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Hybrid Cognitive Behavioral Therapy Intervention for Adolescents with Co-Occurring Migraine and Insomnia: A Single-Arm Pilot Trial

Emily F. Law, PhD[1,2], **See Wan Tham, MB, BS**[1,2], **Rachel V. Aaron, PhD**[2], **Joanne Dudeney, PhD**[2], and **Tonya M. Palermo, PhD**[1,2]

[1]Department of Anesthesiology & Pain Medicine, University of Washington School of Medicine & Seattle Children's Hospital, Seattle, WA, USA

[2]Center for Child Health, Behavior & Development, Seattle Children's Research Institute, Seattle, WA, USA

Abstract

Objective—This study aimed to evaluate feasibility and acceptability of a hybrid cognitive behavioral therapy intervention for adolescents with co-occurring migraine and insomnia.

Background—Many youth with chronic migraine have co-occurring insomnia. Little research has been conducted to evaluate behavioral treatments for insomnia in youth with migraine.

Design and Methods—We conducted a single arm pilot trial to evaluate the feasibility and acceptability of delivering cognitive-behavioral therapy for insomnia to 21 youth (mean age 15.5, standard deviation 1.6) with co-occurring chronic migraine and insomnia. Adolescents completed up to six individual treatment sessions over six to twelve weeks, and one booster session one month later. Assessments included a prospective 7-day headache and sleep diary, and self-report measures of insomnia, sleep quality, sleep habits, and activity limitations at pretreatment, immediate posttreatment, and three-month follow-up.

Results—Adolescents demonstrated good treatment adherence and families rated the intervention as highly acceptable. Preliminary analyses indicated improvements from pre-treatment to post-treatment in primary outcomes of headache days ($M = 4.7$, $SD = 2.1$ vs. $M = 2.8$, $SD = 2.7$) and insomnia symptoms ($M = 16.9$, $SD = 5.2$ vs. $M = 9.5$, $SD = 6.2$) which were maintained at three-month follow-up ($M = 2.7$, $SD = 2.8$; $M = 9.3$, $SD = 5.0$, respectively). We also found improvements in secondary outcomes of pain-related activity limitations as well as sleep quality, sleep hygiene, and sleep patterns.

Conclusions—These preliminary data indicate that hybrid cognitive-behavioral therapy is feasible and acceptable for youth with co-occurring chronic migraine and insomnia. Future

Corresponding author: Emily F. Law, PhD, Center for Child Health, Behavior & Development, Seattle Children's Research Institute, 2001 8th Ave, Seattle, WA, USA 98121. Phone: 206-884-1197, emily.law@seattlechildrens.org.

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randomized controlled trials are needed to test treatment efficacy on migraine, sleep, and functional outcomes.

Keywords

Cognitive-behavioral therapy; insomnia; headache; migraine; child; adolescent

Introduction

Migraine and insomnia are among the most common reasons adolescents present to pediatric health-care providers [1,2]. These disorders frequently co-occur; up to 50% of adolescents with migraine report insomnia symptoms [3–5]. When considered separately, chronic migraine (defined as migraine ≥15 days per month for ≥3 months) and insomnia (characterized by difficulties falling or staying asleep with associated daytime impairment) in youth are linked to poor quality of life, anxiety and depression, and functional disability [1,6].

A growing body of research suggests that insomnia may contribute to the onset, maintenance and progression of migraine and other primary headache disorders. In cross-sectional studies, insomnia has been associated with more frequent and disabling headache [3,4]. Longitudinal studies of adolescents and adults suggest that insomnia increases risk for the persistence of headache over time as well as progression from episodic to chronic headache status [7,8]. Temporal daily associations between sleep and headache have revealed that poor sleep is a strong predictor of the onset and severity of next-day headache in adolescent and adult samples [9,10]. Taken together, these data suggest that insomnia may be a promising treatment target for interventions that aim to reduce headache frequency and related disability [11,12].

Cognitive-behavioral therapy for insomnia (CBT-I) is the frontline treatment for insomnia in adults [13] and numerous randomized controlled trials (RCTs) have demonstrated efficacy for improving sleep outcomes[14]. There have been a few RCTs which have demonstrated benefit of CBT-I for improving sleep in adolescents with insomnia [15–18], however, most have excluded youth with co-morbid conditions. As an exception, our research team recently demonstrated feasibility and preliminary efficacy of CBT-I for improving sleep in youth with insomnia and co-occurring psychiatric and physical health conditions [19]. Research is needed to understand the feasibility and efficacy of insomnia treatment for youth with chronic migraine.

CBT-I has demonstrated efficacy for improving sleep in adults with chronic migraine [20] and other chronic pain conditions [21,22]. However, effects on pain have been inconsistent. It is possible that more favorable results could be achieved with a hybrid CBT intervention that simultaneously targets headache and insomnia. Hybrid CBT has demonstrated feasibility and acceptability in two small pilot studies of adults with chronic pain and insomnia [23,24]. There has also been one randomized controlled trial comparing hybrid CBT to CBT for pain management in adults with osteoarthritis and insomnia, which found superior efficacy for hybrid CBT on both sleep and pain outcomes [25]. Research is needed to determine whether hybrid CBT would be feasible and beneficial for youth. Indeed, CBT for pain management is a well-established intervention for youth with headache and has demonstrated benefit for

reducing headache frequency and disability in large clinical trials[26] and meta-analyses[27,28]. However, most CBT for pain management protocols either do not include sleep as a treatment target, or provide very brief (≤1 session) sleep hygiene education[29].

