Published in final edited form as:

Headache. 2015 November ; 55(10): 1410–1425. doi:10.1111/head.12635.

Pilot Randomized Controlled Trial of Internet-delivered Cognitive-Behavioral Treatment for Pediatric Headache

Emily F. Law, PhD^{1,2}, Sarah E. Beals-Erickson, PhD², Melanie Noel, PhD², Robyn Claar, PhD³, and Tonya M. Palermo, PhD^{1,2}

¹University of Washington School of Medicine, Department of Anesthesiology and Pain Medicine, Seattle, USA

²Seattle Children's Research Institute, Center for Child Health, Behavior and Development, Seattle, USA

³Harvard Medical School and Boston Children's Hospital, Department of Anesthesiology, Perioperative and Pain Medicine, Boston, USA

Abstract

Objective—To evaluate the feasibility and preliminary effectiveness of an Internet-delivered cognitive-behavioral therapy (CBT) intervention for adolescents with chronic headache.

Background—Headache is among the most common pain complaints of childhood. Cognitive-behavioral interventions are efficacious for improving pain among youth with headache. However, many youth do not receive psychological treatment for headache due to poor access, which has led to consideration of alternative delivery modalities such as the Internet.

Methods—We used a parallel arm randomized controlled trial design to evaluate the feasibility and preliminary effectiveness of an Internet-delivered family-based CBT intervention, Web-Based Management of Adolescent Pain (Web-MAP). Adolescents were eligible for the trial if they were a new patient being evaluated in a specialized headache clinic, between the ages of 11–17 years old, and had recurrent headache for three months or more as diagnosed by a pediatric neurologist. Eighty-three youth enrolled in the trial. An online random number generator was used to randomly assign participants to receive Internet CBT adjunctive to specialized headache treatment ($n = 44$) or specialized headache treatment alone ($n = 39$). The primary treatment outcome was headache days.

Results—Youth and parents in the Internet CBT group demonstrated high levels of engagement with the web program and reported satisfaction with the intervention. Multi-level modeling was used to conduct hypothesis testing for continuous outcomes. For our primary treatment outcome of headache days, adolescents reported a statistically significant reduction in headache days from baseline to post-treatment and baseline to three-month follow-up in both treatment conditions (main effect for time $F(2, 136) = 19.70, p < .001$). However, there was no statistically significant difference between the Internet CBT group and the specialized headache treatment group at post-

treatment or follow-up (group x time interaction $F(2, 134) = .94, p = .395$). For our secondary treatment outcomes, findings from multilevel modeling (MLM) showed that adolescents in both groups demonstrated statistically significant improvement headache pain intensity, activity limitations, depressive symptoms and parent protective behaviors from baseline to post-treatment and these gains were maintained at three-month follow-up. Adolescent anxiety symptoms and sleep did not change during the study period for either group. There were no statistically significant group differences on any secondary outcomes at post-treatment or follow-up ($p > 0.05$ for all outcomes). No adverse events were reported.

Conclusion—Although adjunctive Internet CBT did not lead to additional benefit in this population, future research should evaluate whether it is an effective intervention for adolescents with headache who are unable to access specialized headache treatment.

Keywords

headache; children; adolescents; pediatric; cognitive-behavioral therapy; Internet intervention; randomized controlled trial

Introduction

Headache is among the most common pain complaints of childhood and adolescence, and prevalence rates appear to have increased over the past several decades [1, 2]. Headache can impact youth across nearly every domain of functioning. With increasing headache frequency, youth with headache report greater activity limitations, school absences, and anxiety and depressive symptoms [3–7]. Youth with headache also demonstrate greater sleep disturbances and excessive daytime sleepiness compared to youth without headache [8, 9]. The impact of headache often extends beyond the individual adolescent to the family, resulting in lost work time, financial burden, emotional distress, and family conflict [10]. Left untreated, headache can persist well into adulthood [10–13]; therefore, effective prevention and treatment of headache in childhood could reduce the negative impact of this condition across the lifespan.

Cognitive-behavioral therapy (CBT), which is usually delivered in a face-to-face format, is efficacious in reducing pain and disability in youth with headache at post-treatment and longer-term follow-up [14]. This intervention typically includes cognitive coping skills and relaxation training for youth and may also include operant training for parents to decrease protective responses that inadvertently reinforce pain behaviors. Despite evidence for the efficacy of face-to-face CBT for pediatric headache in reducing pain and disability [14], there has long been a concern regarding access to evidence-based behavioral pain treatment in this population [15, 16]. Indeed, many youth with headache do not receive behavioral pain treatment due to barriers such as access, distance from trained providers, and cost [15]. This has led to the consideration of remote modes of treatment delivery such as via the Internet.

Currently, there is limited research examining the efficacy of remotely-delivered behavioral interventions for youth with headache. In several pilot trials of CBT delivered via audio tapes, CD-ROM and telephone, remotely-delivered therapies have demonstrated preliminary

efficacy in improving headache outcomes (e.g., headache days, intensity) and physical functioning among youth with headache [17–19]. Results pertaining to the efficacy of Internet CBT in pediatric headache are mixed. A few studies of Internet CBT in youth with mixed chronic pain conditions including headache have shown efficacy compared to standard medical care in reducing headache pain intensity and activity limitations [20, 21], but benefits were not found in other areas such as depression, parent behaviors, or sleep [20–22]. In the only randomized controlled trial to examine Internet CBT for a pediatric headache *only* sample [23], outcomes among youth receiving Internet CBT were not statistically significantly different from youth receiving Internet relaxation training or youth in an Internet education control group. All groups showed reductions in headache days, duration, and pain catastrophizing, although the within-group effect size was largest in the Internet CBT group. Given the limited number of trials examining Internet CBT among youth with headache, additional research is needed to establish the feasibility and efficacy of these interventions in this vulnerable population of youth.

Specific Aims and Hypotheses

This study sought to test the feasibility and preliminary effectiveness of an Internet-delivered family-based CBT intervention for pain management in youth with headache as an adjunct to specialized treatment in a tertiary pediatric headache clinic. The Internet program included interventions for adolescents (e.g., education, relaxation, cognitive strategies, sleep hygiene education) and their parents (e.g., operant training, communication). To address limitations of prior research, we followed the recommendations put forth by PedIMPACT [24] to include validated measures of treatment effects in core outcome domains of pain, physical functioning (activity limitations), emotional functioning (depression, anxiety), and sleep. Given that protective parent behaviors were targeted in the intervention, effects on parent responses to adolescent pain behaviors were also examined. We expected that youth and parents in the Internet CBT group would demonstrate high levels of engagement with the web program and report satisfaction with the intervention. We hypothesized that youth in families receiving Internet CBT adjunctive to specialty headache treatment would show greater reductions in headache pain (headache days, pain intensity), activity limitations, depression, anxiety, and parent protective behaviors, as well as improvements in sleep compared to youth receiving only specialized headache treatment. We expected that treatment improvements would be maintained at three-month follow-up.

Methods

Study Design

Adolescents presenting as new patients were recruited over a 2-year period (2008–2010) from a multidisciplinary pediatric headache clinic at an academic health center in the northeastern United States. This pilot randomized controlled trial used a parallel-group design to compare Internet CBT adjunctive to specialized headache treatment vs. specialized headache treatment alone. The study was approved by the academic health center Institutional Review Board. Parents gave informed consent for participation and adolescents gave assent prior to initiating research procedures. The trial was terminated as planned at the end of the 2-year recruitment period. The trial was not pre-registered.

