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Complementary and Integrative Medicine (CIM) in Primary Care

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Background: Many patients seek the advice from their primary care providers (PCPs) to provide insight into alternative treatment options, however, little is known about the practices of primary care providers (PCPs) and the referring of Complementary and Integrative Medicine (CIM) treatments for patients with migraine pain. CIM is the practice of evidence informed modalities such as traditional Chinese medicine and mind-body strategies to assist in the health and healing processes.

Purpose: The purpose is to determine if Ascension St. Vincent Indianapolis PCPs are referring CIM treatments to their migraine patients, and if not, what prohibits providers from utilizing these treatments with their migraine patients.

Methods: A 10-question survey was distributed to 243 primary care providers (PCPs) of the Ascension St. Vincent Indianapolis network.

Implementation Plan: The 10- question survey was distributed to the PCPs of Ascension St. Vincent Indianapolis via their Ascension emails. The collection and analysis was conducted through the online database, REDCap from September 29 to October 31, 2021.

Results: 29 responses were received (11.90%). There was no significant correlation between the provider's professional background and their perceptions of CIM. There was a significant correlation between the provider survey responses and the provider's gender.

Conclusions: Findings suggest there is a lack of education, knowledge, and comfort in regards to CIM therapies amongst the PCPs of Ascension St. Vincent Indianapolis.

Keywords: Complementary and Integrative Medicine (CIM), Complementary Alternative Medicine (CAM), primary care providers (PCPs), randomized controlled trial (RCT)

Complementary and Integrative Medicine (CIM) & Migraines in Primary Care

Introduction

Migraine headaches are a chronic debilitating neurological condition affecting over 36 million Americans and are the second- most disabling condition worldwide (Patel & Minen, 2019). Although migraine headache disorders are one of the most prevalent chronic pain conditions, migraines continue to be extremely difficult for practitioners to treat. Despite many advances in the medical prevention and treatment of migraine headaches, many patients are unable to find an effective treatment regimen. A wide variety of treatment options are available, however, many pharmacological options are accompanied by serious side effects or drug interactions, resulting in discontinuation of use. Primary care providers (PCPs) play a key role in guiding patients in their choices of treatment and should be aware of complementary and integrative medicine (CIM) treatments available for migraine headache patients such as mindfulness based stress reduction (MBSR), acupuncture, and herbal supplements.

Background

A migraine is a primary headache disorder involving recurrent headaches characterized as one-sided moderate or severe pulsating intensity frequently accompanied by nausea lasting from hours to days. Migraine headaches are ranked sixth highest cause worldwide for years lost due to disability. The burden for migraine sufferers not only includes pain, but an impaired quality of life affecting all aspects of life including their family, employment, and social life (World Health Organization, 2016).

Currently, migraine treatment regimens are tailored to the individual's symptoms in respect to severity of episodes, comorbidities and patient preferences. The process of finding an effective treatment regimen typically requires a trial and error approach. There are wide varieties of medications available for migraine headache treatment such as NSAIDs, anti-epileptics, ergotamine derivatives, beta-blockers, serotonin-norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants and opioids. Unfortunately, serious side effects can be associated with the use of these drugs, which deter their use by patients (The American Headache Society, 2018). In order to avoid the associated side effects, patients seek alternative treatments to medications for migraine headache pain.

Complementary and Integrative Medicine (CIM) uses evidence informed modalities such as nutrition, movement practices, manual therapy, traditional Chinese medicine, and mind-body strategies to assist patients in their health and healing processes. Many of the most frequently sought after CIM treatments have been incorporated from the traditional Chinese medicine including acupuncture, massage, meditation, yoga, and biofeedback. Some other effective CIM techniques for the treatment of migraine headache pain include supplements, botanicals and diet alteration. Evidence continues to grow to support the effectiveness of CIM therapies for treatment of migraine headache pain (Millstine et al, 2017).

Despite the increasing evidence to support the use of CIM in the treatment of migraine headache pain, research is limited on how patients suffering from migraine headache pain gain knowledge and access to CIM resources. Patients experiencing migraine headaches are most often first seen by their PCPs while 15% seek care from

either a headache specialist or a pain management specialist (Lipton, 2019). Since PCPs are the first point of care for many migraine patients, it is essential PCPs are knowledgeable of how CIM therapies may benefit their patients suffering from migraine headaches.

Problem Statement

CIM therapies cannot be effectively utilized if PCPs are unaware of such therapies to offer as management for migraine headache pain. This project intends to review PCP attitudes and their implementation of CIM techniques in order to recognize barriers to utilizing these treatments by asking if the PCPs of Ascension St. Vincent Indianapolis are referring their migraine patients to CIM therapies, and if not, what prohibits them from referring.

Practice Gap Analysis

According to a survey conducted by Malone and Tsai (2017), only 28% of providers were comfortable referring CIM therapies to their patients. A lack of knowledge and exposure to CIM therapies may play a direct role in a provider's ability to refer their patients to CIM. This quality improvement project will ascertain the CIM referral practices of primary care providers caring for migraine headache patients in a facility in central Indiana, Ascension St. Vincent Indianapolis.