To address this gap, we developed a hybrid cognitive-behavioral therapy intervention (hybrid CBT) for adolescents with chronic headache and co-occurring insomnia and evaluated whether the intervention was feasible to implement and acceptable to patients in a single arm pilot clinical trial. We hypothesized that treatment feasibility would be demonstrated through favorable study recruitment/enrollment statistics, session attendance, therapist ratings of participants' treatment engagement, and completion of study assessments. We also expected that adolescents and parents would rate the intervention as highly acceptable on self-report measures. To inform sample-size estimates for future trials, we also conducted preliminary analyses examining changes in headache frequency and insomnia symptoms (primary outcomes), as well as pain intensity, pain-related activity limitations, sleep quality, sleep hygiene, and sleep patterns (secondary outcomes) from pre- to posttreatment and three-month follow-up.

Methods

Study Design

Adolescents were recruited over a 12-month period (9/2016 – 9/2017) from a pediatric neurology clinic and a pediatric pain clinic at an academic medical center in the Pacific Northwest. Given the predominant focus on feasibility and acceptability, we chose to use a pre-post single arm trial design with three measurement points (baseline, immediate posttreatment, and 3-month follow-up). All participants received up to six sessions of hybrid CBT over a period of six to 12 weeks as well as a booster session one month after completing treatment. For our primary aim to evaluate feasibility and acceptability of the treatment protocol, our target enrollment was 20 participants for this pilot trial. The trial was terminated as planned after all three-month follow-up assessments were completed. Our Institutional Review board approved this study. Parents provided informed consent and adolescents provided assent prior to the initiation of study procedures. This trial was registered at clinicaltrials.gov: NCT03137147.

Participants

Eligible participants met the following criteria: 1) 11 to 17 years old (representing peak prevalence of chronic headache in childhood [30, 31]); 2) evaluated by a medical provider in the pediatric neurology or pain clinics; 3) diagnosed with chronic migraine or tension-type headache by a pediatric neurologist or pediatric pain physician using the *International Classification of Headache Disorders*, 3rd Edition Beta (ICHD-IIIβ) [32] criteria, 4) headache frequency of 15 or more days in the past month based on a telephone administered screening, and 5) met research diagnostic criteria for insomnia based on a telephone administered screening (self-reported difficulty initiating or maintaining sleep 3 or more nights during the past month and at least one daytime sleep-related problem). Potential participants were excluded for any of the following reasons: 1) serious co-morbid chronic medical condition (e.g., cancer, diabetes), 2) did not read or speak English, 3) active

psychosis or suicidal ideation, or 4) previous psychological treatment for insomnia or headache in the six months prior to screening.

Procedures

Potential participants were identified by providers during clinic visits and were given a study flyer. Providers requested permission to share contact information with the study staff. Potentially eligible families underwent a telephone administered screening twice over a six-week period to determine whether they met study eligibility criteria. Headache frequency was determined based on responses to the following question: "On how many days in the past month did you have a headache or migraine?" The presence of insomnia was determined using a pediatric version of the Research Diagnostic Criteria for Insomnia [19,33]. Adolescents and parents completed informed consent and assent prior to initiating any study procedures.

At pretreatment, parents completed online questionnaire measures assessing demographics, adolescent emotional and behavioral functioning (the Child Behavior Checklist; CBCL), and sleep disordered breathing (the Pediatric Sleep Questionnaire). At all three assessment time points, adolescents completed online questionnaire measures about pain-related activity limitations and sleep, as well as a prospective online 7-day headache and sleep diary. All questionnaire measures and diaries were completed privately in patients' homes via the secure web-based application REDCap [34]. All assessment procedures were administered by a research assistant who was not involved in treatment delivery.

Following completion of the pretreatment assessment, adolescents and their parents scheduled up to 6 treatment sessions over a 6–12 week period, as well as 1 booster session scheduled 1 month after the final treatment visit. Each session was 60–90 minutes in duration. All sessions were completed in person at our research institute. Families were provided with gift cards for completion of assessments ($80/family) and transportation/parking was reimbursed ($20/visit) for participation in intervention visits.

