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Incorporating Complementary Alternative Methods in the Management of Chronic Pain into a

Primary Care Practice in New York

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Abstract

Background: Pain is a physical, emotional, and psychological symptom that causes discomfort and leads to physiological consequences that can damage tissue, alter neurological pathways, and cause severe psychological distress. The combined use of complementary and alternative medicine (CAM) therapies can reduce pain and lead to an improvement in patient health.

Purpose: The purpose of this quality improvement project/evidence-based practice intervention was to review concepts related to pain and analyze the current use of music and massage CAM therapies in a primary care setting.

Methods: The Gate Control Theory was used in this project describing pain as "a category of experiences signifying a multitude of different and unique experiences, having different causes, and characterized by different qualities varying along a number of sensory and affective dimensions." Patients in an outpatient New York City clinic were asked to assess their pain levels after the use of CAM therapies. Patients received music and/or massage therapy two times a week, every two weeks for 12 weeks and pain was categorized using self-assessment tools. Patients were instructed to complete a pre- and post-procedure evaluation at two weeks intervals throughout the 12-week evaluation to document their pain levels.

Results: The results show that patients using music and/or massage therapy in combination with medications for pain management had reduced pain.

Conclusions: Based on the final 12 weeks pre/post assessment, all 14 participants reported better sleeping patterns, moods, and reduced pain after the two therapies. Further, music therapy participants showed a relatively better mood outcome over massage participants because they could choose positive music.

Keywords: pain, complementary and alternative medicine, hypnosis, massage, music

Complementary Management and Treatment of Pain

Introduction

Pain is difficult to describe and define. The perception and tolerance of pain may vary from one individual to another, and hence cannot be ignored or considered as subjective. Pain is the way the brain interprets signals regarding painful sensations. These sensations are sent through the nerve pathways to the brain (Ojong et al., 2014). The way the brain interprets these pain signals can be affected by external factors as well, but can be controlled by non-pharmacological techniques (Ojong et al., 2014).

Complementary and alternative medicine (CAM) provides a useful adjunct to the management of acute and chronic pain. Chronic pain management is a severe problem in the 21st century. The cost of unrelieved pain can result in longer hospital stays, increased rates of hospitalization, and increased outpatient visits (Hauser, 2012). As such, a patient's unrelieved chronic pain can lead to an inability to work and subsequently the ability to maintain health insurance, therefore chronic pain can be detrimental to a patient's long-term health. The conventional method for pain management in Western culture is to treat severe chronic pain with opioids. This form of pain management has many adverse side effects. Research shows that people who take opioids for pain management feel as if they had no control over their pain and develop an addiction, which is another public health concern that is reaching crisis levels. Other patients report that they experience breakthrough pain one or more times daily, which severely impacts their quality of life (QOL) and overall well-being. The negative side effects of opioids can cause depression, problems with concentration and sleeping patterns, and decreased energy levels (Hauser, 2012).

Background

Pain can be acute or chronic. Acute pain lasts for a short period of time and results from trauma, surgery, injury or illness (Ojong et al., 2014). On the other hand, chronic pain is caused by ongoing conditions such as migraine, headaches, fibromyalgia, diabetic neuropathy, neuropathic pain, cancer pain, osteoarthritis, rheumatoid arthritis, cervical pain, low back pain, etc. With these conditions, it is less likely that the pain will be completely cured, but CAM can reduce the amount or intensity of pain felt by the patient (Ojong et al., 2014).

Chronic pain affects the quality of life of nearly 100 million Americans — this is more than heart disease, cancer, and diabetes combined (Johnson, 2015). Chronic pain is one of the primary drivers of the opioid epidemic, although acute pain can be an initiating event. The medical practice of excessive prescription of opioids to manage chronic pain has resulted in a widespread and uncontrollable opioid epidemic. Opioid abuse is the reason for the death of more than 72,000 lives in 2017 and millions of other deaths in previous years. Evidently, chronic pain is a multi-faceted, complex public health issue that needs to be managed carefully to reduce addiction and public healthcare costs. Medications, lifestyle changes, and often, psychological support have all proven to be beneficial in the treatment of chronic pain. The use of CAM, which is a deviation from standard Western medical practice and care, falls within these categories. Usually, CAM is popular with patients suffering from pain from musculoskeletal conditions (Khatta, 2007). CAM modalities are found to be useful in treating chronic and persistent pain, which is often associated with physical disability, anxiety, depression, and sleep disturbance (Khatta, 2007). The use of CAM has progressively risen in recent decades. By implementing medical practices that use CAM, the medical field can change the outcomes for many pain-afflicted patients. However, many practitioners do not use CAM and other alternative practices.

This capstone project focuses on the application of two CAM treatments: music therapy and massage therapy. The project measured the outcomes of using CAM to reduce pain using a pain scale that indicates a reduction in the physical and emotional states of those affected by chronic pain. The long-term goal is to measure the effectiveness of CAM, in an effort to develop further public health policies that will decrease the number of opioid addicted persons. A combination of traditional drug therapy and CAM has proven to be more effective than solely using medical pain management treatments. In some cases, CAM pain management works as well as medications or better (Johnson, 2015). With more knowledge on the subject, researchers can develop methods, which will be able to decrease directly the number of mortalities related to opioid use for pain management.

