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Randomized Controlled Trial of the Acceptability, Feasibility, and Preliminary Effects of a Cognitive Behavioral Skills Building Intervention in Adolescents with Chronic Daily Headaches: A Pilot Study

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Abstract

Introduction—The treatment challenge of adolescents with chronic daily headaches (CDHs) creates an urgent need for evidence-based interventions. Therefore, the purpose of this pilot study was to evaluate the acceptability, feasibility, and preliminary effects of a brief cognitive behavioral skills building intervention (CBSB) with thirty-six, 13-17 year-old, adolescents with CDHs and mild to moderate depressive symptoms.

Methods—Participants were randomly assigned either to the Creating Opportunities for Personal Empowerment Headache Education Program (COPE-HEP) or to a headache education comparison group.

Results—Adolescents and parents found the COPE-HEP to be highly acceptable. Medium to large positive effects were demonstrated on the adolescents' depression in both groups and on anxiety and beliefs in the COPE-HEP group. COPE-HEP offered additional benefits of a larger decrease in adolescent anxiety over time and stronger beliefs in the teens' ability to manage their headaches.

Discussion—Adolescents with CDHs and elevated depressive and anxiety symptoms should be offered headache hygiene education plus cognitive-behavioral skills building interventions. A full-scale trial to determine the more long-term benefits of COPE-HEP is now warranted.

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Conflict of Interest The authors report no financial incentives that may create a conflict of interest.

Keywords

Adolescents; chronic daily headaches; behavioral interventions; psychological

INTRODUCTION

As the prevalence of chronic daily headaches (CDHs) in adolescents increase, so does the treatment challenge for healthcare providers. According to recent reports, approximately 3.5% of adolescents in the United States have chronic daily headaches (Seshia, 2012). Chronic daily headaches are defined as headaches occurring for 15 or more consecutive days per month for at least 3 or more consecutive months (Silberstein & Lipton, 1996). Management of CDHs is a challenge as they cause significant morbidity if not treated effectively and in a timely manner (Galli et al., 2004; Spittler, 2008). Chronic daily headaches adversely impact the adolescent's daily functioning (Hershey, Gladstein, & Winner, 2007), emotional/mental health (Wang, Fu, Lu, & Juang, 2006), work and academic performance (Tenhunen & Elander, 2005; Wang, et. al., 2006), and overall functional performance (Gilman, Palermo, Kabbouche, Hershey, & Powers, 2007). Current clinical management is based largely on interventions focusing on adults, findings from childhood episodic studies, and expert opinion (Mack, 2010), with many interventions focusing on adult-studied pharmacological treatment modalities (Lopez & Rothrock, 2008). For example, approximately 5.6 million prescriptions were written in 2009 for opioids in children and adolescents between ages 5 and 19 years with chronic pain (Schoffenfeld, 2012). While adult-borrowed approaches have demonstrated some efficacy in adolescents, CDHs in many adolescents are, oftentimes, refractory to typical treatment (Hershey et al., 2007). These adolescents may experience increased pain, stress, comorbid symptoms, and overall disability, which may result in ineffective coping behaviors.

Over the past decade, there has been extensive research examining prevalence and risk factors among adolescents with chronic daily headaches (Dooley, Gordon, & Wood, 2005; Mazzone, Vitiello, Incorpora, & Mazzone, 2006; Pakalnis, Butz, Splaingard, Kring, & Fong, 2007; Palermo, Putnam, Armstrong, & Daily, 2007; Scher, Midgett, & Lipton, 2008; Seshia, 2012; Wang, Juang, Fuh, & Lu, 2007a; Wang et al., 2007b). In addition, many studies have examined chronic or recurrent headaches in children and adolescents, using different criteria for chronic daily headaches than that described by Silberstein and Lipton (1996; 2001). A few studies have found a substantial comorbidity of mental health problems in adolescents affected by CDHs (Pearlman, 2007; Wang et al., 2007b; Singh, Shukla, Trivedi, & Singh, 2013). The chronicity of CDHs increases in the presence of psychiatric comorbidities such as anxiety and depressive symptoms (Shuster, 2007), which makes treating these headaches more difficult (Gladstein & Mack, 2005). Inadequately treating adolescents with CDHs and comorbid depression and anxiety increases their risk for significant impairment, morbidity, and mortality (Rosenbaum & Covino, 2005).