Review of Literature

Complementary and integrative medicine (CIM) is a collection of diverse practices and products that are outside the realm of conventional medicine (Wells et al., 2017). Complementary and integrative medicine is a multidimensional, multidisciplinary approach to health and wellness. CIM involves many aspects of life including social,

spiritual, behavioral, environmental, demographic, and cultural. Primary care management should be evidence based, but holistic in nature that incorporates both pharmacological and non-pharmacological treatment approaches (Mills, Torrance, & Smith, 2016; Stanos et al., 2016). The treatment of patients with pharmacological approaches often lead to poor analgesic responses, little functional improvements, and frustration for both the patient and provider (Stanos et al., 2016). The role of the PCP is to identify the barriers within this realm that may be hindering the patient's health such as behavioral changes including nutritional, physical activity, exercise, sleep and stress management. It is also important for providers to teach patients that although they suffer from a neurological condition, it is multifactorial and stems from a biological foundation (Ring & Mahadevan, 2017). For patient suffering from migraines, effective CIM practices would include meditation, mindfulness based stress reduction (MBSR), acupuncture, and herbal supplements.

Mindfulness Based Stress Reduction (MBSR)

One of the most common triggers identified by migraine sufferers is stress. Complementary and integrative medicine methods are focused on targeting the cause of stress with teaching coping strategies to decrease the patient's migraine frequency. To assist in combating stress, mind-body practices such as meditation, mindfulness-based stress reduction (MBSR), and cognitive behavioral therapy have been found to be beneficial for migraine sufferers. A systemic review of 16 randomized controlled trials (RCTs) and a single RCT assessing non-pharmacological self-management interventions in patients diagnosed with migraine or tension headaches, authors reported MBSR techniques to be more effective in improving pain intensity, headache related disability, quality of life and medication consumption. Similar results were found in a meta-analysis of 10 randomized controlled trials that compared mindfulness meditation effects on primary headache pain intensity and frequency (Probyn et al., 2017; Bakhshani, Amirani, Amirifard, & Shahrakipoor, 2015).

Acupuncture

The American Headache Society (2019) does not recommend the use of opioids for migraine pain control. Instead, a wide variety of preventative and symptom management medications are available. For example, long-term use of non-steroidal anti-inflammatory drugs (NSAIDs) have been linked to causing hepatotoxicity and nephrotoxicity, sumatriptan can increase blood pressure and mental cloudiness, and beta-blockers can cause hypotension and increase the risk of bronchospasm. Therefore, many patients look to CIM treatments such as acupuncture for relief.

Acupuncture is an ancient Chinese therapy based on the theory that disease is the result of energy imbalances throughout the body. The insertion of needles at acupoints, points along specific energy meridians, allows the release of obstructed energy that brings the body back into balance (Patel et al, 2019). In a meta-analysis of 22 trials with 2985 patients determined that acupuncture led to a 50% reduction in headache frequency in 41% of patients compared to no treatment and 57% compared to prophylactic medications (Patel & Minen, 2019). The authors suggest that acupuncture is as, if not more effective than prophylactic medications for migraine treatment. There were similar findings in another 4 RCTs and a systemic review of 14 RCTs with 1,155 participants showing that acupuncture had a significant reduction in migraine frequency and intensity (Bega, 2017; Wells, Baute, & Wahbeh, 2017; Millstine, Chen, & Bauer, 2017; Xu, Zhang, Pei, & Ji, 2018). Acupuncture was also deemed more tolerable compared to traditional pharmacological migraine treatments due to fewer side effects with only 6% after 24 acupuncture sessions compared to 66% with daily topiramate use. Unfortunately, many patients were deterred from further acupuncture treatments because most US insurance companies did not cover acupuncture treatments (Wells, Baute, & Wahbeh, 2017; Xu, Zhang, Pei, & Ji, 2018).

Vitamins and Herbals

Despite the lack of adequate regulation by the U.S. Food and Drug Administration (FDA) in terms of their safety and efficacy, there has been an increase in the use of vitamins, minerals, and herbal preparations amongst migraine sufferers. A meta-analysis of 5 RCTs and 2 single RCTs, there was a significant 43% reduction in migraine attacks in participants with oral magnesium treatment (Patel & Minen, 2019; Bega, 2017; Millstine, Chen, & Bauer, 2017). In a meta-analysis of 11 RCTs and 2 individual RCTs showed a significant reduction in migraine attack frequencies and days after 400 mg daily use of riboflavin for 3 months of treatment compared to the placebo (Patel & Minen, 2019; Bega, 2017; Millstine, Chen & Bauer, 2017).

CIM in Primary Care

Approximately 50% of adults who suffer from neurological conditions such as migraines use CIM, however, many patients have not discussed their use of CIM therapies with their PCP (Wells, Baute, & Wahbeh, 2017). This highlights the importance of PCPs being knowledgeable concerning alternative therapies based on each patient's individual needs. The goal of complementary and integrative medicine is to change the focus from illness and disease to health and healing by using lifestyle modification approaches (Ring & Mahadevan, 2017). PCPs are in a position where they have the ability to educate their patients about the use of integrative medicine and how it could be beneficial in providing patient-centered care. Unfortunately, there are barriers that prevent primary care professionals from discussing lifestyle changes and the potential CIM options with their patients.

Conventional medical education does not adequately prepare providers to counsel patients about lifestyle modifications. Authors have indicated providers are not comfortable suggesting alternative therapies to patients. Furthermore, PCPs have expressed negative views concerning abilities to manage non-pharmacological aspects of care due to lack of time, reimbursement, knowledge and resources (Ring & Mahadevan, 2017). However, PCPs have the ability to incorporate complementary and integrative

medicine into their current practices through personal education, use of tools and resources, identifying local organizations and creating a relationship with CIM professionals.

