score and outcome measures at posttreatment and follow-up. Thus, the pretreatment CBCL Total Problems score was added as a time invariant covariate to the linear growth models. Other considered covariates (i.e., adolescent age, Pediatric Sleep Questionnaire Sleep-Related Breathing Disorders scale, medication use, comorbidity status) were not robustly associated with outcomes and thus were not included in outcomes analyses. Multilevel modeling models were specified based on standard procedures.[28] In order to test for changes from pretreatment to posttreatment and from pretreatment to follow-up, time was treated as a categorical variable in the models. The full conditional models tested the effects of time, controlling for pretreatment CBCL Total Problem score.

We computed means and standard deviations for subjective and actigraphic sleep outcome variables, psychological symptoms and HRQOL outcomes. The beta, p value, and effect size are reported for each outcome. Significance was set at $p < 0.05$. Effect sizes are reported as Cohen *d* for repeated measures.[29] Guidelines to interpret the effect size estimates are as follows: $d = 0.20$ indicates a small effect, $d = 0.50$ indicates a medium effect, and $d = 0.80$ indicates a large effect.[30]

To detect changes in insomnia severity, analyses of frequencies were conducted at each time point to assess the proportion of the sample falling in the ISI categories as follows: not clinically significant, subthreshold, moderate, and severe insomnia symptoms. A Wilcoxon signed-rank test was used to test the differences in distributions of insomnia categories from pretreatment to posttreatment and from pretreatment to follow-up.

RESULTS

Sample Characteristics

Table 2 shows descriptive characteristics of the 40 participating adolescents. Adolescents were on average 14.9 y old (standard deviation [SD] = 1.9) and 75% were female. Per parent report, the most common comorbidities were anxiety disorders (n = 25, 62.5%), chronic pain (n = 21, 52.5%), and depressive disorders (n = 16, 40.0%). As indicated by their referring sleep medicine physician, several youth also had additional sleep disorder diagnoses: sleep apnea (n = 4, 10.0%); restless legs syndrome (n = 3, 7.5%); and parasomnias (n = 1, 2.5%). On the Pediatric Sleep Questionnaire, few youth were reported to have elevated symptoms of sleep-disordered breathing (n = 3, 7.5%). Parent-reported CBCL scores indicated that more than half of the sample had clinically elevated Internalizing Problems and nearly one-third had clinically elevated Total Problems scores. Parents reported that most youth were taking medications (87.5%), including various prescription and OTC medications. Descriptive statistics for subjective and objective sleep and for psychosocial outcomes are shown in **Tables 3** and **4** respectively.

Changes in Sleep Outcomes

As shown in **Table 5**, significant changes from pretreatment to posttreatment and pretreatment to follow-up were detected for most sleep outcomes.

Table 2—Sample demographics and baseline characteristics (n = 40).

Age, mean (SD)	14.9 (1.9)
Sex (female), % (n)	75.0 (30)
Race, % (n)	
White	85.0 (34)
Black	5.0 (2)
Asian	5.0 (2)
Multiracial	5.0 (2)
Family annual income, % (n)	
$10,000–69,999	15.0 (6)
$70,000–100,999	17.5 (7)
> $100,999	60.0 (24)
not reported	7.5 (3)
Comorbidities, % (n)	
Physical only	25.0 (10)
Psych only	27.5 (11)
Both physical & psych	47.5 (19)
Specific comorbid diagnoses, % (n)	
ADHD	12.5 (5)
Anxiety	62.5 (25)
Asthma/Eczema	15.0 (6)
Chronic Pain	52.5 (21)
Depression	40.0 (16)
Organic Sleep Disorder	22.5 (9)
Medications, % (n)	
Antidepressants	42.5 (17)
Anticonvulsants	7.5 (3)
Prescription pain medications	22.5 (9)
OTC pain medications	47.5 (19)
Prescription sleep medications	12.5 (5)
OTC sleep medications	27.5 (11)
Other prescription medications	47.5 (19)
Other OTC medications	22.5 (9)
CBCL Total Problems, mean (SD)	57.2 (10.4)
% above clinical cutoff, % (n)	30.0 (12)
CBCL Internalizing Problems, mean (SD)	63.6 (10.9)
% above clinical cutoff, % (n)	57.5 (23)
CBCL Externalizing Problems, mean (SD)	48.1 (8.8)
% above clinical cutoff, % (n)	7.5 (3)
PSQ SDB, mean (SD)	0.1 (0.2)
% above clinical cutoff, % (n)	7.5 (3)

