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Los Angeles

The Use of Complementary Alternative Medicine for Pediatric Chronic Headaches

A dissertation submitted in partial satisfaction of the
requirement for the degree Doctor of Nursing Practice

by

Yvette Loretta Goodridge

2020

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ABSTRACT OF THE DISSERTATION

Complementary Alternative Medicine for Pediatric Chronic Headaches

by

Yvette Loretta Goodridge

Doctor of Nursing Practice

School of Nursing, University of California, Los Angeles, 2020

Professor Nancy A. Pike, Chair

Abstract

Pediatric chronic headaches are a common complaint and one of the primary reasons for seeking medical treatment. Headache medications have limited effects on children with chronic headaches. Few studies examined the effects of complementary alternative medicine (CAM) to optimize pain management in children with chronic headaches. The objective is to evaluate whether CAM [acupuncture, cognitive behavioral therapy (CBT), and biofeedback therapy (BFT)] reduces headache frequency and pain scores when used in addition to medications in children with chronic headaches.

This was a retrospective review of electronic health records from September 2016-January 2020 to examine the effects of CAM. Inclusion criteria: children 10 to 18 years,

diagnosis of chronic headaches, and received one or more CAM types. Demographics and clinical information related to headaches were collected (number of headaches per week, pain scores on 0-10 scale, and change in pain quality). Quantitative follow-up telephone surveys were conducted to evaluate the effectiveness and continued use of CAM. Descriptive statistics, Chi-square (categorical variables), Wilcoxon Signed Rank Test (ordinal comparisons) of headache frequency and pain quality and paired *t*-tests used to evaluate pain scores before and after CAM.

Children (n=78; 14 ± 2.4 years) were mostly female (81%), Hispanic (45%), and had chronic migraines (47%). Children received acupuncture (68%) or combined acupuncture and CBT (25%). Pain scores (n=40) were significantly different before (7.0 ± 2.0) and after (2.53 ± 3.1 , $p = 0.03$) treatment. Children who received acupuncture (n=28) had a significant decrease in pain scores before (7.0 ± 1.6) and after (1.8 ± 1.6 , $p < 0.001$) treatment. Children (n=11) who received the combined acupuncture and CBT also indicated a significant decrease in headache pain scores before (7.5 ± 2.1) and after (4.6 ± 3.4 , $p = 0.02$). The survey (n=20) indicated that more than half (55%) agreed that CAM was helpful; the majority (61%) reported relief for two months. Ninety percent were not currently using CAM due to insurance or scheduling conflicts (60%).

Findings from this project indicate that CAM had significant effects on the improvement of headache frequency and pain scores in both children receiving acupuncture or combined acupuncture and CBT. However, insurance and conflict in schedules were significant barriers to continuing use of CAM. Prospective studies are needed to minimize barriers to receiving CAM and evaluate whether CAM may optimize pain control and decrease use of pain medications in children with chronic headaches.

The dissertation of Yvette Loretta Goodridge is approved

Betty Chang

Suzette Glasner

Eufemia Jacob

Nancy A. Pike, Committee Chair

University of California, Los Angeles

2020

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VITA

1998	Associate Degree in Nursing Quincy College Quincy, Massachusetts
1998-2003	Staff Nurse – Pediatrics Dimock Community Health Center Boston, Massachusetts
2002	Bachelors in Science Nursing University of Massachusetts Boston, Massachusetts
2003-2005	Staff Nurse - OBGYN Whittier Street Health Center Boston, Massachusetts
2004-2006	Staff Nurse – Pediatrics Children’s Hospital Boston Boston, Massachusetts
2006-2011	Staff Nurse – Pediatrics Rady Children’s Hospital San Diego, California
2011	Masters in Science (Pediatric Nurse Practitioner) University of San Diego San Diego, California
2011-2014	Staff Nurse – Medical/Surgical ICU Children’s Hospital Boston Boston, Massachusetts
2014-2016	Pediatrics Nurse Practitioner - Pain Treatment Service, Division of Pain Management Children’s Hospital Boston Boston, Massachusetts
2016-Present	Pediatric Nurse Practitioner - Pain Treatment Service, Division of Pain Management Children’s Hospital Los Angeles

The Use of Complementary Alternative Medicine for Pediatric Headache

Headaches are a common pediatric complaint affecting 58.7% of the pediatric population, with 7.7% of them having a migraine, and up to 33% of them having tension-type headaches (Rocha-Filho & Santos, 2014). The current approach to treatment consists of acute and preventative medication in conjunction with lifestyle modifications and behavioral interventions (Steiner et al., 2019). Complementary alternative medicine (CAM) options are often used as a non-pharmacologic preventative or adjunctive treatment for pediatric chronic headache sufferers. Complementary and alternative medicine as an adjunctive treatment for pain management includes techniques such as biofeedback therapy (BFT), cognitive-behavioral therapy (CBT), and acupuncture (Toldo et al., 2017).

The purpose of this project was to explore and describe the use of specific CAM methods (e.g., acupuncture, CBT, and BFT) as potential adjunct management options to reduce headache frequency and pain intensity. The targeted population for the project was pediatric patients with chronic headaches referred to the pain clinic at a children's hospital in the City of Los Angeles. This select population was targeted to evaluate the effects of CAM on a diverse population, and to develop generalizable referral recommendations for CAM.

There are limited studies or national guidelines by the American Academy of Neurology and the American Headache Society with published recommendations on the use of CAM as a potential treatment option or in combination with pharmacologic treatments, in pediatric headache sufferers. Thus, there were variations in the literature on the effectiveness, safety, and feasibility of the use of CAM in pediatric populations. However, parents and patients have reported using CAM with or without recommendations from their providers (Black, Clarke, Barnes, Stussman, & Nahin, 2015).

Conceptual Framework

Avedis Donabedian's model is a widely used and known conceptual framework for evaluating health services and the quality of health care (Ayanian & Markel, 2016). According to the model, three categories are used to evaluate the quality of health care, which include structure, process, and outcomes (See Figure 1). *Structure* refers to factors that affect care delivery (e.g., facility, equipment, staffing, payment), the *process* is the sum of all the actions involved in care delivery, and *outcomes* contain the effects on the patient or populations (e.g., behavior, knowledge, satisfaction, change in health) (Ayanian & Markel, 2016). Donabedian's model is appropriate for evaluating the effect of adjunct therapies such as CAM, in a pediatric pain clinic setting on treatment outcomes among patients with persistent headaches (Ayanian & Markel, 2016). Of note, Donabedian's model has received attention for not incorporating antecedent characteristics (patient and environmental factors) that are essential variables associated with quality of care (Coyle & Battles, 1999). A patient's socioeconomic status (e.g., level of education, insurance status, family income), psychological stress (stress from school or work), and unique environment (culture, beliefs, living situation) are a few of the antecedents that influence a patients' health (Coyle & Battles, 1999).