According to Starling and Dodick (2015), in the primary care setting, non-pharmacological treatments such as cognitive behavioral therapy and biofeedback should be offered to all patients under treatment for chronic migraines. These practices include meditative therapy, progressive muscle relaxation, guided imagery, exercise, and relaxation training. According to a survey conducted by Mills, Torrance & Smith (2017), 70% of patients with chronic pain had used complementary therapies and had higher patient satisfaction rating compared to conventional care. Practices such as mindfulness were also associated with an increase in patient centered care outcomes with a reduction in the utilization of healthcare services.

Theoretical Framework/ Evidence Based Practice Model

The theoretical concept of holism states, “organic or unified wholes have value and being which is inherently different from, and cannot be reduced to the sum of their individual parts,” (Michaelson et al, 2016). In other words, to fully understand complex systems, the components that make up the system cannot be isolated and analyzed individually. Instead, each component and their relationships with one another must be considered when analyzing a complex system. The foundation of holism is centered upon the awareness of relationships. In the healthcare model of holism, there are direct relationships between the tissues causing the symptoms, the symptoms themselves and the contributing factors that affect the person as a whole. The awareness of these relationships is what allows for the concept to be transformed into meaningful practice (Turner, 2017). This concept of holism can be applied to the healthcare setting and would

be essential for primary care providers in creating a treatment plan for patients suffering from migraine headaches.

In patients suffering from chronic migraines, the patient cannot be analyzed and treated appropriately by only treating the symptoms. Within the realm of holistic care, providers must be aware of not just simply treating the pain, but also identifying the cause. The causality of migraine headaches is multifactorial with both biological and physiological processes involved. Due to the multifactorial nature of migraine headaches, it would be appropriate for providers to consider a multimodal treatment method based on combination of the patient's triggers, symptoms and treatment goals. For example, providers should search for possible migraine triggers such as inadequate food intake, lack of sleep, dehydration or muscle tension; all of which would be appropriately treated with non-pharmacological methods such as cognitive behavioral therapy (CBT), mindfulness based stress-reduction (MBSR) or massage therapy. However, the referrals of these therapies are limited by the provider's knowledge, experience and awareness of these non-pharmacological treatment options.

Goals/ Outcomes

The goal of this quality improvement (QI) project is to determine if PCPs are prescribing CIM therapies for migraine headache patients and if not, what obstacles are preventing a provider's referral. The expected outcomes are an increased knowledge and improved acceptance towards prescribing CIM for migraine headache patients. It is the hope of this research project to improve the availability of complementary and integrative practices for patients suffering from migraines by increasing provider awareness of effectiveness of CIM treatments, increasing the number of providers who consider CIM practices, and providing solutions to obstacles providers face in referring CIM treatments. According to the National Health Interview conducted by the Center for Disease Control

and Prevention (CDC), CIM practices have been on the rise from 32% in 2002 to 33% in 2012 (Ring & Mahadevan, 2017). As CIM therapy rises in popularity, providers must be aware of the available treatments and local resources in order to adequately provide effective holistic care based on the treatment preferences of the patient.

Methods

Project Site and Population

St. Vincent Indianapolis Hospital is one of the Ascension based facilities that strives towards excellence in both patient care and nursing practices through the use of evidence-based practices. The Ascension St. Vincent Indianapolis Hospital serves the Indianapolis metropolitan area by providing a variety of patient care services including a Level I Trauma Center, Stroke, and Cancer Care (About Ascension, 2021). St. Vincent Indianapolis was awarded Magnet accreditation by the American Nurses Credentialing Center's (ANCC) Magnet Recognition Program, for achieving the highest standards of excellence in nursing practice. St. Vincent Indianapolis was also the only Indiana hospital named a Leapfrog Group Top Hospital, the most competitive national hospital award in the country awarded to hospitals who excel in patient care, practices to promote patient safety and quality, and appropriately utilizing resources for patient care.

The population of interest for this research study is the PCPs of Ascension St. Vincent Indianapolis. The PCP population educational backgrounds included medical doctor (MD), nurse practitioner (NP), physician assistant (PA), doctor of osteopathic medicine (DO), and medical resident. In order to reach a broader audience of varying years of experience, medical residents were also included in the providers of interest.

Measurement Instruments

A 10-question survey was used to assess provider's demographics and impressions of CIM treatments for migraine patients (Appendix B). The 10-question

survey includes four demographic questions regarding age, gender, race and profession title. The questions do not ask for information pertaining to personal identifiers. There are three questions pertaining to the provider's use and referral of CIM within their practices. The remaining seven questions involve the provider's personal experiences and attitudes towards CIM such as previous knowledge, personal experiences, and attitudes towards its effectiveness. PCP response options were divided using a 4-point Likert scale (strongly disagree, disagree, agree, and strongly agree). Four of the nine questions pertaining to provider's personal experiences were derived from a similar study conducted by Ben-Arye, Frenkel, Klein and Scharf (2008) in Israel, which not only assessed the CIM perspectives of the providers, but also of the patients receiving the treatment (Appendix B).

Ethics and Human Subject Permission

The Institutional Review Board (IRB) of Marian University reviewed this quality improvement project and deemed exempt from the human subjects' protection (Appendix C). The approval of the IRB of Ascension St. Vincent Indianapolis was also obtained prior to initiation of this project (Appendix D).