ADHD = attention deficit hyperactivity disorder, CBCL = Child Behavior Checklist, School-Age version, OTC = over the counter, PSQ = Pediatric Sleep Questionnaire, SD = standard deviation, SDB = sleep-disordered breathing

Insomnia symptoms

Insomnia severity decreased significantly from pretreatment to posttreatment ($b = -5.67$, $p < 0.0001$; M pre = 15.10, SD = 4.34; M post = 9.96, SD = 4.96; $d = 1.23$) and this improvement was sustained at follow-up ($b = -5.69$, $p < 0.0001$; M follow-up = 9.67, SD = 5.98; $d = 1.13$), representing a large magnitude of change. As shown in **Table 6**, clinically significant change in insomnia symptoms on the ISI was demonstrated. Before treatment, all but one participant endorsed insomnia on the ISI, and 60% of adolescents scored in the moderate to severe insomnia range. At posttreatment, 28.9% of youth scored in the range of having no insomnia symptoms, and 50% had

Table 3—Descriptive statistics for subjective and actigraphic sleep by assessment time point.

	Pretreatment mean (SD)	Posttreatment mean (SD)	Follow-up mean (SD)
Subjective Sleep Measures			
Insomnia Severity Index	15.7 (4.3)	10.0 (4.96)	9.7 (6.0)
ASWS-R	3.2 (0.7)	4.0 (0.8)	4.0 (0.8)
Adolescent Sleep Hygiene Scale	4.7 (0.6)	5.1 (0.5)	5.1 (0.6)
Pre-Sleep Arousal	39.5 (12.7)	32.0 (12.3)	30.6 (11.0)
Sleep Diary - TST	8:05 (1:35)	7:43 (1:51)	8:21 (1:20)
Sleep Diary - SE%	82.4 (14.1)	88.0 (17.0)	90.2 (11.4)
Sleep Diary - WASO	0:15 (0:18)	0:07 (0:12)	0:04 (0:06)
Sleep Diary - SOL	1:32 (1:22)	0:59 (1:44)	0:50 (1:04)
Actigraphic Sleep Measures			
Actigraphy - TST	7:23 (0:57)	6:55 (0:54)	7:09 (1:03)
Actigraphy - SE%	82.95 (9.25)	85.40 (5.26)	82.99 (5.35)
Actigraphy - WASO	1:01 (0:28)	0:54 (0:25)	1:04 (0:28)

All times are reported as hours:minutes. ASWS-R = Adolescent Sleep Wake Scale-Revised, SD = standard deviation, SE = sleep efficiency, SOL = sleep onset latency, TST = total sleep time, WASO = wake after sleep onset.

Table 4—Descriptive statistics for psychosocial outcomes by assessment time point.

	Pretreatment mean (SD)	Posttreatment mean (SD)	Follow-up mean (SD)
PROMIS - Depression	54.4 (13.3)	51.2 (10.8)	50.4 (13.1)
PROMIS - Anxiety	54.2 (13.6)	50.3 (13.1)	49.3 (12.8)
PedsQL - Physical	74.5 (14.2)	78.0 (15.6)	83.2 (11.9)
PedsQL - Psychosocial	68.6 (11.8)	72.2 (10.7)	74.8 (11.3)
PedsQL Total	70.7 (11.3)	74.2 (10.9)	77.8 (10.1)

PedsQL = Pediatric Quality of Life Inventory, PROMIS = Patient-Reported Outcomes Measurement Information System, SD = standard deviation.

Table 5—Changes in sleep and health outcomes following cognitive behavioral therapy for insomnia.

