

THE EFFECT OF COMPLEMENTARY AND ALTERNATIVE MEDICINE FOR MIGRAINE
HEADACHES: AN INTEGRATIVE REVIEW

An Integrative Review

Submitted to the

Faculty of Liberty University

In partial fulfillment of

The requirements for the degree

Of Doctor of Nursing Practice

By

Katelyn Vaughn Spangler

Liberty University

Lynchburg, VA

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Scholarly Project Chair Approval:

Dr. Vickie Moore, RN, DNP, FNP-C

Date

ABSTRACT

Migraine headaches continue to be a prominent health concern, affecting a large percentage of the population globally. These headaches have many negative impacts on patients' lives, including decreased productivity, missed time at work or school, increased suicidal tendencies, and a decreased overall quality of life. Pharmacological approaches for treatment are available but often present with safety concerns, unpleasant side effects, rebound headaches, increased expenses, and a higher rate of emergency department visits. Therefore, many people seek treatment options other than conventional medication to address their migraines. Various complementary and alternative medicine therapies have shown promising results in previous clinical trials for migraine management. This integrative review explores the effects of the complementary and alternative medicine therapies of exercise therapy, yoga, chiropractic spinal manipulation, acupuncture, mindfulness-based cognitive therapy, and massage therapy on migraine headache prevention and acute treatment. These alternative methods of migraine treatment have proven to be effective in many studies, but additional high-level evidence studies are needed to validate these findings.

Keywords: migraine headaches, complementary and alternative medicine, treatment, prevention

Dedication

I would like to begin by dedicating this project to my husband, Austin, and my son, Carson. Austin, I would not have made it this far if it wasn't for your continuous support, understanding, and encouragement along the way. Your motivation and determination to succeed is what encouraged me to begin this program three years ago. You believe in me more than I believe in myself, and I thank you for that. You push me to better myself in every aspect of life, and I am forever grateful that God placed us together. Thank you for always working so hard to provide for our family, picking up my slack with no hesitation, and being the absolute best father to our son and soon-to-arrive daughter. Carson, you are our most precious blessing in life. You have motivated me, made me stronger, and shown me a love that I didn't know was possible. I love you unconditionally and will always work my hardest to provide for you and be a supportive and loving mother.

I would also like to dedicate this project to my supportive parents, Jeff and Rhonda Vaughn. They have given me every opportunity to succeed and have provided endless support to me and my aspirations throughout life. This program would not have been possible without them both. Their uplifting words, prayers, unending love, encouragement, and financial support made this program and project achievable and I am forever grateful. I am truly so thankful that God chose me to be their daughter. I also dedicate this work and give special thanks to my brother and number one fan in life, Bradley. Bradley, you have always been a constant source of support and encouragement for me throughout every season of life and I thank you.

Lastly, but most importantly, I dedicate this project to my Lord and Savior, Jesus Christ. He has served as my constant source of wisdom, inspiration, knowledge, and motivation. I owe it all to Him.

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List of Abbreviations

Centers for Disease Control and Prevention (CDC)

Complementary and alternative medicine (CAM)

Emergency department (ED)

Institutional Review Board (IRB)

Integrative review (IR)

Mindfulness-based cognitive therapy (MBCT)

Mindfulness-based stress reduction (MBSR)

Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)

Randomized-controlled trial (RCT)

SECTION ONE: FORMULATING THE REVIEW QUESTION

Migraine headaches affect a large percentage of the population worldwide. According to the Migraine Research Foundation (2021), someone in the United States goes to the emergency department (ED) complaining of head pain every 10 seconds. Moreover, approximately 1.2 million yearly ED visits are for acute migraine headaches. Migraine is the third most prevalent illness globally and affects 39 million men, women, and children in the US and one billion people worldwide (Migraine Research Foundation, 2021). Migraines are often debilitating and are considered one of the leading causes of global disability (Centers for Disease Control and Prevention [CDC], 2020; Kumar et al., 2020). This neurological condition has a negative impact on patients' quality of life when not controlled and may lead to unnecessary time off from work, poor school performance, and decreased productivity (Kumar et al., 2020). Furthermore, migraines are a risk factor for cerebrovascular disease, depression, and an increased suicidal tendency (Kumar et al., 2020). Due to the numerous adverse effects on patients' lives, health care providers must implement evidence-based practice and contribute to future studies to reduce migraine headache occurrences in the general population.

Background

Use of Emergency Department and Opioids for Migraine Headaches

Despite the various preventative and abortive treatment options available, migraines continue to be frequently treated in the acute care setting. Published guidelines recommend non-opioid therapies for migraines. However, opioids continue to be administered for adults who present with migraines in over half of ED visits (American Headache Society, 2021). A literature review by Young et al. (2017) found no significant benefits in overall throughput time in the ED when patients with migraines were treated with opioid medications. The use of opioids to treat

migraine headaches is associated with an increased risk of revisits to the ED (CDC, 2020; Young et al., 2017), increased use of rescue medications (Young et al., 2017), a higher number of hospital admissions, and an increased ED length of stay (CDC, 2020; Young et al., 2017). In addition, routine use of opioids for the treatment of migraines often leads to more frequent and severe headaches (American Headache Society, 2021; Young et al., 2017).

Side Effects of Pharmacological Management

Habitually, over-the-counter and prescribed medications are utilized as the first-line treatment for migraine headaches (Kumar et al., 2020). Although various medications do provide some relief for migraines, they frequently cause undesired side effects. Pharmacological management's associated side effects may include low blood pressure, nausea, depression, and renal damage (Rezaeian et al., 2019). Specific side effects for certain classifications of medications have been identified in the literature. For example, non-steroidal anti-inflammatory drugs may cause heartburn, diarrhea, kidney or liver impairment, gastrointestinal disorders, or an increased risk of bleeding with regular or frequent use (American Migraine Foundation, 2011).

Complementary and Alternative Medicine

Despite their prevalence and negative impact on quality of life, migraines remain underrecognized and poorly treated (Kumar et al., 2020). Complementary and alternative medicine (CAM) treatment options offer a promising alternative therapy for migraine headaches. Health care providers should further explore CAM therapies to prevent and treat migraine headaches to avoid the potential side effects and risks associated with pharmacological management. A wide variety of CAM therapeutic techniques is available for the treatment of migraine headaches. However, the use of CAM is relatively low in the US (Zhang et al., 2017), and little is known about the indications for CAM use and the perceived benefits of CAM use

among the migraine population (Rhee & Harris, 2018). Increased CAM use for migraine headaches has many positive outcomes, such as a decrease in ED visits (Young et al., 2017), improved quality of life (Rhee & Harris, 2018), and less reliance on pharmacological agents for management (Zhang et al., 2017).

Defining Concepts and Variables

Clearly describing the topic of interest while conducting an integrative review (IR) minimizes any ambiguity within the review (Toronto & Remington, 2020). The variables essential to define for this project were migraine headaches and CAM treatment. A migraine may be defined as a disabling neurological disease that causes head pain and is often described as an intense pulsing or throbbing pain in one area of the head (American Migraine Foundation, 2021). Specific diagnostic criteria for migraine headaches from the International Headache Society include at least five headaches that last four to 72 hours if untreated and may include additional symptoms of nausea and vomiting or sensitivity to both light and sound (National Institute of Neurological Disorders and Stroke, 2019). A patient may present with various classifications of migraines, including migraine with aura, migraine without aura, chronic migraine, and episodic migraine (American Migraine Foundation, 2021). This review includes peer-reviewed studies conducted on patients with a diagnosis of migraine without regard to the chronicity or aura status.