Problem Statement

Patients with long-term chronic pain who utilize opioids as their sole form of pain management have a high risk of addiction. Opioid addiction is a public health concern, as it has claimed thousands of lives and entangled millions more in addiction. Reducing the number of patients that are prescribed opioids as a sole source of pain management can greatly reduce public health costs, increase quality of life of patients, and stop an epidemic. By implementing treatment options that include complementary and alternative methods of pain management, such as music therapy and massage therapy, medical practitioners can help halt the growing opioid epidemic.

Organizational “Gap” Analysis of Project Site

Primary care practitioners (PCP) are in an ideal position to provide counseling and suggest non-pharmacologic methods of pain relief. Clinical research, mostly from Japan, Korea and Tibet recommends the use of CAM to avoid the numerous negative side effects associated

with addiction. When patients are educated about alternative ways to manage their pain, they no longer have the need to rely solely on addictive opioids and other pain medications with their associated side effects. PCP's often do not feel knowledgeable about this topic or how to prescribe CAM therapy or are not working in collaboration with CAM specialists to provide this option to their patients with chronic pain. Medical professionals require specific training, research and education about CAM methods so they can educate their patients (Broom & Adams, 2007). This education may persuade more primary care providers to prescribe CAM and more patients to utilize CAM as a viable option for pain management.

Review of the Literature

A literature search was completed using PubMed, DailyMed, U.S National Library of Medicine, and CINAHL databases. Search terms (MeSH) included: "pain" "complementary and alternative medicine", "pain and massage", "pain and music." The documents used focused on the studies with the best patient outcomes. Research shows that CAM was founded in and has been implemented in Eastern countries for many centuries. The research analyzed focuses on research gathered over the last 20 years. All articles chosen were published in English.

During the search, 28 articles were retrieved. Of these articles, 18 were excluded because they were incomplete studies, lacked definitive results, i.e. there may be questionable false positive or false negative data. Ten studies were selected to be reviewed, including four randomized control studies and two meta-analyses systemic reviews. Based on grading criteria, these four randomized-control studies (RCT) and two meta-analysis reviews were chosen as Level I evidence and quality for this review (Harlan, 2001).

Complementary and alternative medicine (CAM) is a group of therapies from a diverse system that is not considered to be a part of conventional medicine. CAM modalities are found to

be useful in treating chronic and persistent pain (Khatta, 2007). CAM provides clinical benefits, which include relief from pain and depression, and overall improved quality of life. Emphasis is placed on maximizing the body's ability to address physical, mental, and spiritual needs in combination with traditional medicine. This has been shown effective in the treatment of numerous chronic and acute illnesses (Jonson, 2015). Some of the CAM modalities that have demonstrated evidence in reducing pain and improving patient's quality of life are acupuncture, spinal manipulation, Ayurveda therapy, herbal remedies, and mind-body therapy (imagery, relaxation, biofeedback, meditation, and hypnosis) (Khatta, 2007).

Though CAM has been popular for chronic and persistent pain, it has also gained prominence as a pain treatment mechanism for cancer patients. Cancer pain is different from other kinds of chronic pain and significantly increases the burden of the disease by causing patients to suffer uncontrolled pain, significant reduction in functionality of patients, increased fatigue, impairment in daily activities, and social impairment (Singh & Chaturvedi, 2015). Evidence shows that use of CAM modalities helps cancer patients and survivors by increasing their sleep, quality of life, regulating mood, reducing levels of anxiety, stress and levels of pain (Singh & Chaturvedi, 2015). For instance, acupuncture has helped cancer patients reduce nausea and vomiting during chemotherapy. It further reduces fatigue and improves quality of life following chemotherapy (Singh & Chaturvedi, 2015). Acupuncture also reduces hot flashes in women with breast cancer and men with prostate cancer following hormone therapy (Singh & Chaturvedi, 2015). Similarly, music therapy is found to reduce nausea vomiting in patients under chemotherapy or radiotherapy. These therapies also can relieve patients from acute pain following surgery for cancer. It reduces stress hormone levels and improves brain waves and brain circulation. Music therapy has a positive impact on cancer patients with respect to pain,

anxiety, mood and quality of life (Singh & Chaturvedi, 2015). While very little research has been conducted in the sphere of music and massage therapy in regards to pain management, it is important to note the positive benefits of those suffering with other long-term chronic pain ailments.

CAM is also called mind-body medicine. Mind-body medicine uses the power of thoughts and emotions to impact physical health. As Hippocrates wrote, "The natural healing force within each one of us is the greatest force in getting well," (Mind-body Medicine, 2010). CAM includes several different techniques. For example, massage therapy involves pressing and manipulating muscles and other soft tissues of the body to allow the pain-relieving oxygenation process to occur. This type of CAM is considered very useful for relieving any pain. It combines body relief with mental relief. In this same fashion, music therapy provides calmness and physical relaxation by suspending the stream of thoughts that normally occupy the mind. Music therapy is used to alter hormone levels and to reduce stress. The key to any mind-body technique is to "train" the mind to focus on the body without distraction. In this state of "focused concentration," a person may be able to improve their health through mindfulness and self-awareness (Mind-body Medicine, 2010). These techniques can be helpful for many medical ailments because they encourage relaxation, improve coping skills, reduce tension and pain, and lessen the need for medication. Patients can calm their minds and treat many health conditions such as sleep deprivation, pain, and high-stress levels (Mind-body Medicine, 2010).

Music Therapy

According to Warth, Kessler, Koenig, Wormit, Hillecke, and Bardenheuer (2014), the effects of music therapy were studied in different settings to see if music decreased pain, anxiety, and stress of patients. A randomized controlled trial was done with a sample of 84 participants.