Prior to participating in the survey, PCPs were provided with additional information including a section of informed consent (Appendix A). An informed consent and brief description of the purpose of the study along with the anonymous and voluntary nature of the study was provided. The survey was expected to take approximately five to ten minutes to complete. The email concluded with describing the goal of the research team in identifying potential limitations or discomforts for Ascension St. Vincent providers in referring their migraine patients to CIM practices. The contact information

of the primary researcher and St. Vincent Human Subject Internal Review Board was provided within the email to allow providers to express concerns or if a confidentiality breach may have occurred (Appendix A).

Data Collection

The online survey was created, distributed and analyzed using the research platform Research Electronic Data Capture (REDCap). REDCap is a secure, HIPPA compliant web-based application used for the creation and management of online databases and surveys. REDCap allows for validated data capturing, audit trails for monitoring the management and distribution of data; automated data downloads for statistical analysis and procedures for data incorporation and transferability to external sources (Harris et al, 2019). After its introduction in 2004 by Vanderbilt University, this research data platform has been utilized by over 3,000 organizations, including Ascension St. Vincent Indianapolis Data Governance. The use of this application was a requirement of the Ascension St. Vincent IRB for the collection and analysis of data regarding the responses of their primary care providers.

After receiving IRB approval by Marian University and Ascension St. Vincent, an email was sent to the Ascension St. Vincent Indianapolis Clinical Research Scientist containing the informed consent and survey link attached. The Clinical Research Scientist forwarded the email to the Ascension St Vincent Indianapolis Hospital primary care resident physicians and providers to complete the survey. The survey data was only accessible to the primary researcher conducting the study through a private REDCap account. The primary researcher only had access to the survey data collected and was responsible for the receipt and transmission of the data. The survey data was not

disclosed to persons outside the Ascension St. Vincent Indianapolis network or the primary research team. The survey responses were stored within the REDCap online program and collected from September 29, 2021 to October 28, 2021.

Data Analysis and Results

The survey was distributed to 243 providers with 29 responses (n=29, 11.90%) received. The 29 survey responses submitted by Ascension St. Vincent PCPs were analyzed using REDCap software. A statistical analysis was performed using a Fisher’s exact test to determine statistical significance between the provider’s demographics (age, gender, race and professional title) with the provider’s overall perception of CIM practices.

Demographics

Based on the 29 provider responses, the median age of the participants was 42 years old (SD 8.95). The gender make-up of the participant sample was primarily female (n= 23, 79.3%) with 6 males (n=6, 20.7%). The majority of the participants were Caucasian (n=25, 86.2%) with 4 participants (n=4, 13.8%) identified as either African American (n=1, 3.4%), Asian (n=2, 6.9%, or Hispanic (n=1, 3.4%). These statistics were determined using a 4-point Likert scale. The professional backgrounds of the 29 providers showed a majority were NPs (n=15, 51.7%) and MDs (n=10, 34.%), while the remaining consisted of a PA (n=1, 3.4%) and 3 DOs (n=3, 10.3%) (Table 1).

Table 1: Demographic Distribution

What is your gender?		
	n	%
Male	6	20.7
Female	23	79.3
Total	29	100.0

What is your race?

	n	%
Caucasian	25	86.2
African American	1	3.4
Asian	2	6.9
Hispanic	1	3.4
Total	29	100.0

What is your professional background?

	n	%
MD	10	34.5
NP	15	51.7
PA	1	3.4
DO	3	10.3
Total	29	100.0

Gender Cross-Tabulation

For the gender examination, each survey question was analyzed comparing the distribution of responses for each question among males and females (Table 2). A Fisher’s exact test was used instead of a Pearson Chi-Square test because the sample size and distribution of responses violated the assumptions of the Pearson Chi-Square test. Specifically, more than 20% of the cells in the matrix had counts less than five. There was a statistically significant difference in the distribution of responses amongst males and females for multiple questions. In question two, which examined provider’s comfort referring CIM for migraine patients, there was a statistical significance (p=0.01) in which males (n=5, 83.3%) were more comfortable referring CIM for a migraine patient with only 26.1% of women (n=6) feeling comfortable as well. However, 73.9% of women (n=17) disagreed stating they were not comfortable referring CIM for a migraine patient. In question three, there was a statistical significance (p=0.03) in which a majority of both males (n=4, 66.7%) and females (n=19, 82.6%) disagreed felt unaware of the CIM practices available for migraine patients within their areas.

Interestingly, in question four, regarding providers receiving education about CIM in school, a statistical significance ($p=0.03$) was made for which no male respondents reported receiving education about CIM in school with 100% of males ($n=6$) strongly disagreeing and disagreeing with the statement. However, a majority of females ($n=14$, 60.8%) reported receiving education about CIM in school with 39.1% of women ($n=9$) having no previous education. Finally, there was another statistical significance ($p=0.04$) in question 10, where females ($n=19$, 82.6%) had a higher proportion of disagreeing with the idea that CIM is dangerous compared to males ($n=2$, 3.3%). In terms of believing CIM is dangerous, 33.5% of males ($n=2$) and 8.7% of women ($n=2$) would agree with that statement.