The second term essential to define was complementary and alternative medicine. CAM may be defined as “a process of manipulation of body parts and stimulation of healing through herbs and substances” (Buttaro et al., 2017, p. 1188). CAM therapies are not part of mainstream conventional medicine, and they are used either in complement with or in place of standard medical treatments (Falci et al., 2016). Examples of CAM include but are not limited to

chiropractic treatments, acupuncture, massage therapy, herbal preparations, and homeopathy (Buttaro et al., 2017). The operational definition of CAM for this review is a nonstandard medical treatment for migraines, including acupuncture, manipulative therapies, and mind/body therapies.

Rationale for Conducting the Review

A vast amount of literature exists regarding various CAM therapies for migraine headaches. Many articles found in the literature support the utilization of CAM therapies for migraine treatment and the importance of education on CAM therapies for providers and patients. However, the literature lacks an overall and comprehensive review of the recent studies regarding CAM therapies. Almost 85% of providers feel they lack the knowledge to inform their patients about CAM (Wells, 2019). This IR is significant because it delivers education to providers and patients on the use and benefits of CAM for migraine headaches. Studies reveal that the use of CAM is associated with improved health-related quality of life outcomes in adults with migraines (Rhee & Harris, 2018). Therefore, providers who treat patients affected by migraine headaches should have a basic understanding of the efficacy and safety of CAM therapies for preventative and abortive migraine treatment.

Purpose of the Project

The purpose of this project was to explore various CAM treatment and prevention options for migraine headaches. This project provides an updated literature review to inform health care providers on the current data and enable them to make informed decisions when formulating the treatment plan for their patients affected by migraine headaches.

Review Question

The following review question guided this IR: What complementary and alternative medicine therapies are available for the treatment and prevention of migraine headaches? The following supporting questions served to focus the review:

1. Is acupuncture an effective CAM option for migraine headaches?
2. Are mind/body methods (yoga and mindfulness-based cognitive therapy [MBCT]) effective for migraine headaches?
3. What are the benefits of manipulative therapies (exercise therapy, chiropractic spinal manipulation, and massage therapy) for migraine headaches?

Project Goals

The goals of this project were as follows:

- To provide an IR of the current research related to the use of CAM for migraine headaches
- To provide recommendations for future research and inform practice
- To identify gaps in the current literature
- To raise awareness of various CAM therapies and their use for migraine headaches
- To provide education to patients and health care providers on the use of CAM for migraine headache treatment and prevention

SECTION TWO: COMPREHENSIVE AND SYSTEMATIC SEARCH

Search Strategy

Liberty University's online Jerry Falwell Library was utilized to perform an extensive literature review. Various databases were used in the search, including CINAHL Plus with Full Text, Sage Research Methods, EBSCO, PubMed, ProQuest, DynaMed Plus, and Cochrane. The

use of multiple databases permitted a comprehensive search of the literature. To focus the review, inclusion and exclusion criteria were set. The writer limited the results to only include articles with full text available, a published date from 2016 to 2021, written in the English language, and peer reviewed. The titles and abstracts were then evaluated for relevancy to the review topic. If deemed appropriate, the full text was then read to ensure the study met all eligibility criteria.

Inclusion and Exclusion Criteria

Studies for this IR were considered if the CAM therapies discussed were applied to migraine headaches. A strict description of the type of migraine was not applied. Keeping a broad definition of the term *migraine* allowed the inclusion of several significant studies that may have been excluded otherwise. Other inclusion criteria included peer-reviewed and full-text articles. Criteria that disqualified a study from the review included:

- Published more than five years ago
- Published in a language other than English
- Content irrelevant to the review question
- Abstracts for which the full-text article was unable to be located.

Quality Appraisal

After the inclusion and exclusion criteria were set, articles were appraised for their study purpose, population sample, study method, level of evidence, study results, limitations, and study design. Melnyk's levels of evidence were utilized to appraise each potential article for inclusion (Melnyk & Fineout-Overholt, 2019). The level of evidence matrix representing the critical appraisal of the articles included in the review may be found in Appendix A. The articles included in the IR represent various levels of evidence. A total of 25 articles were included in the

review: seven Level 1, 10 Level 2, one Level 3, two Level 5, and five Level 6 articles. Each of the articles included in the IR contributes relevant information to assist in answering the clinical question.

PRISMA

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Statement was utilized to improve the reporting of the literature review. The PRISMA Statement consists of a 27-item checklist and a four-phase flow diagram (Moher et al., 2010). The phases presented on the diagram are identification, screening, eligibility, and inclusion. The completed PRISMA for this IR is included in Appendix B. This diagram depicts the flow of information and how the articles were selected throughout the four-phase process.

Synthesis

The literature findings further validate the high prevalence of migraines worldwide and their negative impact on an individual's quality of life. Many CAM therapies, including acupuncture, mind/body therapies, yoga, herbal supplements, massage, and chiropractic, have shown to be effective in managing migraine headaches. Health care providers often lack the knowledge to inform their patients about CAM, and the widespread use of CAM for migraine treatment is relatively low in the US (Zhang et al., 2017). However, the literature notes a need for future well-designed studies with rigorous trials and large sample sizes to offset the risk of bias and validate existing findings (Anheyer et al., 2019; Jiang et al., 2018).

Conceptual Framework

A well-designed IR summarizes past empirical literature and provides a comprehensive understanding of a particular health care problem (Whittemore & Knafl, 2005). In order to compose a well-written IR, a conceptual framework may be utilized to help guide the process.

The Whittemore and Knafl method was the framework utilized for formulating this IR. The framework consists of five stages to guide the review design: problem identification, literature search, data evaluation, data analysis, and presentation (Hopia et al., 2016).

The problem that led this review was migraine headaches. The question for the review was whether or not CAM therapy for migraine headache relief is effective. A literature search of various databases provided by the Jerry Falwell Library was conducted. Studies conducted using various methodologies, such as experimental and nonexperimental research, were included in the literature search as allowed by the Whittemore and Knafl (2005) framework. The data evaluation stage of the framework focused on the authenticity, quality, informational value, and representativeness of the available studies (Hopia et al., 2016). After a thorough literature search and data evaluation, the data were analyzed, which included data reduction, display, and comparison and the development of conclusions (Hopia et al., 2016). Lastly, the information was presented to portray the process and describe the implications for practice, policy, and research. The limitations of the review were recognized and will be later discussed (Hopia et al., 2016). Following the steps of the Whittemore and Knafl (2005) method of IR guaranteed a well-designed and successful research review.

Summary

The purpose of this IR was to examine the current literature on various CAM therapies for migraine headaches. An appropriate framework was utilized to help guide and design the review. Inclusion and exclusion criteria were set to focus the search on the clinical question. After relevant studies were selected, each article was appraised by means of Melnyk's levels of evidence. The findings revealed the high prevalence of migraine headaches, the high frequency of ED visits for migraine headaches, and the negative impact migraines have on patients' quality

of life. As suggested in the literature, many CAM therapies may be considered in the management of migraine headaches. A literature review summarizing the evidence on CAM therapies for migraine treatment will allow providers and patients to better understand CAM and its effectiveness.

SECTION THREE: RESULTS

A comprehensive and well-defined search strategy was utilized to enhance the rigor of this IR and to avoid the potential of inaccurate results (Whittemore & Knafl, 2005). Once the studies were selected for inclusion, the data from these sources were summarized into a unified and integrated conclusion about the use of CAM for migraine treatment (Whittemore & Knafl, 2005). This section discusses the common themes amongst the primary studies and their findings related to the clinical question: Are complementary and alternative medicine therapies effective for the treatment of migraine headaches?