Hybrid Cognitive-Behavioral Therapy for Chronic Headache and Insomnia (Hybrid CBT)

Hybrid CBT interventions have been developed to simultaneously target two or more conditions and have been studied in a variety of areas. Specifically in the context of pain conditions, hybrid CBT simultaneously targets co-moribid conditions known to impact the onset and maintenance of chronic pain [35]. Per the guidelines outlined by Tang (2017), we developed our hybrid CBT protocol by identifying treatment components from existing evidence-based treatment manuals for CBT for insomnia and CBT for pain management[19,29,36], reviews on treatment effectiveness for both interventions [27,37], and research on shared mechanisms between headache and sleep disturbance [3,4,7–10]. For this study, treatment materials were adapted from an existing CBT-I protocol for adolescents with insomnia [19] and an existing CBT protocol for adolescents with chronic pain[38]. A research team composed of pediatric psychologists and a pain physician with expertise in pain management, headache, sleep, insomnia, cognitive-behavioral therapy, and parent and family interventions adapted the treatment materials.

Our hybrid CBT protocol includes three core treatment components from the published CBT-I protocol[19]: 1) sleep hygiene education, which promotes healthy sleep habits (e.g., avoiding caffeine, using an alarm clock); 2) stimulus control, which re-associates the bed with sleep; and 3) sleep restriction, which increases sleep efficiency by limit time spent awake in bed. Based on our prior research evaluating effective treatment components of CBT for pediatric headache [29], we included four core components from the published CBT pain management protocol[38]: 1) headache education, 2) relaxation training, 3) pleasant activity scheduling and positive thought tracking, and 4) parent operant training to reinforce adolescent skills practice and reduce inadvertent reinforcement of pain behaviors (i.e., praise vs. ignoring, reward systems).

We retained two optional treatment modules from the original CBT-I protocol (anxiety management and fatigue management), and adapted the optional treatment content to include a module on activity pacing [38]. As in the original protocol, optional treatment modules could be delivered at any point based on the therapist's clinical judgement. Treatment materials included a therapist manual, a parent manual, an adodlescent manual, and skills worksheets. Treatment materials were reviewed and revised by the research team (available from the first author on request). A brief summary of the treatment content is provided in Table 1.

Based on study therapist feedback from a prior trial of CBT-I for youth [19], we extended the number of treatment sessions from four to six and added a booster session. Adolescents reported on sleep patterns in an electronic daily diary during the intervention period, which study therapists used to calculate average sleep and wake times and sleep efficiency at each session. These data were used to titrate sleep restriction schedules each week. Parents met individually with the study therapist in session 1 and session 4 to receive operant training. Parents were included in all or part of the remaining sessions depending on the developmental needs of the adolescent and the therapist's clinical judgement. Session structure was flexible so that content not covered in one session could be addressed in the next session. Homework was assigned each week to titrate sleep restriction and facilitate skills practice.

Therapist Qualifications, Training, and Treatment Fidelity

Treatment was delivered by two trained postdoctoral psychology fellows who had experience in CBT for youth with chronic pain. Study therapists were trained via a 2-hour in-person workshop that included didactic instruction in pediatric headache and sleep problems, training in the intervention protocol, and discussion of case examples. To support treatment fidelity, the therapist manual was scripted and included structured worksheets to deliver skills training. Fidelity was monitored in weekly supervision using a case conference format led by the first author (a licensed pediatric psychologist with prior experience in hybrid CBT). Corrective feedback was provided as needed to ensure treatment delivery was consistent with the manual.

Measures

Pretreatment sample characteristics—Parents reported on their relationship to the adolescent, marital status, education, household income, age, and race. Parent's also reported on their child's age, race, and current prescription and over-the-counter (OTC) medication use.

To screen for sleep-related breathing disorders, parents completed the 22-item Sleep-Related Breathing Disorders Scale of the Pediatric Sleep Questionnaire [39]. Higher scores indicate a greater risk of sleep-related breathing problems. Scores greater than 0.33 are considered to be clinically elevated. The Pediatric Sleep Questionnaire has demonstrated reliability and validity [39] and has been used in prior studies of youth with co-morbid insomnia and medical symptoms [19].

Parents also completed the 120-item Child Behavior Checklist (CBCL) to screen for adolescent emotional and behavioral concerns [40]. We examined T-scores for the internalizing symptoms, externalizing symptoms, and total problems scales. Higher scores are indicative of greater symptoms, and T-scores greater than 63 are considered clinically elevated. The CBCL has well-established reliability and validity, and has been used in prior studies of youth with chronic medical conditions including headache [41].

Treatment feasibility—Treatment feasibility was assessed using three metrics: 1) study recruitment/enrollment statistics, 2) treatment adherence as demonstrated by session completion, missed/rescheduled treatment sessions, and therapist ratings of participants' homework completion, motivation to learn, understanding of the treatment principles, and rapport on a 0–10 Likert scale (completed at the end of each session and averaged across sessions for analysis), and 3) completion of study assessments.

Treatment acceptability—Parents and adolescents completed an adapted version of the Treatment Evaluation Inventory, Short Form [42] (TEI-SF) at immediate posttreatment. The TEI-SF includes 9 items and was adapted to be specific to pediatric headache and sleep problems (e.g., "I find this treatment to be an acceptable way of dealing with children's headache and sleep problems"). Items are scored on a 5-point Likert scale ranging from 1 ("strongly disagree") to 5 ("strongly agree") and are summed for a total score (range 9 to 45). Scores greater than 27 indicate "moderate" treatment acceptability [42]. The TEI-SF has been used in prior studies of CBT for youth with insomnia [19] and youth with headache [43].