The participants were separated into two sessions of music therapy: either a monochord therapy session, or two sessions of a verbal relaxation exercise with psychologists in clinical settings (Warth et al., 2014). This study found that music therapy elicits pleasant images and visualization within patients. The self-reporting of the participants showed that after a 30-minute session, patients were more balanced, less nervous, and less exhausted. For major disparities between groups, statistical analysis was performed at the baseline using independent samples t-tests, with $\alpha = .20$ to reduce type-II error probability. For all study hypotheses tests, type-I error probability is set to $\alpha = .05$. VAS and QOL data are evaluated with ANCOVA models (Warth et al., 2014). This study design is believed to be appropriate to assess the efficacy of the music therapy relaxation intervention (Warth et al., 2014).

Another team conducted a systematic review and meta-analysis examining the improvement as a result of music-based interventions on psychological and physical outcomes of cancer patients (Fredenburg & Silverman, 2014). Results indicated that music-based interventions had a beneficial effect on anxiety, quality of life, mood, and pain with small reductions in heart rate, respiratory rate, and blood pressure, which could be indicators of decreasing discomfort and pain as a part of this process. The researchers utilized ANCOVA with pre-test scores as a co-variate, post-test scores as the dependent measure. Results were statistically significant for pain ($p = .007$), positive affect ($p = .001$), and negative affect ($p = .003$), with the experimental group having more favorable post-test mean scores than the control group (Fredenburg & Silverman, 2014).

From the results of this study and related medical music therapy research, single receptive music therapy sessions that utilize a patient-preferred setting can be an effective

psychosocial intervention. This is useful concerning positive and negative states of pain for hospitalized patients (Fredenburg & Silverman, 2014).

Massage Therapy

Many researchers in the last decade found that massage therapy sets off a sequence of molecular events in the muscles that helped reduce the discomfort associated with exercise (Fredenburg & Silverman, 2014). Massage reduces the activity of inflammatory cytokines, which are small proteins that trigger inflammation and pain. The massages produce proteins that signal the muscles to produce more mitochondria, thus providing energy and help muscles recover from activity (Fredenburg & Silverman, 2014).

Massage has the same pain-relieving effect as drugs like aspirin, ibuprofen (Advil) and naproxen (Aleve). Nonsteroidal anti-inflammatory drugs, also known as NSAIDS, work by reducing levels of elements called prostaglandins that increase levels of inflammatory cytokines, thus decreasing the pain (Cino, 2016). Another study performed a meta-analysis to reflect the effect of massage on chronic lower back pain. The improvement was noted in nine out of ten measures on a self-reported pain and activity report. The self-reports noted that patients decreased the dosage of pain medications and increased their ability to walk and perform light duties. As a result, the study concluded that massage could produce a positive, timely, and more cost-effective outcome for patients than any other noninvasive procedures.

According to Adams (2010), massage therapy in hospitals and outpatient settings is a very important part of the rehabilitation process. The study demonstrated that the integration of massage therapy revealed not only a significant reduction in pain levels, but also in the depicted interrelatedness of pain, relaxation, sleep, emotions, recovery, and ultimately, the healing process. When patients compared their mean pain levels before and after a massage, the pain

reduction proved to be statistically significant (Adams, 2010). When massage therapy is incorporated as part of the post-surgical protocol, fewer medications are needed, which provides fewer adverse side effects and an effective adjunct or alternative to pharmaceuticals.

In the research study by Crawford et al. (2016), patients who were about to undergo surgery or were currently recovering from surgery were provided massage therapy, and these results were analyzed in a systematic review and meta-analysis. Researchers wanted to determine if the time of massage administration would account for some of the heterogeneity among the studies. To do that, the authors performed sub-analyses on post-surgical population. To determine the methodology regarding pain intensity/severity, five post-surgical intervention studies were pooled (Crawford et al., 2016). The findings suggest that massage therapy appears to be effective in decreasing pain and anxiety in patients who are either about to undergo or are recovering from surgical procedures. This is the first reported attempt to pool the current literature base in regards to massage therapy for patient-reported functional outcomes in the surgical population experiencing pain (Crawford et al., 2016).

Evidence Based Practice: Verification of Chosen Option

A review of articles suggests that both the number and proportion of reports of CAM clinical trials is increasing at a significant rate. More recently, there is an increasing attention to Integrative medicine (IM), which combines mainstream medical therapies and CAM therapies. There is some high-quality scientific evidence of the safety and effectiveness of these modern medical practices (Sackett, 2006). Many CAM interventions (e.g., traditional Chinese medicine, hypnosis, music, and massage therapy) are considered whole systems of care (Sackett, 2006).

Randomized controlled trials, meta-analysis, and the other resources utilized for this review show positive outcomes. The decisions on treatment were evidence-based. Prescribers

selected the most appropriate treatment using all available evidence regarding the intensity of pain. The most significant barrier was the fact that outcome measures do not yet exist (Sackett, 2006). Important outcome domains identified included physical, psychological, social, spiritual, quality of life and holistic measures. Health care participants also mentioned the importance of individualized measures that assess the unique patient-centered outcomes for each research participant to include the context of healing and the process of healing (Sackett, 2006). Thus, there is evidence in the literature to support this quality improvement project.