Data Evaluation

Acupuncture for Migraine Treatment

Several studies indicated that acupuncture has a positive impact on the treatment of migraine headaches (Jiang et al., 2018; Linde et al., 2016; Ni et al., 2020; Wells, 2019; Yang et al., 2016). A systematic review by Jiang et al. (2018) concluded that acupuncture is effective in both the treatment and prevention of migraine headaches. In addition, the findings suggested that acupuncture has a more positive impact on a patient's quality of life and pain relief when compared to medication treatments, no treatment, or sham acupuncture (Jiang et al., 2018; Linde et al., 2016; Ni et al., 2020). Further validating these findings, Linde et al. (2016) determined that adding acupuncture to symptomatic treatment reduced the frequency of migraine headaches.

Literature suggests that patients who receive acupuncture have a significant reduction in their migraine frequency when compared to those only taking drug prophylaxis (Linde et al., 2016). However, it is important to note that there was a decrease in the significance of this difference at follow-up assessments over time in the study by Linde et al. (2016). After three months, headache frequency was cut in half or more in 57% of patients receiving acupuncture and 46% receiving prophylactic drugs. After six months, headache frequency decreased in 59% of those receiving acupuncture and 54% receiving prophylactic drugs (Linde et al., 2016). Despite the narrowing in the differences in treatment outcomes over time, this trial suggests that acupuncture is at least similarly effective as prophylactic drug treatment. Notably, participants in this trial who received acupuncture were less likely to drop out from experiencing or reporting adverse effects than the participants who received prophylactic medications (Linde et al., 2016).

Mind/Body Treatment

Examples of mind and body treatments include meditation, mind/body exercise (yoga, tai chi, and qi gong), guided imagery, biofeedback, deep breathing exercises, MBCT, and progressive muscular relaxation (Zhang et al., 2017). Migraines are often triggered and affected by psychological factors, such as stress and emotion (Jiang et al., 2018). Therefore, learning to control stress and emotion may have a positive impact on management of migraine headaches.

Risks associated with behavioral treatments are important to note and include a vivid recollection of a previous traumatic event. This is a known potential side effect of meditation and relaxation exercises and may occur in those who have experienced a previous psychologically traumatic event even with no symptoms of posttraumatic stress disorder (Seng et al., 2019). Therefore, it is important to assess for disorder in the patient's history that may cause posttraumatic stress to be triggered through these techniques.

Yoga. Yoga is an ancient Indian practice that is based on the principles of mind and body medicine. It is one of the most common forms of CAM therapies utilized worldwide for various disorders or disabilities (Kumar et al., 2020). Previous studies have shown that yoga is beneficial for managing migraine headaches in various measures, including headache frequency, intensity, duration of the attack, nature of pain, and the use of rescue medications (Kumar et al., 2020). Adding yoga therapy to medical treatment is a cost-effective and safe method for the management of migraine headaches. Yoga combined with medical therapy is superior to medical therapy alone in the management of migraine headaches (Kumar et al., 2020).

Yoga utilizes physical activity, breathing regulation, relaxation, and meditation to contribute to stress reduction and migraine management (Sharma et al., 2018). In addition, yoga promotes a significant change in autonomic function through improved vagal tone, reduced sympathetic activity, and improved cardiac autonomic balance (Kumar et al., 2020). Yoga therapy increases nitric oxide, which may help reduce migraine attacks. Lastly, yoga therapy may assist in reducing muscle tension in the head, neck, shoulders, and temporal area, which often serves as a trigger for migraines (Kumar et al., 2020). These physiologic changes describe various reasons yoga may be effective as an add-on therapy in migraine management.

Mindfulness-Based Cognitive Therapy. MBCT is unique from traditional behavioral treatments for migraine headache treatment. MBCT has demonstrated efficacy in the treatment of various diseases and is a promising avenue for treatment of migraine headaches (Seng et al., 2019). MBCT “teaches mindfulness meditation and cognitive-behavioral coping skills and directly applies these skills to address disease-related cognitions and coping” (Seng et al., 2019, p.1450). Various RCTs reveal that MBCT results in a reduction in stress and disease-related disability or impairment across medical conditions (Seng et al., 2019). Mindfulness-based

interventions teach skills to modify the patient's relationship with their experience of a migraine and should be used when the patient's primary goal in their headache management is to reduce the amount of disability related to the headache. MBCT may be a useful treatment to help maintain successful reduction in the number of monthly headache days by other treatments such as relaxation, biofeedback, or preventive pharmacotherapies (Seng et al., 2019).

Two of the studies in the review referred to MBCT as mindfulness-based stress reduction (MBSR) (Seminowicz et al., 2020; Wells et al., 2021). A randomized controlled trial (RCT) revealed that MBSR has the potential to be an effective prophylactic treatment option for migraine headaches and is comparable to other commonly used first-line treatments for migraine prophylaxis. Headache frequency was decreased in 52% of the participants receiving MBSR compared to 23% of the control group (Seminowicz et al., 2020). RCTs have also revealed that MBCT leads to a decrease in headache frequency, improved ability to function with a migraine, significant and sustained improvement in the participants' management of pain, improved quality of life, improved disability, enhanced self-efficacy, and decreased depression (Wells et al., 2021).

Manipulative Therapy

Manipulative therapy is one of the most frequently used methods amongst people who participate in CAM for migraine headaches (Zhang et al., 2017). Examples of manipulative therapy include physical therapy, massage, osteopathic manipulative treatment, chiropractic spinal manipulation, exercise therapy, and daith piercings (Wells, 2019). Many previous studies reveal strong evidence supporting manipulative therapy for migraine treatment (Wells, 2019). Massage therapy, exercise, and chiropractic spinal manipulation will be discussed further based upon the articles included in the review.

Massage Therapy. Two studies included in the review discuss the potential benefits of soft-tissue technique massage therapy. These studies concluded that massage therapy may improve certain aspects of a migraine headache, such as the impact, disability, frequency, and intensity of the headache (Espí-López et al., 2018), as well as drug consumption and pressure pain threshold levels of cervical muscles (Rezaeian et al., 2019). One study included in the review focused on the use of traditional massage therapy for the prophylaxis of migraine and found useful effects but identified the need for larger studies (Happe et al., 2016). Massage therapy and other physical therapy modalities remain inadequately studied (Happe et al., 2016; Rezaeian et al., 2019). Other studies discussing the benefits of utilizing massage therapy as a treatment were found but were excluded from the review because they were published more than five years ago.

Exercise Therapy. Evidence indicates that exercise therapy has the potential to reduce the burden of migraine headaches (Barber & Pace, 2020; Hanssen et al., 2018; Krøll et al., 2018; Lippi et al., 2018). Exercise has been shown to contribute to a decrease in migraine frequency, pain intensity, and duration, as well as an improvement of the patient's quality of life (Barber & Pace, 2020; Krøll et al., 2018; Lippi et al., 2018). Both high-intensity interval training and moderate continuous exercise training are associated with a reduced frequency of migraine attacks (Barber & Pace, 2020; Hanssen et al., 2018). These findings suggest that regular engagement in aerobic exercise may be a reasonable preventative measure to include in the treatment plan of migraine headaches. However, some studies found that exercise is non-inferior when compared to certain pharmacologic prophylactic interventions and should be considered as an addition to traditional preventive measures rather than a single treatment option (Barber & Pace, 2020). This suggestion should not apply to patients who have migraines provoked by

physical activity, as it may, but does not always, worsen or trigger attacks in these patients (Lippi et al., 2018; Varkey et al., 2017). Therefore, the decision to engage in exercise for migraine treatment should be made with consideration of the patient's medical history and determined on an individual basis after discussion with a health care provider.