Headache outcome measures—Our primary headache outcome was headache frequency (number of days with headache). Adolescents completed an electronic 7-day daily diary at each assessment time point, and reported on whether or not they had a headache each day. The total number of days with headache across the 7-day diary period was used in analyses. Adolescents also reported on daily headache pain intensity using an 11-point numerical rating scale (NRS) ranging from 0 ("no pain") to 10 ("worst pain") [44]. Mean pain intensity ratings across the 7-day period were used in analyses. This electronic 7-day daily diary has been used successfully to assess headache frequency and pain intensity in prior studies of adolescents with headache [43].

Adolescents reported on pain-related activity limitations using the Child Activity Limitations Interview-21 (CALI-21) [45]. The CALI-21 includes 21 items rated on a 5-point Likert scale ranging from 0 ("not very difficult") to 4 ("extremely difficult"). Items are summed to create a total score, with higher scores representing greater difficulty with activity participation due to pain. The CALI-21 has been widely used to assess activity limitations in youth with chronic pain conditions including headache and has excellent psychometric properties [43,45].

Sleep outcome measures—Our primary sleep outcome was insomnia symptoms, which we measured using the 7-item adolescent self-report Insomnia Severity Index [46] (ISI). Items are summed to create a total score ranging from 0 to 28. Higher scores indicate more severe insomnia symptoms. The ISI has demonstrated good reliability and validity [46] and has been previously used to assess insomnia symptoms in adolescents with chronic pain conditions [19].

We assessed sleep quality using the 33-item adolescent self-report Adolescent Sleep Wake Scale (ASWS) [47]. Items are scored on a 6-point Likert scale ranging from 1 ("always") to 6 ("never"). The total sleep quality score was used in analyses (range 1–6), with higher scores indicating better sleep quality. This measure has acceptable reliability and validity [47], and has been widely used to assess sleep quality in pediatric populations [48].

Adolescents also completed the Adolescent Sleep Hygiene Scale [47] (ASHS) to assess sleep hygiene behaviors over the past month. The ASHS includes 24-items rated on a 6-point Likert scale ranging from 1 ("always") to 6 ("never"). The total sleep hygiene score was used in analyses (range 24–144), with higher scores indicating better sleep hygiene. The ASHS has demonstrated acceptable psychometric properties [47].

Sleep patterns were assessed using the electronic 7-day daily diary, where adolescents reported on sleep patterns from the previous night. Daily sleep diaries are a low-cost and accurate method of recording sleep patterns in adolescents [49], and have been used to assess sleep patterns in prior studies of youth with insomnia and medical comorbidities [19]. Across each 7-day assessment, average sleep efficiency, WASO (number of minutes awake after sleep onset), sleep onset latency, and total sleep time were extracted for analyses. Sleep efficiency was calculated as the ratio of estimated total sleep time divided by the sleep period, and is reported as a percentage, with values closer to 100 indicating more time asleep and less time awake in bed.

Adverse events—Participants were asked about adverse events due to study procedures at each assessment period in an open-ended manner.

Data Analysis Plan

Analyses were conducted using SPSS v. 25 (IBM Corp, 2015. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp). We conducted descriptive statistics to summarize demographic and pretreatment clinical characteristics of the sample as well as quantitative ratings of treatment feasibility. To inform sample-size estimates for future trials, we conducted preliminary analyses to evaluate change over time in treatment outcomes using multilevel modeling (MLM). Outcome measures were scored and missing data

addressed per published scoring manuals, and all available data were included in analyses. MLM accounts for repeated measures within subjects, accommodates missing data, and includes all available data in analyses. Linear growth model specification procedures were based on Shek & Ma [50]. Using a random intercepts model, time was treated as a categorical variable and pretreatment values were specified as the reference point so that results were interpreted as change from pretreatment to immediate posttreatment and pretreatment to follow-up. Separate linear growth models were conducted for each outcome measure. The beta, p value, and effect size (Cohen's *d*) are reported for each outcome. A significance level of $p = .05$ was used in this pilot trial. Effect size estimates can be interpreted as follows: $d = 0.20$ indicates a small effect, $d = .50$ indicates a medium effect, and $d = .80$ indicates a large effect [51]. As an exploratory analysis, we conducted a Pearson correlation to examine the association between headache frequency change scores from pretreatment to follow-up with insomnia symptoms change scores from pretreatment to follow-up.

Results

Participants

Pretreatment descriptive statistics for the sample are provided in Table 2. Participants were 21 adolescents between the ages of 11–17 years (M = 15.5, SD = 1.6) and their parents. Adolescents were predominantly female (81%) and white (81%), as were their parents (90.5% female, 95.2% white). All of the adolescents had a diagnosis of chronic migraine (100%) per their referring physician. On the Pediatric Sleep Questionnaire, none of the adolescents had clinically elevated symptoms of sleep-disordered breathing. Parent-reported CBCL scores indicated that two-thirds of the sample had clinically elevated Internalizing Problems and over one-third of the sample had clinically elevated Total Problems scores. Per parent report, most youth (90.5%) were using prescription and over the counter medications; most commonly melatonin (42.8%), topiramate (23.8%), gabapentin (19.0%), and amitriptyline (14.2%). Means and standard deviations of headache and sleep outcomes at each assessment time point are presented in Tables 3 and 4, respectively.

