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Parent Perceptions of Biofeedback Treatment Effectiveness for Pediatric Migraine

Andrea Grando Weber
Walden University

Walden University

College of Social and Behavioral Sciences

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Andrea Grando Weber

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Review Committee

Dr. Brandon Cosley, Committee Chairperson, Psychology Faculty

Dr. Jay Greiner, Committee Member, Psychology Faculty

Dr. Peggy Gallaher, University Reviewer, Psychology Faculty

Chief Academic Officer

Eric Riedel, Ph.D.

Walden University

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Abstract

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Andrea Grando Weber

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MA, Marshall University, 1998

BS, West Virginia University, 1990

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

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Abstract

Gate control theory posits the idea that the brain and spinal cord have the ability to control the perception of pain sensation throughout the body. Biofeedback provides a proven way to teach a person how they may control their heart rate, breathing, and skin temperature. Through this process, individuals learn to lessen their migraine frequency and intensity. There are no studies to date that have measured the effectiveness of biofeedback in conjunction with medication for migraines in children despite established evidence of success in adults. In this study, an online format via SurveyMonkey was used to document the perceptions of parents with regard to the observation of their children's migraines. Pre- and posttreatment measures were recorded to document migraine activity with implementation of biofeedback or medication using the Individualized Numeric Rating Scale. A total of 48 participants reported about their children's migraine frequency and intensity. One group of 24 parents were asked to give information on medication only treatment, and an additional 24 parents provided information on biofeedback and medication. The data were processed using 2 mixed model (i.e., 1 within and 1 between) ANCOVAs. Although frequency and intensity of migraines decreased across both groups posttreatment, there was no statistically significant interaction between the within subject factors of time and type. In this particular data set, medication plus biofeedback was not more effective than medication alone. The implications for positive social change using the results of this study are the potential for happier, healthier, migraine free children who are more able to be productive and contribute positively to society.

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Dedication

I would like to dedicate this dissertation to my daughter, Olivia. She has shown great strength to persevere through the adversity of chronic migraine in adolescence. Her struggle has given me insight into what courage it takes to live with an invisible illness. My hope is that the work I have done here will benefit children like Olivia and their families.

Acknowledgments

I would like to acknowledge my dissertation committee, Dr. Brandon Cosley, Dr. Jay Greiner, and Dr. Peggy Gallaher, for their dedication in helping me complete my dissertation. I would also like to thank my husband, Rob, and children, William, Sarah, and Olivia, for acting as my personal cheering squad as I have moved through each stage of the dissertation process. Thank you for your belief in me and in my ability to make a meaningful contribution to this body of literature. I truly hope I have made a difference.

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Chapter 1: Introduction to the Study

Introduction

Migraine is the sixth most disabling illness in the world (Migraine Research Foundation [MRF], 2019). Children of school age show a 10% incidence rate of migraine diagnosis (MRF, 2019). Identifying techniques that reduce the symptoms and frequency of migraines in children could bring about significant positive social change through the increased productivity and participation for those children afflicted with this disabling condition. In this study, I compared parent observation and complimentary integrated medicine (CIM) in the form of biofeedback to medication treatment alone to determine if use of CIM improves the rate and intensity of migraine occurrence.

Background

Migraine headaches in children begin before the age of 5 for one quarter of migraine sufferers and begin before the age of 20 in more than half of child migraine sufferers (National Headache Foundation, 2007). More than 20% of migraine sufferers are considered to be disabled; this number increases with accompanying comorbid conditions (MRF, 2017). Complementary and alternative medicines (CAM) for migraines have proven effective within adult populations. For example, nondrug therapies, such as chiropractic (Tuchin, 1997) and biofeedback and acupuncture (Millstine, Chen, & Bauer, 2017), have proven effective in treating adult migraines. The National Headache Foundation endorses biofeedback, acupuncture, and cognitive behavioral therapy (CBT) as alternative migraine therapies for adults (Guirguis-Blake, 2010). Of the alternative therapies, biofeedback is one of the more effective behavioral approaches and lends itself to use as an alternative or complementary treatment (Nestoriuc & Martin, 2007). Biofeedback helps patients learn to control their personal physiology through the reporting of continuous feedback of their biological response (Nestoriuc & Martin, 2007). Researchers have found biofeedback to be more effective than acupuncture and CBT in adult populations (Goslin, Gray, & McCrory, 1999). Because children are physiologically different than adults, using adult research for children is unreliable; therefore, data specifically regarding children is necessary (Jindal, Ge, & Mansky, 2008).

The CAM treatments may be helpful among children because treating migraines with drug therapies in children has been problematic for researchers. Papetti *et al*. (2010) established that pharmaceutical treatment of migraines in children have many negative side effects. General studies of alternative pain relief methods in children, such as acupuncture (Jindal *et al*., 2008) and distraction (He, Polkki, Pietila, & Vehvilaien-Julkunen, 2006), showed success in the emergency room, postsurgical settings, and abating aftereffects of chemotherapy treatments. Furthermore, researchers have shown positive results for pediatric migraines from nondrug therapies, such as diet (Eidlitz-Markus, Haimi-Cohen, Steier, & Zeharia, 2009); CBT (Powers *et al*., 2013); biofeedback (Herman & Blanchard, 2002); and acupuncture (Jindal *et al*., 2008). However, compared to pharmaceutical interventions, research on CAM therapies among children in conjunction with pharmaceutical treatments have been relatively sparse, especially among the very young (Eidlitz-Markus *et al*., 2010).

In part, the lack of research may have resulted from ethical issues and from the view that children are difficult study subjects. Children may manifest pain differently than adults, necessitating a different process of evaluation (Jindal *et al*., 2008). One method of gaining reliable feedback is to use caregiver responses as a method of understanding the child's response to feedback (Vetter, Bridgewater, & McGwinn, 2012). Studies that focused on general pain relief in children have frequently included parent and caregiver evaluations (He *et al*., 2006). Additionally, researchers found caregivers may be better able to assess pain in their children than health care professionals (Craig, Lily, & Gilbert, 1996; Jylli & Olsson, 1995).

Biofeedback has also been shown to be effective in treating migraine symptoms for children (Eccleston, Morley, Williams, Yorke, & Mastroyannopoulou, 2001; Hermann & Blanchard, 2002; Jindal *et al*., 2008; Levy *et al*., 2010; Powers *et al*., 2013). However, no researchers have measured the comparative effectiveness of biofeedback as a complementary treatment method in child migraine patients using parent and caregiver assessments. Through this study, I addressed this gap in the literature to gain increased understanding of the use of biofeedback in conjunction with pharmaceutical treatment through the parent and caregiver assessments.

Problem Statement

According to the U.S. Department of Health and Human Services, 29.5 million Americans are affected by migraines (Doheny, 2013). Worldwide, 60% of children suffer from headaches of varying intensity and length (Abu-Arafeh, Razak, Silvaraman, &

Graham, 2010). Researchers have proven nonpharmacological CAM therapies, such as acupuncture and chiropractic, effective in the treatment of migraine illness for adults (Molsberger, 2012; Tuchin, 1997); however, children are physiologically different from adults. As a result, research data obtained from adult studies cannot be extrapolated to children (Jindal *et al*., 2008). Biofeedback, acupuncture, and CBT therapies have shown promise for effective pain reduction in child migraine pain (Eccleston *et al*., 2001; Hermann & Blanchard, 2002; Jindal *et al*., 2008).

No studies have measured the effectiveness of medication and biofeedback in child migraine patients, but among adults, biofeedback affords significant symptom improvement more than acupuncture (Goslin *et al*., 1999). In my review, I could locate no extant literature measuring the effectiveness of biofeedback as a complementary treatment for pediatric migraine as measured by parent and caregivers. Through this study, I intended to develop data to determine whether biofeedback as a complementary therapy provides effective symptom improvement in child migraine patients. I measured therapeutic effectiveness by compiling parental perceptions of child migraine responses, thereby demonstrating which and to what extent complementary biofeedback treatment results in fewer migraine episodes during a 1-month period.

I focused on all children under the age of 18 years old who had been previously diagnosed with migraine headaches. Parents and caregivers may be better able to assess pain in children than health professionals, and studies in hospital settings have shown that pediatric pain relief can be managed better when health care providers consider parent and caregiver ratings (Craig *et al*., 1996; Jylli & Olsson, 1995). Likewise, researchers who incorporated parent input into child migraine treatment response have shown parents are able to judge children's pain levels better than medical staff (Jylli & Oslon, 1995). However, scant literature exists specifically on child migraine that involves parent and caregiver evaluations (Eidlitz-Markus *et al*., 2010).

Through this study, I sought to further explore how parent perceptions of child migraine pain may be examined and used to further research. Incorporating parent responses into evaluating effectiveness of migraine treatment lends an additional level of feedback regarding the effectiveness of treatment beyond doctor and child migraine patient feedback. Statistically, parent and child ratings are similar, and adding parent input strengthens support for treatment validity (Vetter *et al*., 2012). It is not known whether and how incorporating biofeedback with pharmaceutical treatment among children with migraines can reduce migraine-related pain according to parent and caregiver responses.

Purpose of the Study

Biofeedback is a recognized alternative migraine therapy for adults (Guirguis-Blake, 2010) that also shows promise for use in children (Eccleston *et al*., 2001; Hermann & Blanchard, 2002; Jindal *et al*., 2008). However, no prior researchers have measured the effectiveness of this therapy in children by using caregiver assessments to more accurately assess the child's pain level. Research focusing on perceptions of medical staff has shown their assessments are not always an accurate assessment of child pain experience (Craig *et al*., 1996; Jylli & Olsson, 1995). The purpose of this quantitative, quasi-experimental study was to measure the effectiveness of biofeedback as a complementary therapy in child migraine patients through surveys completed by caregivers. The two self-selected groups consisted of parents or caregivers of children diagnosed with migraine up to the age of 18 years old and who had treated their migraines with medication only or medication in conjunction with biofeedback. Caregiver reports documented child migraine patient responses during a 1-month period. I intended to identify an effective complementary migraine treatment for children as reported by caregivers, thereby addressing the gap in the existing literature.