Participants and Setting

Participants included 83 adolescents with headache, aged 11–17 years, and their parents (see Table 1 for detailed information on participant demographics). All new patients presenting to the headache clinic were assessed for study eligibility. Inclusion criteria consisted of: (a) ages 11–17 years; (b) recurrent headache for three months or more as diagnosed by a pediatric neurologist; and (c) the adolescent was a new patient being evaluated in the headache clinic. During the first clinic visit, a pediatric neurologist assigned a headache diagnosis based on the International Classification of Headache Diagnoses-II (ICHD-II). For this project, diagnoses were grouped as migraine; tension-type headache; migraine and tension-type headache; or other headache disorders. Participants were excluded for any of the following reasons: (a) the adolescent had a co-morbid chronic medical condition such as diabetes, cancer or sickle cell disease; (b) the adolescent had a developmental disability as reported by their parent; (c) the parent or adolescent was non-English speaking; or (d) the family did not have regular access to the Internet. All participants continued with the medical care recommended by the headache clinic. For the Internet CBT group, the web program was adjunctive to medical care as prescribed by the headache clinic. All participants received gift cards to local stores for participation in the study.

As shown in the CONSORT Flow Diagram in Figure 1, 476 adolescents were assessed for eligibility and 393 were excluded. Of the 393 adolescents that were excluded, 331 did not meet inclusion criteria (the primary reason was not meeting the age criterion); 48 declined to participate due to lack of time or interest; and 14 adolescents were unable to be reached to complete pre-treatment assessments. The randomized sample therefore consisted of 83 participants assigned to receive adjunctive treatment with Internet CBT (Internet CBT; $n = 44$) or not (specialized headache treatment alone; $n = 39$). Twenty-four participants did not complete post-treatment assessments ($n = 13$ Internet CBT; $n = 11$ specialized headache treatment), and an additional 10 participants did not complete the three-month follow-up assessment ($n = 4$ Internet CBT; $n = 6$ specialized headache treatment). Intent-to-treat analysis was used, and therefore the number of cases analyzed was 44 for the Internet CBT group and 39 for the specialized headache treatment group.

Randomization Procedure

Blocked randomization with blocks of 10 was used to assign participants to one of the two treatment conditions. An online number generator was used to produce the blocked randomization. Participants were allocated in a 1:1 ratio. Group assignments were identified by ID number in an excel spreadsheet that was password protected and accessible only to a research coordinator who was blinded to participant recruitment, screening, and informed consent. Following completion of all pre-treatment assessments, the research coordinator accessed the excel spreadsheet to reveal the group assignment. This information was then programmed into the Web-MAP system, which generated a message on the website to each study participant revealing the instructions for their treatment assignment. Because of the nature of the intervention, it was not possible to blind participants or research staff to group status.

Assessment Procedures

Prior to randomization, participants completed pre-treatment assessments which included a 7-day online diary to record pain and activity limitations as well as paper-and-pencil questionnaires that were returned either during the participant's first clinic visit or via postal mail. A research coordinator who was blinded to group status conducted all assessment procedures that occurred in the clinic. Post-treatment and follow-up assessments included the 7-day online diary to monitor headache and activity limitations as well as questionnaires that were sent by postal mail and completed by participants in their homes. Immediate post-treatment assessments were completed at 8-10 weeks, and follow-up assessments were completed at three months.

Optional sleep assessment—After enrollment in the randomized controlled trial and prior to completing the pre-treatment assessment, all participants were informed about the opportunity to complete an optional sleep assessment at pre-treatment and immediate post-treatment. The sleep assessment involved completing a sleep log and actigraphy monitoring for 7 days (described further below). Parents provided informed consent and adolescents provided assent to participate in the sleep assessment. Fifty-three participants enrolled in the sleep assessment (26 = Internet CBT; 27 = specialized headache treatment); Forty-nine completed the sleep assessment at pre-treatment (24 = Internet CBT; 25 = specialized headache treatment). Forty-three participants completed the assessment at immediate post-treatment (20 = Internet CBT; 23 = specialized headache treatment).

Treatment Satisfaction, Acceptability and Engagement

In the Internet CBT group, youth and parents completed the Treatment Evaluation Inventory, short form (TEI-SF) [42, 43]. The TEI-SF is a 9-item self-report measure that assesses participant perceptions of a particular treatment program. Items are scored on a 5-point scale from (1) *strongly disagree* to (5) *strongly agree*. Higher scores indicate higher levels of satisfaction and acceptability of the treatment program. "Moderate" satisfaction and acceptability of a treatment is indicated by a score of "3" for each item [42]. Treatment engagement was assessed by the number of modules completed by youth and their parents, which was automatically recorded in the web program.

Primary Outcome Variable

Headache frequency—As recommended by the American Headache Society and the International Headache Society [25-27], number of days with headache was used as the primary outcome measure. This was assessed using a prospective 7-day online diary that was built into the Web-MAP program where participants recorded whether or not they had a headache that day. All but three participants completed five or more daily diary entries.

We also calculated clinically significant reduction in headache days using a dichotomous rating based on the criterion of 50% reduction in diary-reported days with headache from pre-treatment to post-treatment and pre-treatment to follow-up. This criterion is a standard metric used in previous pediatric headache trials [28] and is consistent with published guidelines from the International Headache Society and the American Headache Society [25-27].

Secondary Outcome Variables

Headache pain intensity—Participants reported daily headache pain intensity using an 11-point numerical rating scale (NRS; 0 = *no pain*; 10 = *worst pain*) via the prospective 7-day online diary. Mean scores across the 7-day period were used in analyses.

We also calculated clinically significant reduction in headache pain intensity using a dichotomous rating based on a criterion of 50% reduction in pain intensity from pre-treatment to post-treatment and pre-treatment to follow-up. This is a standard metric used in pain clinical trials [14] and has been used in previous trials of Internet interventions for pediatric chronic pain [21].

Activity limitations—Activity limitations were assessed using an online diary version of the Child Activity Limitations Interview-21 (CALI) [29]. At study enrollment, adolescents responded to an item-selection list of 21 activities and chose eight activities that were most difficult for them because of pain. Adolescents then rated difficulty of these eight activities daily for 7 days via the online diary. Responses were rated on a 5-point scale from (0) *not very difficult* to (4) *extremely difficult*. Total scores ranged from 0 to 32, with higher scores indicating greater perceived difficulty with activities. Mean scores across each 7-day period were used in analyses.

Emotional functioning—To assess emotional functioning, youth completed the Revised Children's Manifest Anxiety Scale, Second Edition (RCMAS-2) [30] and the Children's Depression Inventory (CDI) [31]. The RCMAS-2 is a widely used 49-item measure that assesses the presence and severity of anxiety symptoms in youth. The CDI is a commonly used measure of depressive symptoms in youth and includes 27-items measuring the presence of depressive symptoms (e.g., negative mood, negative self-esteem) and functional impairments associated with depressive clinical presentation (e.g., interpersonal problems, ineffectiveness). The RCMAS-2 total *t*-score and CDI total *t*-score were used in analyses.

Parent response to pain behavior—Parents completed the Protect subscale from the Adult Responses to Children's Symptoms, which is validated for use with families of youth with chronic pain (ARCS; [32–34]). The Protect subscale assesses parents' self-reported responses that positively reinforce pain complaints through increased parental presence or attention (e.g., “give your child special treats or little gifts”), and negatively reinforce pain complaints through permission to escape or avoid unwanted roles or responsibilities (e.g., “let your child stay home from school”). Responses are rated on a 5-point scale ranging from (0) *never* to (5) *always*. Responses are averaged to provide the subscale score. Higher scores are indicative of more frequent protective and solicitous parenting behaviors.