Treatment Feasibility

Study recruitment and enrollment—Potential participants were recruited sequentially in the order they were referred. Recruitment occurred over 12 months and resulted in 80 referrals. Twenty of the referred patients were unable to be reached during the recruitment period. Of the 60 participants who could be reached, 23 participants did not meet research criteria for insomnia on screening and an additional 16 participants declined due to distance from our research institute. The remaining 21 participants enrolled in the study and were included in analyses (overall recruitment/enrollment rate = 35%).

Treatment adherence—Four of the 21 enrolled families chose to discontinue study participation during the trial due a major health event (i.e., injury or illness) that was unrelated to the study procedures. One family discontinued study participation after completing the pretreatment assessment but prior to starting the intervention, and the remaining three families discontinued study participation after completing the pretreatment assessment and one to three treatment sessions. Of the remaining 17 participants, 100%

completed all six treatment sessions and most (n = 13, 75%) completed the booster session. Families who did not complete treatment did not differ from completers on demographics or pretreatment characteristics.

Participants were adherent to scheduled treatment sessions with few missed sessions (range 0 – 2; M = 0.14, SD = .48) and few rescheduled sessions (range 0–4; M = 1.14, SD = 1.32). Therapists rated participants as highly compliant with homework completion (M = 9.50/10, SD = .74), motivated (M = 9.52/10, SD = .62) and understanding of the treatment principles (M = 9.59/10, SD = .76). Therapists also reported having strong rapport with participants (M = 9.42/10, SD = 1.02).

Assessment completion—Assessment completion was high. All 21 enrolled dyads completed the pretreatment assessment (100%). As described above, 4 families subsequently withdrew from the trial, and all of the remaining 17 dyads (81%) completed the posttreatment and follow-up assessments including self-report questionnaires and prospective 7-day diaries. On average, participants completed 5 of 7 diary days at each assessment time point.

Treatment Acceptability

Parents and adolescents found the intervention to be highly acceptable (TEI-SF M parents = 40.67, SD = 4.48; TEI-SF M adolescents = 39.13, SD = 5.10). Parent and adolescent mean TEI scores exceeded the threshold mean of 27 indicating “moderate” treatment acceptability [42]

Changes in Headache and Sleep Outcomes

Primary headache outcome: Headache frequency—Adolescents reported a significant reduction in headache frequency on the prospective 7-day diary from pretreatment to posttreatment (b =−1.91, p = .004, d = .84) which was maintained at follow-up (b = −2.16, p = .002, d = .87). These were large effects. Twelve of the 17 participants (70.5%) achieved at least a 50% reduction in headache frequency at follow-up.

Secondary headache outcomes: Headache pain intensity and activity limitations—Headache pain intensity did not change from pretreatment to posttreatment (b = .40, p = .25, d = −.28) or follow-up (b = −.15, p = .68, d = −.28). Activity limitations were stable from pretreatment to posttreatment, and significantly improved at follow-up, with a medium effect size (b = −11.57, p = .029, d = .69). Means and standard deviations of headache outcomes at each assessment time point are presented in Table 3.

Primary sleep outcome: Insomnia symptoms—Adolescents reported a significant and large reduction in insomnia symptoms from pre- to posttreatment (b = −7.32, p = .001, d = 1.31), which was maintained at follow-up (b = −7.60, p = .001, d = .50).

Secondary sleep outcomes: Sleep quality, sleep hygiene, and sleep patterns —Sleep quality and sleep hygiene significantly improved from pretreatment to posttreatment (b = .74, p = .001, d = −1.32; b = .51, p = .001, d = −1.09, respectively), with medium to

large effect sizes that were maintained at follow-up ($b = .67$, $p = .002$, $d = -1.06$; $b = .42$, $p = .008$, $d = -.73$, respectively).

Adolescents generally reported improvements in their sleep patterns as assessed by the prospective 7-day diary. Adolescents reported a significant improvement in sleep efficiency from pretreatment to posttreatment ($b = 9.31$, $p = .008$, $d = -.60$) which was maintained at follow-up ($b = 13.51$, $p = .001$, $d = -.95$). These were medium to large effect sizes. Adolescents reported significantly lower WASO and shorter SOL from pretreatment to posttreatment ($b = -22.98$, $p = .012$, $d = .73$; $b = -38.28$, $p = .015$, $d = .71$ respectively) which were medium effects, and these improvements were sustained at follow-up ($b = -23.37$, $p = .01$, $d = .74$; $b = -41.87$, 15.21, $d = .67$). Total sleep time was stable from pretreatment to posttreatment ($b = 7.53$, $p = .776$, $d = -.02$) and increased significantly from pretreatment to follow-up ($b = 89.85$, $p = .003$, $d = -.56$) which was a medium effect. Means and standard deviations of sleep outcomes at each assessment time point are presented in Table 4.