Adolescence is a period of rapid physical and emotional development (Eccleston, Wastell, & Crombez, 2008; Erikson, 1968). Illness threatens the adolescent's autonomy, a major developmental milestone, and can result in poor coping behaviors, which may result in

emotional and social withdrawal (Eccleston et al., 2008). Low autonomy may impact the adolescents' perception of their ability to manage their headaches (Palermo et al., 2007). Developmentally appropriate mastery and control of tasks are key antecedents for effective coping in this age group. To better help adolescents manage and cope with their headaches, treatment decisions need to be based on evidence-based adolescent-focused interventions that have considered the developmental level of the adolescents and the efficacy or receipt of the intervention in this population. Little has been written in the literature about theory-based, developmentally appropriate interventions to support the cognitive and behavioral management of CDHs in adolescents with mild to moderate depressive symptoms. Therefore, to study the preliminary effects of a brief cognitive behavioral skills building (CBSB) intervention in adolescents with CDHs and mild to moderate depressive symptoms, this study adapted the *Creating Opportunities for Personal Empowerment* (COPE) (Melnik, Jacobson, Kelly, O'Haver, Small, & Mays, 2009), an intervention focusing on improving the mental health of adolescents, combined with a headache education program (HEP) as the interventions for the study. This study is a first step in bridging this knowledge gap in the science of intervention research.

THEORETICAL FRAMEWORK

Cognitive Theory (CT) provided the underpinnings for the development of the COPE-HEP program tested in this study (Beck, 1964: 1976). The content of CT is that how one thinks, affects how he or she feels and behaves (Beck, Rush, Shaw, & Emery, 1979). Comorbid psychiatric symptoms, such as anxiety and depression, can be found in adolescents with CDHs. The COPE program has demonstrated efficacy in adolescents with mild to more severe depressive and anxiety symptoms (Lusk & Melnyk, 2011; Melnyk et al., 2013). The content of COPE includes how to: (a) turn negative thoughts into positive thoughts, (b) more effectively communicate with others, (c) cue recognition, (d) set goals, (e) improve and manage stress, and (f) improve problem solving. The COPE-HEP integrated concepts of COPE and healthy headache lifestyle behaviors (e.g. regular sleep and eating patterns, adequate hydration, recognition of triggers, and exercise). The COPE-HEP intervention was proposed to help adolescents recognize that they have control of their headaches and of factors that may predispose, precipitate, or perpetuate their headaches, thereby, empowering the adolescents to take control of their headaches and engage in healthy lifestyle behaviors. Testing this intervention may demonstrate that nurses and other health care providers may be able to provide an intervention that can improve the non-pharmacological approach to CDHs in adolescents with mild to moderate depressive symptoms, and the mental, physical, and psychosocial health and well-being of adolescents with CDH.

The purpose of this study was to determine if a theory-driven COPE-HEP intervention program in adolescents, ages 13 to 17 years, with mild to moderate depressive symptoms was acceptable and feasible to adolescents and their parents. An additional purpose was to determine the preliminary effects of COPE-HEP on anxiety, depression, beliefs, perceived stress, headache disability, and parent perception of pain interference in this population of teens compared to a comparison group. It was hypothesized that adolescents in the COPE-HEP group would have less anxiety and depressive symptoms, higher beliefs, less perceived stress, and less headache disability than teens who received headache hygiene information

alone. In addition, it was hypothesized that the parents of these adolescents would have less perception of pain interference in their adolescents' daily activities post-intervention.

METHODS

Design

Adolescents were randomized to the COPE-HEP intervention or a comparison headache education group. Data were collected prior to the initiation of the interventions and immediately after the completion of the 7 sessions of each intervention. In addition, to demographic information obtained from adolescents and parents, the main outcome measures for the adolescents were anxiety, depression, beliefs, perceived stress, and headache disability. The parent outcome measure was parent perception of pain interference.

Setting and Sample

The study took place in a hospital-based, academic pediatric neurology specialty care clinic in a large metropolitan area of Arizona. The study was approved by the hospital's Institutional Review Board and the IRB of Arizona State University. Participants were screened for depressive symptoms using the Beck Youth Depression Inventory. Participants whose scores indicated mild to moderately elevated depressive symptoms, scores ranging from 55 to 69 inclusive, were enrolled in the study. Parents gave informed consent and adolescents gave assent before starting any process of the research. The convenience sample consisted of 36 adolescents meeting the following inclusion criteria: (a) diagnosis of CDHs, (b) ages 13 to 17 years, inclusive, (c) availability of a parent or guardian to accompany teen to clinic visit, (d) ability to speak English, (e) (f) enrollment in high school, and (g) presence of mild to moderate depression symptoms. Adolescents were excluded if: (a) there was presence of a prior diagnosed mental health condition (e.g. bipolar disorder, posttraumatic stress disorder, schizophrenia, paranoia, etc.), or (b) there was presence of clinical pathology (e.g. brain tumor, pseudo tumor cerebri, concussion, etc.) as the underlying cause of headaches.

Figure 1 illustrates the enrollment and flow of participants during the study as described by the CONSORT statement (Moher, Schulz, & Altman, 2001). As shown, 49 adolescents were assessed for enrollment criteria. Of the 49, 7 refused to participate because of either lack of time or interest and 6 did not meet criteria of mild to moderately elevated depressive symptoms. The final sample consisted of 32 participants randomly assigned to a treatment condition and a treatment as usual group. An online randomization was used to assign participants to one of the two interventions.