Structure, according to Donabedian, is not only the physical setting in which medical services are provided but also the quality of the care providers, and the organizational arrangement (Ayanian & Markel, 2016). Patients with chronic headaches were referred to the pain clinic by neurology when other pain management strategies have failed. The type of providers and their comfort/knowledge of CAM therapies could affect the patient's referral pattern and outcomes. The referral process and patient characteristics (e.g., culture, education, beliefs, and insurance), could reflect follow through with the referral to CAM therapy. The CAM

provider's training, CAM therapy used based on headache type, and follow through with the prescribed number of CAM sessions/appointments could affect patient outcomes.

The **process** is the treatment with CAM for chronic headaches, which can vary in the pain clinic based on type of headache, type of CAM used, frequency of treatment, adverse effects, and duration of effects. Patients will continue their medication regimen for chronic headaches with the addition of CAM. Recommendations or referrals are made for patients to receive some form of CAM therapy for help with headache pain management upon consultation with a pain clinic provider.

Examining the structure and the process measures are important because they can affect the quality of the **outcomes** from the viewpoint of the patient and family. The clinical outcome measures will include headache frequency and pain level that is collected from the electronic health records (EHR). A quality outcome measure included patient satisfaction with CAM treatment and the services of the clinic. If functional measures were available, they were collected (e.g., school absenteeism and activities of daily living).

Literature Search Strategies

The literature search was implemented to find research on chronic pediatric headache management, using the search engines PubMed, CINAHL, and Google Scholar. The searches were filtered to include original articles published in the last five to seven years. The search terms used were "pediatric headache management," "alternative medicine in pediatrics," and "complementary alternative medicine and pediatric headaches". Two hundred articles were reviewed; however, after duplications, conference abstracts, non-CAM, and adult articles were removed, seven were selected (Table 1).

Article selection was based on their relevance to the research question. Articles on pediatric headache management that included integrative treatment strategies (e.g., CBT, BFT, and acupuncture) met the inclusion criteria for this project. Limited studies addressed other CAM options such as vitamins, herbal supplements, aromatherapies, and yoga (Dalla Libera et al., 2014). These studies were not included unless used in addition, or comparison with acupuncture, CBT, and BFT. Acupuncture, CBT, BFT are the most commonly used therapies offered in the pediatric pain clinic for headache sufferers.

Other inclusion criteria used for this project were studies published in the English language, studies that included children with headaches, and studies where CAM was provided in a variety of practice settings (e.g., hospitals, pain clinics, and pediatric pain rehabilitation centers). Articles that discussed CAM use for other medical conditions in pediatrics (e.g., abdominal pain, behavioral conditions, and generalized chronic pain syndromes) were excluded from selection. Systematic reviews, articles not focused on children with headaches, and addressing ‘headache management’ without the use of CAM were excluded from this literature search.

Synthesis of the Literature

The literature search identified seven articles related to different CAM therapies used to treat pediatric migraines or other types of chronic headaches. The types of CAM included acupuncture, mindfulness, nutritional/herbal supplementation, and CBT (both in-person sessions or via internet-based applications). The most frequent self-reported outcome measure was headache frequency or the number of headache days obtained via diaries (paper or electronic) and pain scores using a Visual Analog Scale (VAS, a pain assessment tool) (Graff & McDonald, 2018; Kroner et al., 2016; Kroon Van Diest et al., 2018; Blume, Brockman, & Breuner, 2012).

Some studies measured secondary outcomes using questionnaires on depression, anxiety, sleep, and quality of life (Hesse, Holmes, Kennedy-Overfelt, Kerr, & Giles, 2015; Law, Beals-Erikson, Noel, Claar, & Palermo, 2015). Semi-structured interviews of patients and parents of headache sufferers were either the primary source of data or used to supplement other quantitative studies to evaluate the effectiveness of CAM therapies through thematic analysis (Kroon Van Diest et al., (2018). In general, these studies were non-clinical trial descriptive or feasibility studies, mixed-method studies, and pilot prospective intervention studies with small sample sizes. Behavioral/relaxation techniques like CBT, BFT, and acupuncture were CAM interventions commonly used in the pain clinic and appropriate for the proposed project. These studies are summarized below in three groups. Of the seven studies examined, five used some form of mindfulness or behavioral therapy (Hesse et al., 2015; Kroner et al., 2016; Law et al., 2015; Kroon Van Diest et al., 2018; Dalla Libera et al., 2014), three of the studies were comparative studies (Law et al., 2015; Kroon Van Diest et al., 2018; Dalla Libera et al., 2014), and two of the studies were mixed methods combining the CAM treatment with medication (Kroner et al., 2016; Law et al., 2015).

Auricular acupuncture, used for pediatric patients in the emergency department experiencing a severe migraine, was shown to be effective in decreasing pain scores in a small sample who had not received any additional systematic pain medication (Graff & McDonald, 2018). Ninety percent of the patients enrolled in the study completed the intervention and evidenced an average seven-point drop on their VAS for headache pain at the end of treatment compared to their pre-intervention score (Graff & McDonald, 2018). This prospective interventional study focused on the feasibility, safety, and effectiveness of acupuncture at different time points in migraine management. Although the absence of a control group was a

weakness of the study, a future study employing a control group appears warranted based on these findings. Another future study could compare the effects of auricular acupuncture to intravenous medication for treating migraine in the emergency department (Graff and McDonald, 2018). Of note, the study had a high percentage of females (89%), thereby limiting the generalizability of the study findings, and did not represent how the treatment would affect male migraine sufferers.

Cognitive-behavioral therapy, a well-established form of psychotherapy that focuses on the connection between cognitions, emotions, and behaviors, is used to treat mental health disorders, stressful life events, or chronic physical symptoms and is most effective when used in combination with other medical treatment (Suveg et al. 2018). Relaxation techniques which fits into the scope of CBT, is also used to treat headaches. In a study by Kroner and colleagues (2016), participants who were given amitriptyline received augmentation with either CBT or a control headache education intervention for chronic migraines. The study findings revealed that at twenty weeks after treatment, 47% of children who received CBT and amitriptyline had four or fewer headache days, compared to 20% of the group who had education and amitriptyline (Kroner et al., 2016). These findings support the utility of CBT as an adjunct to pharmacotherapy in other pediatric populations or conditions (Dickerson et al. 2018) and suggest that adding CBT or another type of CAM could potentially decrease headache days and pain intensity. However, the above two studies focused only on migraine headaches and cannot be generalized to all types of chronic headaches (Graff & McDonald, 2018; Kroner et al., 2016).