Exploratory analysis—Improvements in headache frequency from pretreatment to follow-up were highly correlated with improvements in insomnia symptoms from pretreatment to follow-up (r = 0.50).

Adverse Events

Four families reported serious health-related events during the trial (i.e., concussion, surgery); these were unrelated to study procedures.

Discussion

Our preliminary findings demonstrate feasibility and acceptability of a six-session hybrid CBT intervention for adolescents with chronic migraine and co-occurring insomnia. The majority of participants completed assessments, adhered to scheduled treatment visits, and completed homework assigned in therapy. Therapists rated participants as motivated to learn, demonstrating good understanding of the treatment principles, and having strong rapport. Adolescents and parents rated the treatment as highly acceptable. To our knowledge, this study is the first to deliver a hybrid CBT intervention targeting chronic headache and co-occurring insomnia in adolescents.

Although our trial was open to adolescents with chronic migraine and chronic tension-type headache, all of the participants who enrolled in our study had a diagnosis of chronic migraine. This may reflect the higher prevalence of co-morbid insomnia symptoms in youth with migraine compared to youth with other primary headache disorders[5]. Our findings demonstrate that we were able to recruit, screen, and deliver treatment to these youth, including those who had significant impairments in their daily activity participation and psychiatric functioning.

To inform future trials, we conducted preliminary analyses examining change in headache and sleep outcomes from pre- to posttreatment and 3-month follow-up. Given the small size of this single-arm pilot study, these results should be interpreted cautiously. In our small

sample, we found significant and sustained improvements in our primary outcomes of headache frequency and insomnia symptoms. Most youth who received the intervention (70.5%) achieved at least a 50% reduction in headache frequency during the study period. Adolescents also reported significant improvements in sleep quality and sleep hygiene from pretreatment to posttreatment which were maintained at follow-up. We found that activity limitations significantly improved at 3-month follow-up, following sustained improvements in headache frequency and sleep. Effect sizes for most outcomes were medium to large.

We also examined sleep patterns using a prospective 7-day diary. Consistent with the goals of CBT-I, we found that sleep efficiency significantly increased while sleep onset latency and WASO significantly decreased during the study period. We also found that diary-reported total sleep time increased by about 60 minutes from pretreatment to three-month follow-up. Other trials of CBT-I in adolescents with comorbid conditions have demonstrated similar improvements in diary-reported sleep patterns and questionnaire measures of sleep [19]. In our exploratory analysis, we found that improvements in headache frequency were highly correlated with improvements in insomnia symptoms.

Strengths and Limitations

A strength of this study was the use of a brief six-session treatment format, which may support feasibility and efficiency of implementation in busy primary and secondary care clinics. In standard practice, for example, CBT for headache and insomnia are typically delivered in separate courses of 4–8 sessions [3852]. Hybrid CBT, in contrast, provides treatment for two problems simultaneously and requires fewer points of contact for care, which has the potential to address known barriers to care related to cost and distance from trained professionals[53]. Hybrid CBT also enables clinicians to match treatment components to patient's specific treatment needs[35] (i.e., co-occurring conditions), and represents a potential step towards individualized medicine for youth with migraine.

That being said, findings from our study should be considered in light of several limitations. Our sample size was small and our trial did not include a control group. We cannot determine whether improvements in headache and sleep outcomes occurred because of hybrid CBT, other treatments received during the trial (e.g., medications), and/or the passage of time. Many youth were taking medications during the trial including melatonin, topiramate, gabapentin, and amitriptyline which may have impacted results and should be considered in future studies with larger sample sizes that may be able to tease apart differences by medication status in response to treatment. In addition, we used a 7-day prospective diary to measure headache frequency in this pilot trial. It is possible that a different pattern of results could emerge with a longer assessment period (e.g., 28-day headache diary [54]).

Future Directions

Our recruitment/enrollment rate was 35%, and distance from our research institute was cited as a primary reason potential participants delined to enroll in our trial. To improve accessibility, we encourage the consideration of technology (e.g., mobile app, website) to implement intervention, which could address barriers related to distance. Technology-

delivered CBT interventions have previously demonstrated efficacy for children and adolescents with chronic pain [55] and insomnia[18]. We believe that hybrid CBT could be successfully delivered via technology, and this is an important direction for future research.

There is a clear need for large RCTs to definitively evaluate efficacy of hybrid CBT. In addition to primary co-end points of headache frequency and insomnia symptoms, we encourage assessment of additional secondary outcome domains such as psychiatric symptoms and parenting behaviors. Future trials will need to carefully tease apart the impact of medications for headache and sleep on response to intervention. This could be accomplished by directly comparing CBT vs medication treatment arms and their combination. For example, prior large RCTs have demonstrated superior efficacy of CBT for pain management plus amitriptyline compared to amitriptyline only for adolescents with chronic migraine [26]. Large scale RCTs may also provide opportunities to further elucidate shared cognitive or behavioral mechanisms between headaches and sleep disturbance, such as examining treatment processes that change during treatment (e.g., self-efficacy, coping) and their influence on treatment outcomes.