Table 1 illustrates demographic information for adolescents. Adolescents in the sample were predominantly female ($n=23$, 72%). Approximately 70% ($n=21$) of the adolescent participants were in grades 9 and 10. A substantial number of adolescents were Hispanic ($n=14$, 44%). There were some differences on demographic variables between groups, although not statistically significant. The majority of the participants in the COPE-HEP group were female ($n=13$, 81%) with 62% ($n=10$) of participants in the comparison group being female ($p=.22$). This difference was not statistically significant. Twice as many

adolescents in the comparison group (n=4, 25%) worked for pay when compared to the COPE-HEP group ($p = .66$). Table 2 shows the parents demographic characteristics. There were no statistically significant differences between the parents in the two groups.

The majority of parents in both the COPE-HEP (n = 8, 50%) and comparison group (n = 9, 56%) were married. Fifty percent (n = 8) of parents in the COPE-HEP group reported having some college training with fifty-six percent (n = 9) of parents in the comparison group reporting the same. Parents in the comparison group experience more mental health issues than parents in the COPE-HEP group (n = 8, 50%). Approximately sixty-three percent (n = 10) of parents in the COPE-HEP group had history of chronic headaches, with fifty percent (n = 8) of parents in the comparison group reporting this history.

Intervention Conditions

The COPE-HEP consisted of seven sessions of a theory-based, manualized intervention: three 30-minute office sessions and four 20-minute telephone sessions. The goal was to deliver the intervention over a 7 week period, meeting once a week. Clinic sessions were scheduled within the allotted clinic hours. Telephone sessions were scheduled at the convenience of the adolescent, including evenings. The telephone sessions were alternated with the clinic sessions. The primary author with training in cognitive behavior skills building techniques delivered all of the intervention sessions for the COPE-HEP group. The sessions were audiotaped. Treatment fidelity was assessed using a developed manual, which standardized procedure. The content of the 7-session COPE-HEP and comparison headache education are depicted in Table 3. Session 1 focused on how thoughts about headaches affect the adolescents' response to their headaches (i.e., the thinking, feeling, and behaving triangle). Contextual factors that predispose perpetuate, and precipitate headaches (i.e. exposure to triggers, medication use/overuse, dietary and sleep habits, smoke exposure, etc.) and headache hygiene measures (i.e. regular sleep and eating patterns, moderate exercise, avoidance of triggers) were discussed. Session 2 emphasized factors that affect self-esteem. Positive self-talk was introduced as a strategy for building self-esteem and also for dealing with headaches. Session 3 addressed healthy and unhealthy coping behaviors in response to headaches. In session 4, the adolescent was introduced to problem solving using a 4-step problem solving process (i.e. identify the problem, identify the causes of the problem, specify possible solutions with their pros and cons, and identify the best solution and take action. Headache specific case scenarios were used. Session 5 was a discussion of how to deal with emotions in healthy ways and the importance of effective communication (e.g. how to effectively express feelings, how to get and ask for help). Additional strategies for headache management were also discussed (e.g., mental imagery and self-control). The main focus of Session 6 was how to deal with stressful everyday encounters (e.g., conflict, work and school demands, peer and outside pressure). In Session 7, a review was done of all the important concepts covered in each session of the program. The adolescents were given the opportunity to share their perception of the progress they had made in managing their headaches because of their participation in the COPE-HEP program.

The comparison group education sessions focused on potential headache triggers to include lifestyle, environmental, medication, hormonal, and dietary triggers. In addition, the

importance of adequate hydration was emphasized. Good headache hygiene measures (e.g. regular sleep and eating patterns, moderate and routine exercise, and avoidance of caffeine, ETOH, and other drugs) were also discussed.

Measures

Well-established instruments with good reliability and validity were used to measure the study's outcomes. Investigator-developed parent and teen demographic questionnaires were used to collect demographic data. Parent demographics included age, gender, race/ethnicity, learning problems, highest level of education, history or presence of mental illness (parent or family member), presence of chronic illness (parent or family member), and a report of stressful life events. For adolescents, the following data were collected: age, gender, Body Mass Index (BMI), race/ethnicity, grade level, perceived family and social support, and work history.

Teen and Parent Questionnaires—The exit questionnaires collected information about the program's acceptability and feasibility. Questions were asked that provided information regarding the adolescents' and parents' perception of the program's helpfulness, areas of improvement, and ease of participation. Each adolescent and parent was asked to respond to the following questions: 1) Was the format of the program acceptable to you? If no, why was it not acceptable? 2) Was the intervention helpful to you? If yes, how was it helpful? If no, why was it not helpful? 3) What do you think made the biggest improvement in your headaches? 4) How could participation have been made easier for you? And 5) Would you recommend the program to a friend who has headaches?