Theoretical Framework / Evidence-based Practice Model

Most of the time, pain is assessed by taking into consideration the location, intensity, duration and pattern. However, it is also important to assess the psychological effects of pain, such as whether it impacts the quality of life of the patients in terms of sleep, appetite, work, and mood for effective management of pain (Ojong et al., 2014). Therefore, it is very important for nurses to record pain scores with regard to location, quality, duration, intensity, and pattern and aggravating and alleviating factors, which can help in choosing appropriate non-pharmacological techniques to manage pain (Ojong et al., 2014). Understanding a theoretical framework for pain helps nurses in assessing and managing pain in patients which also helps them in facilitating nursing care, thereby promoting healing, reducing suffering, preventing complications and improving quality of life of patients.

The Gate Control Theory developed by Melzack and Wall (1965) is a comprehensive theory related to pain and helps in explaining pain mechanisms. According to Melzack and Wall (1965) pain is considered "a category of experiences signifying a multitude of different and unique experiences, having different causes, and characterized by different qualities varying along a number of sensory and affective dimensions" (as cited in McGuire & Sheidler, 1997). As

per the Gate Control Theory, both small and large fibers of the spinal cord act as transmitters that transmit nociceptive impulses to the central nervous system that are received through specialized skin receptors (Bishop, 2005). Both small and large fibers of the spinal cord end in the substantia gelatinosa that is in the dorsal horn of the spinal cord (Bishop, 2005). The cells that are in the substantia gelatinosa act as a gate and regulate the transmission of the impulses or signals to the central nervous system (Bishop, 2005). However, stimulation of the larger fibers can cause the cells in the substantia gelatinosa to close the gate and this subsequently decreases the transmission of impulses and reduces the perception of pain (Bishop, 2005).

Furthermore, the continuous stimulation of larger fibers can cause adaptation, which allows a small degree of neuron activity to occur and for the larger fibers to open the gate (Bishop, 2005). When the gates are opened it increases transmission of impulses along with pain perception (Bishop, 2005). When gate control happens through small and large fiber stimulation, it causes the central nervous system to partially close or open the gate (Bishop, 2005). This results in increasing the pain perception through cognitive function. Therefore, the pain perception of individuals changes based on interactions between cognitive or evaluation; sensory or discriminative; and motivational or affective systems (Bishop, 2005).

Stimulation techniques in the form of visualization or managed cognitive behavior therapy have selective influence on the large nerve fibers through complementary ways and thereby reduce the effect of pain signals from the affected area to the brain (Melzack, 1996). Similarly, CAM modality – like acupuncture helps in controlling pain by closing the gates of large nerve fibers thereby reducing pain perception (Khatta, 2007). This theory is meant to increase the knowledge of nurses, primary care provider, and CAM specialists to bridge the knowledge gap that exists among patients and providers about pain treatment. The Gate Control

Theory gives researchers the ability to integrate new methods of medicine which are not fully described, approved, and documented in the United States health system. In the Integrative Medicine model, we can combine several methods to provide the best patient outcome. The Gate Control Theory gives us the ability to educate patients and other providers about pain, management and the other possible side effects of conventional Western treatment methods. By implementing CAM therapy into traditional pain management practices much can be achieved in the way of positive patient outcomes, including reducing of anxiety, instances of addiction, and pain perceptions.

Goals, Objectives and Expected Outcomes

The goal and objective of CAM therapy for acute and chronic pain management in a best-case scenario was to eliminate all pain. It needs to be understood that sometimes this is impossible. With this in mind, the goal is to decrease the level of pain and the amount of medication needed for each patient. An additional goal is to manage the unpleasant effects of pain management using opioids and other drugs. The last goal was to facilitate expectable functionality of each patient and increase their quality of life. Those who found conventional pain management not totally successful and were willing to pursue CAM therapies were suitable for this research. The time frame for pre/post pain assessment is at baseline and every four weeks up to 12 weeks and took place in a primary care outpatient clinics/practice. The goal was accomplished using music or massage therapy in combination with medications for pain management. The long-term benefits of people who listened to music while experiencing chronic pain were enjoyment, relaxation, and more focus compared to those who didn't listen to music regularly. Furthermore, those who listened to music more frequently reported had a higher quality of life, suggesting that music can lessen chronic pain. Music has a universal appeal across

cultures, and can elicit a great range of emotions and is now often accessible through MP3 players. Music can also be self-administered to lessen pain whenever someone chooses. Patients with chronic pain often have a low quality of life and music could help them to regain their sense of independence and, thus, improve their lives. Ultimately, patients are expected to report a decrease in pain levels and an increase in quality of life by evaluating feelings, cognitive appreciation and emotional states. The criteria for measurements was a verbal pain assessment scale. It is imperative to set up timely conditions to monitor the patient's progress to a pain-free or reduced-pain state, as well as to motivate and encourage patients in their recovery.

Project Design

This practice intervention is a quality improvement project based on significant core evidence regarding the treatment and management of acute and chronic pain, including how to prevent adverse side effects, improve the education of participants, and enhance the quality of care. Randomized control studies, meta-analysis systematic reviews, and qualitative secondary analyses show that even with a limited sample size, there are significantly proven results that show the positive effect of complementary and/or alternative medicine (CAM) for management and treatment of acute and chronic pain (Lincoln, 2013). The overall project design is to identify patients with chronic pain and then to assess whether the use of music, massage or both decreases their level of self-reported pain from baseline up to 12 weeks. Baseline measures assessed age, gender, employment status, current pain medication (type, dose, and frequency), and the level of pain. Then every two weeks patients was called to assess if they used music, massage, or both and asked to rate their pain using the Universal Pain Assessment Tool (UPAT). If patients were not using music or massage or both they received information about how to access these services and encouraged to use the prescribed CAM therapy.