Table 2: Gender Cross-Tabulation

			I am comfortable referring CIM for a migraine patient?				Total
			Strongly disagree	Disagree	Agree	Strongly agree	
What is your gender?	Male	n	1	0	5	0	6
		% within	16.7%	0.0%	83.3%	0.0%	100.0%
	Female	n	6	11	4	2	23
		% within	26.1%	47.8%	17.4%	8.7%	100.0%
Total		n	7	11	9	2	29
		% within	24.1%	37.9%	31.0%	6.9%	100.0%

			I am aware of the practices within my area that offer CIM treatments effective for migraine patients.			Total
			Strongly disagree	Disagree	Agree	
What is your gender?	Male	n	4	0	2	6
		% within	66.7%	0.0%	33.3%	100.0%
	Female	n	6	13	4	23
		% within	26.1%	56.5%	17.4%	100.0%
Total		n	10	13	6	29
		% within	34.5%	44.8%	20.7%	100.0%

			I received education about CIM in school?				Total
			Strongly disagree	Disagree	Agree	Strongly agree	
What is your gender?	Male	n	3	3	0	0	6
		% within	50.0%	50.0%	0.0%	0.0%	100.0%
	Female	n	4	5	13	1	23
		% within	17.4%	21.7%	56.5%	4.3%	100.0%
Total		n	7	8	13	1	29
		% within	24.1%	27.6%	44.8%	3.4%	100.0%

			CIM is dangerous in that it may prevent patients from getting proper treatment.				Total
			Strongly disagree	Disagree	Agree	Strongly agree	
What is your gender?	Male	n	2	2	1	1	6
		% within	33.3%	33.3%	16.7%	16.7%	100.0%
	Female	n	2	19	2	0	23
		% within	8.7%	82.6%	8.7%	0.0%	100.0%
Total		n	4	21	3	1	29
		% within	13.8%	72.4%	10.3%	3.4%	100.0%

Profession

Due to the high quantity of MD and NP responses, a comparison of these provider’s answers were made (Table 3). For this analysis, due to similarities in practice, the NP and PA responses were combined. In comparing professional background of MDs and NPs plus PAs, there were no statistically significant differences for questions one and two; however, a statistically significant finding was made in question three. When analyzing the responses of MDs and NPs plus PAs in their response to awareness of CIM treatments in their area, there was a statistical significance (p=0.02), however, the difference was between the answers “strongly disagree” and “disagree.” Therefore, this difference was deemed insignificant. There were also no statistically significant findings in questions four through ten.

Table 3: Profession Cross-Tabulation

			I have referred a CIM practice to a migraine patient within the past month?			Total
			Strongly disagree	Disagree	Agree	
What is your professional background? (Reclassify)	MD	n	6	4	0	10
		% within	60.0%	40.0%	0.0%	100.0%
	NPs and PAs	n	8	7	1	16
		% within	50.0%	43.8%	6.3%	100.0%
Total	n	14	11	1	26	
	% within	53.8%	42.3%	3.8%	100.0%	

			I am comfortable referring CIM for a migraine patient?				Total
			Strongly disagree	Disagree	Agree	Strongly agree	
What is your professional background? (Reclassify)	MD	n	4	2	4	0	10
		% within	40.0%	20.0%	40.0%	0.0%	100.0%
	NPs and PAs	n	2	8	4	2	16
		% within	12.5%	50.0%	25.0%	12.5%	100.0%
Total	n	6	10	8	2	26	
	% within	23.1%	38.5%	30.8%	7.7%	100.0%	

			I am aware of the practices within my area that offer CIM treatments effective for migraine patients.			Total
			Strongly disagree	Disagree	Agree	
What is your professional background? (Reclassify)	MD	n	7	2	1	10
		% within	70.0%	20.0%	10.0%	100.0%
	NPs and PAs	n	2	10	4	16
		% within	12.5%	62.5%	25.0%	100.0%
Total	n	9	12	5	26	
	% within	34.6%	46.2%	19.2%	100.0%	

Overall Survey Results

Using a 4-point Likert scale (strongly disagree, disagree, agree and strongly agree), the 29 providers were able to answer the 10 survey questions pertaining to CIM, their personal views, and current practices in regards to CIM for migraine patients (Table 4). Overall, most providers (n=15, 51.7%) have not referred a CIM practice to a migraine patient within the last month. Of the 29 providers; 18 (62.0%) either disagreed or strongly disagreed with being comfortable with referring CIM to a migraine patient and 23 (79.2%) disagreed with being aware of practices within their area that offer CIM treatments. Interestingly, 13 providers (44.8%) agreed with receiving education about CIM where as 7 providers (24.1%) strongly disagreed and 8 providers (27.6 %) disagreed with receiving education about CIM in school. In terms of knowledge, 12 providers (41.4%) disagreed with feeling knowledgeable about CIM while 11 (37.9%) agreed with feeling knowledgeable.

When asked if CIM should only be used for minor ailments, 51.7% (n=15) would disagree and 48.3% (n=14) would agree. Despite the previous responses: 28 (96.6%) respondents either agreed or strongly agreed that there are some cases where CIM would be more appropriate than prescription medication, 21 respondents (72.4%) agreed that CIM could produce longer lasting and more complete clinical results than conventional medicine, and 25 (86.2%) respondents either disagreed or strongly disagreed with the notion that CIM is dangerous in that it may prevent patients from getting proper treatment. Interestingly, 62% (n=18) of participants would agree that CIM should be subject to more scientific testing before being accepted by conventional providers.