Research Questions and Hypotheses

Omnibus Research Question: Is biofeedback in addition to medication treatment more effective in the treatment of child migraines than medication alone?

H_0: Biofeedback in addition to medication is not more effective in the treatment of child migraines than medication alone.

H_a: Biofeedback in addition to medication is more effective in the treatment of child migraines than medication alone.

Research Subquestion 1: Does biofeedback in addition to medication treatment reduce the frequency of reported child migraines when compared to medication alone?

$H_0 1$: Biofeedback in addition to medication does not reduce the frequency of reported child migraines when compared to medication alone.

H_a1: Biofeedback in addition to medication does reduce the frequency of reported child migraines when compared to medication alone.

Research Subquestion 2: Does biofeedback in addition to medication treatment reduce the intensity of reported child migraines when compared to medication alone?

H_02: Biofeedback in addition to medication does not reduce the intensity of reported child migraines when compared to medication alone.

H_a2: Biofeedback in addition to medication does reduce the intensity of reported child migraines when compared to medication alone.

Theoretical Framework for the Study

Melzack and Wall (1965) founded gate control theory, which is a theory of pain. Gate control theorists hold that a person's perception of pain is influenced by her or his mood, previous pain experiences, and current emotional state (Wlassoff, 2014). Before gate control theory emerged, researchers believed that pain was only influenced by the intensity of the pain or extent of physical damage to the body (Wlassoff, 2014).

According to gate control theory, pain signals do not immediately reach the brain following the stimulus (Melzack and Wall, 1965). Signals for pain must pass through neurological gates in the spinal cord, and these gates within the spinal cord choose whether the pain signals will reach the brain (Melzack and Wall, 1965). When the gate "trips" and opens, the brain perceives pain, but when the gate remains closed, the brain perceives little or no pain (Mammis, 2015; McCaffrey, Frock, & Garguilo, 2003). This theory supports the idea that an individual's perception of his or her state of being influences his or her perception of pain (Marchant, 2016; McCaffrey *et al*., 2003). Therefore, gate control theorists use the mind-body connection through biofeedback to improve a patient's susceptibility to pain (McCaffrey *et al*., 2003). I developed the hypotheses in this study as tests of gate control theory, in that the theory suggests biofeedback may help migraine patients by giving a personal sense of control regarding their illness, and in turn, this process will promote healing in the body (see McCaffrey *et al*., 2003).

Nature of the Study

The nature of this study was quantitative because I measured reduced migraine frequency and perceptions of severity of pain using the Individualized Numeric Rating Scale (INRS). I employed a survey completed by primary caregivers of child migraine sufferers. Because conducting a randomized controlled trial was not feasible given limitations in the study population, I employed a quasi-experimental study design using self-selected groups of participants who were treating their children with medication alone or medication plus biofeedback treatment. To address any possible demographic confounders, demographic covariates, such as child's age, family income, and gender, were included in the study.

Definitions

Biofeedback: Electrical sensors connected to an individual that output information on bodily functions (Barnett & Shale, 2013). The awareness of this output helps subjects learn to recognize and eventually regulate their responses to stimuli, thereby improving their health. The most popular types are electromyography, which gives information on muscle tension, and thermal, which measures skin temperature and heart-rate variability (Barnett & Shale, 2013). Biofeedback was the independent variable in the study.

Complimentary alternative medicine (CAM): An alternative medical procedure, such as biofeedback, acupuncture, or hypnosis, used to compliment traditional medical practices, such as medication to address illness (Barnett & Shale, 2013).

Migraine: A neurologically complicated cascade of symptoms consisting of head pain, nausea, vomiting, dizziness, photophobia, phonophobia, sensitivity to odors, abdominal pain, and mood changes (Pezzuto, 2014). The frequency, duration, and intensity of migraines were the dependent variables in this study.

Parent: Parents or caregivers within the body of the study; a person who brings up or cares for another (see Parent, n.d.).

Assumptions

One of the basic assumptions made in this study that I believed to be true, although not proven, was the honest reporting of information by the participants. A researcher must assume that participants will give accurate accounts of what they have experienced, such as with respect to the children’s migraine treatment outcomes in this study. As previously discussed, I assumed based on previous studies (e.g., Craig *et al*., 1996) that caregivers may provide accurate data regarding the pain outcomes of treatments among children who suffer from pain. I also assumed the participants' responses were truthful and accurate to protect the integrity of the study.

Scope and Delimitations

Through conducting this research study, I sought to determine whether the use of biofeedback in the treatment of child migraine affects a noticeable reduction of migraine episodes in the posttreatment period as perceived by the parent or caregiver rater. This focus was appropriate because prior researchers have proven parents are the more accurate raters of child pain behavior (see Craig *et al*., 1996). The boundaries of the study were the age of the children rated by parents. The ages of the children rated ranged from infant to 18 years old. Children had to have been formally diagnosed as having migraine illness to be included in the study. Those older than 18 years of age were considered adults for the purposes of this study and were excluded.

The participants in the study were the caregivers of the aforementioned children. There was no age restriction for the parent raters. Using parent raters was preferable to working directly with the children because of Institutional Review Board (IRB) considerations. The view that parents are the best articulators of their children's pain behaviors is clearly reflected in the literature (e.g., Craig *et al*., 1996). Because some children may not be old enough to speak or may not feel comfortable communicating, the use of parent input was the best course of action.

Additional complimentary treatments for migraine considered for the study were acupuncture, CBT, and chiropractic interventions. The results may not generalize to adult sufferers of migraines regarding the efficacy of biofeedback in conjunction with pharmaceutical therapies. Although the study occurred through an online format, which may have conceivably attracted participants from any location, the text of the survey was in English and, therefore, limited to English reading individuals.

Limitations

A primary limitation of this study was that it was not a randomized trial. Randomized trials reduce both researcher and participant bias (Levin, 2007). However, given that the subjects were pediatric migraine sufferers and members of a vulnerable population, it was difficult to justify intervention as a researcher, particularly for CIM, with no evidentiary basis for doing so. Although prior researchers have examined biofeedback among adults and shown it as an efficacious treatment less evidence exists pertaining to children. A limitation of the quasi-experimental design is that it reduce randomness and may have introduced confounding factors, but the body of current evidence does not support the use of intervention with this vulnerable population. The results of this study lay groundwork for future studies in establishing an understanding of caregivers' perceptions of the efficacy of biofeedback among children with migraines.

One of the potential design weaknesses was relying on parent input instead of child input; however, as previously discussed in this chapter, for children suffering from pain, caregivers are accurate at describing their children's level of pain, especially when compared to medical staff's ratings (Craig *et al*., 1996). One of the methodological weaknesses may have been obtaining the correct number of participants necessary to carry out specific statistical tests. To address this problem, I contacted various migraine support groups for additional participants.

Additional limitations may have stemmed from researcher bias. I am a parent of a child migraine sufferer, which may have lead to some bias. I addressed this by having participants self-administer their own surveys through SurveyMonkey. I did not directly interact with participants and, therefore, could not influence them or the resulting data.

A final limitation to the generalizability of the study was the limited amount of biofeedback practitioners. Use of biofeedback therapies do not come with the side effects that many medications do (Schetzek *et al*., 2013). If the study demonstrated that biofeedback was effective as a CAM therapy for pediatric migraine, the limitation that biofeedback is widely unavailable to those suffering from pediatric migraines could have posed a problem.

Significance

Although researchers have studied alternative therapies for migraine patients generally and analyzed pain management techniques for children to evaluate caregiver assessments, no researchers have attempted to record caregiver assessments of child migraine response to biofeedback as a complimentary therapy. Through the lens of the parent's perception, I examined the effectiveness of biofeedback on child migraine pain symptoms. The findings of this study contribute to filling the gap in the literature through evaluation of the efficacy of biofeedback as a complementary child migraine therapy determined through results obtained from caregiver surveys.

Accordingly, researchers who evaluate alternative therapy methods for pediatric migraine using parent and caregiver evaluations may provide important data to aid in the improvement of treatment methods. The intent of the study was to support all providers of migraine therapy for children (i.e., both medical professionals and caregivers) by providing concrete data that reflects the efficacy of biofeedback as a complementary treatment for migraine in children. The relevance of the study to society is to expand and improve the treatment of child migraine through complementary therapy.

Social change can be brought about through the increased productivity seen with optimum health. Helping children to live pain-free lives puts them in a much better place to achieve goals and accomplish a higher purpose. In finding the best complementary medical treatments to reduce the frequency of migraine pain in children, the results of this study contribute to social change by helping to reduce pain in child migraine sufferers.

Summary

In this chapter, I established the need for additional research in the area of CAM for the treatment of child migraine. The use of techniques like biofeedback lessen the amount of medication needed, frequency of occurrence, and duration of migraine episodes for adults (Nestoriuc, Martin, Reif, & Andrasik, 2008). Because children are more susceptible to medication effects, it is highly likely that children will benefit from CAM therapy, although no existing studies compare children's reaction to biofeedback and medication with medication only. The need for this study was apparent via this gap in the literature, as I will further discuss in Chapter 2.

Chapter 2: Literature Review

Introduction

A large population of children suffer from migraine illness: As of the age of 17, 8% of boys and 23% of girls have experienced a migraine (MRF, 2011). Medication options to treat migraine illness with pharmaceuticals can have negative side-effects (Papetti *et al*., 2010). Behavioral sociophysiological options, such as biofeedback, may offer relief for many children who suffer from migraine in conjunction with pharmaceutical treatments (Hermann & Blanchard, 2002). However, the effectiveness of combining biofeedback with pharmaceutical treatment among children with migraines is not known. Therefore, the purpose of this quantitative study was to measure the effectiveness of biofeedback as a complementary therapy in child migraine patients, as shown through surveys completed by caregivers.