The collaboration of an interdisciplinary team consisting of a nurse practitioner, a CAM specialist, and a PCP identified patients who under conventional pain management treatment for acute and chronic pain. The team communicated with patients and explained the use of CAM and how it works. Patient outcome measures were used to collect data and to evaluate the effectiveness of treatments and procedures. Methods included pre and post assessment using the Universal Pain Assessment Tool (UPAT) that uses a numerical rating scales (NRS) that asked patients to ‘Rate your typical pain on a scale from 0 to 10 where 0 equals no pain and 10 is the worst pain you can imagine.’ In addition, the UPAT also uses a verbal rating scale (VRS) that uses verbal descriptors to ask the patient to report their typical level of pain as mild, moderate, or severe, see Appendix A. The method identified the current state of the participant’s level of pain and pain management, including strength and amount of medication intake. Steps included 1. Initiate CAM treatment intervention on weekly basis with bi-weekly telephone interview and questionnaire. 2. Initiate treatment for up to 12 weeks as a complementary supplement for conventional pain management treatment for initial response. 3. Collect data bi-weekly for evaluation and identification of the outcome.

Project Site and Population

The project site was a primary care practitioner’s office. The office is located in Brooklyn, New York. The project site was the private clinic of the doctor who is an internist in a hospital in Brooklyn, New York. The doctor is an Internal Medicine Specialist in Brooklyn, New York with a diverse experience of several years. He is affiliated with many hospitals in New York. All of these hospitals are acute care hospitals. As a primary care physician with a specialization with Internal Medicine or Allopathic & Osteopathic physician, the doctor has treated patients with acute pain and chronic pain.

The project took place in the doctor's office in Brooklyn where he attended his patients for pain management. Most patients in outpatient settings such as doctor's office are more likely to utilize CAM therapy than in any other settings, such as hospitals or ambulatory settings. The doctor is a strong advocate of CAM therapies, especially massage therapy, music therapy, and hypnosis for pain management, which he does by integrating with CAM specialists. A majority of patients that come to the clinic with chronic pain have a diagnosis of rheumatoid arthritis, headaches, neck pain, low back pain, osteoarthritis, neuropathic pain, fibromyalgia, etc. Patient demographics that come to the clinic included those from age 16 to age 75 and above and from various ethnic backgrounds like African Americans, Whites, Asians, Hispanics, etc.

Participants for this project included patients between ages 18 - 82 years of age and who were mentally alert, oriented, and able to adequately respond to evaluation. This included an initial thorough patient history and a brief screening interview where the patient's current state and behavior was observed. Information was collected with regard to patient history, physical examination, type of pain (chronic or acute), associated illness, and current treatment (pharmacological intervention along with CAM therapy if any). This was performed by the DNP student along with the interdisciplinary team members who assessed the patient and also performed a clinical interview to gather information. At the end of the evaluation an explanation on the use of CAM therapy and possible positive or adverse side effects were discussed with the patients before agreeing to the use of a CAM therapy. Individuals who agreed to use CAM therapy did so on a voluntary basis when asked by their PCP. The severity of pain experienced by the patient was assessed initially using the UPAT, before the use of CAM, in a direct manner and using either the NRS or the VRS and then again at the next follow-up visit(s) at four week intervals. The UPAT NRS and VRS was presented to all participants at baseline and then before

and after the self-reported use of CAM treatment(s) every two weeks. The participants self-reported and quantified their pain intensity by providing a single, general rating from 0 to 10. Among the most commonly used by patients were the UPAT numerical rating scale (NRS). These scales asked patients to ‘Rate your typical pain on a scale from 0 to 10 where 0 equals no pain and 10 is the worst pain you can imagine’ and/or the verbal rating scale (VRS) that use verbal descriptors and ask the patient to report their level of pain as “no pain” “mild pain”, “moderate pain”, or “severe pain?””

Setting facilitators and barriers. The factors identified in this study facilitated CAM care in the primary care setting. There are humanistic and relational aspects of caring for an individual with chronic pain. Positive relationships can contribute to provider satisfaction with CAM management. Additional facilitators to CAM care included the intellectual satisfaction of solving difficult diagnostic, management, and communication problems. System factors included a lack of education, deficient competencies to assess and manage common chronic pain conditions, as well as organizational barriers that impede the enactment of even well-developed comprehensive treatment plans were identified as a significant barrier. The complexity of managing pain in people with multiple comorbidities, especially mental health and substance use disorders were recognized as another barrier. However, the most critical are the interpersonal aspects of pain care, including challenging issues related to sharing care among PCPs and specialists. Furthermore, there are difficult aspects of provider-patient interactions that need to be addressed (Lincoln, 2013). Participants were recruited from the clinical practice setting. Participants were fully aware of their responsibilities when they were presented the information regarding the alternative treatment, as well as, full disclosure of the plan and implications.