Table 4: 4- point Likert Scale Distributions: Survey Results

Question	Strongly Disagree	Disagree	Agree	Strongly Agree
I have referred a CIM practice to a migraine patient within the past month?	15 (51.7%)	12 (41.4%)	2 (6.9%)	0
I am comfortable referring CIM for a migraine patient?	7 (24.1%)	11 (37.9%)	9 (31.0%)	2 (6.9%)
I am aware of the practices within my area that offer CIM treatments effective for migraine patients.	10 (34.5%)	13 (44.8%)	6 (20.7%)	0
I received education about CIM in school?	7 (24.1%)	8 (27.6%)	13 (44.8%)	1 (3.4%)
I am knowledgeable about CIM practices.	5 (17.2%)	12 (41.4%)	11 (37.9%)	1 (3.4%)
There are some cases where CIM would be more appropriate than prescription medications.	0	1 (3.4%)	22 (75.9%)	6 (20.7%)
CIM should only be used for minor ailments and not in the treatment of more serious illness.	2 (6.9%)	13 (44.8%)	12 (41.4%)	2 (6.9%)
CIM can produce longer lasting and more complete clinical results than conventional medicine	1 (3.4%)	7 (24.1%)	19 (65.5%)	2 (6.9%)
CIM should be subject to more scientific testing before they can be accepted by conventional providers.	0	11 (37.9%)	17 (58.6%)	1 (3.4%)
CIM is dangerous in that it may prevent patients from getting proper treatment.	4 (13.8%)	21 (72.4%)	3 (10.3%)	1 (3.4%)

Discussion

This quality improvement study surveyed the CIM knowledge, use, and perception of Ascension St. Vincent Indianapolis primary care providers for patients suffering from migraine headaches. This research seeks to identify if PCPs are referring CIM for their migraine patients, and if not, what are the obstacles that prohibit that referral. There were multiple significant findings made based on the survey results along with similar findings of previous published studies relating to CIM, which add further validity to the results of this study.

One of the most significant findings identified was that lack of education of PCPs directly impacts their referrals for CIM treatments. According to this study, only 48.2% of providers (n=14) had received education about CIM in school. This concept was further confirmed by a majority of providers (n=17, 58.6%) stating they did not feel knowledgeable about CIM practices. These two findings directly contributed to the 93.1% of providers (n=27) denying a CIM referral within the past month and 62.0% of providers (n=18) stating they are uncomfortable with referring CIM to a migraine patient. The provider's lack of knowledge of CIM practices was a predicted finding and has been cited by previous studies as an obstacle prohibiting the acceptance of CIM practices by traditional western medicine. Approximately only 25% of American medical students and resident have received education about CIM as part of their medical training. Although CIM has not been included in the traditional medical training, many schools have made adjustments to their educational curriculum to incorporate classes dedicated to CIM (Ng & Hanna, 2021; Winter & Korzenik, 2017). This lack of education and knowledge of CIM therapies also directly contributes to providers being uncomfortable with referring CIM. Our study concluded that not only are PCPs not educated about CIM, but also a majority of providers have: not referred CIM in the past month (n=27, 93.1%), are uncomfortable referring CIM (n=18, 62.0%), and are unaware of CIM therapies available in their areas (n=23, 79.3%).

When comparing the provider's genders and CIM practices, none of male providers (n=5) had received education about CIM in school, and yet 83.3% of the male providers stated they were comfortable referring CIM. On the other hand, a majority of female providers (n=14, 60.8%) stated they had received prior education about CIM in

school and majority disagreed with the idea with CIM being dangerous (n=21, 91.3%), but still felt uncomfortable referring patients to CIM and were unaware of practices in their area. This finding suggests that despite providers receiving education about CIM in school, they remain uncomfortable with referring CIM for their migraine patients. Based on this discovery, the educational portion of CIM within medical practice comes into question.

At the foundation of western medical practice is the theoretical framework of biomedicine. In biomedicine, there are the definitions of ‘disease’ and ‘illness.’ The term ‘disease’ refers to the physiological manifestations of a condition while the term ‘illness’ refers to the patient’s subjective experiences. According to Kroll (2021), practitioners of biomedicine focus on identifying and treating the disease entity while considering the patient’s symptoms instead of a more holistic approach of analyzing the physiological and subjective manifestations collectively. As a result, the adherence to the biomedical model directly inhibits clinicians from broadening their scope of practice diagnostically. Comparatively, CIM focuses on a holistic approach of treating the person as a whole through assessing multiple interconnected domains including biological, social, behavioral and environmental, rather than simply treating the disease (U.S. Department of Health and Human Services, 2021). These differences in philosophies create further difficulties for practitioners of biomedicine in understanding and referring their patients to CIM. Therefore, it is even more essential that providers receive adequate and thorough education in school about CIM therapies and their effectiveness towards a specific disease and illness.

Despite a lack of education and knowledge of CIM therapies, a majority of providers felt that CIM was not dangerous (n=25, 86.2%), CIM may be more appropriate in certain cases compared to a prescription (n=29, 96.6%) and can produce longer lasting results than conventional medicine (n=21, 72.4%). However, half of the providers believe CIM should only be used for minor ailments (n=13, 44.8%). It can be concluded from these statistics that with the education provided in school and personal knowledge, providers are aware of the advantages of providing CIM therapies.