Chiropractic Spinal Manipulation. The outstanding need for rigorously designed studies with adequate control groups to definitively determine the effect of chiropractic spinal manipulation on migraine headaches was identified in four articles (Bernstein et al., 2019; Chaibi et al., 2017; Moore et al., 2017; Rist et al., 2019). Current data suggest that spinal manipulation may reduce the length of migraines as well as their pain and intensity (Rist et al., 2019). A small case study of three participants highlighted the promise of chiropractic care for migraine treatment with reports of improved pain scores, increased pain-free days, decreased medication usage, and decreased anxiety (Bernstein et al., 2019). The adverse effects of chiropractic spinal manipulation are mild and transient (Chaibi et al., 2017; Rist et al., 2019). Therefore, spinal manipulation may be considered in patients who do not tolerate medication or where other therapeutic options are ineffective (Chaibi et al., 2017). However, further studies are essential to strengthen the evidence on the use of chiropractic spinal manipulation for migraine headaches.

Need for Future Study

Several studies indicate the need for future well-designed studies on the use of various CAM therapies for migraine headache therapy (Anheyer et al., 2019; Bernstein et al., 2019; Chaibi et al., 2017; Moore et al., 2017; Rhee & Harris, 2018; Rist et al., 2019). Numerous ongoing studies and study protocols may be found that further evaluate various CAM therapies for migraine headaches (de Almeida Tolentino et al., 2021; Odell et al., 2019; Pressman et al., 2019; Satpute et al., 2021). However, these studies are currently in process and the outcomes are

not available yet. The results of these high-quality clinical trials will assist in strengthening the evidence on the effects of non-pharmacological treatment and preventative options for the management of migraine headaches.

Synthesis

The literature review findings exhibit the frequent diagnosis of migraine worldwide and the problems that co-exist during acute attacks. Literature on CAM therapies for migraine treatment and prophylaxis is voluminous but is lacking in the number of recent high-level evidence studies available. Many articles provided great information applicable to the study topic but were excluded from the review as they were published more than five years ago. Over half of the studies included in the IR identified the need for future well-designed studies of high-level evidence. Each of the CAM therapies discussed reveals promising benefits for patients who are affected by migraine headaches. However, it is difficult to assuredly recommend CAM therapies for migraines due to the lack of data available to strengthen the validity and generalizability of the findings.

Ethical Considerations

It is imperative to adhere to ethical norms when conducting research. An Institutional Review Board (IRB) is an appropriately established group that formally reviews and monitors research involving human subjects. The purpose of a review by the IRB is to ensure that steps are taken to protect the rights and welfare of human subjects participating in research (U.S. Food and Drug Administration, 2019). A copy of the IRB approval letter for this IR may be located in Appendix D. This IR is not classified as human subject research as it does not involve the collection of identifiable, private information from or about living individuals.

Timeline

This IR was completed during four academic courses. The timeline below ensured timely completion of this IR:

- Sections One and Two: July 9, 2021
- First defense: August 10, 2021
- Section Three: September 30, 2021
- Section Four: October 12, 2021
- Final draft completed and submitted to Dr. Moore (project chair): By November 15, 2021
- Final draft sent to editor: By November 22, 2021
- Final defense: By December 7, 2021
- End of academic term: December 17, 2021

SECTION FOUR: DISCUSSION**Summary of Evidence**

An extensive review of existing literature revealed that strong evidence is lacking on many CAM therapies regarding their benefits for migraine headaches. The overall strength of evidence included in the IR was moderate, as 32% of the studies were Level 3 through 6 on the Melnyk pyramid. Thus, there is a robust need for future studies on the use of CAM therapies for migraine headaches and to increase the awareness of their potential benefits. The results of this review may be utilized to guide future studies. In addition, the positive findings in the studies included substantiate the need for further studies in order to confidently translate these conclusions into practice and improve patient care and quality of life.

Many of the studies integrated revealed benefits of CAM therapies. Acupuncture is superior to no treatment or sham treatment (Linde et al., 2016) and has shown efficacy in both

the treatment and prevention for migraines (Jiang et al., 2018; Linde et al., 2016). However, the evidence is limited due to the low quality of published studies, and future research is needed to provide a reliable basis for wider use (Ni et al., 2020). Mind and body techniques of treatment, such as yoga and MBCT, have proven to be a cost-effective addition to the standard treatment regimen for migraines with minimal side effects. Manipulative therapy, such as exercise, chiropractic spinal manipulation, and massage have also shown beneficial effects on the treatment of migraines. However, there is a strong need for well-designed studies that can provide a high level of evidence.

Implications for Practice

Extensive research revealed that various CAM therapies have a positive impact on the treatment and prevention of migraine headaches. Health care providers may utilize this information when considering the use of CAM therapies for the treatment or prevention of migraine headaches. In addition, the results may be utilized to educate health care providers on the findings of the current literature regarding CAM use. Many of the studies included in the review discuss the need for future research studies on CAM treatments for migraine headaches. The current data do reveal promising findings for CAM therapy and migraine headaches and, therefore, many opportunities exist to create future research studies to strengthen the validity and generalizability of the findings.

Limitations

There were noted limitations to this IR. The initial literature search was complex, as there are many CAM therapies to explore. This further complicated the process of setting the inclusion criteria and keywords for the initial search. To simplify this process, a broad definition of *migraine* was utilized, and studies were not excluded based on the authors' personal inclusion or

exclusion criteria for migraine headaches in their own studies. In addition, the CAM therapies included in the review were chosen based on the preference of the author of this IR. Other CAM therapies are available and were not explored. The efficacy of other CAM treatment and prevention methods are not included in this review and therefore may be overlooked by health care providers utilizing this document for education on CAM treatment approaches to migraine headaches.

The largest barrier to this project was the lack of data that fit within the time range set in the inclusion criteria. Many well-conducted and high-level evidence articles pertinent to this study were outside of the five-year range and were therefore excluded. Studies conducted in the last five years that fit all established inclusion criteria were limited. Seven articles out of the 25 included in the review were systematic or integrative reviews published within the last five years. These systematic reviews included data from clinical trials conducted more than five years ago.

Lastly, many of the studies reported a limitation of a risk of bias, as the data were subjective and based on self-reports of migraine relief. Relying on self-reports on CAM use and its perceived benefits may create the possibility of recall bias or a placebo effect. In addition, the definition of migraines lacks precision and consistency across the included articles.

Dissemination Plan

The results of this IR may be utilized to inform health care providers and patients on the current data regarding CAM therapies for migraine headaches. The findings may also be utilized to help guide individuals conducting further research on this topic. The researcher plans to communicate these results to the primary end users by submitting this article to the *Journal of Alternative & Complementary Medicine*. In addition, the researcher plans to reach out to local

primary care offices and provide lay versions of the IR in hopes of increasing patients' access to the information. Providing lay versions will allow patients to be informed and participate in shared decision-making regarding their care.

Conclusion

Migraine headaches place a significant burden on a patient's quality of life and their ability to function to their normal capacity. Despite their prevalence worldwide, migraine headaches remain underrecognized and poorly treated. Current data represent a promising future for the utilization of various complementary and alternative treatment methods to manage and prevent migraine headaches. Many effective CAM options are available for migraine prevention and treatment of acute attacks. Providers must be educated and understand the efficacy, benefits, and risks of these modalities to discuss them with their patients (Wells et al., 2019).

Overall, the purpose of this study was to provide evidence-based information on CAM use and its effects on migraine headaches. This IR may assist providers in identifying the deficits in the evidence-based literature of several CAM modalities utilized in the US. Understanding the current data and the gaps suggesting the need for further studies will allow health care providers to make informed decisions about the safest and most appropriate approach for managing migraines in their patients (Zhang et al., 2017). Given the high prevalence of migraines, the burden placed on a patient's quality of life, and the potential side effects associated with exclusively pharmacological management, it is imperative that health care providers consider the use of various CAM therapies for the treatment and prevention of migraine headaches.