In this chapter, I will discuss (a) the identification of migraine illness in the pediatric population; (b) human perception of pain, as explained through gate control theory; (c) how biofeedback employs gate control theory techniques to control pain; (d) the mechanism of biofeedback itself to treat specifically migraine; and (e) the role of the parent or caregiver as observer of symptom improvement in pediatric migraine frequency. I undertook a comprehensive literature search to provide information on biofeedback, pediatric migraine, chronic migraine, gate control theory, nonpharmacological approaches to migraine, and parent perceptions of pain relief in pediatric migraine. This chapter will also include an explanation of the need for this study and supporting literature.

Literature Search Strategy

The databases I searched were Google Scholar, Walden University Health Sciences, and Psychology Databases. Within these databases, I used PubMed and PsychInfo most extensively. Search terms included *biofeedback*, *pediatric migraine*, *migraine*, *migraine non-pharmaceutical interventions*, and *behavioral interventions for pediatric migraine*. The literature I reviewed ranged in publication date from 1965 to 2017. The older articles reflect key contributions to the field and were necessary to establish background in the subject matter. The majority of articles referenced for this work were from peer-reviewed journals; only 8.6% (5 out of 58) articles were from non-peer-reviewed publications.

Theoretical Foundation

Gate control theory provides a framework for pain control, which helps to explain how biofeedback works to lessen the pain of those who have migraines. Melzack and Wall (1965) first postulated the theory that pain transmissions may be influenced by the thoughts and emotional state of the individual, contrary to the prior conception of pain as a purely sensory phenomenon linked to physical circumstances. Previous to the use of gate control theory to explain pain, the 17th century philosopher Descartes's theoretical views of specificity were the theory most widely considered. Descartes contended that people, although possessing of a soul, were essentially machines with specific pain fibers and pathways and a center of pain within the brain (Melzack and Wall (1965). This ultimately resulted in the concept of pain as a linear sensory projection mechanism (Melzack, 1993). As late as the 1950s, if a person presented with pain and no physical cause was determined, health care providers summarily referred them to the psychiatrist (Melzack and Wall (1965). The psychological contributions to pain, such as situational meaning, attention, and past experience, were not recognized at this time (Melzack and Wall (1965).

The next attempt at a new pain theory was pattern theory, the precursor to modern gate control theory: Goldschieder's theory proposed that central summation in the dorsal horns is one of the vital aspects of pain (Melzack & Wall, 1965). Noordenbos theory (Melzack, 1993) believed that large diameter fibers inhibited smaller diameter fibers and that substantia gelitinosa found in the dorsal horns played an important place in summation and other processes posited by Livingston. All of these theorists saw the brain as a passive end point to which messages were sent. Emphasis eventually moved toward the spinal cord and out of the periphery for the origins of pain, and Gatchnel and Dennis (1966) subsequently noted that psychologists examined reasons why pain perceptions may change or be lessened.

According to gate control theory, a link exists between the physical and psychological basis for pain (Melzack & Wall, 1965). Pain results from transmission cells sending information through the nerve fibers in the spinal cord, which trigger an activation system within the brain that lead to a behavioral and physiological process that people experience as pain (Melzack & Wall, 1965). The perception of pain may appear greater, less, or completely nonexistent contingent on the emotional state of the person at the time (Melzack & Wall, 1965). For example, when an individual is distracted, her or his pain may not be as apparent as it is when that individual was stressed in some way (Wlassoff, 2014). With this premise, the gate control theory of pain examines three separate systems when considering pain: sensory discriminative, motivational-affective, and cognitive-evaluative (Gatchnel & Dennis, 1966). Each of these different interactions can influence the level of pain a particular individual may feel at a given time.

Gate control theory had a significant influence on the scientific and clinical community (Gatchnel & Dennis, 1966; Wlassof, 2014). Psychological issues considered reactions to pain changed to being thought of as part of the pain processing for which new, nonsurgical types of pain control were used. These interventions depended on Melzack and Wall's (1965) observation that the gates in the fibers could inhibit or facilitate transmission, depending on activity in either the large or small fibers respectively, and that this mechanism was controlled by nerve impulses that could be consciously directed by cognitive activity. Using this theory, practitioners suggested that individuals could manipulate gates to decrease pain. For instance, chiropractic (Tuchin 1997) and acupuncture (Jindal *et al*., 2008) practitioners use gate control to draw on the body's ability to block pain. Biofeedback, the CAM therapy examined in the present study, also has its tenets in gate control theory. In the aforementioned instances, health care providers used gate control theory to refocus pain perception through additional stimuli to lessen or extinguish pain signals (Labbé & Williamson, 1984). The idea of being able to modulate the body's pain perception through modulation of sensory input revolutionized the science of pain and its treatment (McCaffrey *et al*., 2003; Melzack, 1993).

The therapeutic treatment of biofeedback includes the view of pain developed through gate control theory (Gatchnel & Dennis, 1996). By directing the mind to influence bodily processes, such as skin temperature, heart rate, and breathing, people who use biofeedback are able to influence the spinal gating process to block pain (Labbé & Williamson, 1984). Gate control theory put into practice in the form of biofeedback can be used to lessen the frequency and duration of migraine headache in children (Labbé & Williamson, 1984). Because gate control theory holds that psychological and social factors influence biological factors, integrating pain control from all directions may positively influence treatment outcomes (Borrell-Carrio, Suchman, & Epstein, 2004; McInerney, 2015). Integrating gate control theory through biofeedback into the treatment of child migraine may prove beneficial when used in conjunction with pharmaceutical treatment, which I examined in the present study.

Literature Review Related to Key Concepts

Children's Migraines: Symptomatology and Prevalence

Among adolescents, 82% say they have experienced a headache before the age of 15, but only 6% of adolescents experience migraine yearly (Winner, 2009). The International Headache Society (2004) changed its diagnostic criteria and classification system in the 2004 International Criteria for Headache Disorders. Migraines are now considered a hereditary disorder consisting of neuronal initiation of a cascade of neurochemical processes culminating in a spreading wave of cortical neuronal depolarization (Lewis, 2009). The updated criteria include developmentally relevant amendments that give broader consideration to the pediatric population. This new system also takes into consideration the more recent understanding of the physiological changes that occur during migraine.

According to Winner (2009), migraines experienced in the pediatric population have several key features. Pediatric migraines are equally debilitating as those experienced by adults but tend to last for a shorter period, from 1 to 72 hours (Winner, 2009). Furthermore, pediatric migraines are often characterized by bifrontal or bitemporal pain, as opposed to unilateral pain (Winner, 2009). Behavioral changes may include irritability, mood swings, withdrawn behavior, a loss of appetite, food cravings, and frequent yawning (Pezzuto, 2014). Like with general migraines, associated symptoms may include nausea, photophobia, phonophobia, difficulty thinking, lightheadedness, and fatigue (Winner, 2012). Of key importance, Winner (2012) noted that children may have trouble discussing their symptoms; parents or caregivers may need to infer symptoms of pediatric migraines, such as nausea, aversion to light, and aversion to sound, based on their children’s behaviors. This is especially true for younger children (Brudvik, Moutte, Baste, & Morken, 2017).

Social and Academic Aspects of Pediatric Migraines

The general public may not understand the extent of disability those with migraines experience, leading to social stigma (Doheny, 2012). Stigma levels for chronic migraine sufferers rival those of individuals with epilepsy and panic attack (Doheny, 2012). In fact, Thomas Jefferson University's Headache Center noted that those who experienced chronic migraines experienced more stigmas surrounding their illness than those who had epilepsy (Doheny, 2012). Those with invisible illnesses like migraine do not always "look sick," which carries the added stigma that the child may be malingering (Doheny, 2013). According to Berliner (2012), a neurologist and psychiatrist specializing in headache disorders, this type of stigma is a common problem for those with chronic migraine. Berliner noted most people who have not experienced migraines incorrectly assume taking an over-the-counter pain reliever will adequately address a headache, and this is simply not the case with migraine. Without adequate treatment, it may be difficult if not impossible for a child with pediatric migraine to function normally (MRF, 2017).

As with many chronic illnesses, children with chronic migraine are at risk for comorbid mental health disorders (MRF, 2017). The loss of control that occurs with chronic illness can lead to contributing depression or anxiety in child migraine sufferers (MRF, 2017). It is important to keep the child as involved in regular activities as possible (Eckes, Radunovich, & Brumbaugh, 2015). Frequent absences from school and social activities because of migraines can have a significant negative effect on the child's ability to feel connected and productive (Eckes *et al*., 2015). This, in turn, causes stress, which leads to more migraines (Eckes *et al*., 2015). Care should be taken not to engage in this frustrating cycle, and special education supports within the school, such as a 504 Plan or even an Individual Education Plan for Health Impairment, should be considered (Eckes *et al*., 2015). Health education regarding the etiology and disability that accompany migraine illness is also recommended to combat comorbidity associated with pediatric migraines (Eckes *et al*., 2015).

Diagnoses of Migraines in Children

The initial evaluation of children with migraine should start with an in-depth medical history along with a thorough physical and neurologic workup (Winner, 2012). The use of further diagnostic testing, such as neuroimaging, may rule out other conditions or disorders (Winner, 2012). Because children may have trouble with explaining their pain levels, pain scales, such as face or numerical scales, may help to gain a more accurate picture of pain levels of children (Winner, 2009, 2012). In addition, parents and caregivers are often relied on to supplement the account of a child's pain levels (Brudvik *et al*., 2017; Winner, 2012).

Several barriers exist to receiving an initial migraine diagnosis for children. Making the diagnosis of migraine in this population is difficult because of the types of symptoms, which can change markedly throughout childhood (Lewis, 2009). Often, migraines in children do not always manifest in head pain (Pazuto, 2014). Nausea, vomiting, and abdominal pain may accompany the head pain with migraine or may manifest in absence of it (Pezzuto, 2014). Behavioral changes may also be seen in the prodromal phase or first phase of a migraine episode, which may complicate an accurate diagnosis (Lissandrello, 2014). Therefore, the diagnostic criteria established by the International Classification of Headache Disorders-II are at times inadequate for diagnosing pediatric migraines (Winner, 2012).