Beck Anxiety and Depression Scales—Anxiety and depression were measured using the anxiety and depression subscales of the Beck Youth Inventory (2nd edition; BYI-II). The BYI-II measures five constructs, including (a) depressive symptoms, (b) anxiety symptoms, (c) anger, (d) disruptive behavior, and (e) self-concept. Each of the subscales of the BYI-II contains 20 statements about thoughts, feelings, and behaviors pertaining to emotional and social impairment. The BYI-II is used extensively in research and clinical settings, with well-established validity and reliability (Beck, Beck, & Jolly, 2001). Cronbach's alphas for this sample were .88 and .57, respectively. The low Cronbach's alpha for the Beck Depression Inventory is most likely a result of restriction of range in the sample on depressive symptomology in that mild to moderate depression was an inclusion criterion for the study. It is known that statistical range restriction has a tendency to reduce the total variance and the overall reliability coefficient (Fife, Mendoza, & Terry, 2012; Wieberg & Sundstrom, 2009).

Beliefs—Beliefs were measured using the Healthy Lifestyle Beliefs Scale, which was developed by Dr. Bernadette Melnyk to measure beliefs of adolescents regarding healthy lifestyle behaviors (Melnyk et al., 2006c, 2007). The original 16-item instrument was modified for this study, with two headache specific questions being added to the scale, making the scale 18 items. The adapted Healthy Lifestyle Beliefs Scale utilizes a 5-point Likert scale (1 = strongly disagree; 2 = disagree; 3 = don't care; 4 = agree; 5 = strongly agree) and measures the teens' beliefs about leading a healthy lifestyle. Questions include

items on nutrition, physical activity, and ability to handle and cope with various stressors. Higher scores on the scale indicate stronger beliefs about ability to lead a healthy lifestyle. The Healthy Lifestyle Beliefs Scale has demonstrated adequate validity and reliability (Melnik et al., 2007). Cronbach's alpha for this sample was .91.

Perceived Stress (PSS)—Perceived stress was measured using the Perceived Stress Scale, which is 14-item scale that describes the degree to which situations in one's life are appraised as stressful. This Likert scale assessed the frequency and occurrence of stressful feelings and thoughts during past month. Participants rated items from never (0) to very often (4). The PSS has demonstrated good reliability and validity (Cohen, Kamarck, & Mermelstein, 1983). Cronbach's alpha for this sample was .58.

PedMIDAS—The PedMIDAS, a 6-item questionnaire, was used to determine headache disability. The items in this scale report an estimation of the number of full or partial days of school missed in the past three months due to headache and also, the days of school attended but with reduced functioning. Frequency ratings also were measured on the number of days the adolescent was unable to fully participate in activities such as chores, homework, sports, or play. This measure has shown adequate reliability and validity (Hershey, Powers, Vockell, LeCates, Kabbouche, & Maynard, 2001). In this sample, the Cronbach's alpha was .61.

Parent Perception of Pain Interference (PPPI)—The PPPI is an 11-item instrument that asks parents to rate from 0 (no interference) to 6 (extreme interference) how much their adolescent's pain typically interferes with family relationships and daily functioning, such as doing chores, attending school, and participating in and enjoying recreational activities. This measure has shown adequate reliability and validity (Kerns, Turk, & Rudy, 1985). Cronbach's alpha for this sample was .96.

PROCEDURE

Adolescents with a diagnosis of CDHs were identified by neurologists and nurse practitioners when the adolescent was seen at the neurology clinic. The adolescents and parents were provided with an informational flyer, which provided an initial overview of the study. If interested, they were asked to provide their contact information to the first author. Interested parents and guardians and their adolescents were contacted by the first author and a clinic visit was scheduled. All adolescent participants provided assent and their parents provided informed consent before beginning the study. Self-report data were obtained from both the adolescents and their parents prior and just after completion of the interventions in the clinic.

Analytical Strategy

Pre- to post-treatment changes in anxiety, depression, beliefs, perceived stress, headache disability, and parent perception of pain interference were examined using paired t-tests. Significance was considered at $p < .10$ (2-tailed) for all measures. The statistical significance was set at .10 instead of .05 to reduce the probability of a Type II error due to the small sample size. Increasing the level of significance is commonly done when analyzing data in

pilot studies with small samples (Campbell, 2005; Cohen, 1994). This pilot study's main focus was to identify problems of implementing an intervention and was not necessarily looking for an effect.

Chi Square analyses were used for categorical variables and independent t-tests for continuous variables. Chi-Square was performed to determine the comparability of the two groups at baseline. Descriptive statistics were used to characterize the feasibility and acceptability of the COPE-HEP program and the outcome variables. Cronbach's alphas were run on all scales to determine their internal consistency. All analyses were conducted using SPSS (Statistical Package Service Solution) 19. ANCOVA was performed examining both post-test anxiety and post-test depression, controlling for depression and anxiety at baseline.