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Appendix A
Evidence Table

Name: Katelyn Spangler

Clinical Question: What complementary and alternative medicine therapies are available for the treatment and prevention of migraine headaches?

Article	Study Purpose	Sample	Methods	Study Results	Level of Evidence	Study Limitations	Would Use as Evidence to Support a Change?
Anheyer, D., Leach, M. J., Klose, P., Dobos, G., & Cramer, H. (2019). Mindfulness-based stress reduction for treating chronic headache: A systematic review and meta-analysis. <i>Cephalalgia</i> , 39(4), 544–555. https://doi.org/10.1177/0333102418781795	To assess the efficacy and safety of mindfulness-based stress reduction/cognitive therapy in reducing the symptoms of chronic headache.	5 RCTs with a total of 185 participants were included.	A systematic review and meta-analysis of RCTs	No evidence was found that mindfulness-based stress reduction was effective in improving the frequency, duration, or intensity of headache in patients suffering from chronic headaches.	Level 1: systematic review and meta-analysis of RCTs	Small number of RCTs included. Total number of participants in each study was low.	This source does not support a change. It does provide beneficial information in guiding further research.
Barber, M., & Pace, A. (2020). Exercise and migraine prevention: A	To characterize recent literature	17 studies included in the review	Systematic review of RCTs	Exercise is a reasonable evidence-based	Level 1: systematic	Limitations of the review were	Yes, provides evidence on

<p>review of the literature. <i>Current Pain & Headache Reports</i>, 24, Article 39. https://doi.org/10.1007/s11916-020-00868-6</p>	<p>pertaining of the role of aerobic exercise in the prevention of migraine.</p>			<p>recommendation for migraine prevention. Special populations, such as those with neck pain, may benefit from exercise; others may benefit from low-impact exercise such as yoga.</p>	<p>c review of RCTs</p>	<p>not discussed.</p>	<p>the use of exercise therapy for migraine headaches. However, important to note that the limitations of the review were not included.</p>
<p>Bernstein, C., Wayne, P. M., Rist, P. M., Osypiuk, K., Hernandez, A., & Kowalski, M. (2019). Integrating chiropractic care into the treatment of migraine headaches in a tertiary care hospital: A case series. <i>Global Advances in Health and Medicine</i>, 8, 1–5. https://doi.org/10.1177/2164956119835778</p>	<p>To utilize and evaluate an integrated model of care for migraine that combines standard neurological care with chiropractic treatment</p>	<p>3 case studies</p>	<p>A descriptive design</p>	<p>Three patients reported improvement in pain scores, increase in pain-free days, decreased medication usage, and patient reported decreased anxiety.</p>	<p>Level 5: descriptive</p>	<p>Only 3 cases included</p>	<p>Provides information on chiropractic spinal manipulation. States the need for further studies.</p>
<p>Chaibi, A., Benth, J. Š., Tuchin, P. J., & Russell, M. B. (2017). Chiropractic spinal manipulative therapy for</p>	<p>To investigate the efficacy of chiropractic spinal manipulative</p>	<p>104 patients with migraines—17 month duration</p>	<p>RCT</p>	<p>Migraine days were significantly reduced within all three groups</p>	<p>Level 2: RCT</p>	<p>Limitations were not discussed.</p>	<p>Yes – provides high level evidence for the use of</p>

<p>migraine: A three-armed, single-blinded, placebo, randomized controlled trial. <i>European Journal of Neurology</i>, 24(1), 143–153. https://doi.org/10.1111/ene.13166</p>	<p>therapy for migraines.</p>			<p>of the study from baseline to post-treatment. Chiropractic care might be considered in situations where other therapeutic options are ineffective or poorly tolerated.</p>			<p>chiropractic spinal manipulative therapy for migraines.</p>
<p>Espí-López, G.-V., Ruescas-Nicolau, M.-A., Nova-Redondo, C., Benítez-Martínez, J. C., Dugailly, P.-M., & Falla, D. (2018). Effect of soft tissue techniques on headache impact, disability, and quality of life in migraine sufferers: A pilot study. <i>Journal of Alternative & Complementary Medicine</i>, 24(11), 1099–1107. https://doi.org/10.1089/acm.2018.0048</p>	<p>To determine the efficacy of suboccipital inhibitory techniques in people with migraine compared with a control treatment based on myofascial trigger point therapy and stretching.</p>	<p>46 adults diagnosed with migraine with over 6 months duration.</p>	<p>Randomized, double-blind controlled pilot trial.</p>	<p>Soft tissue techniques were helpful for improving certain aspects of migraine, such as the impact and disability caused by the headache, and the frequency and intensity of headache. The benefits were greater when combined with suboccipital soft tissue inhibition.</p>	<p>Level 2: RCT</p>	<p>Risk of bias due to self-reporting of symptoms.</p>	<p>Yes, provides evidence on massage therapy for migraine headaches.</p>

<p>Hanssen, H., Minghetti, A., Magon, S., Rossmeißl, A., Rasenack, M., Papadopoulou, A., Klenk, C., Faude, O., Zahner, L., Sprenger, T., & Donath, L. (2018). Effects of different endurance exercise modalities on migraine days and cerebrovascular health in episodic migraineurs: A randomized controlled trial. <i>Scandinavian Journal of Medicine & Science in Sports</i>, 28(3), 1103–1112. https://doi.org/10.1111/sms.13023</p>	<p>To determine whether various aerobic exercises and high/moderate intensities distinctly affect migraine days.</p>	<p>45 patients included</p>	<p>Three-armed randomized controlled trial</p>	<p>Aerobic exercise at high exercise intensities performed in intervals revealed notable beneficial effects on migraine days, cerebrovascular health, as well as submaximal and maximal fitness levels.</p>	<p>Level 2: RCT</p>	<p>Low sample size.</p>	<p>Provides information at high level of evidence on exercise therapy for migraine headaches.</p>
<p>Happe, S., Peikert, A., Siegert, R., & Evers, S. (2016). The efficacy of lymphatic drainage and traditional massage in the prophylaxis of migraine: A randomized, controlled parallel group study. <i>Neurological Sciences</i>, 37(10), 1627–1632.</p>	<p>To examine the efficacy of lymphatic drainage and traditional massage in the prophylactic treatment of migraine</p>	<p>64 patients</p>	<p>RCT</p>	<p>The results showed useful effects for lymphatic drainage and massage when compared to a control-group for the prophylaxis of migraine.</p>	<p>Level 2: RCT</p>	<p>Low statistical power – unable to detect minor differences between control and experiment group.</p>	<p>Yes – provides information on massage therapy for migraine headaches at a high level of evidence.</p>