Sleep—Sleep patterns at pre-treatment and immediate post-treatment were assessed using wrist actigraphy (Actiwatch 64, Phillips Respironics/MiniMitter Company Inc., Bend, OR) following standardized procedures for actigraphy assessment [35]. This was completed concurrently with the 7-day online diary that recorded headache and activity limitations at pre-treatment and immediate post-treatment. The Actiwatch records sleep patterns based on movement detected by an omnidirectional sensor. Adolescents participating in the sleep

assessment wore the Actiwatch on their non-dominant wrist for 7 consecutive days. Participants pressed an event marker on the Actiwatch at bedtime and when they woke in the morning, and completed a paper-and-pencil sleep log that was used to verify the actigraphy data. Actigraphy data were scored in 1-min epochs using the Actiware Sleep version 5.5 software [36]. The algorithm of the Actiware Sleep software is based on the amplitude and frequency of detected movements. Actigraphy has demonstrated validity in the assessment of pediatric sleep-wake patterns [37, 38], and has been used successfully to evaluate sleep patterns in adolescents with a variety of chronic pain conditions [22, 39–41].

Two sleep variables were computed and used in analyses: total sleep time (in minutes) and sleep efficiency. Total sleep time refers to the total amount of time scored as sleep in minutes from sleep onset to sleep offset. Sleep onset was defined as the first 10-min segment with no more than one epoch of any recorded activity, and sleep offset was defined as the last 10-min segment with no more than one epoch of any recorded activity. 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.

Treatment Conditions

Specialized headache treatment—Participants received one or more of the following interventions as recommended by their providers at the headache clinic: medication management ($n = 21$), psychological therapy ($n = 6$) and physical therapy ($n = 11$). Psychological therapy included face-to-face cognitive behavioral therapy for pain management and/or biofeedback. Adolescents received access to the web program to complete online diary assessments of headache and activity limitations at pre-treatment, immediate post-treatment, and three-month follow-up. Following completion and receipt of their three-month follow-up assessment, families were offered the opportunity to receive Internet CBT using the same procedures below. Of the 39 families in the specialized headache treatment group, 27 (69.2%) chose to access the Internet CBT program after the three-month follow-up assessment.

Internet CBT—Participants received one or more of the following interventions as recommended by their providers at the headache clinic: medication management ($n = 27$), psychological therapy ($n = 10$), and physical therapy ($n = 12$). Psychological therapy included face-to-face cognitive behavioral therapy for pain management and/or biofeedback. In addition, participants received access to an Internet CBT program (Web-based Management of Adolescent Pain; Web-MAP). The design and treatment content of Web-MAP was identical to the original version of the program, which is described elsewhere [21]. The effectiveness of Web-MAP has been previously evaluated in a sample of youth with mixed chronic pain conditions [21]. This study represents a novel trial of Web-MAP in a separate sample of youth recruited from a specialty headache clinic.

Following completion of pre-treatment assessments and randomization, youth and parents were given access to Web-MAP, which consisted of two separate websites, one for adolescents and one for parents. Adolescents and parents were provided unique logins to the

web program. Web-MAP has three main sections that are accessible from the participant home page: treatment modules, message center, and daily diary. Adolescents and parents were asked to complete one module per week over the course of 8 weeks, which were designed to be about 30 minutes in length. Total treatment duration was approximately 9 hours per family (4 hours for adolescents, 4 hours for parents, 1 hour online coach time).

The program is travel-themed. Adolescents completed modules on pain education and goal setting, relaxation training, distraction strategies, cognitive strategies, sleep and lifestyle interventions, and relapse prevention and maintenance. Parents completed modules on pain education and goal setting, operant training, communication strategies, modeling and cognitive strategies, sleep and lifestyle interventions, and relapse prevention and maintenance. The program is interactive and required adolescents and parents to respond to queries which then provided tailored and personalized instruction and assignments. The program also includes videos of peer models and audio files of relaxation exercises. Please see previous publication for a complete description of the web program [21].

In six of the eight modules, parents and adolescents were given behavioral assignments focused on practice of skills taught in that module. Participants were instructed to work on the assignment for one week, and then to log back into the website to report on their progress with learning the skills in that module. These assignments were similar to weekly assignments used in face-to-face CBT for pain management. Assignment completion was required before participants were allowed to move on to the next module.

All completed assignments were reviewed by an online coach, a PhD-level psychology post-doctoral fellow with experience delivering face-to-face CBT for pain management to youth with chronic pain and their families. The online coach provided asynchronous feedback on each assignment via an online message center. A manual was developed to guide therapist responses to assignments [21]. Responses focused on review of progress, encouraging skills practice, and problem-solving barriers to implementing skills. Integrity to the manual was maintained via supervision led by the fifth author (Palermo). Online coach time was estimated at 5 minutes per assignment for a total of 60 minutes per family.

Sample Size and Data Analysis Plan

As is consistent with other pediatric headache trials [28], a priori power analysis was performed on the primary outcome of number of headache days using a standardized group mean difference of 0.6 (representing a clinically significant group difference in headache days), which indicated that a sample size of 40 per group yielded power of 0.80.

All analyses were conducted using IBM SPSS v21 [44]. The criterion used to designate statistical significance was $p < 0.05$ for all analyses. To verify that randomization produced equivalent groups, independent samples *t*-test and chi-square analyses were conducted. Primary hypothesis testing for continuous outcome measures was conducted using the full intent-to-treat sample with missing data handled via multilevel modeling (MLM) procedures, which assumes the data are missing at random and accounts for repeated measures within subjects and allows for inclusion of cases with missing data. Time was treated as a categorical variable, with baseline values specified as the reference to test

change in outcome measures from baseline to immediate post-treatment and baseline to three-month follow-up. Change over time across groups was tested via the main effect for time. Between-group differences were tested via the group x time interaction. Effect size estimates (reported as Cohen's *d*) were calculated per Feingold (2009), which accounts for change in outcome variables due to time and group status.

We also conducted primary hypothesis testing for continuous outcomes using an intent-to-treat sample with the last observation carried forward method to replace missing data, which yielded similar results. In addition, a completer analysis was conducted that yielded similar results. Therefore, only the MLM analyses are reported below.

Two separate dichotomous responder analyses were conducted to evaluate clinically significant improvement in headache days and headache pain intensity, respectively. The criterion for both outcome variables was 50% reduction from pre-treatment to post-treatment and pre-treatment to follow-up. For these analyses, we used the intent-to-treat sample with the last observation carried forward method for imputation of missing values. Chi-square analysis was used to evaluate the association between clinically significant improvement and group status.

Results

Participant characteristics

Table 1 details the demographic and pain-related characteristics of the sample. Participants were 83 adolescents (15 males, 68 females) between the ages of 11–17 years ($M = 14.5$, $SD = 1.7$) and one of their parents/guardians. This sample included predominantly White/Caucasian (91.6%), Non-Hispanic (98.8%) youth from married families (75.9%) with highly educated parents (mean maternal years of education = 16.5 years; mean paternal years of education = 16.4 years). At baseline, youth reported on average 6 headache days per week and moderate pain intensity ($M = 4.5$ out of 10; see Table 2 for additional descriptive statistics). See Figure 1 for CONSORT diagram detailing participant flow from recruitment to analysis. No adverse events were reported by participants during the course of the study in either condition.