RESULTS

Acceptability and Feasibility

Forty-nine adolescents and parents were asked to participate. Six were ineligible due to not having mild to moderate depressive symptoms and seven refused to participate. The main reason for not participating were: 1) unable to commit to the amount of time required, 2) transportation issues, 3) lack of interest, and 4) anticipated difficulty getting to clinic visit. Eleven percent ($n = 4$) of participants discontinued the study. In the intervention group, one participant withdrew after completing session 3, indicating that her headaches were too severe to continue. A second adolescent discontinued after completing session 1, indicating that the sessions interfered with sports. In the comparison group, 1 adolescent dropped from the study after session 1 because of anticipated difficulty getting to clinic sessions in that family lived approximately 5 hours from clinic. A second adolescent withdrew after session 1 because of loss of interest in the study. The proportion of families withdrawing from the COPE-HEP group ($n = 2$) was exactly the same as those withdrawing from the comparison group ($n = 2$).

The adolescents in both groups completed all 7 sessions, although at varying times. In the COPE-HEP group, fifty percent of the adolescents completed the intervention in 7 weeks. By week 10, seventy-five percent of the adolescents had completed the intervention. Of the twenty-five percent ($n = 4$) completing after 10 weeks, one participant completed the intervention in 11 weeks, two participants completed the intervention in 12 weeks and one participant completed the intervention in 14 weeks. In the comparison group, 37.5% completed the sessions in 7 weeks, with 62% completing the study in 10 weeks. Three participants completed the study in 16, 18, and 20 weeks, respectively. Fifteen appointments were missed and rescheduled for the COPE-HEP group and 31 sessions were missed and rescheduled for the comparison group. Overall, completion of the COPE-HEP intervention for this group of adolescents ranged from 7 to 14 weeks ($m = 8.94$, $SD = 2.35$) weeks. Completion for the comparison group education ranged from 7 to 20 weeks ($m = 10.56$, $SD = 4.21$).

Participants were asked to complete weekly homework assignments. The homework was reviewed at the beginning of each clinic and telephone session. The average completion rate of the homework was 79%. Findings indicated that COPE-HEP adolescents who had good

homework completion (completion of 5 or more homework sessions) had statistically significant stronger beliefs ($m = 76.36$, $SD = 6.99$) in their ability to manage their headaches compared to those with poor homework completion (completion of 4 or less sessions) ($M = 67.00$, $SD = 10.84$, $t(14) = 2.10$, $p = .06$).

Adolescents' ratings on the Teen Exit Questionnaire were very positive. Ninety-four percent ($n = 15$) of the adolescents who completed the COPE-HEP rated it as helpful. One adolescent commented that, by attending the program, she learned new ways to cope with her headaches. Another adolescent responded that the program helped him to control his anger and cope with his headaches. Eighty-eight percent ($n = 14$) of the parents rated the intervention as helpful. In general, the overall theme of comments from parents as to the helpfulness of the intervention for their teens reflected that through the program the teens had learned positive ways to cope and manage stress, better ways to manage their headaches, how to self-regulate and use relaxation, and to use knowledge of headache triggers and headache hygiene measures (e.g. avoidance of triggers, adequate hydration, regular sleep and eating patterns, moderate exercise) to avoid headache exacerbations. Evaluations from the comparison group of headache education alone rated the intervention as helpful.

Both adolescents and parents found the length of the COPE-HEP highly acceptable. All parents and adolescents responded that they would recommend the program to a friend or to the parent of an adolescent with headaches. All parents found the format of the COPE-HEP highly acceptable. One adolescent thought the program consisted of too many sessions. Fifteen ($n = 94\%$) of adolescents indicated that the number and length of sessions were adequate. Ninety-seven percent of parents expressed interest in having their adolescent attend a future program to help their adolescent cope with chronic headaches. Two parents provided suggestions for improving the program such as offering the intervention in more geographically convenient areas and using a flow chart to provide a general overview of the program for participants. Adolescents provided the following suggestions for improvement: (a) don't repeat the same content (1), (b) provide more biofeedback training (1), (c) increase length of the sessions (1), and (d) increase the number of clinic sessions (1). Overall, the results showed that both parents and adolescents' comments reflected change in lifestyle behaviors by the end of the treatment for both the COPE-HEP and comparison group.