An additional problem is that medical professionals may underestimate children's complaints of pain (Brudvik *et al*., 2017). Children's complaints may be dismissed as "just a virus" or a plea for attention (Masters, 2006). In fact, as recently as the 1980s, pediatric textbooks did not talk about pain management for children at all (Schechter, Berde, & Yaster, 2003). It was believed that children did not experience pain like adults because of an undeveloped neurological system (Roberts & Steele, 2009). In addition, there are conflicting antiquated philosophies through which practitioners view pain; either it is "real" or the child is "malingering" (Robbins, Smith, Glutting, & Bishop, 2005). Such views can lead poorly informed professionals to dismiss children's pain and erroneously label them with psychological disorders because their pain is not clearly tied to physical pathology; these children are unnecessarily given medications and medical procedures rather than empirically supported approaches to deal with their presenting illness (Masters, 2006). More than half of all migraine sufferers are never diagnosed (MRF, 2017). Frustrated parents are left to address their child's migraines by administering over-the-counter medications, only to find them useless in alleviating their child's pain. As of 2017, there are 500 certified headache specialists within the United States and 38 million people who have migraines (MRF, 2017).

Parent Role in Pain Control for Children with Migraines

Having a sick child is distressing; parents of children with a chronic illness reported much greater general parenting stress than those parenting healthy children (Cousino & Hazen, 2013). Depending on health care workers to communicate the disposition of a child's illness leaves parents with a multitude of conflicting information and diverse opinions, resulting in anxiety and confusion (Levetown, 2008). However, parents of children with migraines often serve at the front lines of pediatric migraine treatment (Brudvik *et al*., 2017).

Because of their unique position in the treatment of child migraine, parents and caregivers are often the first observers of pain and symptom improvement (Craig *et al*., 1996). Parents know their children's typical pain-related behaviors better than those who are unfamiliar with them; living in the home with the child and observing their level of functioning during lengthy periods of time when migraines may be active gives parents a baseline with which to compare children's pain behaviors and overall level of functioning (Brudvik *et al*., 2017; Solodiuk & Curley, 2003; Solodiuk *et al*., 2009). Moreover, in an unfamiliar place, like an emergency room or a doctor's examination room, a child may not feel comfortable expressing him or herself to the medical staff attending them (Brudvik *et al*., 2017). Thus, a parent must advocate for their child to ensure they receive the best treatment for their pain. Moreover, parents and caregivers may serve as important data sources in understanding and managing children's pain (Craig *et al*., 1996; Winner, 2012).

Pharmaceutical Treatments for Children with Migraines

Several pharmaceutical treatments may be prescribed to children with migraines. The typical pharmaceutical treatment of pediatric migraine requires a three-pronged approach: (a) integration of migraine friendly behavioral practices, (b) medication for addressing acute migraine treatment, and (c) daily preventive medications as needed (Lewis, 2002). The acute treatment medications of migraine most researched are ibuprofen, acetaminophen, and sumatriptan nasal spray (Winner, 2009). For preventive treatment in children with frequent, disabling migraines, antiepileptic agents topiramate, disodium valproate, levetiracetam, the antihistamine cyproheptadine, and the antidepressant amitriptyline are typically used. However, these medications are not without significant side-effects that can affect the developing brain.

Antiepileptic agents have positive outcomes for migraine prevention but come with potentially severe side effects. Topiramate is an antiepileptic drug effective in treating many neuropsychiatric disorders and is used as a migraine preventative approved for children's use (Mula, 2012). Cognitive dysfunction is observed in patients who take it; memory impairment, significant decrease in psychomotor reaction time, parathesia, concentration problems, as well as behavioral disturbances occur in children administered this drug (Mula, 2012). Disodium valproate is an anticonvulsant drug approved for use in children for migraine and epilepsy (Egger & Brett, 1981). Side effects of this drug include severe weight gain, gastrointestinal disturbance, liver disease, pancreatitis, hair loss, tremor and blood coagulation issues, and eneuresis (Egger & Brett, 1981).

Levetiracetam, sold under the brand name Keppra, is also an antiepileptic drug that moderates the transmission of nerve impulses to the brain (Everyday Health, 2017). Common side effects from this medication include weakness, dizziness, irritability, becoming aggressive, decreased appetite, sleepiness, and developing Stevens-Johnson's syndrome; in addition, some children may develop psychotic symptoms and hallucinate (Everyday Health, 2017).

Additional pharmaceutical treatments involve the use of antihistamines or antidepressants. Cyproheptadine or periactin is an antihistimine preventative medication given to children for migraine (Marks, 2017). It can cause weight gain, blurred vision, constipation, drowsiness, excitability, nausea, and restlessness (Marks, 2017). Amitriptyline is an antidepressant prescribed to children for migraine prevention. It is an older tricyclic antidepressant associated with irregular heart rhythms, dizziness constipation, and weight gain (About Kids Health, 2018).

Although a pediatric neurologist may be able to recognize and correctly diagnose migraine in children (Winner, 2009), many pharmacological treatment options that are among the first lines of defense may have many undesirable negative side effects (Papetti *et al*., 2010; Winner, 2009). Children are physiologically different from adults and metabolize medication differently (Jindal *et al*., 2008). Their bodies are still growing and developing; they may be more at-risk when taking different classes of pharmaceuticals (Papetti *et al*., 2010). The severity and frequency of the migraine incidences must be considered to justify the use of these migraine preventative medications.

Nevertheless, Lewis (2004) noted that data regarding pharmacologic treatment of migraine in children were limited. Integration of a nonpharmaceutical treatment, like biofeedback, may be prudent in helping a child to manage pain. However, a gap in the literature exists regarding the use of biofeedback in conjunction with pharmaceutical intervention among children with migraines. The following section includes a review of CAM therapies, in general, to lead into the discussion of CAM therapies as a complement to pharmaceutical treatments.

CAM Therapies

It is common for those with chronic pain to look for other solutions to help address their pain beyond traditional medications (Woolston, 2017). Traditional treatments for pain, like narcotics, have decreased because of the opioid misuse epidemic, which further highlights the need for other effective alternatives for pain management (Millstine, *et al*., 2017). CAM, more recently referred to as complimentary integrative medicine (CIM), are add on treatments to traditional medical therapies (Woolston, 2017). Many pain centers incorporate acupuncture, biofeedback, massage, and hypnosis into their treatment practices to further address pain (Woolston, 2017).

The National Center for Complementary and Integrative Medicine shows a steadily growing amount of data support CAM therapies when used in addition to traditional medical care (Millstine *et al*., 2017). The use of CIM is increasing; in Europe, headache clinics report an 81.7% use of various CIM techniques (Millstine *et al*., 2017). Biofeedback, in particular, shows promise as a useful CIM therapy. A meta-analysis of

94 studies and 3,500 participants regarding biofeedback techniques using peripheral skin temperature feedback, blood, volume pulse feedback, and electromyography reflected a significant medium sized effect on the frequency, duration, and intensity of migraine headaches (Nestoriuc & Martin, 2007).

Case for CAM to Complement Pharmaceutical Therapies

After a child is diagnosed formally with migraine and the doctor establishes a medication regiment, parents may wish to consider complimentary therapy. As the name suggests, complimentary therapy compliments, or goes along with, another form of therapy simultaneously. Lewis (2002) explained behavioral modification is already used as a method of treating migraines; a noninvasive intervention, such as biofeedback, may further improve outcomes. In the case of biofeedback and the migraine patient, as the patient learns to monitor his or her physiological condition, he or she is better able to stave off the triggers that herald the coming of the migraine and thereby prevent or lessen its effects (Lipchik, 2008).

Researchers have noted several benefits of CAM therapies. For example, CAM may improve the efficacy of migraine treatment. Lipchick (2008) determined that when either biofeedback or Inderal were used by themselves, a 55% reduction in migraines occurred, but when used together, the average improvement increased to 70%. Researchers have found that through complimentary therapies, less medications are needed to achieve the desired therapeutic effect (Nestoriuc *et al*., 2008). Thus, the conjunction of CAM and pharmaceutical treatment in treating pediatric migraine may reduce the amount of medication required to treat pain and improve the efficacy of that treatment (Nestoriuc *et al*., 2008). In the following section, I further detail biofeedback, a CAM therapy.

Role of Pain and Biofeedback in Treating Pediatric Migraine

Biofeedback is an effective treatment for migraine among adults. In a meta-analysis done by Nestoriuc and Martin (2007), the researchers reviewed 55 studies that revealed improved migraine symptoms over more than 17 months. Reduced frequency of migraine episodes and perceived self-efficacy were outcomes in the studies. Of the three types of biofeedback used in the reviewed studies, Nestoriuc and Martin found blood-volume-pulse feedback yielded the highest effect sizes compared with peripheral skin temperature feedback and electromyography feedback. Additional researchers have found biofeedback effective for migraine treatment with symptom improvement in 40% of subjects (Blanchard *et al*., 1980; Blanchard & Andrasik, 1987; Penzien *et al*., 1985).

Although research supports the use of biofeedback to compliment migraine treatment for adults, a dearth of literature supports its use for children. However, children can be taught to do biofeedback and experience success (Allen & Shriver, 1998). After children become aware of the physiological changes that precede migraine and learn how to control them through biofeedback, they can improve and lower their frequency of migraine episodes (Allen & Shriver, 1998). Because children are more vulnerable to the side effects of the medications often prescribed for migraine (Mula, 2012), using biofeedback as an alternative or compliment to medication offers another way to bring improvement to a difficult-to-treat illness (Nicholson, Buse, Andrasik, & Lipton, 2011).

Influence of Demographics on Migraines and Biofeedback

Socioeconomic status. Access to care for those of lower socio-economic status (SES) was a significant concern. Higher SES is associated with higher prevalence of migraines in a household (Le, Hansen, Skytthe, Kyvik, & Olesen, 2011; Stewart, Roy, & Lipton, 2013). The income levels of pediatric migraine sufferers directly influence their access to proper care. Lower income level families were less likely to seek medical care and less likely to get quality care when they did. Complimentary medical care, such as biofeedback, were rarely covered by insurance companies, which made it out of reach for most lower- and middle-income families.