Group equivalence on demographic and pre-treatment outcome variables

The Internet CBT group and the specialized headache treatment group were statistically equivalent with respect to all demographic and pre-treatment outcome variables. In addition, participants who dropped out of the study and those who completed the study did not differ on any demographic or pre-treatment outcome variables.

Feasibility: Treatment engagement, satisfaction and acceptability

The majority of adolescents and parents in the Internet intervention group demonstrated high treatment engagement based on module completion. Adolescents completed an average of 7 of 8 modules ($SD = 1.42$), with 38 adolescents (86.4%) completing a minimum of 6 out of 8 modules. Parents completed an average of 6 modules ($SD = 2.78$), with 28 parents (63.6%) completing a minimum of 6 out of 8 modules. Parent-adolescent dyads completed, on

average, 13 of 16 modules ($SD = 3.52$) and 30 dyads (68.2%) completed a minimum of 12 of 16 modules. Adolescent, parent and dyad module completion were not related to any post-treatment or follow-up outcomes (all $ps > 0.05$).

Youth and parents in the Internet treatment group were generally satisfied with the intervention immediately post-treatment (Youth $M = 3.35$ out of 5, $SD = .50$; Parent $M = 3.73$ out of 5, $SD = .47$) and at three-month follow-up (Youth $M = 3.33$ out of 5, $SD = .59$; Parent $M = 4.18$ out of 5, $SD = .65$). Youth and parents rated the Web-MAP intervention as moderately to highly acceptable at immediate post-treatment (Youth $M = 3.38$ out of 5, $SD = .74$; Parent $M = 3.89$ out of 5, $SD = .55$) and at three-month follow-up (Youth $M = 3.43$ out of 5, $SD = .63$; Parent $M = 3.89$ out of 5, $SD = .65$).

Primary outcome analyses

Means and standard deviations for primary outcome variables at pre-treatment, post-treatment and three-month follow-up are shown in Table 2. For each MLM analysis, omnibus F -tests for the main effect for time and the group x time interaction effect are reported in the text. Post-hoc tests probing group x time interaction effects at post-treatment and follow-up are summarized in Table 3. Effect size estimates for each analysis are shown in Table 4.

Headache frequency—Our primary treatment outcome was headache days. Adolescents reported fewer headache days from baseline to post-treatment and baseline to three-month follow-up in both treatment conditions (main effect for time $F(2, 136) = 19.70, p < .001$); however, there was no statistically significant difference between the Internet CBT group and the specialized headache treatment group at post-treatment or follow-up (group x time interaction $F(2, 134) = .94, p = .395$).

We also conducted a dichotomous responder analyses to evaluate clinically significant improvement in headache days. Twelve of 44 youth (27.3%) in the Internet CBT group and 7 of 39 youth (17.9%) in the specialized headache treatment group reported clinically significant improvement in headache days immediately post-treatment; this was not a statistically significant difference between groups, $X^2(1) = .90, p = .34$. At follow-up, 43.2% of youth ($n = 19$) in the Internet CBT group had a clinically significant reduction in headache days compared to 25.6% of youth the specialized headache treatment group ($n = 10$), which was not statistically different, $X^2(1) = 2.54, p = .11$.

Secondary outcome analyses

Headache pain intensity—Adolescents reported a statistically significant reduction in headache pain intensity from baseline to post-treatment and baseline to three-month follow-up in both treatment conditions (main effect for time $F(2, 131) = 6.84, p = .001$); however, there was no statistically significant difference between treatment groups at post-treatment or follow-up (group x time interaction $F(2, 129) = .59, p = .555$).

We also conducted a dichotomous responder analysis to evaluate clinically significant improvement in headache pain intensity. From pre-treatment to immediate post-treatment, 10 of 44 youth (22.7%) in the Internet CBT group and 7 of 39 youth (17.9%) in the

specialized headache treatment group reported a clinically significant reduction in pain intensity post-treatment. This does not represent a statistically significant difference in rates of pain intensity improvement ($X^2(1) = .23, p = .63$). At follow-up, 18.2% of participants ($n = 8$) in the Internet CBT group had a clinically significant reduction in headache pain intensity at follow-up compared to 23.1% of the specialized headache treatment group ($n = 9$), which was not statistically different ($X^2(1) = .38, p = .54$).

Activity limitations—Adolescents reported a statistically significant reduction in activity limitations from baseline to post-treatment and baseline to follow-up in both treatment conditions (main effect for time $F(2, 130) = 10.10, p < .001$). There was no statistically significant difference between the Internet CBT group and the specialized headache treatment group at post-treatment or follow-up (group x time interaction $F(2, 128) = .11, p = .89$).

Emotional functioning—Adolescents reported a statistically significant decrease in depressive symptoms (as reported on the CDI) from baseline to post-treatment and baseline to follow-up (main effect for time $F(2, 98) = 5.91, p = .004$). However, there was no statistically significant difference between the Internet CBT group and the specialized headache treatment group at post-treatment or follow-up (group x time interaction $F(2, 96) = 1.64, p = .20$). Regarding adolescents' anxiety symptoms (as reported on the RCMA-2), there was no statistically significant change from baseline to post-treatment or baseline to follow-up (main effect for time $F(2, 105) = 1.40, p = .25$). Between-group differences also were not statistically significant (group x time interaction $F(2, 103) = .71, p = .50$).

Parent response to pain behavior—Parent protective behaviors (as reported by parents on the ARCS Protectiveness subscale) showed a statistically significant reduction from baseline to post-treatment and from baseline to follow-up in both treatment conditions (main effect for time $F(2, 101) = 4.06, p = .02$). There was no statistically significant difference between the Internet CBT group and the specialized headache treatment group at post-treatment or follow-up (group x time interaction $F(2, 99) = .51, p = .60$).

Sleep—For the subset of youth ($n = 49$) who completed the sleep assessment via actigraphy monitoring, there was no statistically significant change from baseline to post-treatment on average total sleep time (main effect for time $F(1, 45) = .13, p = .72$) or sleep efficiency (main effect for time $F(1, 45) = .09, p = .77$). Between-group differences on average total sleep time and sleep efficiency also were not statistically significant at post-treatment (group x time interaction $F(1, 44) = 1.09, p = .30$; group x time interaction $F(1, 44) = 1.09, p = .30$, respectively). The sleep assessment was not conducted at follow-up and therefore no data are reported for that time point.

Discussion

The primary goal of this study was to evaluate the feasibility and preliminary effectiveness of Internet CBT for adolescents with headache. Internet CBT was well received by the youth and parents in this study. Families were satisfied with the intervention, rated it as acceptable, and engaged with the web program by completing treatment modules. In addition, 70% of

families initially assigned to specialized headache treatment alone chose to access the Internet CBT program after completion of the study. Taken together, these results suggest that families of youth with headache are interested in Internet CBT and perceive it as helpful.

We also examined preliminary effectiveness using a pilot randomized controlled trial. Adolescents in both treatment conditions received evaluation and treatment through a specialty headache clinic, and in addition the active treatment group also received access to an Internet CBT program. Our findings indicate that both treatment groups demonstrated statistically significant improvements in the primary treatment outcome of headache frequency as well as statistically significant improvements on secondary outcomes of headache pain intensity, activity limitations, depressive symptoms and parent protective behaviors from pre-treatment to immediate post-treatment. Gains were maintained at three-month follow-up. Adolescents' anxiety symptoms and sleep patterns did not change in either condition. These findings suggest that specialized headache treatment with and without adjunctive Internet CBT can reduce headache pain and associated disability among youth with headache.