<p>https://doi.org/10.1007/s10072-016-2645-3</p>							
<p>Jiang, Y., Bai, P., Chen, H., Zhang, X. Y., Tang, X. Y., Chen, H. Q., Hu, Y. Y., Wang, X. L., Li, X. Y., Li, Y. P., & Tian, G. H. (2018). The effect of acupuncture on the quality of life in patients with migraine: A systematic review and meta-analysis. <i>Frontiers in Pharmacology, 9</i>, Article 1190. https://doi.org/10.3389/fphar.2018.01190</p>	<p>To evaluate the efficacy and safety of acupuncture for the treatment of migraine.</p>	<p>62 RCTs were included for the systematic review</p>	<p>A systematic review and meta-analysis of RCT</p>	<p>Findings indicate that acupuncture exhibits certain efficacy both in the treatment and prevention of migraines, which is superior to no treatment and medication. Acupuncture enhanced the quality of life more than did medication.</p>	<p>Level 1: systematic review</p>	<p>Only the overall efficacy and safety of acupuncture were evaluated rather than the acupoint itself. The different acupoints may cause different effects.</p>	<p>Provides good information on the use of acupuncture for migraines and implication for future research.</p>
<p>Kumar, A., Bhatia, R., Sharma, G., Dhanlika, D., Vishnubhatla, S., Singh, R. K., Dash, D., Tripathi, M., & Srivastava, M. V. P. (2020). Effect of yoga as add-on therapy in migraine: A randomized clinical trial. <i>Neurology, 94</i>(21), e2203–e2212. https://doi.org/10.1212/WNL.00000000000009473</p>	<p>To evaluate the effectiveness of yoga as an adjuvant to conventional medical management on clinical outcomes in patients with migraine.</p>	<p>114 patients completed the trial. Inclusion criteria: age 18–50 years, written informed consent, headache frequency ≥ 4 per month but < 14 per month,</p>	<p>RCT</p>	<p>Yoga as an add-on therapy for migraine treatment is superior to medical therapy alone. Yoga is a cost-effective and safe intervention for management of the migraine.</p>	<p>Level 2: RCT experimental design</p>	<p>Outcome measures are subjective and questionnaire based. Follow-up period was not long enough to assess persistence of the effect</p>	<p>Provides good information at a high level of evidence.</p>

		residing in Delhi, no contraindications for yoga therapy, and if on drug prophylaxis no change of drug for at least 3 months and no change of dose for at least 1 month prior to enrollment.				of intervention.	
Krøll, L. S., Sjødahl Hammarlund, C., Gard, G., Jensen, R. H., & Bendtsen, L. (2018). Has aerobic exercise effect on pain perception in persons with migraine and coexisting tension-type headache and neck pain? A randomized, controlled, clinical trial. <i>European Journal of Pain</i> , 22(8), 1399–1408. https://doi.org/10.1002/ejp.1228	To evaluate aerobic exercise in migraine and co-existing tension-type headache and neck pain.	52 participants in the study	RCT	Exercise significantly reduced the burden of migraines. Exercise reduced migraine frequency, pain, intensity and duration.	Level 2: RCT experimental design	There were no specificities of level of physical activity for participants.	Yes – reports positive findings on physical activity for the management of migraines.

<p>Linde, K., Allais, G., Brinkhaus, B., Fei, Y., Mehring, M., Vertosick, E. A., Vickers, A., & White, A. R. (2016). Acupuncture for the prevention of episodic migraine. <i>The Cochrane Database of Systematic Reviews</i>, 6, Article CD001218. https://doi.org/10.1002/14651858.CD001218.pub3</p>	<p>To investigate whether acupuncture is more effective than no prophylactic treatment/routine care only, whether it is more effective than placebo acupuncture, and as effective as prophylactic treatment with drugs in reducing headache frequency in adults with episodic migraine.</p>	<p>Twenty-two trials including 4985 participants were included in the review.</p>	<p>Systematic review</p>	<p>Findings suggest that adding acupuncture to symptomatic treatment of attacks reduces the frequency of headaches. They also suggest that acupuncture may be at least similarly effective as treatment with prophylactic drugs.</p>	<p>Level 1: Systematic review— included randomized trials</p>	<p>The quality of the included trials was variable.</p>	<p>Provides useful information on the use of acupuncture for migraine headaches</p>
<p>Lippi, G., Mattiuzzi, C., & Sanchis-Gomar, F. (2018). Physical exercise and migraine: For or against? <i>Annals of Translational Medicine</i>, 6(10), Article 181. https://doi.org/10.21037/atm.2018.04.15</p>	<p>To provide a narrative review of published articles that have explored the association between physical</p>	<p>14 articles</p>	<p>Narrative review of various epidemiological and intervention studies.</p>	<p>A general reduction of frequency, severity and duration of migraine attacks as well as improved quality of life has been</p>	<p>Level 6: descriptive design</p>	<p>Limitations were not discussed.</p>	<p>Despite low evidence, provides beneficial information on exercise and migraines.</p>

	exercise and migraine.			observed after the exercise intervention periods.			
Moore, C., Adams, J., Leaver, A., Lauche, R., & Sibbritt, D. (2017). The treatment of migraine patients within chiropractic: Analysis of a nationally representative survey of 1869 chiropractors. <i>BMC Complementary & Alternative Medicine</i> , 17, Article 519. https://doi.org/10.1186/s12906-017-2026-3	To evaluate the prevalence and characteristics of chiropractors who frequently manage patients with migraine.	1,869 chiropractors completed the survey	Cross-sectional survey	Chiropractic care is often used for migraines. There is a need for more high-quality research.	Level 6: descriptive design	Findings relied on the practitioners understanding of classification criteria of migraine headache. Risk of selection bias.	Yes – provides information on the need for future studies on chiropractic spinal manipulation for migraine headaches.
Ni, X., Dong, L., Tian, T., Liu, L., Li, X., Li, F., & Zhao, L. (2020). Acupuncture versus various control treatments in the treatment of migraine: A review of randomized controlled trials from the past 10 years. <i>Journal of Pain Research</i> , 13, 2033–2064. https://doi.org/10.2147/JPR.S259390	To review the effectiveness of acupuncture in the treatment of migraine by comparing treatment and various control groups.	49 studies	Systematic review	Acupuncture reduced headache frequency compared with no treatment. Frequency did not significantly differ between patients who received real vs sham acupuncture.	Level 1: systematic review of RCTs	Articles were limited to those in either the English or Chinese language. Risk of bias present.	Yes, provides beneficial information on acupuncture for migraines.

<p>Rezaeian, T., Mosallanezhad, Z., Nourbakhsh, M. R., Ahmadi, M., & Nourozi, M. (2019). The impact of soft tissue techniques in the management of migraine headache: A randomized controlled trial. <i>Journal of Chiropractic Medicine</i>, 18(4), 243–252. https://doi.org/10.1016/j.jcm.2019.12.001</p>	<p>To investigate the efficacy of soft tissue techniques in the management of migraine headache.</p>	<p>40 participants</p>	<p>RCT</p>	<p>The treatment group showed a significant reduction in headache parameters when compared to control group. Soft tissue techniques were helpful in improving headache parameters, drug consumption, and functional disability.</p>	<p>Level 2: RCT</p>	<p>The effect of other treatments such as medications and other nondrug interventions were not investigated. Short duration of therapy.</p>	<p>Yes, high level of evidence. Well-written study on the use of massage for migraines.</p>
<p>Rhee, T. G., & Harris, I. M. (2018). Reasons for and perceived benefits of utilizing complementary and alternative medicine in U.S. adults with migraines/severe headaches. <i>Complementary Therapies in Clinical Practice</i>, 30, 44–49. https://doi.org/10.1016/j.ctcp.2017.12.003</p>	<p>To determine Reasons for and perceived benefits of utilizing complementary and alternative medicine</p>	<p>The 2012 National Health Interview Survey was used for data collection.</p>	<p>Case report</p>	<p>CAM use was associated with an improvement in several health-related quality of life outcomes in U.S. adults with migraines/severe headaches.</p>	<p>Level 6: Review of a descriptive study</p>	<p>The definition of migraine was self-reported. CAM use and its benefits were self-reported.</p>	<p>This article provides beneficial information on CAM use despite the low level of evidence.</p>