	Change from Pretreatment to Posttreatment				Change from Pretreatment to Follow-up			
Measure	**beta**	**standard error**	**p**	***d* [95% CI]**	**beta**	**standard error**	**p**	***d* [95% CI]**
Insomnia Severity Index	−5.67	0.93	**< 0.0001**	1.23 [0.72, 1.73]	−5.69	0.94	**< 0.0001**	1.13 [0.71, 1.55]
Adolescent Sleep Wake Scale - Revised	0.74	0.10	**< 0.0001**	−1.03 [−1.38, −0.69]	0.73	0.11	**< 0.0001**	−0.92 [−1.17, −0.67]
Adolescent Sleep Hygiene Scale	0.43	0.05	**< 0.0001**	−0.81 [−1.03, 0.59]	0.38	0.05	**< 0.0001**	−0.70 [−0.90, −0.49]
Pre-Sleep Arousal	−6.97	1.29	**< 0.0001**	0.60 [0.35, 0.85]	−8.42	1.31	**< 0.0001**	0.73 [0.53, 0.92]
Sleep Diary - TST	−18.64	16.67	0.27	0.21 [−0.11, 0.53]	18.12	16.48	0.28	−0.19 [−0.49, 0.12]
Sleep Diary - SE%	5.65	2.29	**0.02**	−0.36 [−0.66, −0.05]	7.19	2.27	**0.002**	−0.59 [−0.82, −0.37]
Sleep Diary - WASO	−8.22	2.61	**0.003**	0.51 [0.18, 0.83]	−9.50	2.58	**0.001**	0.70 [0.35, 1.04]
Sleep Diary - SOL	−33.03	14.90	**0.03**	0.35 [0.03, 0.67]	−38.05	14.73	**0.01**	0.54 [0.31, 0.78]
Actigraphy - TST	−25.66	11.61	**0.03**	0.52 [0.12, 0.91]	−11.13	11.61	0.34	0.23 [−0.15, 0.61]
Actigraphy - SE%	2.75	1.49	0.07	−0.32 [−0.73, 0.09]	0.26	1.49	0.86	−0.004 [−0.31, 0.30]
Actigraphy - WASO	−7.19	4.77	0.14	0.25 [−0.10, 0.61]	3.82	4.77	0.43	−0.13 [−0.36, 0.10]
PROMIS - Depression	−3.36	1.56	**0.04**	0.25 [0.02, 0.48]	−3.58	1.59	**0.03**	0.30 [0.04, 0.55]
PROMIS - Anxiety	−3.32	1.44	**0.02**	0.29 [0.10, 0.48]	−4.13	1.46	**0.006**	0.37 [0.15, 0.59]
PedsQL - Physical	2.83	2.20	0.20	−0.23 [−0.50, 0.03]	8.38	2.24	**< 0.0001**	−0.66 [−1.03, −0.29]
PedsQL - Psychosocial	2.59	1.80	0.16	−0.32 [−0.63, −0.006]	5.26	1.84	**0.006**	−0.54 [−0.88, −0.21]
PedsQL Total	2.68	1.67	0.11	−0.32 [−0.62, −0.03]	6.34	1.70	**< 0.0001**	−0.66 [−1.01, −0.31]

Multilevel models controlling for pretreatment Child Behavior Checklist, School-Age version Total Problems. CI = confidence interval, PedsQL = Pediatric Quality of Life Inventory, SE = sleep efficiency, PROMIS = Patient-Reported Outcomes Measurement Information System, TST = total sleep time, SOL = sleep onset latency, WASO = wake after sleep onset. Bold indicates statistically significant p values.

Table 6—Insomnia severity category (ISI) from pretreatment to posttreatment and follow-up.

Insomnia Severity Category (ISI score)	Pretreatment, n = 40 n (%)	Posttreatment, n = 38 n (%)	Follow-up, n = 36 n (%)
Absence of insomnia (0–7)	1 (2.5)	11 (28.9)	15 (41.7)
Subthreshold insomnia (8–14)	15 (37.5)	19 (50.0)	11 (30.6)
Moderate insomnia (15–21)	20 (50.0)	8 (21.1)	10 (27.8)
Severe insomnia (22–28)	4 (10.0)	0 (0.0)	0 (0.0)

decreased symptoms that fell in the subthreshold insomnia category. At follow-up, there was further reduction of insomnia severity as 41.7% of youth had no insomnia and 30.6% indicated subthreshold insomnia symptoms. Results of the Wilcoxon signed-ranks tests indicated that changes in insomnia severity from preintervention to postintervention ($Z = -3.87$, $p < 0.0001$) and from preintervention to follow-up ($Z = -3.83$, $p < 0.0001$) were statistically significant.