To improve access and evaluate the feasibility and effectiveness of CBT for adolescents with chronic headaches, Law, Beals-Erikson, Noel, Claar, and Palermo (2015) trialed its use through internet delivery. Adolescents were randomized to receive either on-line CBT as an

adjunct to their headache treatment (internet adjunctive CBT and medical care prescribed by the headache clinic) or specialized headache treatment alone (medical care by the headache clinic). Adolescents in both groups experienced a reduction in the number of headache days, pain intensity, and functional disability at the time of follow up and three months post-intervention. However, the difference between groups was not statistically significant, and this may have been attributed to some participants receiving face-to-face CBT or biofeedback in the headache treatment alone group. These findings were similar to the findings of Kroner and colleagues (2016) in that a reduction in headache days was observed when CBT was provided as an adjunct therapy to medical management.

Kroon Van Diest, Ernst, Vaughn, Slater, and Power's (2018) qualitative study overall supports the helpfulness of a CBT only intervention as an adjunct to headache treatment in reducing headache frequency as identified through semi-structured interviews of patients and parents. However, there were some mixed reports from patients and their parents on the helpfulness of CBT (Kroon et al., 2018). Most parents reported that the mind and body relaxation skills (e.g., deep breathing, muscle relaxation) as part of CBT were the most effective and frequently used skills by participants.

Studies on CAM for other chronic headaches like tension-type headaches and idiopathic headaches were limited as migraine sufferers were more likely to seek medical attention. Mindfulness-based interventions have been explored as an adjunct treatment for pediatric migraine sufferers (Hesse, Holmes, Kennedy-Overfelt, Kerr, & Giles, 2015). Mindfulness is a form of psychotherapy used to reduce stress and promote good mental and physical health by the recipients being aware and focusing on the present moment. Recipients are then able to experience events, thoughts, and emotions without becoming immersed or overwhelmed and can

accept and balance those emotions (Hesse et al., 2015). A pilot study on a mindfulness intervention for adolescent females with recurrent headaches (e.g., defined as four or more headaches per month) failed to demonstrate changes in headache frequency or severity of headaches; nevertheless, the intervention had beneficial effects on depression and quality of life (Hesse et al., 2015). Other beneficial effects emerged, including evidence that mindfulness-based interventions can help with relaxation, sleep, focus, and coping with pain during headaches (Hesse et al., 2015). This study had several limitations, including small sample size, absences of reported effect sizes, and a sample with limited generalizability, given that the cohort comprised predominantly Caucasian females.

Biofeedback therapy (BFT), another behavioral and relaxation technique, is a well-known treatment for pediatric migraine patients (Blume, Brockman, & Breuner, 2012). Patients learn to control bodily processes that are generally involuntary, such as muscle tension and gain control over autonomic function such as heart rate and skin temperature. Blume and colleagues (2012) examined the effects of BFT on pediatric patients with chronic and episodic headaches retrospectively. Among children who attended two or more BFT sessions, median headache frequency decreased from 3.5 (IQR: 1 to 7) to 2.0 (IQR: 1 to 7) days per week between the first and last sessions. Multivariate analysis identified the ability to raise hand temperature and the use of selective serotonin reuptake inhibitors (SSRIs) to be associated with a positive response to BFT. Overall, BFT appears to be an effective treatment for pediatric headache sufferers. The relationship between SSRIs and positive responses to BFT is unclear and warrants further investigation (Blume, Brockman, & Breuner, 2012).

Mixed CAM therapies are other types of CAM (e.g., vitamins, herbal supplements, yoga) used alone or in combination with acupuncture, CBT, or BFT. Mixed CAM therapies are used by

patients or their parents, trying to reduce headache frequency, functional disability (e.g., school absenteeism), and the number of daily medications used (Dalla Libera, Colombo, Pavan, & Comi, 2014). A study by Dalla Libera and colleagues (2014), examined 124 pediatric patients with different types of headaches (12% migraines with an aura, 18% tension-type headaches, 70% migraine without an aura) on the type of CAM used and its effects on other comorbid conditions. Complementary alternative medicine therapies that participants reported using included herbal remedies, aromatherapies, multivitamins, acupressure, and yoga. Similar to other studies, patients using any component of CAM in conjunction with pharmacological management reported lower headache-associated pain scores, a decrease in the number of headaches, and improvement in daily functioning (Dalla Libera et al., 2014). Of interest, there were significant correlations between CAM use and improvement in other comorbid conditions such as anxiety, allergies, and abdominal illnesses (Dalla Libera et al., 2014). Other studies have identified depression as a common comorbid condition among chronic pediatric headaches sufferers, and CAM has shown to be effective at treating depressive symptoms (Hesse et al., 2015; Dickerson et al., 2018).

Methodology

Institutional review board (IRB) exemption was attained from the Children's Hospital Los Angeles and University of California Los Angeles before the commencement of the scholarly project.

Project Design: The project was a retrospective review of EHR for pediatric patients (age 8 to 18 years) with chronic headaches (e.g., tension-type and migraine) seen in the pain clinic. A telephone patient satisfaction survey on CAM (acupuncture) treatment was completed on a random sample of patients who received acupuncture in 2018-2019.

Sample Setting: The sample comprised pediatric patients (predominately age 8 – 18 years) identified in the pain clinic database seeking or referred for CAM therapy for chronic headaches not relieved by medical management alone. The pain clinic is located in a large freestanding children's hospital in Los Angeles. Complementary alternative medicine (CAM) is a relatively new service for the pain clinic, and they receive approximately eight new consults for patients per month for chronic headache management. The Division of Pain Medicine (pain clinic) is a multispecialty team consisting of anesthesiologists, physicians' assistants, nurse practitioners, psychologists, psychiatrists, and acupuncturists who work with families to meet the particular needs of each child experiencing pain issues or pain associated with a chronic illness. The clinic evaluates various types of pain, which include headaches, postoperative pain secondary to a trauma injury, acute exacerbation of chronic pain, specific illness, or disease-causing pain (e.g., oncology, chronic regional pain syndrome, sickle-cell disease) and recurrent abdominal pain. Complementary alternative treatments most commonly provided are acupuncture, cognitive behavioral therapy, and biofeedback therapy. These CAM programs are relatively new additions to most pain clinics across the country and can be resource-intensive for the pain clinic. Medical insurance coverage for some forms of CAM is limited and, at times, not available. Therefore, periodic program evaluations are sought to assess the need and benefits of these specialized CAM treatments.