Age. Age of a pediatric migraine sufferer can influence the ability to articulate symptoms. Younger children are not able to voice their discomfort verbally and may need caregivers to interpret for them (Brudvik *et al*., 2017). Older children may mask their discomfort and present as if they have a mood disorder. All ages should be taught to their best ability to articulate their symptoms for health care professionals to adequately assist.

Gender. Migraines occur more often in males during childhood (Pezzuto, 2014; Winner, 2012). It is not known why males tend to have more migraines during childhood. During adolescence, females tend to have higher incidence of migraine, which continues into adulthood (Pezzuto, 2014; Winner, 2012). Females are thought to have more migraine onset in adolescence because of fluctuating hormone levels associated with the menstrual cycle (Pezzuto, 2014; Winner, 2012).

Summary and Conclusions

Migraine illness treated with medication in conjunction with biofeedback in adults has been successful (Nestoriuc & Martin, 2007). Comparatively, less research exists regarding children and pharmacologic therapy for migraine (Lewis, 2004). Although some study findings demonstrated biofeedback is useful in migraine treatment for children (Allen & Shriver, 1998; Herman & Blanchard, 1997; Labbé & Williamson, 1984), no research has compared biofeedback and medication to medication alone through the input of a parent. Parent input is key because pain observations of parents are often more accurate than those of health care professionals (Brudvik *et al*., 2017; Craig *et al*., 1996). By conducting a study to determine whether medication and biofeedback or medication alone alleviates children migraine symptoms best through the input of parents, I helped to fill a gap in the existing literature on the subject of complementary migraine treatment for children. Chapter 3 will include an outline of the methodology used for the purpose of this study.

Chapter 3: Research Method

Introduction

Little literature exists on child migraine sufferers' parent perceptions regarding the improvement of symptoms of their illness when comparing conventional medical treatment to those of a complimentary nature. The purpose of this quantitative study was to measure effectiveness of biofeedback as a complementary therapy in child migraine patients, as shown through surveys completed by caregivers. This chapter contains a review of the research design, methodology, population, and sample selection.

Research Design and Rationale

In this study, I employed a quantitative methodology with a quasi-experimental research design. As a research tool, quantitative methodology was first used in 1250 A.D. when experimenters felt it was important to quantify their data (Williams, 2007). Since then, quantitative research has been the primary research method of choice throughout Western culture (Williams, 2007). This type of research is built from existing theory and the data collected are used to objectively measure reality (Williams, 2007). Results obtained through quantitative research are meaningful because of the objectivity of the data collection process (Williams, 2007). Through the quantitative methodology, data that represents key outcomes can be measured and statistically analyzed, which allows for hypothesis testing in an empirical manner (Williams, 2007).

My study was quasi-experimental because of the nonrandom selection of participants. The design choice was necessary because of the relative rarity of participants who fit the design criteria. Child migraine patients can be difficult to determine or access, and because this control was somewhat limited, experimentation in the truest form was not possible. This limited the validity of the study to some degree.

The quantitative methodology used for this study was in contrast to the qualitative and mixed methods approaches that are less structured and more involved in describing and explaining the data on a first-hand basis and would have heavily involved the researcher in the actual experiences of the participants. These approaches were not appropriate; such close involvement with study participants could have biased the results. A quantitative, objective approach using numerical data ensured objectivity and validity. As such, the quantitative methodology was more appropriate because of its objectivity and focus on numerical data.

The quasi-experimental research design involves the nonrandom assignment of study participants to groups. The opposite design is a true experimental design, which involves randomly assigned participants. In this study, the self-selected groups consisted of parents who were treating their children's migraines with medication alone or medication plus biofeedback treatment. The use of a true experimental design was not practical because it would have involved withholding a medical treatment from some members of the sample. I employed two mixed model ANCOVAs to assess group differences over time. The between-subjects factor was treatment (i.e., biofeedback and medication vs. medication alone), and the within-subjects factor was time (i.e., pre and post). The dependent variables were frequency of migraines and intensity of migraines.

This design allowed me to target the response of those who were most able to give the best report of child migraine response to treatment because parents are thought to be most accurate at judging their children's responses to pain. As such, this design aided in advancing knowledge in the areas of pain response to migraine treatment.

Methodology

Population

The population consisted of parents and caregivers of children who have experienced migraine episodes and who were treating those migraines. Approximately 10% of school-aged children in the United States suffer from migraines (MRF, 2017). Furthermore, migraine attacks have been diagnosed in children as young as 18 months old, and infant colic is being investigated as a possible form of migraine (MRF, 2017). Parents of child migraine sufferers often have migraines themselves and have a 50% chance of passing the trait to their offspring (MRF, 2017).

Sample and Sampling Procedures

I used convenience sampling to recruit participants for this study. This process involved advertising the link to the study survey through online and in-person migraine support groups and word-of-mouth referrals to the link to the survey. Truly random sampling was not practical because the population was highly specialized. Participants were contacted through their responses to the survey links. The study only included parents or caregivers of children diagnosed with migraine up to the age of 18 years old who had treated their migraines with medication only or medication in conjunction with biofeedback for participation. Potential participants had a child under the age of 18 years old at the time of the study who experienced migraine episodes and received either medication only treatment or medication and additional biofeedback therapy for their migraines. Participants who had children older than the age of 18 years old; children who had not been formally diagnosed with migraine; or treated with another therapy, such as acupuncture or hypnosis, were not included in the study.

I determined the appropriate sample size for this study through G*Power, a power calculator. For the determination of an appropriate power level or sample size, Cohen (1988) recommended a medium effect size and a .80 power level. For mixed models ANCOVA with one independent variable with two groups, two time measurements, three covariates with a total of six groups, a medium effect, and a generally accepted power level of .80, 96 participants would be necessary (see Faul, Erdfelder, Buchner & Lang, 2008). However, in similar studies, researchers found large effect sizes (Herman & Blanchard, 2002; Stokes & Lappin, 2010). When assuming a large effect size, a mixed model ANCOVA with the previously specified information would require 48 participants.

Procedures for Recruitment, Participation, and Data Collection

Potential participants self-identified by responding to a link connected to migraine support group sites. This link sent them to the study survey, hosted on SurveyMonkey. The link also contained a description of the study, what their participation would look like, and a description of how their information would be used. If the potential participant clicked on the link, they were taken to an informed consent page on SurveyMonkey that contained the complete informed consent document, which detailed the nature of the study, participants' rights, my contact information, the voluntary nature of the study, and the maintenance of confidentiality. In a question at the end of this page, I asked whether they understood and agreed to provide their informed consent. If they answered *yes*, they were indicating they provided their informed consent to participate in the study and were directed to the survey. Participants who answered *no* were redirected to a page that thanked them for their time; they were not allowed to take the survey. Appendix A includes the recruitment materials; Appendix B includes the informed consent form.

Participants received a short demographic survey that requested information regarding their age, gender, and SES. First, the survey asked whether their child was under the age of 18 years old, had migraines, and was being treated for the migraines. A negative response to that question disqualified the participant from the study, and they were taken to a thank you page for their time. The survey then asked whether the child was being treated using medication only or medication plus biofeedback therapy. The survey also asked how many migraines their child had 1 month before the intervention and how many migraines their child had 1 month following treatment. Participants were then presented with the INRS (Solodiuk & Curley, 2003) twice. In the first iteration, I directed participants to think of their child's migraines before treatment. In the second iteration, participants were directed to think of their child's migraines after treatment. After successful completion of the survey, participants were thanked for their time and again provided with my contact information. After an appropriate number of survey responses, I closed the survey and downloaded the data from SurveyMonkey. The data did not contain any identifying information and are kept on a password-protected computer, accessible only by me and my committee.

Instruments and Operationalization of Constructs

The instruments used in this study were a demographic survey and the INRS. In the following subsections, I detail these instruments. The constructs measured by the study variables are operationalized following a description of the instruments.

Demographic survey. I created the demographic survey used in this study to ask questions regarding the sampling frame (i.e., whether the participant's child has migraines), how the child was treated for the migraines, as well as their gender and age. The survey also asks for the gender, age, and SES of the parent completing the survey. I used this survey to gather data for the dependent variables of frequency of migraines and treatment type. Appendix C includes a copy of this survey.

INRS. Solodiuk and Curley (2003) created the INRS and designed it to describe the numerical intensity of pain the child experiences using responses given by a parent or nurse attendant. I specifically chose the INRS because of its personalized assessment tool based specifically on the parents' knowledge and assessment of their child. The INRS was based on nonverbal responses by the child observed by the parent (Solodiuk & Curley, 2003). As such, this assessment was appropriate for younger nonverbal children and those who do not communicate well in medical settings. According to Solodiuk *et al*.

(2010), preliminary data for reliability and validity of this instrument were good for assessing pain in nonverbal children with a severe intellectual disability in an acute care setting. Solodiuk *et al*. indicated that interrater reliability was high (i.e., ICC 0.82–0.87) and that the instrument had strong convergent validity ($r > .60$). I obtained permission from the copyright holder to use this instrument (see Appendix D). Appendix E includes a copy of the scale.

Independent variables. This study involved two categorical independent variables: treatment type and time.

Treatment type. The independent variable of treatment type was measured by the demographic survey item that asked: "What type of treatment does your child receive for their migraine?" This was a dichotomous variable with the categories of medication only and biofeedback plus medication.

Time. The second variable was elapsed treatment time, measured at two time points: pre and post.

Dependent variables. Two dependent variables were included in this study: migraine frequency and migraine intensity.

Migraine frequency. The dependent variable of frequency of migraines was measured by the demographic survey items that asked: "How many migraines did your child experience 1 month before treatment?" and "How many migraines did your child experience 1 month after treatment?' This was a continuous variable where participants could indicate exactly how many migraines were experienced. As this study was set up using a repeated measures design, the dependent variable consisted of two measurements: pre and post.