We are also aware of several small trials in adults and children with headache which have demonstrated efficacy of brief sleep hygiene education alone for reducing migraine frequency [56,57]. It is possible that some youth may benefit from brief sleep hygiene education, whereas others may require more intensive treatment such as hybrid CBT or a combination of hybrid CBT with medication management. To develop adaptive interventions that can be adjusted based on patient's individual treatment needs, we encourage consideration of novel approaches to clinical trial designs such as Sequential Multiple Assignment Randomized Trial (SMART) [58,59] approaches which can be used to determine optimal sequencing of treatment components (e.g., what is the ideal sequence for delivering sleep hygiene education, hybrid CBT, and medication management and for which patients?).

Conclusions

Our findings have several clinical implications. First, neurologists and pediatric pain physicians should be prepared to screen for sleep disturbances in adolescents with chronic headache and consult with sleep medicine specialists when needed. Second, our findings indicate that it is feasible to deliver hybrid CBT to youth with chronic migraine and co-occurring insomnia and that families found hybrid CBT to be highly acceptable and satisfactory.

Insomnia is among the most common comorbid conditions experienced by youth with chronic migraine. Hybrid CBT interventions targeting both headache and insomnia have the potential to improve outcomes for these youth while also improving efficiency of treatment delivery. Hybrid CBT is deserving of further attention by clinicians and researchers.

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Abbreviations

CBT	cognitive-behavioral therapy
CBT-I	cognitive-behavioral therapy for insomnia
RCT	randomized controlled trial
WASO	minutes awake after sleep onset

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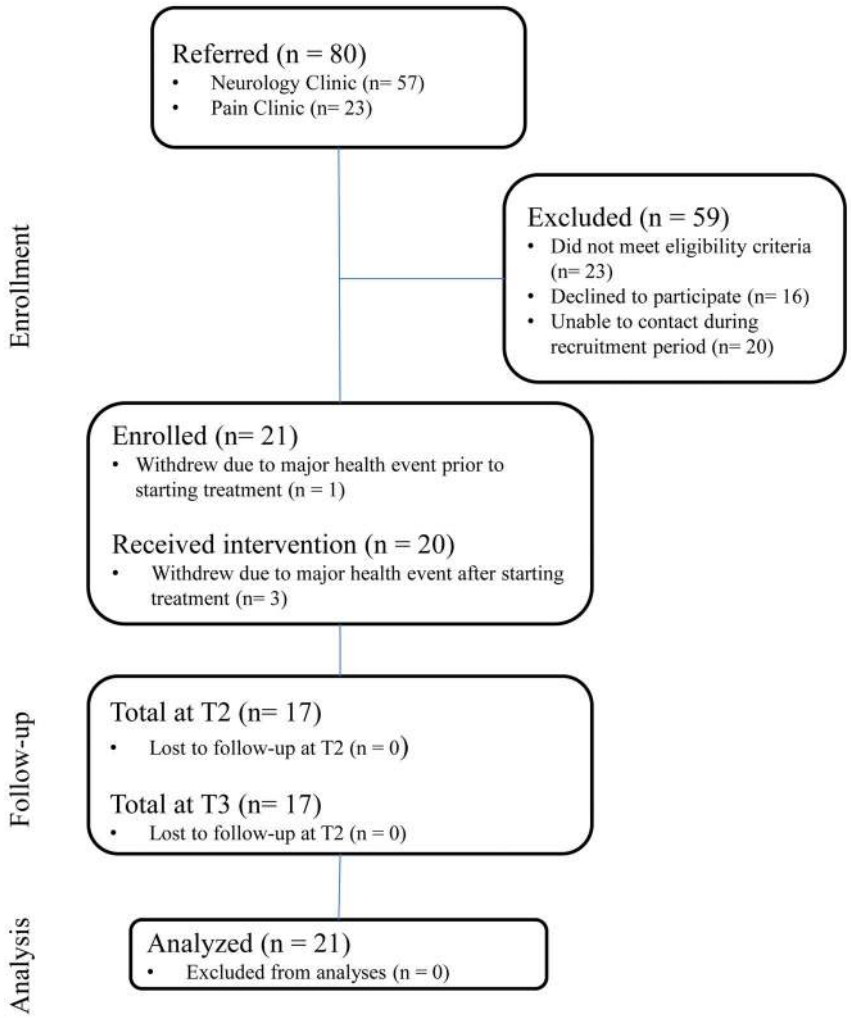

Figure 1.