Beliefs, Stress, and Headache Symptomology

Pre/Post Study Anxiety and Depression—Table 4 presents means and standard deviations for adolescent and parent ratings. Adolescent ratings of anxiety were significantly reduced from pre- to post-treatment in both groups. However, the COPE-HEP group demonstrated a greater reduction in anxiety from pre-intervention (mean = 59.25, $SD = 9.57$) to post-intervention ($m = 52.56$, $SD = 7.36$), ($t(15) = 3.45$, $p = .01$) when compared to changes in the comparison group from pre-treatment ($m = 50.94$, $SD = 8.31$) to post-intervention (mean = 47.38, $SD = 6.10$), ($t(15) = 1.92$, $p = .07$). Ratings of depression decreased significantly from pre- to post-treatment in both the COPE-HEP and comparison groups, with Cohen's effect sizes of 1.46 and 1.53, respectively. An ANCOVA was performed examining both post-test anxiety and post-test depression, controlling for anxiety

and depression at baseline. There was no statistically significant difference in post-intervention anxiety ($F(1, 30) = .02, p = .89$) when controlling for baseline differences in anxiety. In addition, there was no statistically significant difference in post-intervention depression between groups, when controlling for baseline differences in depression ($F(1, 30) = .48, p = .50$).

Pre/Post Study Beliefs and Perceived Stress, PedMIDAS (headache disability), and PPPI—As expected, adolescent ratings of beliefs about their ability to lead a healthy lifestyle and to better manage their headaches increased significantly from baseline (mean = 68.25, SD = 10.31) to post-treatment (mean = 73.44, SD = 9.17), ($t(15) = -2.21, p = .04$) in the COPE-HEP group. Ratings of beliefs in the comparison group did not demonstrate a significant mean change from pre- (mean = 72.25, SD = 7.60) to post-treatment (mean = 75.25, SD = 11.23), ($t(15) = -1.41, p = .18$). Independent t-tests indicated no differences in perceived stress scores from T1 to T2 between the COPE-HEP and comparison groups (all p 's > .40, Table 4).

There was a significant reduction in PedMIDAS (headache disability) in the COPE-HEP group from pre-treatment (mean = 56.13, SD = 51.62) to post-treatment (mean = 38.25, SD = 32.21), ($t(15) = 1.90, p = .08$) and also in the comparison group from baseline (mean = 53.81, SD = 56.04) to post-treatment (mean = 30.88, SD = 30.02), ($t(15) = 2.18, p = .05$). The parents' perception of the degree of pain interference in the adolescents' daily activities showed no significant changes over time in both groups. On average, parents in the COPE-HEP group had a slightly higher perception of pain interference (mean = 41.88, SD = 13.24) than parents in the comparison group (mean = 37.63, SD = 13.29, $t(30) = .91$).

DISCUSSION

A theory-based, brief CBSB intervention was highly acceptable to adolescents with CHDs and mild to moderate depressive symptoms and their parents in a specialty care neurology clinic. The feasibility of implementing the intervention in this setting with this population was challenged by some adolescents not completing all of the homework assignments, which may be due in part to delivery of some sessions by telephone instead of in-person. The expectation was that the intervention would be delivered in 7 sessions in 7 consecutive weeks. However, due to some missed and rescheduled appointments, the number of weeks for participants in the COPE-HEP averaged 8.9 weeks, with participants in the comparison education group averaging 10.6 weeks. COPE-HEP participants rated the length and number of sessions as adequate. However, completion of homework posed a challenge for some of the adolescents. The addition of a headache education program (HEP) to the CBSB mental health lengthened the sessions beyond the time it takes to deliver COPE alone (i.e., 20 to 25 minutes). The COPE-HEP program might be more feasible in a specialty clinic if the amount of homework and number of sessions are reduced; however, reduction of the program's dose (i.e., the number of sessions) might lessen the program's positive outcomes as prior studies have supported the efficacy of COPE in improving depression, anxiety, and self-esteem with seven face to face sessions with a healthcare provider (Lusk & Melnyk, 2011; Melnyk et al., 2014).

As expected, adolescents completing the majority of homework sessions (5 or more) had higher beliefs than those completing less sessions. This finding is supported by studies that have shown that compliance with homework assignments improves the treatment outcomes of psychotherapy (Cummin-Nowak et al., 2013; Mautbach, Moore, Roesch, Cardenas, & Patterson, 2010).

Some challenges were encountered in delivering the COPE-HEP in a specialty outpatient setting, which might affect large scale adoption of the program. While the intervention content was delivered consistently in the 7-session program as per the COPE protocol (Melnik & Lusk, 2011), modifications to the program were made in order to incorporate headache education, which lengthened the time of delivering the intervention. Therefore, future testing of the program might consider shortening the sessions somewhat in order that they can be easily scheduled into half hour visits/phone contacts.

The results of this study support the overall feasibility and preliminary positive effects of a relatively brief CBSB with headache hygiene intervention for adolescents with CDHs who have mild to moderate depressive symptoms. Specifically, the attrition rate (11%) in this study was low compared to the attrition rate presented in the literature review that supported this study, which ranged from 9.7% to 40%. In addition to supporting acceptability and feasibility of COPE-HEP, the findings also support the preliminary efficacy of this brief CBSB intervention in adolescents with CDHs and mild to moderate depressive symptoms. The COPE-HEP group had higher healthy lifestyle beliefs and a greater decline in anxiety over time than the comparison group along with improvements in other outcomes. These findings extend the previous work of Lusk and Melnyk (2011) and Melnyk and colleagues (2013, 2014), which support that use of a brief manualized cognitive behavioral therapy based intervention can improve mental health outcomes in adolescents.