Migraine intensity. I measured the dependent variable of intensity of migraines using the INRS. This instrument consists of 0-10 rating scale, with higher scores representing a greater intensity and pain of a migraine. The identification of specific behaviors are used to help score the pain intensity and categorize the amount of pain the child is experiencing. Each response is categorized into its own outcome section to clearly describe the response and how it has been measured. As participants completed the INRS twice, once in regard to before their child's treatment and once in regard to after their child's treatment, I obtained scores for pre and post.

Covariates. Several control variables were included. These categorical variables accounted for potential confounding variables. ANCOVA presumes covariates are quantitative.

Gender. Child's gender was a categorical control variable, with categories of male and female.

Child's age. Child's age was a categorical control variable. The age categories were birth to 12 years, and 13 to 18 years.

Socioeconomic status. SES of the family was a categorical control variable. The categories were *lower to middle ($124,999 and below) and upper ($125,000 and above).*

Data Analysis Plan

After downloading the data from SurveyMonkey, I uploaded it to IBM's Statistics software (SPSS). I used SPSS for all data management and analysis. The data were assessed for significant cases of missing data. Cases missing more than 50% of data were removed. Outliers on continuous variables were assessed using the guidelines suggested by Tabachnick and Fidell (2013), in which standardized scores are created and then assessed for values beyond ± 3.29. Values beyond this number suggest that the associated score is an outlying value. I considered outliers for removal.

I then conducted descriptive statistics. Next, I calculated means and standard deviations for the continuous variables and calculated frequencies and percentages for categorical variables. The following sections present the analyses used for hypotheses testing.

Omnibus Research Question: Is biofeedback in addition to medication treatment more effective in the treatment of child migraines than medication alone?

H_0: Biofeedback in addition to medication is not more effective in the treatment of child migraines than medication alone.

H_a: Biofeedback in addition to medication is more effective in the treatment of child migraines than medication alone.

Research Subquestion 1: Does biofeedback in addition to medication treatment reduce the frequency of reported child migraines when compared to medication alone?

$H_0$1: Biofeedback in addition to medication does not reduce the frequency of reported child migraines when compared to medication alone.

H_a1: Biofeedback in addition to medication does reduce the frequency of reported child migraines when compared to medication alone.

Research Subquestion 2: Does biofeedback in addition to medication treatment reduce the intensity of reported child migraines when compared to medication alone?

$H_0$2: Biofeedback in addition to medication does not reduce the intensity of reported child migraines when compared to medication alone.

H_a2: Biofeedback in addition to medication does reduce the intensity of reported child migraines when compared to medication alone.

I answered the omnibus research question based on the answers to the sub-research questions. The sub-research questions were answered using two mixed models ANCOVAs. This is the appropriate analysis to perform when seeking to assess group differences in a single continuous dependent variable while controlling for potentially confounding variables (Field, 2013). Prior to each analysis, I assessed the assumptions of the mixed models ANCOVA. The first assumption is that of normality, assessed using a Kolmogorov-Smirnov (KS) test. If the KS test is not significant, normality can be assumed (Tabachnick & Fidell, 2013). The second assumption is that of homogeneity of variances, assessed using Levene's test. As with the KS test, if Levene's is not significant, the assumption is met (Tabachnick & Fidell, 2013). Sphericity is the third assumption, measured by Mauchley's test of sphericity. If Mauchley's test is not significant, sphericity can be assumed and the assumption is met (Tabachnick & Fidell, 2013).

For each ANCOVA model, findings for the main effect of time (i.e., *pre* and *post* scores on the dependent variable) and the main effect of treatment type (i.e., *biofeedback plus medication* and *medication alone*) were reported. The covariates of child's age, child's gender, and family socioeconomic status were control variables. An interaction term between time and treatment type was included in the model. If this interaction term was significant at $p < .05$, it indicated a significant difference between groups over time (Field, 2013) and provided support for the rejection of the null hypothesis. The first ANCOVA was used to answer Sub-Research Question 1 and included the dependent variable of frequency of migraines. The second ANCOVA was used to answer Sub-Research Question 2 and included the dependent variable of intensity of migraines. I used the results of both models to evaluate the omnibus research question. If the null hypothesis for each sub-research question is rejected, then the omnibus null hypotheses can be rejected.

Threats to Validity

Internal validity refers to the possibility of the effects being observed in a study as a result of the changing of the independent variable and not some other factor (McCleod, 2013). This means a causal relationship exists between the independent and dependent variables. A possible threat to internal validity in this study was the length of time between treatment onset and the participant's completion of the survey. The internal validity improved by controlling for the confounding variables of age, gender, and SES.

External validity refers to the extent to which the results of a study can be generalized to other settings, other people, and over time. Threats to external validity include the lack of a truly random sample because of the specialized participant population (McCleod, 2013). A random sample was beyond the score of the current study and posed a limitation to external validity. Additionally, threats to external validity tend to occur when generalizations are made to inappropriate populations (McCleod, 2013). As such, I did not generalize beyond the populations from which the data were sampled.

Ethical Procedures

The American Psychological Association (2010) mandates that researchers make the ethical protection of their subjects a priority. All subjects were required to read and sign a detailed consent form that fully disclosed their rights as participants and their ability to ask questions at any point during the study. My contact information was included as well as the research purpose, procedures, risks and benefits of participation, and rights to confidentiality and privacy. Participation in the research was completely voluntary and the participants could withdraw from the study at any time without negative repercussions.

This study pertained to children with a chronic health condition and, as such, they may be considered a potentially sensitive population that requires additional care. I gathered information gathered through the parents and caregivers of these children to minimize any potential negative effects from the study. I completed the IRB application to gain approval before conducting research. The information contained in the application illustrates the positive aspects of conducting this study outweighed the potential for negative outcomes. I also ensured that the procedures used in this study focused on the use of the ethical principles of beneficence, justice and personal respect (American Psychological Association, 2010). Data are stored electronically on a password-protected personal computer to which only I have access. All data used in the study will remain confidential and anonymous.

Summary

This chapter included the research questions and hypothesis for the purpose of the study. I also detailed the operational definitions that support the study and the theories employed herein. The quasi-experimental research design involves nonrandom selection of study participants. I conducted two mixed model (one-within one-between) analyses of covariance (ANCOVAs) to assess group differences over time. The independent variable was treatment (biofeedback and medication vs. medication alone). The dependent variables were frequency of migraines and intensity of migraines. I discussed the aspects of validity and potential threats as well as reviewed participant recruitment, eligibility, and selection. In Chapter 4, I will present the results of data analysis.

Chapter 4: Results

Introduction

The purpose of this quasi-experimental quantitative research was to determine if a difference in treatment perception was apparent between the parents of children who received biofeedback and medication or medication only for treatment of their chronic migraines. Through this study, I measured the effectiveness of biofeedback as a complementary therapy in child migraine patients using surveys completed by parents and caregivers. The following research questions and hypotheses guided the study:

Omnibus Research Question: Is biofeedback in addition to medication treatment more effective in the treatment of child migraines than medication alone?

H_0: Biofeedback in addition to medication is not more effective in the treatment of child migraines than medication alone.

H_a: Biofeedback in addition to medication is more effective in the treatment of child migraines than medication alone.

Research Subquestion 1: Does biofeedback in addition to medication treatment reduce the frequency of reported child migraines when compared to medication alone?

$H_0 1$: Biofeedback in addition to medication does not reduce the frequency of reported child migraines when compared to medication alone.

$H_a 1$: Biofeedback in addition to medication does reduce the frequency of reported child migraines when compared to medication alone.

Research Subquestion 2: Does biofeedback in addition to medication treatment reduce the intensity of reported child migraines when compared to medication alone?

$H_0$2: Biofeedback in addition to medication does not reduce the intensity of reported child migraines when compared to medication alone.

H_a2: Biofeedback in addition to medication does reduce the intensity of reported child migraines when compared to medication alone.

I conducted two mixed-model ANCOVAs to test the research questions and corresponding hypotheses. The results of the study are organized in this chapter into three corresponding sections: data collection, results, and summary of findings. In the data collection section, I review responses of participants, statistical discrepancies, and various characteristics of those participants involved in the survey process. In the results section, I present a report of the findings of the statistical calculations.

Data Collection

Data collection began June 4, 2018 shortly after I received IRB approval on May 24, 2018 (Approval Number: 05-24-18-0152150) and ceased August 15, 2018. I used the online survey tool SurveyMonkey to recruit participants using the Audience feature, which targeted specific participants in SurveyMonkey's large participant pool to complete this survey. I found that many of the responses gained through this medium were incomplete and, therefore, not useable.

I posted a survey link in migraine support groups and public areas, such as coffee shops near university campuses. The responses to the link yielded more complete data than those of the Audience feature of SurveyMonkey. Average time to complete the 10-question survey was 1 minute and 31 seconds, according to SurveyMonkey data. In total, the survey yielded 56 participants. I postulated that those who were more familiar with migraine in children were more intrinsically motivated to answer the less than 2-minute survey more fully and completely than those randomly assigned the survey through Audience. Data collection occurred as planned with little to no variation from initial expectations.

Data Management

I extracted data from SurveyMonkey, coded the data, and imported them into SPSS Version 25. Through SPSS, I assessed the data for missing data and outliers. Three cases were removed for missing data. Outliers are values that have a corresponding standardized score with an absolute value higher than 3.29 (Tabachnick & Fidell, 2013). One case contained an outlier and was removed from the data set.

Descriptive Statistics

I performed descriptive statistics to characterize the sample. Frequencies and percentages for categorical variables were then calculated. Next, I calculated means and standard deviations for continuous variables.

Frequencies and percentages. Table 1 presents full frequencies and percentages. Most parents' children were treated with medication only (n = 28, 54%). The majority of parents or caregivers who responded to the survey were female (*n* = 36, 69%). Most of the children in question were also female (*n* = 31, 60%). Most families were considered middle class ($42,000–125,000; *n* = 27, 52%).

Means and standard deviations. Table 2 presents the minimum, maximum, mean, and standard deviation of parental and child ages. On average, the parents who responded were 43.52 years of age (*SD* = 9.56 years). Their children were, on average, 11.96 years old (*SD* = 4.73 years).