Sample Size: Over the past three years (2016-2019), approximately 124 patients had a consultation in the pain clinic for persistent headache management. However, only 95 received CAM treatment and were eligible for the project.

Inclusion/Exclusion Criteria: The eligibility criteria for selecting medical records of patients who were 1) age 8 to 18 years, 2) had a diagnosis of headaches, and/or headache

disorder lasting greater than three months, and 3) documented to have received acupuncture, CBT, or biofeedback therapy. Children with chronic headaches were excluded if they 1) had an organic cause (e.g., brain tumor, and structural abnormalities), and/or 2) had documented developmental delay.

Data Collections: The primary investigator (PI) had direct access to the medical records of children with persistent headaches in the past three years. The PI collected data using information indicated in the Data Collection Form (Appendix A). Demographics (age, gender, ethnicity, insurance, type of headache, and age at the time of diagnosis), type of provider referral (physician, nurse practitioner, physician assistant), headache information (the type of headache, headache frequency (number per week or month) and pain scores (0-10) numerical rating scores (NRS) and visual analog scale (VAS) score were collected before and after CAM treatments. Additional variables collected if recorded in the EHR were 1) patient's level of function (e.g., school absenteeism, activities of daily living, 2) Headache interference with sleep and sleep hygiene, 3) Comorbidities (anxiety, depression), 4) Duration of symptom relief, 5) Adverse effects experienced during and after treatments, 6) Dietary adjustments, 7) Anticipatory guidance.

Using a telephone survey (Appendix B), the PI collected information on the type of CAM the patient received, the headache pain score, if available, after receiving CAM, and if the CAM received helped reduce the frequency and intensity of headaches. The length of time the patient received CAM, satisfaction with CAM, and the likelihood of continuing to use CAM was also of importance for data recording to evaluate outcomes. Patients who received CAM treatments in the last 24 months (2018 to 2019) in the proposed data collection period (2016 to 2019) were targeted for the telephone survey. All patients with a documented in-service phone number, who

answered the call, and verbalized willingness to participate were included in the survey. Specific CAM therapies could not be evaluated due to the majority of the sample receiving acupuncture.

Primary Outcomes: The primary outcome measure is pain score using the numeric rating scale (NRS-11) or the VAS scale (tools clinicians and patients use to measure and report on pain), and headache frequency. In addition, the overall satisfaction with the CAM treatment, the effectiveness of the treatment, the duration of effect, and whether the patient is continuing to use CAM will be evaluated by a telephone survey in about 30% of the total sample from 2019 (Appendix B).

Data Analysis: The Statistical Package for Social Sciences (SPSS) version 25 (IBM; Somers, NY) was used for statistical analysis of the data. Descriptive statistics (means, standard deviations, and frequencies) were used to summarize the demographic characteristic (e.g., age, gender, ethnicity, and insurance type), headache, and CAM variables. Paired *t*-tests were used to evaluate differences in pain scores pre- and post-CAM treatment and based on CAM type. Wilcoxon signed-rank test was used for nominal variables (e.g., change in pain rating and headache frequency) pre- and post-CAM. Statistical significance was measured with a *p*-value ≤ 0.05 .

Results

One hundred twenty-four children with chronic headache received consultation for chronic headache management in the pain clinic (2016-2019). There were 116 who were receiving CAM; 95 had one or more types of CAM. After removing patient medical records with missing data, 78 had documented pain ratings and headache frequency change (qualitative) pre- and post-CAM and 40 having actual pain scores (Figure 2). Children ($n=78$; 14 ± 2.4 years) were mostly female (81%), Hispanic (45%), received public insurance (56%), had chronic migraines (47%), taking

three or more headache medications and referred by Neurology (54%). Children received acupuncture (68%) or combined acupuncture and CBT (25%) (Table 2).

Children (n=78) had statistically significant qualitative pain rating and headache frequency (increased, no change, decrease) pre- and post-CAM ($p < .001$). Actual pain scores (n=40) were significantly different pre- (7.0 ± 2.0) and post- (2.53 ± 3.1 , $p = 0.03$) CAM. Pre-CAM NRS pain scores ranged 8-10 in 44% and post-CAM range 0-3 in 62% of participants. Children (n=28) who received acupuncture had a significant decrease in pain scores from pre- (7.0 ± 1.6) to post- (1.8 ± 1.6 , $p < 0.001$) treatment. Children (n=11) who received the combined acupuncture and CBT indicated a significant decrease in headache pain scores from pre- (7.5 ± 2.1) to post- (4.6 ± 3.4 , $p = 0.02$) treatment (Table 3).

The telephone surveys (n=20) indicated that 100% received acupuncture, more than half (55%) agreed that CAM was helpful; the majority (61%) had relief for two months after all treatments were completed. Post-CAM mean headache pain scores (4.7 ± 3.4 ; n=18) was moderately severe. Ninety percent were not currently using CAM due to insurance or scheduling conflicts (60%) (Table 4).

Discussion and Implications for Practice

The findings showed that CAM, primarily acupuncture or combined acupuncture and CBT, had significant effects in the improvement of pediatric headache frequency and pain scores. One prospective pilot study showed similar findings of improvement or resolution of migraine pain in children, predominantly Caucasian females, using auricular acupuncture (Graff & McDonald, 2018). Interestingly, most pain intervention studies tend to have samples that are predominately females (Sullivan, Tripp, & Santor, 2000). The above project also highlighted the feasibility, safety, and effectiveness of acupuncture at different time points in migraine management. Our

retrospective study was also predominantly female and found very few adverse effects associated with acupuncture in a more ethnically diverse pediatric population in Los Angeles. Furthermore, Dalla Libera et al. (2014) identified that children receiving CAM in conjunction with pharmacological management reported lower pain scores and a decrease in the number of headaches. Our findings also reflect chronic headache sufferers receiving medical/pharmacologic management in addition to CAM, which could account, in part for our positive outcomes.

The combination of acupuncture and CBT also showed a significant decrease in pediatric headache pain scores. Although acupuncture alone had lower post-CAM pain scores, this could be related to the combined group having slightly higher pre-CAM pain scores. Unfortunately, other CAM methods (e.g., CBT alone and BFT) were not as frequently used in the pain clinic, and children were referred out to community providers. Those referrals could reflect the lack of trained professionals in the pain clinic to perform these therapies, availability of clinic space, and appointment times.