Internet CBT may be a promising adjunctive intervention for youth with headache that has the potential to increase access to behavioral pain management intervention in this population. Further research is needed to evaluate the efficacy of this intervention using a large-scale, multi-site randomized controlled trial. The present pilot RCT was powered to test group differences on our primary outcome of headache days; it is possible that a different pattern of results could be obtained with a trial design that is powered to detect effects on multiple outcomes over a longer period of time. It is also important to acknowledge that the Internet CBT program was designed for use with youth with mixed chronic pain conditions. It is possible that the efficacy of the intervention could be enhanced by including treatment components that are known to be effective for youth with headache, such as headache-specific education and biofeedback [28, 50].

Another important aspect of our study design that should be considered is the selection of our sample. Youth were recruited from a specialized multidisciplinary headache clinic, which may represent greater severity of headache symptoms and/or an identified need for interdisciplinary treatment due to pain-related disability, emotional distress, family dysfunction, or other pain-related impact. Indeed, youth in this sample reported an average of 6 headache days per week at pre-treatment and many received multidisciplinary treatment during the study period including medication management, psychotherapy, and physical therapy. Although results from this trial suggest that Internet CBT may not enhance the efficacy of specialized pediatric headache treatment, it is possible that a low-intensity intervention such as Internet CBT may be a beneficial adjunctive approach for youth with less complex presentations such as those who are treated in primary care or neurology clinics. Indeed, primary care and neurology clinics typically do not employ pediatric psychologists with specialized expertise in headache treatment [15], making access to evidence-based psychological pain treatment more limited in these settings compared to specialized headache clinics. Future studies are needed to examine the efficacy of Internet CBT for youth with headache who are treated in primary care and neurology clinic settings,

as well as youth in the community who do not seek out medical care for their headache symptoms. Research is also needed to help physicians to prospectively identify those youth and families who are most in need of adjunctive behavioral pain management intervention to inform allocation of this scarce treatment resource.

Previous pilot trials of remotely-delivered behavioral treatment for youth with headache have recruited youth from specialty pediatric headache clinics [19], neurology clinics [17, 18], and the community [18, 23]. These trials have demonstrated mixed results, with some showing preliminary efficacy in improving one or more headache outcomes [17–19] and others demonstrating no benefit when compared to active control conditions [23]. It is important to note that comparisons across these existing trials is limited by a variety of methodological differences, such as whether headache was diagnosed by a neurologist using ICHD criteria, type of headache diagnosis, assessment of headache days, mode of treatment delivery, and comparator conditions. Remotely-delivered behavioral treatment for youth with headache is a growing field, and guidance is needed to inform the design and reporting of future clinical trials in this area. A notable strength of our trial compared to this previous body of work is the use of an expanded outcome assessment protocol that included additional core outcome domains recommended for assessment in pediatric chronic pain trials including sleep, anxiety symptoms, and parent behaviors.

An important innovation included in this study is the objective assessment of sleep patterns to evaluate changes in response to treatment. To our knowledge, this is the first randomized controlled trial of CBT for youth with headache to include an assessment of sleep outcomes [45]. Sleep is a potentially important treatment target for youth with headache given known associations between poor sleep, higher pain intensity, and poor psychosocial functioning among youth with chronic pain [46, 47]. Across both treatment groups, youth demonstrated insufficient sleep with an average of about 6 hours of nightly sleep and a substantial amount of time spent awake in bed at night as assessed by actigraphy at pre-treatment. This is consistent with previous research indicating impairments in sleep among youth with headache [48].

Our preliminary findings indicate that sleep patterns among youth with headache do not improve in response to specialized headache treatment alone or with adjunctive Internet CBT. This is consistent with previous research evaluating Internet CBT in youth with mixed chronic pain conditions, which also showed no change in sleep patterns in response to pain treatment as assessed by actigraphy [22]. It is important to consider whether sleep-specific interventions are needed for this population. Although specific interventions targeting sleep disturbance have been evaluated in adults with chronic pain with promising results for both sleep and pain outcomes [49], similar work has not yet been conducted in adolescents with headache. Further research is needed to determine whether specific interventions targeting sleep disturbance (e.g., CBT for insomnia) would enhance outcomes for youth with headache.

Our preliminary findings also indicated that anxiety symptoms do not improve in response to specialized headache treatment with and without adjunctive Internet CBT. This is consistent with a previous meta-analysis of psychological interventions for youth with

headache, which found that anxiety symptoms did not change in response to behavioral pain treatment [45]. This is not entirely surprising given that cognitive and behavioral pain management interventions do not typically target anxiety symptoms. It is possible that the effects of headache treatment could be enhanced by interventions that specifically target emotional distress, particularly for those youth with elevated anxiety or depressive symptoms at pre-treatment. Further research in this area is warranted.

There are several additional limitations to consider when interpreting results from this trial. One important consideration is the relatively short timeframe used to assess headache frequency and intensity in this trial (7 days). According to the American Headache Society guidelines for clinical trials in headache populations, a minimum of 4 weeks of daily diaries is recommended to assess headache activity at baseline and post-treatment [25]. Although this guideline was developed for adult populations, it is accepted as applicable to clinical trials for pediatric headache populations [28, 51]. The use of a 7-day headache diary in this trial limits comparisons that can be drawn to other pediatric headache trials that have used the standard 28-day daily diary. Comparisons to other trials may also be limited by our decision to include youth with mixed headache diagnoses. While this enhances the generalizability of our results to clinical practice, it may have impacted the potency of the Internet CBT intervention and complicates comparisons to other trials that focus on youth with a single headache diagnosis.

In addition, standard medical care received by youth in both groups was variable. It is likely that youth in the control group received interventions that overlapped with those delivered in the Web-MAP program, particularly for those youth who received face-to-face cognitive-behavioral therapy for pain management. Our follow up period was also limited to only a three-month assessment. Given that youth made further improvements in headache outcomes at three-month follow-up, it is possible that a long-term follow-up assessment would have revealed further improvements and may have indicated differential gains between treatment conditions. Finally, youth who enrolled in this trial were primarily Caucasian and middle class, which is consistent with previous trials of youth with headache [28] but limits generalizability of results to other racial and social economic status groups.

In conclusion, Internet CBT may be an effective adjunctive treatment for some youth with headache. Youth with headache and their parents rate Internet CBT as an acceptable intervention, demonstrate good treatment engagement, and have high interest in pursuing this treatment modality. This low-intensity approach has the potential to be widely disseminated at low cost, and could fill an important gap in treatment delivery for those youth with headache who would benefit from cognitive-behavioral pain treatment but are unable to receive this care due to distance, access, cost, or other barriers. Research is needed to determine whether treatment outcomes for youth with headache can be optimized by prospectively identifying those youth with headache who are most likely to benefit from low-intensity adjunctive Internet CBT compared to those who need more intensive intervention and then matching youth to the correct intervention based on treatment needs.

Acknowledgments

Financial support: This research was supported by Grant K24HD060068 from the National Institutes of Health/ National Institute of Child Health and Human Development. (PI: Palermo).