Another noteworthy discovery of this study was that a majority of providers believe CIM should be subject to more scientific testing (n=18, 62.0%). The skepticism for many providers in regards to CIM therapies is due to the perception there is a lack of adequate data. In 2019, the World Health Organization (WHO) identified a “lack of research data” as a significant hurdle in the advancing towards integrating CIM practices into our current health systems. Along with the limited data, the data supporting CIM practices came from small or uncontrolled studies. Another area of uncertainty for providers is the lack of a standardized regulating body, which directly contributes to the difficulties of conducting a large study. For example, the FDA does not regulate the vitamins and herbs frequently used in CIM treatments and as a result, their ingredients and efficacy are put into question (Schweitzer et al, 2021; Ng & Hanna, 2021). Therefore, it can be concluded that the lack of PCP referrals for CIM therapies are multifactorial in nature and cannot be directly contributed to lack of knowledge or lack of evidence based practices alone.

Limitations

There were several limitations of this study. The timeframe within which this study was conducted was less than a month in duration. The duration of availability of the survey to providers was based upon the submission date the project. This short timeframe also limited the amount of time providers had to complete the survey and contributed to the low completion rate of 11.90%. Another limitation of this study was that providers at a single institution, Ascension St. Vincent Indianapolis, which also may have directly contributed to the low completion rate, completed the survey. Although this study can definitively say these findings are based on views of PCPs within Ascension St. Vincent Indianapolis, this limited the point of view of the providers in question. In future studies, a broader range of providers should be used to include all PCPs within the Ascension St. Vincent network of Indiana. One aspect of the study that may have yielded more efficient results would have been to alter the survey questions. The questions used focused on provider's education and comfort with referring CIM, however, questions regarding specific treatments such as acupuncture, MBSR and herbal remedies may have provided more beneficial results. If the questions including specific remedies, it could have been determined whether one specific therapy or all CIM therapies caused providers confusion and discomfort.

Conclusion

With an increase in public awareness of CIM practices, PCPs should be knowledgeable of the available CIM therapies, supporting research, and accessible local resources. It was hypothesized that the survey results would indicate that Ascension St. Vincent PCPs are not knowledgeable or comfortable referring migraine sufferers to CIM therapies regardless of age, gender, race or area of practice. In literature, as well as this

doctorate project, it has been confirmed and demonstrated that there is a distinct lack of Ascension St. Vincent PCP education, knowledge, and comfort towards CIM therapies for their migraine patients. As a result, these effective treatment options are not offered by providers or made available to those patients to whom it may benefit; in this case migraine headache patients. In order to increase provider knowledge and comfort with CIM therapies, it is proposed by this research committee that Ascension St. Vincent Indianapolis to encourage their providers to expand upon their knowledge of CIM therapies by completing educational modules through web based trainings (WBTs). The project aimed to expand Ascension St. Vincent provider's awareness of the effectiveness of CIM therapies in the hope that these treatments will be considered by PCPs for their future patients suffering from migraine headaches. This project determined there is a lack of knowledge of CIM treatments for migraine headache suffers by the providers of Ascension St. Vincent Indianapolis. It is the hope of this research committee that future projects will build upon this finding and strive to identify how to provide providers with adequate education of CIM therapies for migraine patients.

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Appendix A

Hello and thank you in advance for your potential participation. The purpose of this research survey is to explore the current practices of Ascension St. Vincent primary care providers in relation to complementary and integrative practices (CIM) for migraine treatment. The survey will be asking for some personally identifiable information, but we also want you to know that we will make every effort to keep your information confidential. The results of the survey will inform researchers of potential limitations and discomforts for Ascension St. Vincent providers in terms of referring CIM practices for patients suffering from migraine headaches.

Participation in this survey is voluntary and completing the survey designates your consent to participate in this research study. It should take you approximately 5 minutes to complete this survey. Your healthcare and employment status will not be altered in any way by choosing not to participate. If you would like to discuss aspects of this study at a later time, feel free to contact Jacqueline Thompson BSN, RN at 317-370-4629 or by email at jthompson535@marian.edu. If you have complaints, concerns, or believe you may have had your privacy violated related to this research, you may also contact an advocate at the Ascension St. Vincent Human Subjects Internal Review Board by calling (371) 338-2194.

REDCap Link: <https://redcap.ascension.org/inind/surveys/?s=FYN9LDWXdJLEYA74>

Appendix B

1. Age (years): _____
2. Gender
 - a. Male
 - b. Female
3. Race
 - a. Caucasian
 - b. African American
 - c. Asian
 - d. Hispanic
 - e. Other
4. Profession
 - a. MD
 - b. NP
 - c. PA
 - d. DO
 - e. Resident
5. I have referred a CIM practice to a migraine patient within the past month.
 - a. Strongly disagree
 - b. Disagree
 - c. Agree
 - d. Strongly agree
6. I am comfortable referring CIM for a migraine patient.
 - a. Strongly disagree
 - b. Disagree
 - c. Agree
 - d. Strongly agree
7. I am aware of the practices within my area that offer CIM treatments.
 - a. Strongly disagree
 - b. Disagree
 - c. Agree
 - d. Strongly agree
8. I received education about CIM in school.
 - a. Strongly disagree
 - b. Disagree
 - c. Agree
 - d. Strongly agree
9. I believe I am knowledgeable about CIM practices.
 - a. Strongly disagree
 - b. Disagree
 - c. Agree
 - d. Strongly agree
10. There are some cases where CIM would be more appropriate than prescription medications.
 - a. Strongly disagree