Sleep quality and sleep hygiene

Significant improvements with medium to large effect sizes were also found for changes in sleep quality ($b = 0.74$, $p < 0.0001$; ASWS-R total M pre = 3.23, SD = 0.69; M post = 3.99, SD = 0.77; $d = -1.03$; M follow-up = 3.96, SD = 0.84; $d = -0.92$), and sleep hygiene ($b = 0.43$, $p < 0.0001$; Adolescent Sleep Hygiene Scale total M pre = 4.65, SD = 0.59; M post = 5.11, SD = 0.53; $d = -0.81$; $b = 0.38$, $p < 0.0001$; M follow up = 5.05, SD = 0.55; $d = -0.70$). Both effects were maintained at follow-up.

Pre-sleep arousal

Adolescents also reported significant reduction in pre-sleep arousal from pretreatment to posttreatment ($b = -6.97$, $p < 0.0001$; Pre-Sleep Arousal Scale total M pre = 39.50, SD = 12.73; M post = 31.97, SD = 12.32; $d = 0.60$) with a medium effect size that was sustained at follow-up, (M follow-up = 30.56, SD = 10.98; $d = 0.73$).

Subjective diary-reported sleep

Changes in sleep patterns assessed via sleep diaries generally reflected improvements in self-reported sleep. Small effect sizes were detected for improvements in SOL from pretreatment to posttreatment ($b = -33.03$, $p < 0.03$; SOL M pre = 92.4 min, SD = 82.7 min; M post = 59.0 min, SD = 104.6 min; $d = 0.35$) and for improvements in SE ($b = 5.65$, $p = 0.02$; SE M pre = 82.4%, SD = 14.1; M post = 88.0%, SD = 17.0; $d = -0.36$). Both effects were maintained at follow-up, with medium effect sizes. Adolescents reported significantly lower WASO from pretreatment to posttreatment ($b = -8.22$, $p = 0.003$; WASO M pre = 15.3 min, SD = 18.2 min; M post = 7.2 min, SD = 12.3 min; $d = 0.51$) and from pretreatment to follow-up (M follow up = 4.8 min, SD = 6.2 min; $d = 0.70$), with medium effect sizes. TST did not significantly change across assessments.

Actigraphic sleep

In contrast to subjective sleep, very few changes were detected in actigraphic-measured sleep patterns. A medium effect was detected for changes in TST from pretreatment to posttreatment in the direction of shortening of total sleep time following sleep restriction ($b = -25.66$, $p = 0.03$; $d = 0.52$), but at follow-up TST was similar to pretreatment. WASO and SE did not change from pretreatment to posttreatment or follow-up.

Changes in Psychological Symptoms and HRQOL Outcomes

Psychological symptoms

Anxiety symptoms significantly decreased from pretreatment to posttreatment ($b = -3.32$, $p = 0.02$; PROMIS-Anx M pre = 54.2, SD = 13.6, M post = 50.3, SD = 13.1; $d = 0.29$) and this small effect was maintained at follow-up (PROMIS-Anx M follow-up = 49.3, SD = 12.8; $d = 0.37$). Similarly, improvements in depressive symptoms were significant from pretreatment to posttreatment ($b = -3.36$, $p = 0.04$; PROMIS-Dep M pre = 54.4, SD = 13.3, M post = 51.2, SD = 10.8; $d = 0.25$) and to follow-up ($b = -3.58$, $p = 0.03$; PROMIS-Dep M follow-up = 50.4, SD = 13.1; $d = 0.30$).