Abbreviations

Web-MAP	Web-based Management of Adolescent Pain
CBT	Cognitive-behavioral therapy

References

1. Goodman JE, McGrath PJ. The epidemiology of pain in children and adolescents: A review. *Pain*. 1991; 46(3):247–264.10.1016/0304-3959(91)90108-A [PubMed: 1758709]
2. King S, Chambers CT, Huguet A, MacNevin RC, McGrath PJ, Parker L, MacDonald AJ. The epidemiology of chronic pain in children and adolescents revisited: A systematic review. *Pain*. 2011; 152(12):2729–2738. doi:0.1016/j.pain.2011.07.016. [PubMed: 22078064]
3. Lipton RB, Manack A, Ricci JA, Chee E, Turkel CC, Winner P. Prevalence and burden of chronic migraine in adolescents: Results of the chronic daily headache in adolescents study (C-DAS). *Headache*. 2011; 51(5):693–706.10.1111/j.1526-4610.2011.01885.x [PubMed: 21521206]
4. Powers SW, Andrasik F. Biobehavioral treatment, disability, and psychological effects of pediatric headache. *Pediatric Annals*. 2005; 34(6):461–465.10.3928/0090-4481-20050601-11 [PubMed: 16018228]
5. Hershey AD, Powers SW, Benti AL, LeCates S, de Grauw TJ. Characterization of chronic daily headaches in children in a multidisciplinary headache center. *Neurology*. 2001; 56(8):1032–1037.10.1212/WNL.56.8.1032 [PubMed: 11320174]
6. Powers SW, Gilman DK, Hershey AD. Headache and psychological functioning in children and adolescents. *Headache*. 2006; 46(9):1404–1415.10.1111/j.1526-4610.2006.00583.x [PubMed: 17040337]
7. Powers SW, Patton SR, Hommel KA, Hershey AD. Quality of life in childhood migraines: Clinical impact and comparison to other chronic illnesses. *Pediatrics*. 2003; 112(1 Pt 1):e1–5.10.1542/peds.112.1.e1 [PubMed: 12837897]
8. Bursztein C, Steinberg T, Sadeh A. Sleep, sleepiness, and behavior problems in children with headache. *Journal of Child Neurology*. 2006; 21(12):1012–1019.10.1177/7010.2006.00239 [PubMed: 17156690]
9. Miller VA, Palermo TM, Powers SW, Scher MS, Hershey AD. Migraine headaches and sleep disturbances in children. *Headache*. 2003; 43(4):362–368.10.1046/j.1526-4610.2003.03071.x [PubMed: 12656707]
10. White KS, Farrell AD. Anxiety and psychosocial stress as predictors of headache and abdominal pain in urban early adolescents. *Journal of Pediatric Psychology*. 2006; 31(6):582–596.10.1093/jpepsy/psj050 [PubMed: 16049263]
11. Bille B. A 40-year follow-up of school children with migraine. *Cephalalgia*. 1997; 17(4):488–491. discussion 487. 10.1046/j.1468-2982.1997.1704488.x [PubMed: 9209767]
12. Brna P, Dooley J, Gordon K, Dewan T. The prognosis of childhood headache: A 20-year follow-up. *Archives of Pediatrics & Adolescent Medicine*. 2005; 159(12):1157–1160.10.1001/archpedi.159.12.1157 [PubMed: 16330740]
13. Wang SJ, Fuh JL, Lu SR. Chronic daily headache in adolescents: An 8-year follow-up study. *Neurology*. 2009; 73(6):416–422.10.1212/WNL.0b013e3181ae2377 [PubMed: 19605771]
14. Eccleston C, Palermo TM, Williams AC, Lewandowski Holley A, Morley S, Fisher E, Law E. Psychological therapies for the management of chronic and recurrent pain in children and adolescents. *Cochrane Database of Systematic Reviews*. 2014; 2014(5)10.1002/14651858.CD003968.pub4

15. Connelly M. Cognitive behavioral therapy for treatment of pediatric chronic migraine. *Journal of the American Medical Association*. 2013; 310(24):2617–2618.10.1001/jama.2013.282534 [PubMed: 24368460]
16. McGrath PJ, Humphreys P, Keene D, Goodman JT, Lascelles MA, Cunningham SJ, Firestone P. The efficacy and efficiency of a self-administered treatment for adolescent migraine. *Pain*. 1992; 49(3):321–324.10.1016/0304-3959(92)90238-7 [PubMed: 1408297]
17. Connelly M, Rapoff MA, Thompson N, Connelly W. Headstrong: A pilot study of a cd-rom intervention for recurrent pediatric headache. *Journal of Pediatric Psychology*. 2006; 31(7):737–747.10.1093/jpepsy/psj003 [PubMed: 16861397]
18. Cottrell C, Drew J, Gibson J, Holroyd K, O'Donnell F. Feasibility assessment of telephone-administered behavioral treatment for adolescent migraine. *Headache*. 2007; 47(9):1293–1302.10.1111/j.1526-4610.2007.00804.x [PubMed: 17927645]
19. Rapoff MA, Connelly M, Bickel JL, Powers SW, Hershey AD, Allen JR, Belmont JM. Headstrong intervention for pediatric migraine headache: A randomized clinical trial. *Journal of Headache and Pain*. 2014; 15(12):1186/1129-2377-15-12
20. Hicks CL, von Baeyer CL, McGrath PJ. Online psychological treatment for pediatric recurrent pain: A randomized evaluation. *Journal of Pediatric Psychology*. 2006; 31(7):724–736.10.1093/jpepsy/psj065 [PubMed: 16093516]
21. Palermo TM, Wilson AC, Peters M, Lewandowski A, Somhegyi H. Randomized controlled trial of an internet-delivered family cognitive-behavioral therapy intervention for children and adolescents with chronic pain. *Pain*. 2009; 146(1): 205–213.10.1016/j.pain.2009.07.034 [PubMed: 19695776]
22. Fales J, Palermo TM, Law EF, Wilson AC. Sleep outcomes in youth with chronic pain participating in a randomized controlled trial of online cognitive-behavioral therapy for pain management. *Behavioral Sleep Medicine*. 2015; 13(2):107–123.10.1080/15402002.2013.845779 [PubMed: 24484373]
23. Trautmann E, Kroner-Herwig B. A randomized controlled trial of internet-based self-help training for recurrent headache in childhood and adolescence. *Behaviour Research and Therapy*. 2010; 48(1):28–37.10.1016/j.brat.2009.09.004 [PubMed: 19782343]
24. McGrath PJ, Walco GA, Turk DC, Dworkin RH, Brown MT, Davidson K, Zeltzer L. Core outcome domains and measures for pediatric acute and chronic/recurrent pain clinical trials: Pedimmpact recommendations. *Pain*. 2008; 9(9):771–783.10.1016/j.jpain.2008.04.007
25. Penzien DB, Andrasik F, Freidenberg BM, Houle TT, Lake AE 3rd, Lipchik GL, Wittrock DA. Guidelines for trials of behavioral treatments for recurrent headache, first edition: American headache society behavioral clinical trials workgroup. *Headache*. 2005; 45 (s2): S110–132.10.1111/j.1526-4610.2005.4502004.x [PubMed: 15921503]
26. Andrasik F, Powers SW, McGrath PJ. Methodological considerations in research with special populations: Children and adolescents. *Headache*. 2005; 45(5):520–525.10.1111/j.1526-4610.2005.05104.x [PubMed: 15953269]
27. Tfelt-Hansen P, Pascual J, Ramadan N, Dahlof C, D'Amico D, Diener HC, Schwedt T. Guidelines for controlled trials of drugs in migraine: Third edition. A guide for investigators. *Cephalalgia*. 2012; 32(1):6–38.10.1177/0333102411417901 [PubMed: 22384463]
28. Powers SW, Kashikar-Zuck SM, Allen JR, LeCates SL, Slater SK, Zafar M, Hershey AD. Cognitive behavioral therapy plus amitriptyline for chronic migraine in children and adolescents: A randomized clinical trial. *Journal of the American Medical Association*. 2013; 310(24):2622–2630.10.1001/jama.2013.282533
29. Palermo TM, Witherspoon D, Valenzuela D, Drotar D. Development and validation of the child activity limitations interview: A measure of pain-related functional impairment in school-age children and adolescents. *Pain*. 2004; 109(3):461–470.10.1016/S0304-3959(04)00103-4 [PubMed: 15157707]
30. Reynolds, CR.; Richmond, BO. Revised Children's Manifest Anxiety Scale, Second Edition (RCMAS-2): Manual. Western Psychological Services; Torrance, CA: 2008.
31. Kovacs, M. Children's Depression Inventory (CDI): Technical manual. Multi-Health Systems, Inc; North Tonawanda, NY: 1992.