<p>Rist, P. M., Hernandez, A., Bernstein, C., Kowalski, M., Osypiuk, K., Vining, R., Long, C. R., Goertz, C., Song, R., & Wayne, P. M. (2019). The impact of spinal manipulation on migraine pain and disability: A systematic review and meta-analysis. <i>Headache: The Journal of Head & Face Pain</i>, 59(4), 532–542. https://doi.org/10.1111/head.13501</p>	<p>To evaluate the evidence regarding spinal manipulation as an alternative or integrative therapy in reducing migraine pain and disability.</p>	<p>Six RCTs were included in the review.</p>	<p>Systematic review</p>	<p>The results suggest that spinal manipulation may be an effective therapeutic technique to reduce migraine days and pain/intensity.</p>	<p>Level 1: Systematic review of RCTs</p>	<p>The results of this meta-analysis are considered preliminary due to the limitations of the studies included.</p>	<p>The results of this study are useful as they suggest spinal manipulation is effective for migraines. It also discusses the needed for studies of higher quality to validate the findings.</p>
<p>Seminowicz, D. A., Burrowes, S. A. B., Kearson, A., Zhang, J., Krimmel, S. R., Samawi, L., Furman, A. J., Keaser, M. L., Gould, N. F., Magyari, T., White, L., Golubeva, O., Goyal, M., Peterlin, B. L., Haythornthwaite, J. A., & Zhang, J. (2020). Enhanced mindfulness-based stress reduction in episodic migraine: A randomized clinical trial</p>	<p>To evaluate the efficacy of an enhanced mindfulness-based stress reduction vs stress management for migraine headaches.</p>	<p>98 adults</p>	<p>RCT</p>	<p>Fifty-two percent of the MBSR group showed a response to treatment (50% reduction in headache days) compared with 23% in the stress management group. Reduction in disability was</p>	<p>Level 2: RCT</p>	<p>Limited generalizability due to possible selection bias that results from the strenuous requirements of participation</p>	<p>Yes, high level evidence suggesting that enhanced mindfulness-based stress reduction is an effective treatment option for episodic migraine.</p>

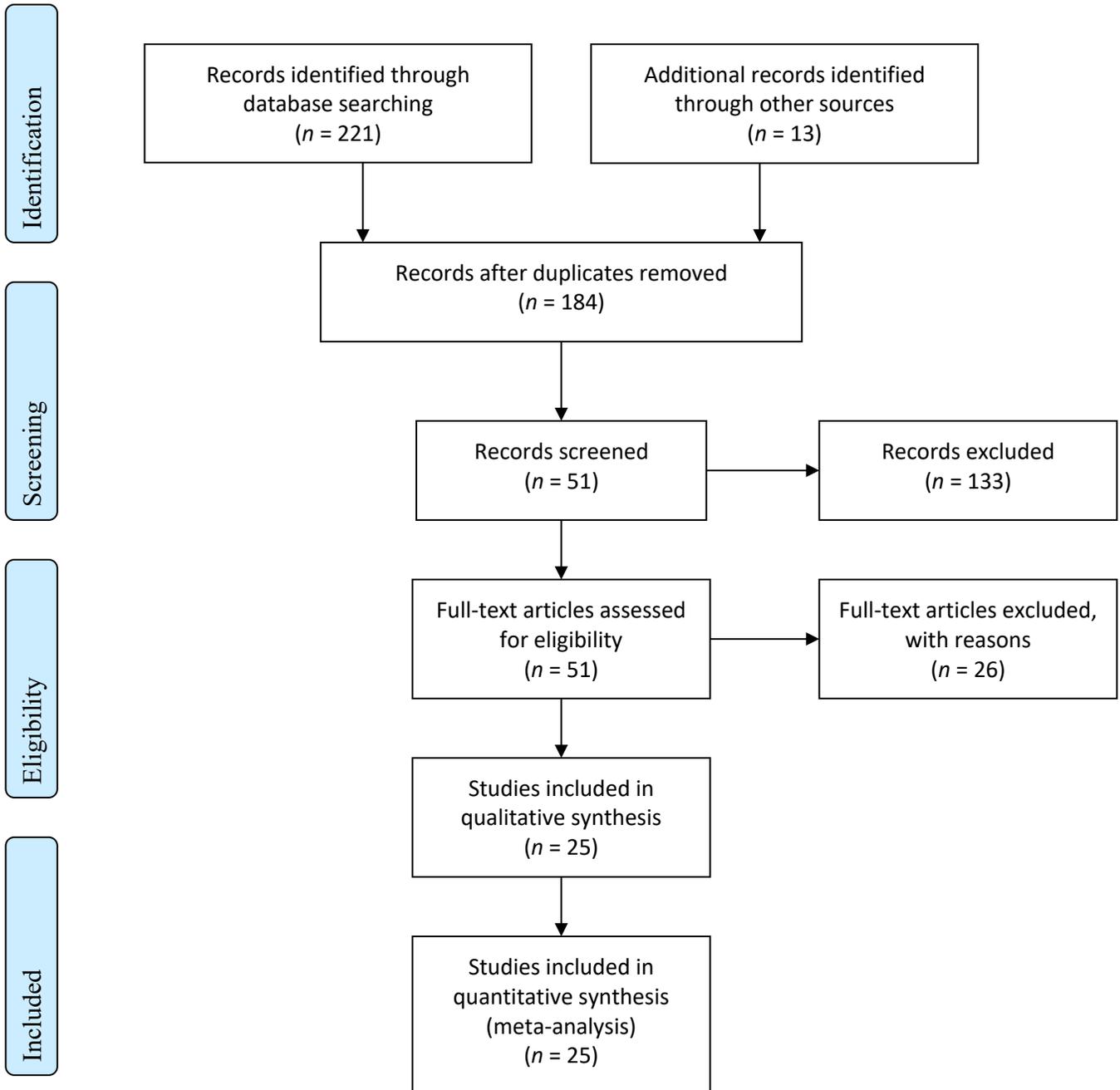
<p>with magnetic resonance imaging outcomes. <i>PAIN</i>, 161(8), 1837–1846. https://doi.org/10.1097/j.pain.0000000000001860</p>				<p>greater in the MBSR group.</p>			
<p>Seng, E. K., Singer, A. B., Metts, C., Grinberg, A. S., Patel, Z. S., Marzouk, M., Rosenberg, L., Day, M., Minen, M. T., Lipton, R. B., & Buse, D. C. (2019). Does mindfulness-based cognitive therapy for migraine reduce migraine-related disability in people with episodic and chronic migraine? A phase 2b pilot randomized clinical trial. <i>Headache: The Journal of Head & Face Pain</i>, 59(9), 1448–1467. https://doi.org/10.1111/head.13657</p>	<p>To evaluate the efficacy of mindfulness-based cognitive therapy for migraine to reduce migraine-related disability.</p>	<p>Participants with a diagnosis of migraine were recruited from neurology office referrals. 60 participants received mindfulness-based cognitive therapy.</p>	<p>RCT</p>	<p>The participants who received the mindfulness-based cognitive therapy had a significant reduction in headache-related disability when compared to those on the waitlist.</p>	<p>Level 2: RCT</p>	<p>Collected data was self-reported. The participants were highly educated white women which limits the generalizability of findings.</p>	<p>Yes. This article provides high level evidence for mindfulness-based cognitive therapy.</p>
<p>Sharma, V. M., Manjunath, N. K., Nagendra, H. R., & Ertsey, C. (2018).</p>	<p>To understand the efficacy of Ayurveda and yoga in the</p>	<p>60 participants – 30 in the controlled</p>	<p>Matched controlled trial</p>	<p>Yoga therapy reduces symptoms, intensity of pain</p>	<p>Level 3: Quasi-experimental</p>	<p>Risk for bias as the patients were aware</p>	<p>Yes. Provides good information</p>