Both groups demonstrated significant decreases in anxiety, depression, and headache disability. Parent perception of pain interference was unchanged at post-intervention in both groups. This finding is surprising in that both parents and adolescents reported improvements in the adolescents' ability to better manage their headaches and the adolescents' rating of decreased headache disability at the end of both programs. This lack of change may have been influenced by the following factors: 1) no daily log for monitoring of adolescent's activities over several weeks, 2) the assessment of this measure was based on parent recall of the adolescent's activities over several weeks, and 3) the adolescents' level of participation in home chores and activities may not have been related to their headaches.

IMPLICATIONS FOR CLINICAL PRACTICE

Clinicians should emphasize the importance of healthy headache hygiene measures, such as regular eating and sleep patterns, routine and moderate exercise, adequate hydration, and identification and avoidance of headache triggers and encourage adolescents to utilize strategies to engage in healthier lifestyle behaviors and choices. Regular sleep patterns, regular mealtimes, regular exercise or physical activity, non-caffeinated beverages, and adequate hydration are important for maintaining a healthy lifestyle.

In addition, pediatric health care providers are in ideal positions to identify and treat adolescents with CDHs who also have mild to moderately depressive symptoms. Because the prevalence of depressive and anxiety symptoms is high in adolescents with CDH, clinicians should screen these teens routinely for depression and anxiety. Based on prior findings with interventions to address adolescent depression, clinicians are encouraged to incorporate CBSB programs into their practices in order to help adolescents see how their thoughts about their headaches are impacted by their cognitive appraisal of events as well as their emotions and lifestyle beliefs. Teaching CBSB skills to adolescents can empower them to take control of triggers or measures that may predispose, perpetuate, or precipitate their headaches, thereby leading to improve healthy lifestyle behaviors and better headache control.

Strengths, Limitations, and Recommendations for Future Research

The strengths of this study include: (a) use of a randomized controlled trial design, (b) use of a theory-based manualized intervention, (c) low attrition rate compared to prior studies, (d) delivery of the intervention with high fidelity, and (e) overwhelming acceptability of both programs by parents and adolescents. Limitations of this study included: (a) self-report on survey measures, (b) homogenous sample of adolescents with CDHs and mild to moderate depressive symptoms, which make the findings not generalizable to adolescents with CDHs without mild to moderate depressive symptoms, (c) adolescents referred to a specialty neurology center, which may not be representative of adolescents with CDHs and mild to moderate depressive symptoms in other settings, (d) small convenient sample, (e) lack of control for changes in anti-migraine medications during the intervention, (f) two scales with Cronbach's alphas less than .70 (i.e. Beck Youth Depression and Perceived Stress Scale), (g) predominantly female sample, (h) intervention delivered by the primary researcher, and (i) lack of a prior power analysis to determine sample size for this pilot study.

A potential limitation of the COPE-HEP program is the amount of provider time that is required to deliver the intervention compared to a headache education only program. However, headache education alone would not target depressive and anxiety symptoms experienced by so many teens with CDHs. Cognitive-behavior skills building is the most effective evidence-based gold standard treatment for mild to moderate depression and anxiety. Therefore, COPE-HEP would be most appropriate intervention for adolescents who have both CDHs and associated depressive and anxiety symptoms.

Future studies should examine the optimal dose (timing and number of sessions) of the COPE-HEP intervention required to achieve the maximal results in ways that are most cost-effective, acceptable, feasible, and individualized to adolescents and their families. The program also could potentially be delivered via technology (e.g. social media; web-based); although, future trials are needed to determine the efficacy of this methodology. A full-scale randomized controlled trial is now warranted to determine the more long-term effects of the intervention on teen outcomes. Future studies may also examine the use of technology as a mechanism for delivery of daily individualized interventions regarding headache education and cognitive behavioral skills building to adolescents with chronic headaches. Furthermore, findings from this study support the need for a future large-scale efficacy trial, which

evaluates both the short and more long-term effects of the intervention. For future studies, power analysis indicated that a minimum sample size of 42 is needed for a large effect (0.8), 102 for a medium effect (0.5), and 620 for a small effect (0.2) for an 80% chance of detecting an effect at the 0.05 level of significance.

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Figure 1.
Participant flow diagram.