Table 1

Treatment Description: Hybrid CBT for Adolescents with Co-Occurring Headache and Insomnia

Session	Goals and content
1	• Establish rapport by obtaining sleep and headache history. • Provide headache and sleep education, and orient to treatment. • Begin training in sleep hygiene; select 2 healthy sleep habits for homework. • Introduce parental operant strategies (praise vs. ignoring).
2	• Review sleep diary and orient to use of diary data for sleep schedule. • Review success/barriers with sleep hygiene homework. • Introduce sleep restriction. Develop new sleep schedule using sleep diary data. • Introduce stimulus control. Develop nesting place and wind down routine. • Introduce relaxation methods for pain management. Training in deep breathing, plan for daily practice.
3	• Review sleep diary and success/barriers with homework. • Set new sleep schedule based on sleep diary. Revise stimulus control plans as needed. • Develop wake up routine. • Training in mindful breathing, plan for daily practice.
4	• Review sleep diary and success/barriers with homework. • Set new sleep schedule based on sleep diary. Revise stimulus control plans as needed. • Continue parent operant training (reward systems).
5	• Review sleep diary and success/barriers with homework. • Set new sleep schedule based on sleep diary. Revise stimulus control plans as needed. • Training in pleasant activity scheduling and positive piggy bank, plan for daily practice. • Training in progressive muscle relaxation, plan for daily practice.
6	• Review treatment skills, plan for maintenance and relapse prevention.
Booster	• Review treatment skills, plan for maintenance and relapse prevention.
Optional Interventions	• Anxiety management: Positive self-talk, scheduled worry time, cognitive restructuring • Activity pacing

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Session	Goals and content
	• Fatigue management

Table 2

Adolescent and parent demographic characteristics at pre-treatment (n=21).

Adolescent characteristics	
Age, M (SD)	15.5 (1.6)
Sex (female), n (%)	17 (81%)
Race, n (%)	
Anglo-American	17 (81%)
Black or African-American	1 (4.8%)
Asian	1 (4.8%)
American Indian or Alaskan Native	1 (4.8%)
Other	1 (4.8%)
Headache diagnosis, n (%)	
Chronic migraine	21 (100%)
Chronic tension-type	0 (0%)
Medications, n (%)	
Antidepressants	5 (23.8%)
Anticonvulsants	2 (9.5%)
Prescription pain medications	10 (47.6%)
OTC pain medications	15 (71.4%)
Prescription sleep medications	4 (19%)
OTC sleep medications	7 (33.3%)
Other prescription medications	14 (66.7%)
Other OTC medications	9 (42.9%)
CBCL Total problems, M (SD)	59.10 (10.03)
Above clinical cutoff, n (%)	8 (38.1%)
CBCL Internalizing problems, M (SD)	64.52 (11.72)
Above clinical cutoff, n (%)	12 (66.7%)
CBCL Externalizing problems, M (SD)	48.52 (10.73)
Above clinical cutoff, n (%)	2 (9.5%)
PSQ Sleep disordered breathing M, (SD)	.13 (.06)
Above clinical cutoff, n (%)	0 (0%)
Parent characteristics	**M (SD) or n (%)**
Age, M (SD)	49.9 (6.8)
Sex (female), n (%)	19 (90.5%)
Race, n (%)	
Anglo-American	20 (95.2%)
Black or African-American	1 (4.8%)
Marital status (married), n (%)	15 (71%)
Education, n (%)	
High school or less	1 (4.8%)
Vocational school/College	13 (61.9%)

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Adolescent characteristics	
Graduate/Professional school	7 (33.3%)
Annual household income, n (%)	
< $69,999	8 (38.0%)
$70,000 – $100,999	3 (14.3%)
> $100,999	10 (47.6%)

Table 3

Descriptive statistics for headache outcomes by assessment time point.

Treatment outcome	Pretreatment *M* (SD)	Posttreatment *M* (SD)	Follow-up *M* (SD)
Headache frequency (days per week) [a, b]	4.7 (2.1)	2.8 (2.7)	2.7 (2.8)
Headache pain intensity	5.2 (1.6)	5.6 (1.6)	4.6 (2.1)
Activity limitations [b]	32.7 (17.2)	24.8 (14.6)	21.19 (15.8)

Notes.

[a] $p < .05$ from pre-treatment to post-treatment;

[b] $p < .05$ from pre-treatment to follow-up.

Table 4

Descriptive statistics for sleep outcomes by assessment time point.

Treatment outcome	Pretreatment *M* (SD)	Posttreatment *M* (SD)	Follow-up *M* (SD)
Insomnia symptoms [a, b]	16.9 (5.2)	9.5 (6.2)	9.3 (5.0)
Sleep quality [a, b]	3.3 (0.4)	4.1 (0.8)	4.0 (0.9)
Sleep hygiene [a, b]	4.5 (0.5)	5.0 (0.4)	4.9 (0.6)
Sleep patterns			
Sleep efficiency (%) [a, b]	80.8 (12.3)	88.1 (12.0)	90.8 (6.5)
Wake after sleep onset [a, b]	32.0 (35.1)	11.5 (11.4)	10.6 (12.6)
Sleep onset latency [a, b]	1:15 (0:52)	0:39 (0:48)	0:43 (0:39)
Total sleep time [b]	7:36 (1.29)	7:38 (1:30)	8:25 (1.23)

Notes. Times are reported as hours:minutes;

[a] $p < .05$ from pre-treatment to post-treatment;

[b] $p < .05$ from pre-treatment to follow-up.