<p>Combination of ayurveda and yoga therapy reduces pain intensity and improves quality of life in patients with migraine headache. <i>Complementary Therapies in Clinical Practice</i>, 32, 85–91. https://doi.org/10.1016/j.ctcp.2018.05.010</p>	<p>management of migraine headache.</p>	<p>group and 30 in the intervention group</p>		<p>and improves quality of life in migraine patients when used as add-on therapy with Ayurveda.</p>		<p>which group they were in.</p>	<p>on yoga use in migraine treatment.</p>
<p>Varkey, E., Grüner Sveälv, B., Edin, F., Ravn-Fischer, A., & Cider, Å. (2017). Provocation of migraine after maximal exercise: A test-retest study. <i>European Neurology</i>, 78(1–2), 22–27. https://doi.org/10.1159/000477166</p>	<p>To evaluate whether migraine can be triggered by exercise.</p>	<p>19 patients</p>	<p>Clinical trial</p>	<p>Maximal aerobic exercise can trigger migraine attacks but does not always provoke an attack even in those who report exercise as a migraine trigger.</p>	<p>Level VI: Descriptive study design</p>	<p>Small study sample. The researchers did not inform about sufficient fluid intake or assess sleep quality, anxiety, and stress prior to the test.</p>	<p>Yes, information on exercise effects on migraines.</p>
<p>Wells, R. E. (2019). Complementary and integrative medicine for episodic migraine: An update of evidence from the last 3 years. <i>Current Pain and Headache Reports</i>, 23, Article 10.</p>	<p>To educate patients and providers about the most recent evidence of complementary and integrative</p>	<p>Research published from 2015-2018 obtained from Pubmed, Embase, and</p>	<p>Overview of current evidence.</p>	<p>More than 50% of patients do not tell their provider about their CAM usage. Almost 85% of providers feel</p>	<p>Level 5: Systematic review of descriptive studies.</p>	<p>No clinical assessment to evaluate the diagnosis of migraines. Lack of clarity of</p>	<p>Provides information on the limitations of CAM use. Also provides information</p>

<p>https://doi.org/10.1007/s11916-019-0750-8</p>	<p>treatment options for migraine to increase comfort with discussing these options</p>	<p>Cochrane databases was used.</p>		<p>they lack the knowledge to inform their patients about CAM. The most limiting factor with many patients for CAM treatment includes time, money, and effort.</p>		<p>how baseline measures were assessed.</p>	<p>on various CAM options – mind/body, yoga, physical therapy, acupuncture, supplements</p>
<p>Wells, R. E., O’Connell, N., Pierce, C. R., Estave, P., Penzien, D. B., Loder, E., Zeidan, F., & Houle, T. T. (2021). Effectiveness of mindfulness meditation vs headache education for adults with migraine: A randomized clinical trial. <i>JAMA Internal Medicine</i>, 181(3), 317–328. https://doi.org/10.1001/jamainternmed.2020.7090</p>	<p>To determine if mindfulness-based stress reduction (MSBR) improves migraine outcomes and affective/cognitive processes compared with headache education</p>	<p>Included 89 adults who had between 4 and 20 migraines a month.</p>	<p>RCT</p>	<p>MBSR improved disability, quality of life, self-efficacy, pain catastrophizing, and depression out to 36 weeks, with decreased experimentally induced pain suggesting a potential shift in pain appraisal</p>	<p>Level 2: RCT</p>	<p>Most participants were female. Therefore, limited ability to generalize findings.</p>	<p>Provides good information on the benefits of mindfulness-based stress reduction at a high level of evidence.</p>
<p>Yang, Y., Que, Q., Ye, X., & hua Zheng, G. (2016). Verum versus sham manual acupuncture for</p>	<p>To identify the effectiveness of verum acupuncture compared with</p>	<p>A total of 10 RCT studies with 997 participants were</p>	<p>Systematic review</p>	<p>The results reveal that verum manual acupuncture appears more</p>	<p>Level 1: Systematic review of RCTs</p>	<p>Variability in the selected acupuncture sites may</p>	<p>This article provides a review of high-quality RCTs on the</p>

<p>migraine: A systematic review of randomized controlled trials. <i>Acupuncture in Medicine</i>, 34(2), 76–83. https://doi.org/10.1136/acupmed-2015-010903</p>	<p>sham acupuncture for the treatment of migraine.</p>	<p>included in the review.</p>		<p>effective at improving overall response rates in migraine than sham acupuncture.</p>		<p>present performance bias.</p>	<p>effectiveness of acupuncture. It also includes information on the need for additional studies.</p>
<p>Zhang, Y., Dennis, J. A., Leach, M. J., Bishop, F. L., Cramer, H., Chung, V. C. H., Moore, C., Lauche, R., Cook, R., Sibbritt, D., & Adams, J. (2017). Complementary and alternative medicine use among us adults with headache or migraine: Results from the 2012 National Health Interview Survey. <i>Headache: The Journal of Head & Face Pain</i>, 57(8), 1228–1242. https://doi.org/10.1111/head.13148</p>	<p>To determine which CAM modalities are used most frequently among migraine sufferers and what are the self-reported reasons for CAM use?</p>	<p>The survey included 34,525 adults</p>	<p>Analysis of 2012 US NHIS data – a cross-sectional survey</p>	<p>The use of CAM for migraine treatment is relatively low in the US. However, those who suffer from migraines are more likely to use CAM than others. Manipulative therapy is the most frequently used CAM.</p>	<p>Level 5: Review of a descriptive study</p>	<p>The study analyzed relies on cross-sectional self-reported data.</p>	<p>Provides good information on many different CAM therapies – manipulation, mind-body therapies, herbal supplements.</p>

Appendix B
PRISMA Diagram



Appendix C

CITI Training Certificate



Completion Date 10-Jun-2021
Expiration Date 09-Jun-2024
Record ID 42661005

This is to certify that:

Katelyn Spangler

Has completed the following Citi Program course:

Not valid for renewal of certification through CME.

Biomedical Research - Basic/Refresher

(Curriculum Group)

Biomedical & Health Science Researchers

(Course Learner Group)

1 - Basic Course

(Stage)

Under requirements set by:

Liberty University



Verify at www.citiprogram.org/verify/?w6fdf3789-7c7c-43c6-aa8d-103ef56a0b0e-42661005

Appendix D**IRB Approval Letter****LIBERTY UNIVERSITY.**
INSTITUTIONAL REVIEW BOARD

September 10, 2021

Katelyn Spangler
Vickie Moore

Re: IRB Application - IRB-FY21-22-163 THE EFFECT OF COMPLEMENTARY AND ALTERNATIVE MEDICINE ON MIGRAINE HEADACHES: AN INTEGRATIVE REVIEW

Dear Katelyn Spangler and Vickie Moore,

The Liberty University Institutional Review Board (IRB) has reviewed your application in accordance with the Office for Human Research Protections (OHRP) and Food and Drug Administration (FDA) regulations and finds your study does not classify as human subjects research. This means you may begin your project with the data safeguarding methods mentioned in your IRB application.

Decision: No Human Subjects Research

Explanation: Your study is not considered human subjects research for the following reason:

(1) It will not involve the collection of identifiable, private information from or about living individuals (45 CFR 46.102).

Please note that this decision only applies to your current application, and any modifications to your protocol must be reported to the Liberty University IRB for verification of continued non-human subjects research status. You may report these changes by completing a modification submission through your Cayuse IRB account.

Also, although you are welcome to use our recruitment and consent templates, you are not required to do so. If you choose to use our documents, please replace the word *research* with the word *project* throughout both documents.

If you have any questions about this determination or need assistance in determining whether possible modifications to your protocol would change your application's status, please email us at irb@liberty.edu.

Sincerely,

G. Michele Baker, MA, CIP
Administrative Chair of Institutional Research
Research Ethics Office