The telephone survey identified that the majority of children post-CAM are not continuing to use acupuncture due to lack of insurance coverage, the ability to pay out-of-pocket, and schedule limitations. Over half of the study participants had public health insurance (e.g., Medi-Cal), which typically covers about eight acupuncture visits. In addition, private insurance also has a limitation on the number of CAM visits covered. Schedule conflicts were also highlighted by parents in that the clinic hours were not conducive to children in school or working parents. Thus, parents tended to seek CAM services in the community or with the school district. Despite patient and parent reports of CAM helpfulness, the limitations on the amount of CAM visits set by insurance companies, and the limited clinic hours resulted in discontinuation of therapy.

Other pediatric CAM studies report the barriers of insurance coverage to continued CAM use (Dalla Libera et al., 2014). Hospital pain clinics that provide CAM services may want to consider variable hours (e.g., evening or weekend) to optimize utilization and potentially reduce chronic headache pain and improve quality of life.

The cost-effective use of CBT for some comorbid conditions associated with chronic headaches, like depression, was studied by Dickerson et al., (2018). Results from that study can be pondered for this project bearing in mind the amount of missed school days patients reported, thus missed workdays by their parents. Effective CAM treatments can decrease the gravity of some comorbid conditions associated with chronic headaches like depression and anxiety (Dickerson, et al., (2018). Conversely, the clinical psychologist and psychiatrist did not directly provide CBT or BFT for chronic headache patients at the time of their visits for headaches. Instead, patients were required to schedule a separate appointment to receive CBT and BFT, just as they would for acupuncture. Multiple appointments to the clinic proved to be challenging for headache patients, as revealed from data on the telephone survey.

Limitations

Inconsistent provider documentation of pain scores, including headache intensity and frequency, was a limiting factor when evaluating post CAM effectiveness at follow up visits. Clinic providers follow a biopsychosocial model of pain management, shifting the emphasis from pain scores and intensity to reporting on the cognitive and emotional state and the responses that impact the recounted pain experiences of patients; thus, documentation of the pre- and post- pain rating score were lower. Additionally, sample sizes for CBT and BFT were too small to evaluate the statistical significance of those methods of CAM.

Conclusion

CAM had significant effects on the improvement of headache frequency and pain scores in predominately Hispanic females receiving either acupuncture or combined acupuncture and CBT. However, insurance and conflict in schedules were significant barriers to continuing use of CAM. Prospective studies are needed to minimize barriers to receiving CAM and evaluate whether CAM may optimize pain control and decrease use of pain medications in children with chronic headaches.

Appendix A

Complementary Alternative Medicine: Pediatric Headache Data Collection / Chart Review Form (Investigator Only)

Subject ID #: _____

Date of service: _____

1. Demographic Information of Patient:

- Male • Female •
- Age _____ years
- Ethnicity:
 - Caucasian •
 - Hispanic •
 - African American •
 - Asian •
 - Mix _____
- Type of Insurance
 - Public / State Health •
 - Private •
 - Self-pay / Uninsured •

2. Type of Provider Referral:

- Doctor •
- Nurse Practitioner •
- Physician's Assistant •

3. Referral Type:

- Neurology •
- Primary Care Provider •

4. Headache Information:

- Type of Headache
 - Migraine •
 - Tension •
 - Cluster •
 - Other _____
- Age at diagnosis _____ years

- Meet definition of chronic headaches (>3 months) Yes • No •
- Medication regimen (include OTC):
 - _____
 - _____
 - _____
- Other recommendations or remedies used (non-pharmacologic)
 - Dietary changes •
 - Vision checked •
 - Sleep hygiene •
 - Other _____

5. CAM information:

Type of CAM received

- Acupuncture •
- Biofeedback •
- Cognitive Behavioral Therapy (CBT) •
- Combination _____

CAM Provider

- Acupuncturist •
- Pediatric Pain Psychologist •
- Pediatric Pain Psychiatrist •
- Other •

Pre - CAM pain score: NRS-11 _____

Pre - CAM pain score: increasing / same / decreasing (circle)

Pre - CAM number of headaches _____ per week / month (circle)

Pre-CAM headaches: increasing / same / decreasing (circle)

Pre - CAM function ability:

- Missed school days: Yes, • No • If yes how many _____
- Missing sports or social activities Yes, • No •

Pre – CAM outcome measures collected: _____ days / weeks / months
before CAM

Number of CAM Sessions: _____

Post - CAM pain score: NRS-11_____

Post - CAM pain score: increasing / same / decreasing (circle)

Post - CAM number of headaches _____ per week / month (circle)

Post - CAM headaches: increasing / same / decreasing (circle)

Post - CAM functional ability:

- Missed school days: Yes, • No • If yes how many_____
- Missing sports or social activities Yes, • No •

Adverse Effects of CAM: Yes, • No • ; If Yes, what type: _____

Duration of pain relief post CAM intervention_____ hours / days / weeks (circle)

Post – CAM outcome measures collected: _____ days / weeks / months after
CAM

Appendix B

Telephone Follow-Up / Patient Satisfaction Survey

Study ID # _____

Dated Contacted: _____

1. Type of CAM used? • Acupuncture, • CBT, • Biofeedback, • Combination _____

- 2. Pain score after CAM on a scale of 0 to 10?**

0 1 2 3 4 5 6 7 8 9 10
No pain Worst pain ever

3. Was the method of CAM used (type _____) helpful at reducing pain?

Strongly agree • Agree • Neither agree or disagree • Disagree • Strongly disagree. •

4. How long did the effects of CAM last? _____ Days/Weeks/Months (circle)?

- 5. Are you continuing to use CAM for headache treatment?**

- Yes
- No, why? _____

Figure 1. Avedis Donabedian's Model for Quality Health Care Improvement

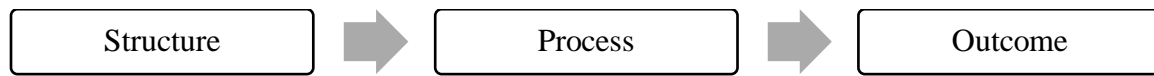


Figure 2. CAM Chart Review Diagram.