Methods

Measurement Instruments

Numerous pain intensity measures have been developed and validated. This project utilized the Universal Pain Assessment Tool (UPAT) that incorporates the numeric rating scale (NRS), verbal rating scale (VRS), and the faces pain scale to assess patients who participated in the QI project (See Appendix A). Several tools provide a numeric rating of pain intensity (e.g., visual analog scale, numeric rating scale (NRS) (Fink, 2000). A simpler tool, such as the verbal rating scale, which classifies pain as mild, moderate or severe, also is commonly used. For patients with limited cognitive ability or ones who are unable to fully communicate their pain, sliding scale levels with drawings or pictures are available (e.g., the FLACC scale) (Merkel, Voepel-Lewis, Shayevitz, & Malyvia, 1997). No non-verbal patients were used in this study. Verbal patients were asked to rate and describe their pain using the scale and descriptors on the UPAT (Fink, 2000). To assess the effectiveness of this quality improvement project the prescriber assessed pain levels at baseline and then before and after the use of CAM therapy(ies). The quality of these measurements has been validated and approved for use by many institutions, including the Nation Initiative on Pain Control (NIPC), which concludes their validity as measures of pain intensity (Fink, 2000). The prescriber used the UPAT Numerical Rating Scale (NRS) asking patients to rate their pain from 0-10 mentioned above when collecting raw data for my project.

The UPAT VRS that uses adjectives to describe different levels of pain (Haefeli & Elfering, 2006) was also used. Patients were asked to tick or describe the adjective that best fits their pain intensity (Haefeli & Elfering, 2006). Like UPAT NRS, UPAT VRS has two end anchor points, “no pain” to the “worst pain possible” and then between these endpoints different

adjectives are used that describes different levels of pain intensity placed in the order of pain severity from less to more. The UPAT VRS has 0 to 10 points on the UPAT and is found to have better compliance even though it is time consuming and sometimes difficult for the patient to choose the best possible answer.

Data Collection Procedures

A multidisciplinary team (patient care provider, nurse practitioner, and CAM specialist) used two types of evaluation tools: the UPAT and interview. Data was collected at baseline and then every four weeks at each office visit. Patients were called every two weeks to assess their pain level and to assess the use of the prescribed CAM therapy. Telephone interviews were also conducted every two weeks, to enable direct communication with the respondent and allow them to self-report their level of pain and the use of the prescribed CAM therapy(ies). This type of communication allowed patients to ask follow-up questions and have the team address any questions or concerns of the patient . Data was collected at baseline, during, and after each visit over a scheduled time frame period up to 12 weeks. The same interdisciplinary team members collected Pre/Post-treatment data and combined it for analysis by the nurse practitioner. The DNP student collected data on the patient's demographics, including gender, pain medication they currently use, including the dosage, frequency, and diagnosis. Data about the patient's initial level of pain, current pain management use, preferred CAM, and post-treatment evaluation was recorded. Certain methods pertain specifically to participants using music therapy. These participants selected their own music intervention based on their preference. They were instructed to complete a pre- and post-procedure evaluation, specific to listening to music. The questionnaire was given to patients at two weeks intervals throughout the 12-week evaluation. Participants were asked to listen to a preselected music list when they woke up and before they

slept. The participants also listened to the music of their own private preferences. The patient's response about their level of pain was recorded on a spreadsheet. All 14 patients filled out the form included.

Data Analysis

Descriptive analysis was used to evaluate the effectiveness of the quality improvement project using data from the UPAT that uses both the NRS and VRS and helped conclude whether or not this clinical practice change was successful over time. Qualitative data was recorded from the verbal comments of the patients over the course of the QI project. The use of descriptive statistics and qualitative data guided researchers in the proper characterization, summarization, presentation, and interpretation of the project. It also helped identify the potential positive and negative sides of CAM therapy.

Results

A total of 14 patients who were all white participated in this QI project ranging from 42-82 years of age, see Table 1. The average age for the males was 66; and the average age of the females was 68, see Table 2. There were seven men and seven women who agreed to use massage and music for various conditions as outlined. Six out of the 14 patients had a diagnosis of either arthritis, osteoarthritis, or rheumatoid arthritis, see Table 3.

To determine whether the use of CAM therapy had a positive patient effect we graphed the dosage of pain medication for each patient in conjunction with a graph of the level of pain report using the UPAT where patients rated their pain from 0-10 (no pain to worst possible pain), see Appendix B.

Table 1: Patients

Patient	Age	Gender	Race	Medical condition
1	64	Male	White Caucasian	Arthritis
2	72	Male	White Caucasian	Arthritis
3	68	Male	White Caucasian	Fibromyalgia
4	64	Male	White Caucasian	Arthritis
5	64	Female	White Caucasian	Arthritis
6	68	Female	White Caucasian	Plantar Fasciitis
7	54	Male	White Caucasian	Irritable Bowel Syndrome
8	72	Female	White Caucasian	Neck Pain
9	48	Female	White Caucasian	Low Back Pain From Obesity
10	68	Female	White Caucasian	Diabetic Neuropathy
11	70	Male	White Caucasian	Osteoarthritis
12	74	Female	White Caucasian	Diabetic Neuropathy
13	82	Female	White Caucasian	Fibromyalgia
14	70	Male	White Caucasian	Rheumatoid Arthritis

Table 2: Average age

Subjects	#	Average age (range)
Male	7	$\chi = 66$ (54-72)
Female	7	$\chi = 68$ (48-82)

Table 3 Diagnosis

Diagnoses	Male	Female
Arthritis/RA/OA	5	1
Diabetic neuropathy	0	2
Fibromyalgia	1	1
Lower back pain (obesity)	0	1
Neck pain	0	1
Irritable bowel syndrome (IBS)	1	0
Plantar fasciitis	0	1

Based on the final 12 weeks pre/post assessment, all 14 participants showed a positive outcome when using massage and music therapy. During the study, two sessions per week were dedicated to keeping everyone in a good physical state before therapy started. Music therapy showed a relatively better mood outcome than before because all participants chose music from their young adulthood. The decision made on music choice was informed by conversations initiated on life experiences, choices, and preferences in their 20s and 30's. Music therapy also showed a positive outcome in improving patients' psychological states. It is imperative to indicate that family members were included in post therapy assessment and they all stated that the smile on participants' faces was proof to them that the therapies were effective.