32. Claar RL, Guite JW, Kaczynski KJ, Logan DE. Factor structure of the adult responses to children's symptoms: Validation in children and adolescents with diverse chronic pain conditions. *Clinical Journal of Pain*. 2010; 26(5):410–417.10.1097/AJP.0b013e3181cf5706 [PubMed: 20473048]
33. Van Slyke DA, Walker LS. Mothers' responses to children's pain. *Clinical Journal of Pain*. 2006; 22(4):387–391.10.1097/01.aip.0000205257.80044.01 [PubMed: 16691093]
34. Walker LS, Levy RL, Whitehead WE. Validation of a measure of protective parent responses to children's pain. *Clinical Journal of Pain*. 2006; 22(8):712–716.10.1097/01.aip.0000210916.18536.44 [PubMed: 16988567]
35. Morgenthaler T, Alessi C, Friedman L, Owens J, Kapur V, Boehlecke B, Swick TJ. Practice parameters for the use of actigraphy in the assessment of sleep and sleep disorders: An update for 2007. *Sleep*. 2007; 30(4):519–529. Retrieved from <http://www.journalsleep.org/>. [PubMed: 17520797]
36. Webster JB, Kripke DF, Messin S, Mullaney DJ, Wyborney G. An activity-based sleep monitor system for ambulatory use. *Sleep*. 1982; 5(4):389–399. Retrieved from <http://www.journalsleep.org/>. [PubMed: 7163726]
37. Meltzer LJ, Montgomery-Downs HE, Insana SP, Walsh CM. Use of actigraphy for assessment in pediatric sleep research. *Sleep Medicine Reviews*. 2012; 16(5):463–475.10.1016/j.smrv.2011.10.002 [PubMed: 22424706]
38. Sadeh A. Commentary: Comparing actigraphy and parental report as measures of children's sleep. *Journal of Pediatric Psychology*. 2008; 33(4):406–407.10.1093/jpepsy/jsn018 [PubMed: 18310663]
39. Haim A, Pillar G, Pecht A, Lerner A, Tov N, Jaffe M, Hardoff D. Sleep patterns in children and adolescents with functional recurrent abdominal pain: Objective versus subjective assessment. *Acta Paediatrica*. 2004; 93(5):677–680.10.1111/j.1651-2227.2004.tb02996.x [PubMed: 15174794]
40. Palermo TM, Toliver-Sokol M, Fonareva I, Koh JL. Objective and subjective assessment of sleep in adolescents with chronic pain compared to healthy adolescents. *Clinical Journal of Pain*. 2007; 23(9):812–820.10.1097/AJP.0b013e318156ca63 [PubMed: 18075410]
41. Tsai SY, Labyak SE, Richardson LP, Lentz MJ, Brandt PA, Ward TM, Landis CA. Actigraphic sleep and daytime naps in adolescent girls with chronic musculoskeletal pain. *Journal of Pediatric Psychology*. 2008; 33(3):307–311.10.1093/jpepsy/jsm117 [PubMed: 18056139]
42. Kazdin AE. Acceptability of alternative treatments for deviant child behavior. *Journal of Applied Behavior Analysis*. 1980; 13(2):259–273.10.1901/jaba.1980.13-259 [PubMed: 7380752]
43. Kelley ML, Heffer R, Gresham F, Elliot S. Development of a modified treatment evaluation inventory. *Journal of Psychopathology and Behavioral Assessment*. 1989; 11(3):235–247.10.1007/BF00960495
44. IBM Corp. IBM SPSS Statistics for Windows. IBM Corp; Armonk, NY: 2012.
45. Fisher E, Heathcote L, Palermo TM, de CWAC, Lau J, Eccleston C. Systematic review and meta-analysis: Psychological therapies for children with chronic pain. *Journal of Pediatric Psychology*. 2014; 10.1093/jpepsy/jsu008
46. Palermo TM, Wilson AC, Lewandowski AS, Toliver-Sokol M, Murray CB. Behavioral and psychosocial factors associated with insomnia in adolescents with chronic pain. *Pain*. 2011; 152(1):89–94.10.1016/j.pain.2010.09.035 [PubMed: 21030151]
47. Palermo TM, Law E, Churchill SS, Walker A. Longitudinal course and impact of insomnia symptoms in adolescents with and without chronic pain. *Pain*. 2012; 13(11):1099–1106.10.1016/j.jpain.2012.08.003
48. Gilman DK, Palermo TM, Kabbouche MA, Hershey AD, Powers SW. Primary headache and sleep disturbances in adolescents. *Headache*. 2007; 47(8):1189–1194.10.1111/j.1526-4610.2007.00885.x [PubMed: 17883524]
49. Vitiello MV, Rybarczyk B, Von Korff M, Stepanski EJ. Cognitive behavioral therapy for insomnia improves sleep and decreases pain in older adults with co-morbid insomnia and osteoarthritis. *Journal of Clinical Sleep Medicine*. 2009; 5(4):355–362. Retrieved from <http://www.aasmnet.org/jcsm/>. [PubMed: 19968014]

50. Guarnieri P, Blanchard EB. Evaluation of home-based thermal biofeedback treatment of pediatric migraine headache. *Biofeedback and Self Regulation*. 1990; 15(2):179–184.10.1007/BF00999148 [PubMed: 2400797]
51. Andrasik F, Schwartz MS. Behavioral assessment and treatment of pediatric headache. *Behavior Modification*. 2006; 30(1):93–113.10.1177/0145445505282164 [PubMed: 16330521]

Figure 1.
CONSORT Flow Diagram.

Table 1

Sample characteristics.