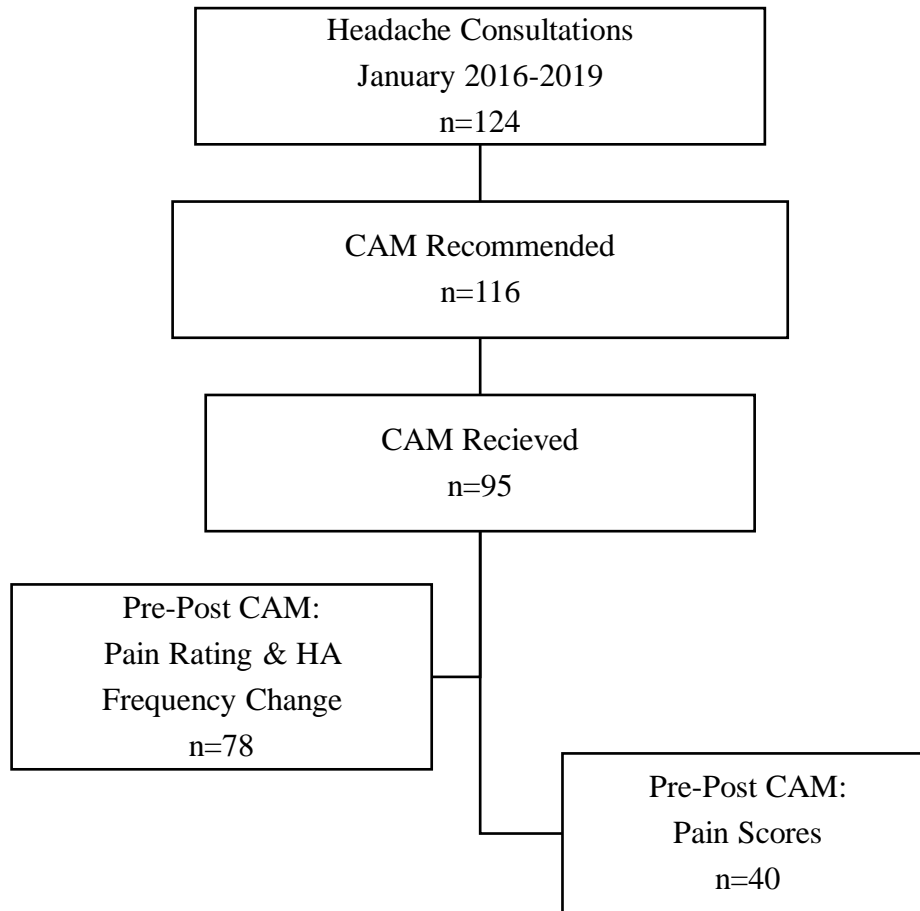


Table 1. Table of Evidence

Citations	Purpose	Sample and Setting	Methods (design, intervention measures)	Results	Discussion Interpretation on Limitations of Findings
Blume, H. K., Brockman, L. N., & Breuner, C. C. (2012). Biofeedback therapy for pediatric headache: Factors associated with response. <i>Headache: The Journal of Head and Face Pain</i> , 52(9), 1377-1386. doi:10.1111/j.1526-4610.2012.02215.x	<ul style="list-style-type: none"> *To measure the effect of biofeedback therapy on pediatric headache patients. *To identify factors associated with the response to biofeedback therapy. 	* $n = 132$ children ages 8 to 18years, seen in a pediatric biofeedback therapy (BFT) clinic between 6/2004 and 7/2008 in Seattle Children's Hospital.	<ul style="list-style-type: none"> * Retrospective chart review. * Charts excluded from the review were children with <2 sessions of BFT and whom the responder status could not be determined ($n=61$). * Patients and parents completed intake surveys, on HA characteristics, medication, PMH, depression, anxiety, and somatization. * Children attended at least 8 sessions of BFT. 	<ul style="list-style-type: none"> * 58% Response rate, 48% for chronic headaches, and 73% for episodic headaches. * Median HA frequency dropped from 3.5 to 2 HA days per week $p<0.001$) and HA severity ($P<0.001$). * Ability to raise hand temp, $>30^{\circ}\text{F}$, and SSRI use to be associated with a positive response to BFT. *Anxiety, depression, and somatization were 	<ul style="list-style-type: none"> * Retrospective chart review with no control group, and limited to only data the EHR. * Only documented results from the effect of thermal biofeedback (one category of biofeedback). No data on heart rate and muscle relaxation.

			<ul style="list-style-type: none"> * Outcome measure was HA frequency severity. * Used descriptive statistics, Fisher exact tests, Wilcoxon signed-rank test, multivariable logistic regression model. 	not significantly associated with BFT.	
<p>Dalla Libera, D., Colombo, B., Pavan, G., & Comi, G. (2014). Complementary and alternative medicine (CAM) use in an Italian cohort of pediatric headache patients: The tip of the iceberg. <i>Neurological Sciences</i>, 35(1), 145-148. doi:10.1007/s10072-014-1756-y</p>	<ul style="list-style-type: none"> * The use of CAM for migraines compared to pharmacologic treatments. * The effects of CAM on other comorbid conditions (e.g., anxiety and depression) that are often seen in children with chronic headaches 	<ul style="list-style-type: none"> *<i>n</i> =124 age 4-16. *Pediatric headache center in Milan, Italy. * 90% white, 5% African, 5% Asian. * 67% of females * 82% with migraine * 18% with tension headache. 	<ul style="list-style-type: none"> *Semi-structured interviews with children and parents on admission. On the type, method, reason for, perceived benefits of, life experiences and attitudes with CAM. * Descriptive statistics measured demographics and the most common CAM used (e.g., 	<ul style="list-style-type: none"> *53% of patients who used CAM had migraine with aura, followed by 38% with tension-type headache (TTH). * Females, younger, and a higher level of parental occupation correlated to CAM use ($p<0.05$) compared to the 	<ul style="list-style-type: none"> * CAM was used for coping with headache triggers and emotional distress. * The national insurance system did not cover CAM, so costs were out of pocket. * Patients used CAM without any scientific backing for its use