Table 1

Frequency Table for Categorical Variables

Variable	*n*	%
Treatment		
Medication only	28	53.85
Biofeedback and medication	24	46.15
Missing	0	0.00
Parent gender		
Male	16	30.77
Female	36	69.23
Missing	0	0.00
Child gender		
Male	21	40.38
Female	31	59.62
Missing	0	0.00
Socioeconomic class		
Lower: Below $42,000	8	15.38
Middle: $42,000-125,000	27	51.92
Upper: Over $125,000	17	32.69
Missing	0	0.00

Note. Due to rounding errors, percentages may not equal 100%.

Table 2

Summary Statistics for Parent and Child Age

Variable	Min	Max	*M*	*SD*
Parent age	24.00	60.00	43.52	9.56
Child age	1.00	17.00	11.96	4.73

Results

To answer this omnibus research question, I created two research subquestions involving the frequency and intensity of reported child migraines, respectively. I addressed these research questions using two ANCOVAs. These ANCOVAs each had independent variables of treatment type (i.e., medication only or biofeedback plus medication), time (i.e., before and after treatment), covariates of child's gender (i.e., male or female), child's age (i.e., continuous), and SES (i.e., lower to middle [$124,999 and below] or upper [$125,000 and above]). The dependent variables were child migraine frequency and intensity, respectively. Prior to interpreting the results of the ANCOVAs, I performed assumption testing.

I assessed the assumption of normality for the continuous variables for each level of each categorical variable using KS tests. Table 3 presents the results of the KS tests. The KS tests were significant for several combinations of variables, indicating normality was not met for those variables. However, the KS test can be sensitive to sample size and often gives false positive results (Ghasemi & Zahediasl, 2012). Additionally, the *F* test used in ANOVA procedures is robust against nonnormality (Stevens, 2009; Tabachnick & Fidell, 2013).

I assessed homogeneity of variances through Levene's test. Levene's test was not significant for the first ANCOVA ($p = .148$ and $p = .286$) and was not significant for the second ANCOVA ($p = .085$ and $p = .119$). These findings indicated the assumption of homogeneity of variances was met for both analyses. Although sphericity is a common assumption of repeated measures analyses, it was not applicable in this case because only two time points were measured (see Tabachnick & Fidell, 2013).

Table 3

Results of KS Tests

Continuous variable	Categorical cariable	*D*	*p*
	Treatment type:		
Frequency before treatment	Medication only	0.14	.159
	Biofeedback	0.17	.059
Frequency after treatment	Medication only	0.20	.005
	Biofeedback	0.15	.154
Intensity before treatment	Medication only	0.20	.005
	Biofeedback	0.25	.000
Intensity after treatment	Medication only	0.14	.168
	Biofeedback	0.24	.001
Child's age	Medication only	0.19	.012
	Biofeedback	0.19	.020
	Gender:		
Frequency before treatment	Female	0.13	.191
	Male	0.17	.133
Frequency after treatment	Female	0.14	.129
	Male	0.28	.000
Intensity before treatment	Female	0.20	.003
	Male	0.26	.001
Intensity after treatment	Female	0.28	.000
	Male	0.16	.176
Child's age	Female	0.17	.019
	Male	0.17	.139
	Socioeconomic class:		
Frequency before treatment	Lower to middle class	0.14	.088
	Upper class	0.26	.003
Frequency after treatment	Lower to middle class	0.13	.145
	Upper class	0.21	.044
Intensity before treatment	Lower to middle class	0.24	.000
	Upper class	0.19	.117
Intensity after treatment	Lower to middle class	0.19	.002
	Upper class	0.21	.044
Child's age	Lower to middle class	0.16	.020
	Upper class	0.21	.050

Research Subquestion 1

The main effect for treatment type was significant, $F(1, 47) = 5.21$, $p = .027$, indicating significant differences in migraine frequency among the values of treatment. In other words, without taking into account the repeated measurements, differences occurred in migraine frequency between treatment types. Those who took medication only had significantly less migraine frequency on average than those who also took biofeedback. On average, between time points, those who took medication only had 1.14 fewer migraines per month. Table 5 presents full descriptive statistics for each treatment type and time point.

The main effect for the within-subjects factor (time) was significant, $F(1, 47) = 5.92$, $p = .019$, indicating significant differences in migraine frequency 1 month before and 1 month after treatment. In other words, without taking into account what type of treatment was received, a significant difference occurred from before and after treatment. Both medication only and medication plus biofeedback groups experienced a significant decrease in migraine frequency over time. On average, participants reported 1.39 fewer migraines from before to after (see Table 5).

The interaction effect between the within-subjects factor and treatment type was not significant, $F(1, 47) = 0.28$, $p = .600$, indicating no significant differences in migraine frequency between treatment types and time points. In other words, medication plus biofeedback does not seem to be more effective than medication alone in reducing migraine frequency. The null hypothesis for Research Subquestion 1 was not rejected.

Table 4 presents the ANCOVA results, while Table 5 presents means and standard deviations for each factor level combination and row and column averages.

Table 4

Results of Mixed Model ANCOVA Involving Frequency of Migraines

Source	*SS*	*df*	*MS*	*F*	*p*	η_p^2
Between subjects						
Treatment type	31.29	1.00	31.29	5.21	.027	.10
Child age	8.47	1.00	8.47	1.41	.241	.03
Child gender	0.51	1.00	0.51	0.09	.772	.05
Socioeconomic status	15.23	1.00	15.23	2.53	.118	.051
Residuals	282.41	47.00	6.01	-	-	-
Within subjects						
Time	5.20	1.00	5.20	5.92	.019	.11
Time x Treatment	0.24	1.00	0.24	0.28	.600	.01
Time x Child Age	0.03	1.00	0.03	0.03	.866	.00
Time x Child Gender	0.82	1.00	0.82	0.93	.340	.02
Time x Socioeconomic Status	0.58	1.00	0.58	0.66	.422	.01
Error (time)	41.26	47.00	0.88	-	-	-

Table 5

Means and Standard Deviations for Factor Level Combinations Involving Migraine Frequency

	Frequency before	Frequency after	Row average
Treatment	*M* (*SD*)	*M* (*SD*)	*M* (*SD*)
Medication only	3.64 (1.95)	2.11 (1.81)	2.88 (2.02)
Biofeedback and medication	4.62 (2.08)	3.42 (1.64)	4.02 (1.95)
Column average	4.10 (2.05)	2.71 (1.84)	3.40 (2.06)

Research Subquestion 2

The main effect for treatment type was significant, $F(1, 47) = 6.71$, $p = .013$, indicating significant differences in migraine intensity among the values of treatment. In other words, without taking into account the repeated measurements, differences occurred in migraine intensity between treatment types. On average, those in the medication only group had lower migraine intensity than those in the medication plus biofeedback group. Those in the medication only group had 1.31 units lower migraine intensity. Table 7 presents full descriptive statistics by group and timepoint. The main effect for the within-subjects factor (time) was not significant, $F(1, 47) = 2.74$, $p = .105$, indicating no significant differences in migraine intensity 1 month before and 1 month after treatment.

The interaction effect between the within-subjects factor and treatment type was not significant, $F(1, 47) = 0.40$, $p = .528$, indicating no significant differences in migraine intensity between treatment types and time points. In other words, medication plus biofeedback does not seem to be more effective than medication alone in reducing migraine intensity. The null hypothesis for Sub-Research Question 2 was not rejected. Table 6 presents the ANCOVA results. Table 7 presents means and standard deviations for each factor level combination and row and column averages. As the null hypotheses for both Sub-Research Question 1 and 2 could not be rejected, the null hypothesis for the Omnibus Research Question could not be rejected.

Table 6

Results of Mixed Model ANCOVA Involving Intensity of Migraines

Source	*SS*	*df*	*MS*	*F*	*p*	η_p^2
Between-Subjects						
Treatment Type	14.45	1.00	14.45	2.42	.126	.05
Child Age	1.82	1.00	1.82	0.31	.583	.01
Child Gender	3.09	1.00	3.09	0.52	.475	.01
Socioeconomic Status	40.00	1.00	40.00	6.71	.013	0.125
Residuals	280.136	47.00	5.96	-	-	-
Within-Subjects						
Time	3.55	1.00	3.55	2.74	.105	.06
Time x Treatment	0.52	1.00	0.52	0.40	.528	.01
Time x Child Age	4.46	1.00	4.46	3.44	.070	.07
Time x Child Gender	1.98	1.00	1.98	1.53	.222	.03
Time x Socioeconomic Status	0.41	1.00	0.41	0.31	.578	.01
Error (Time)	60.95	47.00	1.30	-	-	-

Table 7

Means and Standard Deviations for Factor Level Combinations

	Intensity Before	Intensity After	Row Average
Treatment	*M* (*SD*)	*M* (*SD*)	*M* (*SD*)
Medication only	6.71 (1.98)	4.04 (2.27)	5.38 (2.50)
Biofeedback and medication	7.83 (1.74)	5.54 (1.53)	6.69 (1.99)
Column Average	7.23 (1.94)	4.73 (2.09)	5.98 (2.36)

Summary

The purpose of this quasi-experimental quantitative research was to determine if a difference in treatment perception was apparent between the parents of children who received biofeedback and medication or medication only for treatment of their chronic migraines. Of the 52 participants, most were female, had female children, and characterized themselves as middle class. Results indicated that although decreases occurred in reported migraine frequency and intensity in both the medication only and medication plus biofeedback groups, no statistically significant interaction occurred between the within-subjects factor of time and treatment type. This indicates that, for this sample, medication plus biofeedback treatment was not more effective at reducing the frequency and intensity of children's migraines than medication only treatment. Biofeedback and medication treatment is not as effective at reducing the frequency and intensity of children's migraine headaches as medication only. As such, the null hypothesis for the Omnibus Research Question was not rejected.

In Chapter 5 I will present further interpretations and implications of these findings. I will also detail the limitations and recommendations. Additionally, I will examine considerations for future research and positive social change in Chapter 5.