Characteristic	Total sample (<i>n</i> = 83) <i>N</i> (%) / <i>M</i> (<i>SD</i>)	Internet CBT (<i>n</i> = 44) <i>N</i> (%) / <i>M</i> (<i>SD</i>)	Specialized headache treatment (<i>n</i> = 39) <i>N</i> (%) / <i>M</i> (<i>SD</i>)
<i>Age</i> (years)	14.5 (1.7)	14.6 (1.8)	14.3 (1.6) <i>t</i> (81) = -.61, <i>p</i> = .54
<i>Gender</i>			
Male	15 (18.1)	7 (15.9)	8 (20.5) χ^2 (1) = .30, <i>p</i> = .59
Female	68 (81.9)	37 (84.1)	31 (79.5)
<i>Race</i>			
White/Caucasian	76 (91.6)	43 (97.7)	33 (84.6) χ^2 (3) = 5.37, <i>p</i> = .15
Black/African American	1 (1.2)	0 (0.0)	1 (2.6)
Asian/Asian American	3 (3.6)	1 (2.3)	2 (5.1)
Multiracial	3 (3.6)	0 (0.0)	3 (7.7)
<i>Ethnicity</i>			
Non-Hispanic	82 (98.8)	44 (100.0)	38 (97.4) χ^2 (1) = 1.14, <i>p</i> = .29
Hispanic	1 (1.2)	0 (0.0)	1 (2.6)
<i>Headache type</i>			
Migraine	21 (25.3)	7 (15.9)	14 (35.9) χ^2 (3) = 4.44, <i>p</i> = .22
Tension-type	16 (19.3)	10 (22.7)	6 (15.4)
Both	22 (26.5)	13 (29.5)	9 (23.1)
Other	24 (28.9)	14 (31.8)	10 (25.6)
<i>Parent Marital Status</i>			
Married	63 (75.9)	32 (72.7)	31 (79.5) χ^2 (4) = .86, <i>p</i> = .93
Separated	2 (2.4)	1 (2.3)	1 (2.6)
Divorced	14 (16.9)	9 (20.5)	5 (12.8)
Never married/single	2 (2.4)	1 (2.3)	1 (2.6)
Widowed	2 (2.4)	1 (2.3)	1 (2.6)
<i>Parent Education</i> (years)			
Mother	16.5 (2.3)	16.1 (2.2)	16.9 (2.4) <i>t</i> (79) = 1.57, <i>p</i> = .12
Father	16.4 (2.7)	16.2 (2.4)	16.6 (3.0)
<i>Services</i>			
Medication Management	48 (57.8)	27 (61.4)	21 (53.8) χ^2 (1) = .73, <i>p</i> = .39

Author Manuscript

Author Manuscript

Author Manuscript

Author Manuscript

Characteristic	Total sample (<i>n</i> = 83) <i>N</i> (%) / <i>M</i> (SD)	Internet CBT (<i>n</i> = 44) <i>N</i> (%) / <i>M</i> (SD)	Specialized headache treatment (<i>n</i> = 39) <i>N</i> (%) / <i>M</i> (SD)	
Psychotherapy	16 (19.7)	10 (22.7)	6 (15.4)	$\chi^2 (1) = 1.41, p = .24$
Physical Therapy	23 (27.7)	11 (27.2)	12 (28.2)	$\chi^2 (1) = 1.67, p = .45$

Table 2

Descriptive statistics for primary and secondary outcomes by treatment group.

Variable	Internet CBT (N = 44)		Specialized headache treatment (N= 39)	
	<i>M (SD)</i>	<i>n</i>	<i>M (SD)</i>	<i>n</i>
<i>Total headache days</i>				
Pre-treatment	5.82 (1.72)	44	5.18 (2.00)	39
Post-treatment	4.63 (2.14)	40	4.70 (2.23)	37
Follow-Up	3.86 (2.19)	28	3.91 (2.39)	22
<i>Pain intensity</i>				
Pre-treatment	4.97 (2.47)	44	4.35 (2.15)	39
Post-treatment	4.13 (2.42)	40	3.83 (2.26)	37
Follow-Up	4.19 (2.45)	28	3.70 (2.54)	22
<i>Activity limitations</i>				
Pre-treatment	6.54 (4.79)	44	6.12 (4.34)	39
Post-treatment	4.83 (4.78)	20	4.86 (4.40)	37
Follow-Up	5.19 (5.02)	28	5.27 (4.61)	22
<i>Sleep duration</i>				
Pre-treatment	371.75 (56.76)	24	371.40 (65.79)	25
Post-treatment	369.52 (75.39)	21	383.83 (58.92)	24
<i>Sleep efficiency</i>				
Pre-treatment	75.89 (9.53)	24	76.50 (11.60)	25
Post-treatment	75.79 (12.42)	21	78.33 (9.30)	24
<i>Anxiety</i>				
Pre-treatment	49.68 (10.50)	40	49.03 (10.96)	38
Post-treatment	46.33 (8.99)	30	48.32 (10.81)	25
Follow-Up	45.82 (10.96)	28	45.36 (9.90)	22
<i>Depression</i>				
Pre-treatment	48.56 (10.48)	39	49.59 (9.67)	32
Post-treatment	46.30 (10.03)	27	47.48 (9.50)	23
Follow-Up	44.75 (9.52)	28	43.74 (6.45)	23
<i>Parent behaviors</i>				
Pre-treatment	1.66 (.49)	41	1.45 (.48)	38
Post-treatment	1.40 (.52)	31	1.44 (.58)	28
Follow-Up	1.36 (.39)	29	1.34 (.59)	23

Table 3
Results of multilevel modeling analyses: Post-hoc tests probing effects at post-treatment and follow-up compared to baseline.

Outcome	Estimate (SE)					
	Effect of Time ¹			Time X Group Interaction Effect ²		
	Intercept	Group	Post-treatment	Follow-up	Post-treatment	Follow-up
Headache days	5.82 (.31)	-.64 (.46)	-.85 (.25)	-1.83 (.29)	.68 (.50)	.44 (.59)
Pain intensity	4.97 (.36)	-.63 (.52)	-.67 (.22)	-.84 (.26)	.27 (.45)	-.30 (.53)
Activity limitations	6.54 (.70)	-.42 (1.02)	-1.61 (.39)	-1.49 (.46)	.37 (.78)	.14 (.92)
Sleep duration ³	371.75 (13.14)	-.35(18.39)	2.85 (7.94)	—	16.54(15.88)	—
Sleep efficiency ³	75.89 (2.21)	.61 (3.09)	.42 (1.41)	—	2.92 (2.81)	—
Anxiety	49.07 (1.64)	.07 (2.37)	-1.13 (1.07)	-1.82 (1.11)	1.95 (2.15)	-.66 (2.25)
Depression	48.37 (1.54)	2.05 (2.28)	-2.16 (1.17)	-3.99 (1.17)	.16 (2.33)	-3.68 (2.32)
Parent behaviors	1.65 (.08)	-.20 (.11)	-.11 (.05)	-.18 (.06)	.18 (.10)	.15 (.11)

¹ Parameter estimates reflect the effect of time, from baseline to post-treatment and from baseline to follow-up.
² Parameter estimates reflect the effect of the interaction between time and group status (treatment vs. control), from baseline to post-treatment and from baseline to follow-up.
³ Sleep assessment was not conducted at follow-up

Table 4

Effect size estimates for group differences across time in multilevel modeling analyses¹.

Outcome	Effect Size (d)	
	Baseline to Post-treatment	Baseline to Follow-up
Headache days	-.40	-.34
Pain intensity	-.07	.26
Activity limitations	-.04	.04
Sleep duration ²	-.29	—
Sleep efficiency ²	-.34	—
Anxiety	-.24	.09
Depression	.06	.46
Parent behaviors	-.27	-.26

¹ Effect size calculations indicate the differences in the change in outcome over time between the Internet treatment group and the specialized headache treatment group. Formula per Feingold (2009, 2013): (M Change Treatment group /SD Baseline Treatment Group) – (M Change Control group /SD Baseline Control Group). This method accounts for change due to time in addition to change by group.

² Sleep assessment was not conducted at follow-up.