Furthermore, participants received both therapies at the same time. It is important to also indicate that the therapies were not performed at the PCP's office. Massage therapy was done in physical rehabilitation office and prescription and transportation costs were covered by Medicaid /Medicare. Participants were generally satisfied and no complaints were reported. Music therapy was done twice a day at homes of the participants, in the morning after they wake up and

evening before sleep. Better sleeping patterns and better moods were noted after the two therapies.

Qualitative Observations

The qualitative results were based on self-reported verbal comments where individuals reported that they felt better and were more in control of their pain. The patients who agreed to use the CAM therapies as an adjunctive therapy also self-reported an overall increase in the level of quality of life and were satisfied with using CAM therapies. The PCP lauded better pain management during the 12 weeks trial time for the reason that during reassessment, participants were seen to be more active and positive. Massage therapy has been proven effective in treating chronic pain and breakthrough pain. Massage therapy targets specific muscle groups to promote relaxation and release endorphins to increase a positive mood. Massage therapy is a therapeutic intervention or technique, which increases blood flow, alleviates pain and stiffness, and moves internal tissues. The physical benefits are in addition to the psychological benefits, which include a better mood, positive outlook, increased self-esteem, self-reported feelings of happiness, and reduction of anxiety. Massage therapy has proven useful in patients with chronic pain, including breakthrough pain or idiopathic pain. By localizing muscles and increasing blood circulation, massage therapy increases feelings of happiness and reduces feelings of pain in patients.

Moreover, music therapy is a form of CAM that is personal, subjective, and is proven to increase the patient's mood. Music therapy is a therapeutic intervention that uses music to assist in pain management. Music can be listened to or created by the patient. Although participating in the music making process is the most effective in relieving physical and psychological pain, listening to music is also effective. If music therapy is part of a structured environment, patients can see an improvement in mood and a reduction of pain. Patients who listen to music for

therapeutic purposes regularly get to choose the music of their preference. Further adding to music therapy's appeal to traditional pain management techniques is that it is an inexpensive and readily available supplement to pain management. Music can be shared almost instantly with today's technology and the Internet makes music from a variety of different countries and genres available. With easy access to music, patients can be in control of their healing. Studies show that patients who experienced chronic pain reported less pain after listening to the music of their choice. Therefore, based on this study, music and massage therapies as alternative methods of pain management, were largely beneficial in reducing and managing pain

Interpretation/Discussion

The implementation of this QI project demonstrated positive outcome for the 14 patients who chose to use the CAM therapies, massage and music during the 12 weeks of the project. The interpretation of our data is that we noted an improvement in pain control based on the data where we graphed the level of pain medication accompanied by a graph of the pain level over the course of the project, see Appendix B. This QI project indicates that it was safe to implement and use and that PCP's should consider using these CAM therapies more regularly as a part of their practice.

Furthermore, we found that use of massage twice per week and listening to music at least twice a day in the morning and the evening improved pain management and control for the patients who agreed to use these CAM therapies. Thus, we encourage others to consider the use of these CAM therapies along with the prescription of pain medication.

Cost-Benefit Analysis/Budget

The current standard for CAM is the cost-effective analysis (CEA). As health care costs continue to rise, decision makers must allocate their increasingly scarce resources toward

therapies, which offer the most benefit per unit of cost. The amount and quality of economic evaluations of CEA have increased in recent years. Furthermore, more CAM therapies have proven their positive value. Besides, the majority of CAM therapies remain to be evaluated. CEA are useful for a specific disease or condition and providing a specific outcome. The CEA can be directly compared using a metric of effectiveness relevant to that condition, such as pain. A significant benefit of this project could be the reduction in the cost of prescription of pain management drugs on the economy. This analysis considers only direct health care costs (hospital admissions, laboratory and diagnostic tests, and medications) (Herman, 2005). Based on the Bureau of Labor Statistics, the hourly mean wage of the Office of Physicians and Outpatient care centers is \$97. For this project, there was an hourly service charge, which was billed through insurance companies or paid out-of-pocket (Herman, 2005). As part of the project, the DNP student recommended that the patient participate in three CAM visits per week at a provider of their choice for the initial trial time frame of 6 - 12 weeks. At these visits, patients received either a massage and/or music therapy. These visits and the patient's subsequent analysis of these visits and their pain management were the subject of the project. The cost of out-of-pocket expenses based on a general hourly rate was \$97 per hour for three sessions per week and \$1,746 for six weeks. After the deduction of office expenses, the student and team created an approximate budget for the initial trial time. After the initial trials, it was expected that the participants would increase their quality of life and decrease the amount of consumed medicine. CAM therapies may be considered useful compared to conventional medicine for specific procedures, such as a massage for pain management, because CAM therapies cannot involve placebo trials and we unfortunately had no methodological advantage to comparing groups (Herman, 2005).

Timeline

The project timeline was from baseline up to 12 weeks. After the initial response was made and recorded, and participants identified and agreed to use the CAM therapies, the participants continued with CAM therapies based on their current health state. It was expected that they would report a positive increase in quality of life. These outcomes were measured by recording anecdotal comments. These questions were asked at baseline and every two weeks and at each office visit every four weeks. See Appendix C for the timeline and outline of the data to be collected at each timepoint to keep the project on track.