			<p>nutritional supplements, yoga essential oils, and aromatherapy).</p> <p>* Mann-Whitney U and Kruskal-Wallis tests were used for multiple comparisons and Spearman's rho for correlations.</p>	<p>parental occupation.</p> <p>* 80% of CAM users had a family history of headaches, of which 65% of their mothers used CAM.</p> <p>* Correlation between the use of CAM and other medical comorbid conditions was identified. CAM was used to treat anxiety 55%, 23% insomnia, and 20% for muscle disorder.</p> <p>* 57% of CAM recipients reported the benefits of its use.</p> <p>* CAM was used by 76% of the patients.</p>	<p>(nutritional and herbal remedies).</p> <p>* The researchers noted CAM was useful for migraines but needed further studies to investigate safety and efficacy.</p> <p>* The list of CAM methods used was very diverse, and the efficacy of products like essential oils, aromatherapy, and nutritional supplements was not noted.</p>
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				<ul style="list-style-type: none"> * 43% of children used more than one CAM therapy. * 64% used herbal remedies. * 80 % used CAM for an average of 12months, and 5% used it for acute therapy * 47% used homeopathy * 45% used physical treatment 	
<p>Graff, D. M., & McDonald, M. J. (2018). Auricular acupuncture for the treatment of pediatric migraines in the emergency department. <i>Pediatric Emergency Care</i>, 34(4). Doi: 10:1099 /PEC.00000000000000789</p>	<p>* To evaluate the effectiveness of auricular acupuncture and any adverse effects in the treatment of pediatric migraine in the ED.</p>	<p>* $n = 19$ ages 8-18 years with headaches being seen in the pediatric ED in Louisville, KY. * Excluded patients if pain medication was used during the ED visit.</p>	<p>* A prospective interventional cohort study. * Pre and post-acupuncture pain scores were obtained using a visual analog scale (VAS). * 15 minutes of observation after acupuncture</p>	<p>*The mean pre-intervention VAS scores 7.63 (IQR of 7-8.5) and post-intervention VAS @ 15minutes was 0.55 (IQR of 0-0.5) range of 0-4.5. * The mean change in scores</p>	<p>* Two patients withdrew from the study despite a reduction in pain scores without complete resolution of symptoms. Researchers concluded their withdrawal was</p>

			<p>needles were placed on efficacious ear sites (auricular migraine lines).</p> <p>* Descriptive statistics and related sample Wilcoxon signed-rank test to assess the difference between pre and post-intervention scores.</p>	<p>was 7.03 (IQR of 6-8.5.) $p < 0.001$</p> <p>* No adverse events were identified.</p>	<p>likely due to needle discomfort.</p> <p>* Study findings are not generalizable to all headache sufferers due to the small sample size and mostly female gender.</p> <p>* Fast, efficient treatment times decreased wait times in the ER.</p> <p>* Auricular acupuncture was proven support effective at reducing migraine HA in children.</p> <p>* Future studies are needed to evaluate the duration of symptom resolution.</p>
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<p>Hesse, T., Holmes, L. G., Kennedy-Overfelt, V., Kerr, L. M., & Giles, L. L. (2015). Mindfulness-based intervention for adolescents with recurrent headaches: A pilot feasibility study. <i>Evidence-based Complementary & Alternative Medicine (eCAM)</i>, 2015, 1-9. doi:10.1155/2015/508958</p>	<p>*To examine the effects that a mindfulness intervention would have on reducing headaches in with a recurrent headache.</p>	<p>* $n=20$ adolescent females (11-16 years with recurrent headaches). * 94% Caucasian. *Participants were from the pediatric and neurology clinic. * Exclusion criteria were headache patients with developmental delay, autism, and abnormal neurological exam.</p>	<p>*A pilot nonrandomized clinical trial. * Study participants had 7/8 mindfulness sessions. * Participants continued taking recommended pharmacologic agents for their headaches. *Participants kept daily diaries to record the number of headaches. * Self-reported questionnaires were completed pre and post-intervention. Peds QL, The Center for Epidemiological Studies Depression Scale for Children (CES-DC),</p>	<p>* No reduction in headache frequency. * Patients reported that mindfulness was beneficial overall in helping them relax and cope with pain and depression per the results from the CES-DC scores. * 93% of parents felt the classes were beneficial to their daughters * Participants slept better, remained more focused, and were overall calmer.</p>	<p>* The study size was small; only 15 of the 20 adolescents completed the sessions; not all participants completed 7/8 sessions. *Low study participation was likely due to a study occurring during the school year, per researchers. · Mindfulness-based interventions for persistent headache patients can potentially decrease other comorbid conditions they may endure (e.g., depression) and</p>
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			<p>Multidimensional Anxiety Scale for Children (MASC), and the Chronic Pain Acceptance Questionnaire, Adolescent version (CPAQ-A).</p> <p>*A two-tailed paired samples <i>t</i>-test was used to assess the mean differences in pre and post-treatment scores.</p>		<p>improve their quality of life.</p> <ul style="list-style-type: none"> · Mindfulness is a form of CBT, and patients receiving CBT are likely to engage in some form of mindfulness.
<p>Kroner, J. W., Hershey, A. D., Kashikar-Zuck, S. M., LeCates, S. L., Allen, J. R., Slater, S. K., . . . Powers, S. W. (2016). Cognitive-behavioral therapy plus amitriptyline for children and adolescents with chronic migraine reduces headache days to ≤ 4 per</p>	<p>*To compare headache frequency between patients who received CBT and amitriptyline (CBT+A) and patients who received headache education (HE)</p>	<p>* $n = 135$ patients ages 10-17 years diagnosed with chronic migraines at Cincinnati Children's Hospital between 10/2006 and 09/2012.</p> <p>* 79% female, 89% white.</p>	<p>*Secondary analysis from a previously published RCT.</p> <p>* Study participants completed a baseline assessment and kept headache diaries.</p>	<p>*At 20 weeks post-treatment, 47% of the CBT+A group had ≤ 4 HA days compared to 20% of the HE+A group ($p=0.0011$)</p> <p>* 32% of the CBT +A group had ≤ 3 HA days</p>	<p>* Both groups of patients experienced fewer headache days; however, the patients who received CBT +A had the most HA days between the two groups.</p>

month. <i>Headache: The Journal of Head and Face Pain</i> , 56(4), 711-716. doi:10.1111/head.12795	and amitriptyline (HE+A).	* 64 CBT+A, and 71 to HE+A (the control group).	* All patients attended eight one-hour sessions during weeks 1 to 8, and additional sessions at weeks 12 and 16 and a post-visit at week 20. * Chi-square test of independence to determine differences and by time point.	at 20 weeks compared to 16% of the HE + A group ($p=0.0304$) * At the 12 months, 72% of the CBT + A group had ≤ 4 HA days compared to 52% of the HE + A group ($p=0.0249$) and 61% of the CBT + A group had ≤ 3 HA days compared to 40% of the HE + A group ($p=0.0192$)	* Results from this study have shown that both CBT and HE, when added to pharmacological treatments, were effective at reducing HA. * Some results are limited to diary documentation, which was subjective despite guidelines to diary documentation for the participants.
Kroon Van Diest, A. M., Ernst, M. M., Vaughn, L., Slater, S., & Powers, S. W. (2018). CBT for pediatric migraine: A qualitative study of patient and parent experience. <i>Headache: The Journal of Head and Face Pain</i> , 58(5), 661-	* To determine which CBT-HA treatment patients would report as being most helpful and essential in reducing headache frequency and disability. * To develop a streamlined	* $n = 10$ patients ages 13 – 17 years, and 9 parents at a Midwestern medical center outpatient clinic. * 8 females. * Used only patients treated by two psychologists	* All participants received CBT-HA and given at least 3 components of evidence-based treatment pain management. * Conducted semi-structured interviews on the parent and patient	* 90% of patients were in the mild range of disability (3 of 4 patients originally in the moderate range moved to the mild range). * Most patients described CBT-HA as being	* Small sample size reducing the generalizability of study results. Also, a time-lapse since treatment and the interview creating recall bias. * Future research is needed to