Chapter 5: Discussion, Conclusions, and Recommendations

Introduction

Biofeedback is an alternative therapy for migraines that has demonstrated efficacy in the adult population (Guirguis-Blake, 2010). Biofeedback may also work for children (Eccleston *et al*., 2001; Hermann & Blanchard, 2002; Jindal *et al*., 2008). To date, no researchers have measured the effectiveness of biofeedback therapy in children using caregiver ratings to record the child's pain level. Previous research focusing on perceptions of medical staff have shown that medical staff's assessments are not always accurate concerning a child's pain experience (Craig *et al*., 1996; Jylli & Olsson, 1995). The purpose of this quantitative, quasi-experimental study was to measure the effectiveness of biofeedback as a complementary therapy in child migraine patients as shown through surveys completed by caregivers. Although both medication only and biofeedback and medication groups showed improvement when compared through pre- and posttreatment phases, results of the parent ratings surveys indicated no significant difference between those children who were treated with biofeedback and medication and those who were treated with medication alone.

In this chapter, I provided additional discussion of the findings, including an interpretation in terms of extant literature and the theoretical framework. Subsequently, I outline the limitations of the study and offer recommendations to further the literature on the treatment of children with migraines. Finally, I conclude with the implications of the study and final conclusions.

Interpretation of Findings

Omnibus Research Question

The findings disconfirmed the hypothesis that those receiving biofeedback and medication treatment would experience less migraine frequency and intensity than those who received medication only. The overall findings of this study indicated that those who were in the medication plus biofeedback group had more migraines and more intensity than those in the medication only group; however, the differences between the two groups was not great. Both treatment groups displayed a decreased frequency and intensity of migraines at 1-month posttreatment. When comparing the results of the study to the existing literature, I expected a more apparent improvement in the group receiving biofeedback plus medication, and there was not. It is possible that those who were having more frequent and intense migraines are more difficult to treat than those who were treated by medication only. This theory is substantiated by the initially higher scores for both frequency and intensity for the biofeedback plus medication group in the pretreatment phase. It is also possible that those in the medication only group were influenced to some degree by placebo effect; in addition, those placed in the biofeedback plus medication group may have been those with more severe cases because those in the medication only group had lower overall migraine frequency. Biofeedback has been shown to be successful in treating both migraines with aura and those without aura (Vasudeva, Claggett, Tietjen & McGrady, 2003). Because of this finding I did not screen for presence or absence of this condition.

Demographic variables showed that more participants were female (i.e., female parents: n = 36, 69.23% and female child migraine sufferers: n = 31, 59.62%) as opposed to male (male parents: n = 16, 30.77% and male child migraine sufferers: n = 21, 40.38%). The age of the adult participants ranged from 24 to 60 years old, with a median of 46.5 years old and a mode of 49 years old. Child migraine sufferer ages ranged from 1 year of age to 17 years old, with a median of 13 years old and a mode of 17 years old. The mean age of all parent respondents was 43.5 years old and mean age for child migraine sufferers was 11.9 years old. The SES of most of the participants (51.9%, n = 27) fell in the middle range of $42,000 to $ 125,000 with only 15% (n = 8) falling in the low range of below $42,000. There were 32.6% (n = 17) in the over $125,000 upper socioeconomic category. These demographics are comparable to the existing literature on the subject.

Frequency of Migraines

Considering the findings of the study regarding frequency of migraines between treatment types, I found an improvement in lesser frequency of migraines in both treatment groups. However, I hypothesized that less migraine frequency would occur in the biofeedback group, and this did not occur. One possible mitigating factor for this may be attributed to the 1-month treatment period not providing an adequate amount of time for biofeedback skill acquisition. Lipchik (2001) suggested it may take many sessions to acquire biofeedback techniques in adults. This study had a lack of longitudinal data, and it is quite reasonable to expect children to take at least as long as adults to learn biofeedback skills and probably longer. Therefore, there may not have been enough time to adequately assess the outcomes of the biofeedback in this sample. This may explain the similar rates of migraines in the two groups and lack of efficacy shown through the data for biofeedback at post-1 month of treatment. A lengthier period of time to acquire biofeedback skills may make a significant difference in the outcome.

Intensity of Migraines

Considering the findings regarding intensity between treatment types, I hypothesized that migraines would occur with less intensity following treatment with biofeedback and medication than with medication alone. This was not proven in this study. It is postulated that those in the biofeedback plus medication group had higher rates of symptoms; therefore, this group may have been more difficult to treat from the outset. It is important to remember that both groups did show improvement 1 month after treatment. The biofeedback group simply did not show more improvement than the medication only group as predicted.

Theoretical Framework

In this study, I initially focused on gate theory and its ability to interrupt pain impulses with the postulation that biofeedback may use that means to mitigate pain. This framework could be widened to include not only the interaction of biofeedback as an effective pain relief method but also the additional placebo effect of medications (Weimer, 2013). The marked difference between pain assessments of pretreatment and posttreatment migraine sufferers may suggest that children who receive treatment are more likely to feel better than those who do not. Alternately, it could be that the medication alone is successfully treating the migraines. However, in many instances, medications are not immediately effective in stopping migraines or lessening their severity, especially in a brief time period (American Migraine Foundation, 2019). Because it typically takes a bit longer than 1 month to get positive results from migraine preventative medication, the medication group results may be because of a placebo effect as opposed to an actual improvement in symptoms. A longer period of study may provide more accurate results.

Limitations of the Study

The biggest limitation of the study was my short-term approach to child migraine pain treatment. A longitudinal study could follow participants for months or years far beyond the initial 1 month before treatment and 1 month after treatment. This approach may reveal different results. Specifically, because biofeedback skills are acquired over time, at only 1 month into treatment many children may not have developed the means with which to employ those skills (Lipchik, 2008).

An additional potential limitation was that the results relied on parents' ratings of their children's pain. Although parents or caregivers may answer the ratings scales with the best of intentions, they may not be able to record all the improvements children may feel as treatment takes place. Therefore, relying on caregivers or parents may provide a more accurate pain assessment than that of a medical worker it could likely not be as accurate as ratings done by the children themselves.

Recommendations

This study relied on parents' ratings of children's pain. Having a reliable numerical rating scale for a parent or caregiver to contribute in migraine treatment may help the parent more accurately assess the pain and contribute directly to more effective management of the child's pain overall. I recommend that a standardized instrument be developed to help future researchers more accurately assess interventions into children's migraines. Future researchers should consider a longitudinal approach to data collection in biofeedback for child migraine. If a longer amount of time were devoted to posttreatment assessment, results may be more favorable for the reasons I expressed in the Limitations section. More time to acquire biofeedback skills could ultimately improve the chances for long-term positive effects from the therapy. Use of gate control theory to lessen migraine pain may be more readily apparent in those who are able to spend more time learning to employ biofeedback successfully (Lipchik, 2008). One month of treatment is simply not enough time; adults typically require several months to master this skill (Lipchik, 2008).

Implications

Parent feedback can be helpful in overall child pain assessment. As stated in Chapter 2, children may not always be able to communicate effectively in medical settings. A simple numerical rating scale can provide valuable information on how children are experiencing their pain, and getting parental input provides medical personnel with valuable insight from those familiar with the child's characteristic behaviors. Theoretical implications suggest that gate theory and placebo effect were at work in this study. Although participants may have experienced the effects of gate theory with biofeedback controlling pain impulses to improve migraine, the placebo effect may have been at work in helping those who received medication feel better even before the medications could properly take effect. Empirical implications gleaned from this study suggest that parents placed higher significance in medication as a treatment for children's migraines. This may have affected the children's response to the medications as well as those of their parents, which were reflected in turn by the parent rating of the medication only group being higher than that of the medication and biofeedback group (see Faria *et al*., 2017). Data reflected improvement after a 1-month medication trial. Although some medications may take effect quickly, others may take much longer than 1 month to show positive effects. This calls for further investigation. Knowing specifically which medications were prescribed to participants would be helpful. For medications that do not take effect quickly but still reflect improvement, the placebo effect may be considered (Faria *et al*, 2017). Theory reflecting the placebo effect may contribute to the differences in the study results. Finding effective treatments for children with migraines frees them to participate in daily life and become productive members of society.

Positive social change is immediately apparent when a sick child with migraine becomes well. Children who experience less migraine frequency and intensity can go to school and learn. A parent may go to work without the worry of their child's health distracting them. This makes for a better workplace and, in turn, a stronger economy.

Children's health and wellness is an important topic that affects people at both the individual and global levels. Keeping children healthy and productive ensures both children and parents have a bright future.

Conclusions

In this study, parents with children suffering from migraine headaches rated their child's pain in frequency and intensity both 1 month before and 1 month after treatment with medication and medication and biofeedback. I found that parents who treated their children with medication and biofeedback did not report better relief for their children at 1 month of treatment than those who received only medication to treat their migraines. For future studies, a longer trial period for children to practice biofeedback skills is recommended. As biofeedback skills improve with practice, long-term improvement of migraine symptoms is hypothesized. Finding the answers to cure child migraine often are elusive. Medications are not always effective or a quick fix and may have additional unwanted side effects. An open mind to alternative or complementary treatments may offer relief and succeed in conjunction with other methods or alone.

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Appendix A: Demographic Survey

1).How is your child treated for migraines?

Medication only or Biofeedback and medication (pick one)

2).What is your age? What is your child's age?

3). What is your gender? Gender of your child?

4). How would you describe you and child's Socioeconomic Status :

Lower/ Middle or Upper class?

5. How many migraines did your child experience in 1 month BEFORE treatment?

6). How many Migraines did your child experience in 1 month AFTER treatment?

Appendix B: Permission to use INRS Instrument

From: "Curley, Martha A.Q."
Date: August 1, 2017 at 8:33:57 PM EDT
To: Andrea Weber
Subject: Re: Permission for use letter requested: INRS
OK --- I'm happy to have you use the INRS for your project. Best wishes for continued success.

Martha A.Q. Curley, RN, PhD, FAAN