- b. Disagree
 - c. Agree
 - d. Strongly agree
11. *CIM should only be used for minor ailments and not in the treatment of more serious illness.
- a. Strongly disagree
 - b. Disagree
 - c. Agree
 - d. Strongly agree
12. *CIM can produce longer lasting and more complete clinical results than conventional medicine
- a. Strongly disagree
 - b. Disagree
 - c. Agree
 - d. Strongly agree
13. *CIM should be subject to more scientific testing before they can be accepted by conventional providers.
- a. Strongly disagree
 - b. Disagree
 - c. Agree
 - d. Strongly agree
14. *CIM is dangerous in that it may prevent patients from getting proper treatment.
- a. Strongly disagree
 - b. Disagree
 - c. Agree
 - d. Strongly agree

* Derived from Ben-Arye et al (2008).

Appendix C



Institutional Review Board

DATE: 06-29-2021
TO: Jacqueline Thompson
FROM: Institutional Review Board
RE: IRB #S21.282
TITLE: Complementary and Integrative Medicine in Primary Care
SUBMISSION TYPE: New Project
ACTION: Determination of Exempt Status
DECISION DATE: 06-29-2021

The Institutional Review Board at Marian University has reviewed your protocol and has determined the procedures proposed are appropriate for exemption under the federal regulations. As such, there will be no further review of your protocol and you are cleared to proceed with your project. The protocol will remain on file with the Marian University IRB as a matter of record. Please be mindful of the importance of reporting only de-identified, HIPAA-compliant information about the patient in any exhibit or publication.

Although researchers for exempt studies are not required to complete online CITI training for research involving human subjects, the IRB **recommends** that they do so, particularly as a learning exercise in the case of student researchers. Information on CITI training can be found on the IRB's website: <http://www.marian.edu/academics/institutional-review-board>.

It is the responsibility of the PI (and, if applicable, the faculty supervisor) to inform the IRB if the procedures presented in this protocol are to be modified or if problems related to human research participants arise in connection with this project. Any procedural modifications must be evaluated by the IRB before being implemented, as some modifications may change the review status of this project. Please contact me if you are unsure whether your proposed modification requires review. Proposed modifications should be addressed in writing to the IRB. **Please reference the above IRB protocol number in any communication to the IRB regarding this project.**

A handwritten signature in black ink, appearing to read 'Amanda C. Egan', written over a horizontal line.

Amanda C. Egan, Ph.D.
Chair, Marian University Institutional Review Board

Appendix D



**INSTITUTIONAL REVIEW BOARD
EXEMPT DETERMINATION**

September 23, 2021

Jackie Thompson
2001 W. 86th St.
Indianapolis, IN 46260

Dear Ms. Jackie Thompson:

On 9/22/2021, the Ascension St. Vincent (Indiana) IRB reviewed the following submission and determined that this study has met the criteria for exempt classification:

Type of Review:	Initial Study
Exempt Category:	(2)(ii) Test, surveys, interviews, or observation (low risk)
Title:	Complementary and Integrative Medicine and Primary Care
Investigator:	Jackie Thompson
IRB ID:	R20210095
Funding:	Name: 01 Unfunded
Grant Title:	None
Grant ID:	None
IND, IDE, or HDE:	None
Documents Reviewed:	See list at close of letter below signature line

Research classified as exempt is not subject to the continuing review requirement of 45 CFR 46 (however, when the project is complete, it needs to be officially closed with the IRB office).

Reminders and Considerations:

- Research is expected to be conducted in accordance with the proposal approved by the IRB and the Investigator Manual (HRP-200), which can be found by navigating to the IRB Library within the Ascension eIRB system.
- If there are changes to the protocol that impact its exempt status, you must obtain IRB approval before implementing those changes. Other changes are not required to be submitted to the IRB.
- Reportable events: Unanticipated problems involving risk, significant protocol deviations/noncompliance, and new safety information must be reported to the IRB.
- If the study includes obtaining informed consent a copy of the IRB approved informed consent form with the IRB approved from/to stamp must be used unless a waiver of written documentation of consent has been granted. You can access all materials approved by the IRB in your study space of the eIRB system.
- Approval by the IRB does not indicate institutional commitment of resources nor does it indicate privileges to perform new procedures. You are responsible for assuring and

maintaining other relevant organizational approvals. This research protocol should not commence until all relevant approvals have been obtained.

The Ascension St. Vincent (Indiana) Institutional Review Board is a duly constituted Institutional Review Board under 21 CFR Part 56 and 45 CFR Part 46 and operates in compliance with Good Clinical Practices, all applicable regulatory requirements, and the Ascension Ethical and Religious Directives.

Sincerely,

Tina G. Noonan, MBA, CHRC, CIP
Executive Director, Research
Human Research Protection Program Administrator

Documents Reviewed for this Submission:

- CIM Survey Consent Form.docx, Category: Study Tools (Data Collection Sheet, Surveys, etc.);
- citiCompletion.pdf, Category: CITI Training Certificate;
- citiCompletionReport8534691.pdf, Category: CITI Training Certificate;
- FRM-1001 Investigator Agreement.docx, Category: Other;
- FRM-704 Request for Waiver or Alternation of Consent (4).docx, Category: Other;
- J. Thompson CV, Category: CV/Resume;
- Jackie Thompson, Category: IRB Protocol;