Health-related quality of life

Total quality of life, and physical and psychosocial quality of life did not change significantly from pretreatment to posttreatment. However, as hypothesized, significant improvements were detected from pretreatment to follow-up on total HRQOL scores ($b = 6.34$, $p < 0.0001$; Pediatric Quality of Life Inventory Total M pre = 70.7, SD = 11.3, M follow-up = 77.8, SD = 10.1; $d = -0.66$), physical quality of life (Physical QOL M pre = 74.5, SD = 14.2, M follow-up = 83.2, SD = 11.9; $d = -0.66$), and psychosocial quality of life (Psychosocial QOL M pre = 68.6, SD = 11.8, M follow-up = 74.8, SD = 11.3; $d = -0.54$). These changes reflected a medium effect size.

DISCUSSION

Preliminary findings indicate that youth with insomnia and mixed comorbid conditions receiving a brief, four-session CBT-I intervention demonstrated improvements in sleep and psychological symptoms from pretreatment to immediate posttreatment. Gains for these outcomes were maintained at 3-mo follow-up, and in addition, HRQOL outcomes showed significant improvement at follow-up. Effect sizes for most outcomes were moderate to large. Importantly, results from this trial demonstrate statistically and clinically significant improvement in insomnia symptoms. At posttreatment, nearly 30% of

youth no longer had insomnia, and 50% of youth no longer had insomnia at follow-up.

These data can be used to inform future, larger scale randomized controlled trials to more rigorously evaluate the efficacy of CBT-I for youth with insomnia and mixed comorbid conditions. A major strength of this trial is the use of a real-world clinical sample of youth with insomnia and commonly occurring psychiatric and physical health comorbidities, which enhances generalizability of our findings to clinical practice. A second strength of this trial is the use of a brief, four-session treatment format, which enhances feasibility of treatment delivery in the context of busy tertiary care clinical settings.

Similar to other trials, we also found improvements in self-reported sleep patterns via 7-day sleep diaries.[9,11,13] Consistent with the goals of CBT-I to reduce time awake in bed, youth reported significantly shorter SOL, significantly higher SE, and significantly lower WASO from pretreatment to posttreatment. These gains were maintained at 3-mo follow-up. In contrast, we did not observe similar improvements in actigraphic assessment of SE or WASO. Although several CBT-I trials have demonstrated improvement in both sleep diary and actigraphic variables, a number of studies have demonstrated changes in only sleep diary data.[31,32] Especially relevant to the current study, in Bootzin and Steven's trial of CBT-I in adolescents with comorbid insomnia and substance use, a similar phenomenon was observed in that sleep diary results indicated significant changes after treatment whereas actigraphy-measured sleep did not change.[13]

The lack of change in actigraphic sleep data compared to the moderate to large changes in sleep-diary and self-report data in our trial could be reflective of several issues related to using actigraphy in context of a brief intervention. Although used as a standard objective measure of sleep in children and adolescents, actigraphy in youth has been shown to consistently have low specificity to accurately determine WASO.[33] A number of authors have also reported low correlations between sleep diary and actigraphy estimates for sleep duration and WASO, specifically in adolescents.[25,34] These measurement issues could have led to the lack of observed gains in actigraphic variables in this study. Furthermore, some have suggested that sleep diary data is mostly indicative of the subjective sleep quality and perception of sleep whereas actigraphy provides a quantitative measure of sleep. Therefore, as CBT-I corrects dysfunctional beliefs or misperceptions about sleep relatively quickly, one might expect significant change in subjective sleep diary data even in a 4 to 6 w intervention period.[35] Sleep quantity, however, may be much slower to change, especially in light of the temporary acute sleep restriction that is experienced during the treatment phase. Nonetheless, our findings indicate that it may be important to include both subjective and actigraphic daily assessments of sleep patterns in future studies of CBT-I for this population.

In contrast to our hypothesis, youth's self-reported TST did not change with intervention. Within the CBT-I trial literature, it is not uncommon for TST to show minimal or no improvement posttreatment.[6,11] Given the brevity of the intervention period (4 to 6 w) and the focus on sleep restriction, it is not entirely surprising that changes in TST were not observed. Indeed, actigraphic sleep assessment showed shorter TST from the pretreatment to posttreatment period, which is consistent with the goals of sleep restriction (i.e., to minimize time awake in bed). It is possible that extensions in TST could be observed at later follow-up time points (e.g., 6 mo postintervention). It is also possible that additional or booster sessions may be needed to help adolescents continue to titrate their bedtimes in order to increase TST while continuing to minimize time awake in bed.