Table 1

Demographic Characteristics of Teen Respondents (N = 36)

	COPE-HEP (N-16)	Comparison (N-16)
Demographics	M, SD	M, SD
Mean Age (years)	15.38, 0.96	14.8, 1.17
Mean BMI	23.01, 3.90	23.4, 6.70
BMI Percentile/BMI	64.84/ 29.99	63.09/ 27.04
Gender	N (%)	N (%)
Male	3 (18.8)	6 (38)
Female	13 (81.2)	10 (62)
Ethnicity	N (%)	N (%)
White	5 (31)	5 (31)
Black	4 (25)	1 (6.3)
American Indian/AlaskanNative	1 (6.3)	1 (6.3)
Asian/Pacific Islander	0 (0)	1 (6.3)
Hispanic	6 (37.5)	8 (50)
Hours Worked per Week	N (%)	N (%)
0 hours	14 (87.5)	12 (75)
1-9 hours	0 (0)	4 (25)
10-19 hours	2 (12.5)	0 (0)
Grade Level	N (%)	N (%)
9th Grade	3 (18.8)	7 (43.8)
10th Grade	7 (43.8)	4 (25)
11th Grade	5 (31.3)	5 (31.3)
12th Grade	1 (6.3)	0 (0)

Note: SD = standard deviation

M = mean

BMI = Body Mass Index

Table 2

Demographic Characteristics of Parent Respondents (N = 16)

	COPE-HEP (N = 16) N (%)	Comparison (N = 16) N (%)
Demographics		
Marital Status		
Married	8 (50)	9 (56.3)
Never Married	1 (6.3)	3 (18.8)
Separated, Widowed	1 (6.3)	0 (0)
Divorced	2 (12.5)	2 (12.5)
2 nd Marriage	4 (25)	2 (12.5)
Years of School Completed		
Did not finish high school	1 (6.3)	2 (12.5)
Finished high school/GED	3 (18.8)	2 (12.5)
Some college or training	8 (50)	9 (56.3)
Finished college	4 (25)	2 (12.5)
Master's degree or PhD	0 (0)	1 (6.3)
Learning Problem		
Yes	1 (6.3)	1 (6.3)
Parent Mental Health Problem		
Yes	8 (50)	11 (68.8)
Family hx Chronic Headaches		
Yes	12 (75)	10 (62.5)
Family Member Mental Health Issues		
Yes	5 (31.3)	6 (37.5)
Parent w/Chronic Headaches		
Yes	10 (62.5)	8 (50)
Stressful Events		
Yes	9 (56.3)	9 (56.3)

Table 3

Intervention Curriculum

COPE-HEP content		Headache Education content	
Session # Title		Session # Title	
1. Thinking, feeling, behaving/Headache triggers		1. Lifestyle triggers of headaches	
2. Self-esteem; Positive thinking/Headache hygiene		2. Environmental headache triggers	
3. Stress and coping		3. Medication triggers of headaches	
4. Problem solving and goal setting		4. Hormonal headache triggers	
5. Dealing with emotions; Effective communication/ Headache triggers		5. Dietary triggers of headaches	
6. Personality and effective coping		6. Headache management tips	
7. Wrap-up		7. Importance of hydration/wrap-up	

Table 4

Preliminary Effects of Intervention within Groups (n = 32)

Variable	Mean T0	SD T0	Mean T1	SD T1	Cohen's D	Mean Diff	t	df	p
Anxiety									
Comparison	50.94	8.31	47.38	6.10	-.488 ⁺	3.56	1.92	15	.07 [*]
COPE-HEP	59.25	9.57	52.56	7.36	-.784 ⁺⁺⁺	6.69	3.45	15	.01 ^{**}
Depression									
Comparison	57.56	3.35	49.69	6.46	-1.529 ⁺⁺⁺	7.88	4.83	15	.01 ^{**}
COPE-HEP	60.00	4.51	51.69	6.65	-1.457 ⁺⁺⁺	8.31	5.71	15	.01 ^{**}
Beliefs									
Comparison	72.25	7.60	75.25	11.23	.313 ⁺	-3.00	-1.41	15	.18
COPE-HEP	68.25	10.31	73.44	9.17	.532 ⁺⁺	-5.19	-2.21	15	.04 ^{**}
Perceived Stress									
Comparison	29.38	3.78	28.44	6.13	-.185	.94	0.76	15	.46
COPE-HEP	31.06	6.43	30.75	5.05	-.054	.31	0.23	15	.82
PedMIDAS									
Comparison	53.81	56.04	30.88	30.02	-.510 ⁺⁺	22.94	2.18	15	.05 ^{**}
COPE-HEP	56.13	51.62	38.25	32.21	-.416 ⁺	17.88	1.90	15	.08 [*]
PPPI									
Comparison	37.63	13.30	32.94	16.49	-.313 ⁺	4.69	1.15	15	.27
COPE-HEP	41.88	13.24	34.88	18.20	-.44 ⁺	7.00	1.57	15	.14

⁺ *Note.* = small effect size;⁺⁺ = medium effect size;⁺⁺⁺ = large effect size

PedMIDAS = Headache Disability. PPPI = Parent Perception of Pain Interference

^{*} = .05 level of significance;^{**} = .10 level of significance