675. doi:10.1111/head.13285	treatment package that is accessible to patients and families.	whose work is related to pediatric migraine pain and experts in CBT.	<p>perspectives regarding CBT-HA.</p> <ul style="list-style-type: none"> * Both parent and patient completed questions regarding demographics and HA characteristics. * Qualitative analyses using grounded theory with thematic coding. 	<p>helpful, and a variety of techniques were useful for HA improvement.</p> <ul style="list-style-type: none"> * Two parents noted that it was difficult to determine if treatment was helpful, either not seeing the patients' use of the skill or simultaneous treatment with physical therapy. * Mixed reports on the effects of different CBT-HA skills. * Most patients reported that the mind and body relaxation skills of CBT-HA were the most effective and 	examine the streamlined pediatric migraine nonpharmacologic interventions.
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				frequently used skill.	
Law, E. F., Beals-Erickson, S. E., Noel, M., Claar, R., & Palermo, T. M. (2015). A pilot randomized controlled trial of internet-delivered cognitive-behavioral treatment for pediatric headache. <i>Headache: The Journal of Head and Face Pain</i> , 55(10), 1410-1425. doi:10.1111/head.12635	* To evaluate the feasibility and effectiveness of the internet-delivered CBT intervention for adolescents with chronic headaches.	* $n = 83$ ages 11-17 years, 15 males, 68 females with HA > 3 months diagnosed by neurologist. * $n = 44$ internet & CBT & $n = 39$ specialized treatment alone. * Conducted at a pediatric HA clinic in the northeastern United States between (2008-2010)	* Parallel arm randomized control trial used to compare internet-based CBT to a specialized headache treatment vs. specialized headache treatment alone. * HA frequency was assessed using a prospective 7-day on-line diary. * Secondary outcome measures via questionnaires were pain, activity, emotion, and sleep. * Independent sample t-test and chi-square used to	* Patients reported a reduction in HA days for primary treatment $p < 0.001$; No statistical difference between groups ($p = 0.395$). * For secondary treatment outcomes, both groups had statistically significant improvement of HA pain, activity level, depressive symptoms were maintained at 3-month follow-up but were statistically significant	* Adjunct internet-based CBT did not lead to additional benefits for HA treatment. * A short time frame (7 days) was used to assess HA frequency and intensity for the trial. The American Headache Society recommends a minimum of 4 weeks of daily diaries * The study had mixed HA diagnoses, which enhanced generalizability but could have impacted the

			<p>assess groups. Intent to treat analyses were used to handle missing data</p>	<p>between groups (all with $p > 0.05$).</p>	<p>potency of the CBT intervention. * Standard medical care was variable, and interventions could have overlapped in both groups.</p>
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Table 2. Sample Characteristics (n=78)

Variable	n (%) or mean \pm SD
Age [range 8-18]	14.3 \pm 2.4
Gender [Female]	64 (81%)
Ethnicity	
Hispanic	35 (45%)
White	26 (33%)
African American	6 (9%)
Mix / Other	11 (13%)
Insurance	
Public	44 (56%)
Private	32 (41%)
Uninsured / Self-Pay	2 (3%)
Referral Service	
Neurology	42 (54%)
Primary Care	29 (37%)
Other	7 (9%)
Headache Type	
Migraine	37 (47%)
Persistent	27 (35%)
Tension	6 (8%)
Mixed	6 (8%)
Other	2 (2%)
HA lasting > 3 months	73 (94%)
[Yes]	
Age at Diagnosis	12.5 \pm 3.2
[range 4-18]	
# HA Medications	
1	6 (8%)
2	18 (23%)
3	21 (27%)
4	19 (24%)
>5	14 (18%)
CAM Type Received	
Acupuncture	53 (68%)
CBT	4 (5%)
BFT	1 (1%)
Massage	1 (1%)
Mixed	19 (25%)
Mixed Types (n=19)	
Acupuncture + CBT	14 (73%)

HA = Headache; CAM = Complementary and Alternative Medicine;
 CBT=Cognitive Behavioral Therapy; BFT = Biofeedback Therapy.

Table 3. Pre- and Post-CAM Pain and Headache Frequency

Variable	Pre-CAM [n (%) or mean \pm SD]	Post-CAM [n (%) or mean \pm SD]	P-Values
Pain Rating (n=78)			<.001*
Increase	31 (40%)	1 (1%)	
No Change	45 (58%)	13 (17%)	
Decrease	2 (2%)	64 (82%)	
HA Frequency (n=78)			<.001*
Increase	30 (37%)	1 (1%)	
No Change	44 (55%)	15 (19%)	
Decrease	4 (5%)	62 (79%)	
Pain Rating (n=40)	7.0 \pm 2.0	2.5 \pm 3.1	.030†
0-3	2 (5%)	25 (62%)	
4-5	5 (13%)	7 (17%)	
6-7	15 (37%)	5 (13%)	
8-10	18 (44%)	3 (8%)	
CAM Type Pain Rating (n=40)			
Acupuncture (n=28)	7 \pm 1.6	1.8 \pm 2.7	.000†
Mixed (n=11)	7.5 \pm 2.1	4.6 \pm 3.4	.020†

CAM = Complementary and Alternative Medicine; *Wilcoxon Signed Rank Test; Paired t-test

Table 4. CAM Telephone Satisfaction Survey [n=20]

Survey Question	Response (n=20) [n (%) or mean \pm SD]
Type of CAM used? Acupuncture	20 (100%)
Post-CAM HA Pain Score (n=18)	4.7 \pm 3.4 (range 0-10)
Was CAM Helpful?	
Strongly Agree	2 (10%)
Agree	9 (45%)
Neither Agree nor Disagree	7 (35%)
Disagree	2 (10%)
How long did CAM effects last? (n=18)	7 (39%)
< 1 week	4 (22%)
1-2 months	3 (17%)
3-5 months	4 (22%)
>6 months	
Are you still using CAM?	
Yes	2 (10%)
No	18 (90%)
If No, why? (n=18)	
Insurance	6 (33%)
Conflicts in Schedule	5 (28%)
Not helpful	4 (22%)
No further pain	3 (17%)

CAM = Complementary and Alternative Medicine

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