In this trial, we were also interested in identifying a signal for effects of CBT-I on psychological symptoms and HRQOL, which are important outcomes to consider in youth with psychiatric and physical health comorbidities given the potential bidirectional influences between sleep, emotional functioning, and physical health.[36,37] We found small, significant improvements in anxiety and depressive symptoms from pretreatment to posttreatment that were maintained at follow-up. We also found significant improvements in HRQOL (Total scores, Psychosocial, and Physical subscales) from pretreatment to 3-mo follow-up. These data add to a growing literature base on the downstream effects of changes in sleep on subsequent health-related outcomes and support the idea that these effects may take several months to observe. Findings suggest that future, large-scale randomized controlled trials of CBT-I for this population should examine effects of CBT-I on psychological symptoms and HRQOL outcomes over a longer follow-up period.

The findings of this study should be considered in the context of several limitations. As a pilot trial with a single-arm design with no control group, it is challenging to untangle treatment effects with the effect of time alone; however, we did use advanced analytic techniques to account for the effects of time. The sample size was small, so replication in a larger sample and across multiple sites would improve and confirm generalizability. Additionally, comorbidities were established based on parent report and medical record review. A more rigorous method appropriate for a future trial would be to administer a diagnostic interview to participants to establish behavioral and emotional comorbidities. Youth were permitted to receive a range of other treatments including medications for sleep and psychiatric symptoms during this trial, making it possible that some treatment effects were derived from interventions outside of the CBT-I protocol. Future trials should also examine a more complete range of possible covariates, and consider incorporating medication changes as an outcome variable.

The findings from this study make the case for the importance of assessing insomnia symptoms in youth with emotional and physical health problems. Furthermore, because of the high frequency of comorbidities that occur with and exacerbate insomnia, sleep clinicians should be prepared to coordinate care with practitioners across other specialties or disciplines to provide effective care that targets the transdiagnostic properties of insomnia in adolescents. CBT-I has been well established in adults as a first-line treatment option for both primary insomnia and insomnia in comorbid populations, and this study contributes to the burgeoning literature of the efficacy of CBT-I in adolescents. Of note, our study demonstrated that even a very brief course of CBT-I can improve adolescent insomnia symptoms, suggesting that CBT-I intervention could easily be

incorporated into existing evidence-based interventions for children with chronic medical and mental health conditions.

As most of the trials of CBT-I in adolescents are small scale, there is a clear need for a large, rigorously designed randomized controlled trial, parallel to what has been done in adult populations. Furthermore, the field would greatly benefit from efforts to standardize what treatment components constitute CBT-I, as there is great variance across protocols.[38] Additionally, greater attention is needed to study more accessible forms of delivering CBT-I to youth. Viable options for widening the reach and accessibility of CBT-I include internet and mobile applications. Internet-delivered CBT-I already has some support of efficacy, but additional mobile- and app-delivered programs are just now under development.[39,40] Additional replications of these treatment modalities and their comparison to in-person CBT-I are needed in order to better understand which modality is best suited for individual patients.

ABBREVIATIONS

ADHD, attention deficit hyperactivity disorder
ASWS-R, Adolescent Sleep Wake Scale-Revised
CBCL, Child Behavior Checklist, School-Age version
CBT-I, cognitive behavioral therapy for insomnia
CI, confidence interval
HRQOL, health-related quality of life
ISI, Insomnia Severity Index
OTC, over-the-counter
PedsQL, Pediatric Quality of Life Inventory
PROMIS, Patient Reported Outcomes Measurement Information System
PSQ, Pediatric Sleep Questionnaire
SBD, sleep-disordered breathing
SD, standard deviation
SE, sleep efficiency
SOL, sleep onset latency
TST, total sleep time
WASO, time awake after sleep onset

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Address correspondence to: Tonya M. Palermo, PhD, Seattle Children's Research Institute, M/S CW8-6, PO Box 5371, Seattle, WA 98145; Tel: (206) 884-4208: Fax: (206) 985-3562; Email: tonya.palermo@seattlechildrens.org

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