Ethical Considerations/Protection of Human Subjects

Review of the project by the Institutional Review Board (IRB) to use CAM therapy for a QI project was secured prior to the initial date of the project. Due to the nature of this project, and because it was conducted in a healthcare setting, there was no need to obtain informed consent from the participants to implement the QI project, see Appendix D. Since quality improvement projects do not meet the definition of "research under 45 CFR 46.102(d), which is '...a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge...'" (Estanol, 2016). According to the Department of Human Health and Services' (HHS) regulations protecting human participants, the Institutional Review Board (IRB) can waive the requirements for informed consent from participants of quality improvement projects. The risk in participating in this project was minimal and the waiver did not adversely affect the rights and welfare of the participants. In addition, HIPPA only requires patients to be made aware of how their health information will be used through a privacy notice. Therefore, this project can be initiated with patient consent for treatment rather than the use of informed consent for research purposes.

Review for this quality improvement project was obtained from the University of Massachusetts, Amherst (UMass) Institutional Review Board (IRB) before initiating the DNP project. The official IRB Determination Form was submitted as soon as the proposal was approved by the faculty advisor, see Appendix D. Each participant in the project was protected by the Health Insurance Portability and Accountability Act (HIPAA). HIPPA rules are very simple; they require professionals to maintain the confidentiality of personal/medical/historical records and other identifiable protected health information (PHI) used by or disclosed to us in any form, whether electronic, on paper, or spoken. In this case, the DNP student adhered to HIPPA Privacy laws and no HIPAA data was collected for the analysis to determine the effectiveness of the CAM therapy to reduce pain. The HIPAA law establishes the conditions under which protected health information may be used or disclosed by covered entities for research purposes.

This was a quality improvement project where the use of CAM therapies was used to implement a clinical practice change to improve patient response. Research on the other hand is defined in the Privacy Rule as inquiry, including research development, testing, and evaluation, designed to develop or add to general knowledge (HHS, 2014). The Privacy Rule also defines the means by which individuals should be informed of the uses and disclosures of their medical information for research purposes, and their rights to access information about them held by covered entities. Under the Privacy Rule, a covered entity may use and disclose protected health information that was created or received for research, either before or after the compliance date (HHS, 2014). Before any public health information is disclosed, a consent form or an Authorization Form of Acknowledgement has to be signed. Informed consent is used for research and is one of the main ways of promoting subject autonomy, or self-determination,

which is the right of free choice based on one's values. However, this is a quality improvement project and not research, so informed consent for research was not obtained.

Though informed consent was not a prerequisite for QI projects involving human participants, sometimes QI projects that involve direct patient care or clinical observation may seem to overlap with human subject research (HSR) (Raval, Sakran, Medbery, Angelos, & Hall, 2014). Hence, some healthcare settings may require use of admission consent form, which serve as permission for treatment and also part of consent to participate in QI activities (Raval et al, 2014). In this QI project, participants were not required to consent to participate in the QI activities, but were given a general consent form for treatment as they were taking part in the intervention as part of the CAM Therapy. As per the HIPAA regulation participants were informed of how their health information such as patient health history was used and for what purpose through explanation of privacy rule (Estanol, 2016). This ensured that patient privacy was maintained and that patient health information would not be shared to any other entities apart from the healthcare professionals participating in the QI activities within the healthcare setting.

Though QI activities and human subject research (HSR) often overlap, QI activities are distinct from HSR (Raval et al, 2014). A QI project is often performed to improve patient care by aligning current treatment with established best practices or evidence based-intervention (Raval et al, 2014). Therefore, QI activities are safe for patients as they do not cause any risk or harm to the patients (Raval et al, 2014). Nevertheless, participants were informed and CAM therapies explained as a part of the alternative treatment plan so that participants would perceive the goal and purpose of the QI project. The long-term goal of this project was to improve outcomes and reduce pain in individuals using CAM to decrease and/or alleviate the opioid crisis in America.

The results of the project will produce options that benefit patients in terms of safety, efficiency, quality, satisfaction, cost and improved patient outcomes (Raval et al, 2014).

Standards of care and ethical issues of CAM research, practice, and policy embrace five commitments. A social commitment obligates CAM providers to provide public access to all information. Patient protection is based on the Hippocratic Oath. Patient autonomy respects the rights of participants to make decisions according to their values. Recognition of medical pluralism, which includes paying attention to a notion of efficacy is not readily measurable by current scientific research. The use of CAM modalities is one of the junctures of the medical evolution. Without rejecting the research that has been conducted and its great value, it is important that ethical norms are brought under critical scrutiny and evolve along with medicine's expanding knowledge base and how they affect the larger social aims and meanings of medical practice (Cohen, 2004). No patients with cognitive limitations were used for this project. The PCP confirmed that every participant made their own treatment decisions as well as being able to respond for data collection.

Conclusion

The DNP student has concluded their study regarding the effectiveness of Complementary and Alternative (CAM) treatments regarding pain management utilizing two forms of CAM therapy: music and massage therapy. The participants were regular patients within a private practice in Brooklyn, New York. The CAM treatment was introduced on a bi-weekly basis for 12 weeks, the data was collected via questionnaires and interviews, and the outcomes were analyzed.

A literature review supported the conclusion that participants of the study would experience less pain and an increase in their quality of life after partaking in repeated CAM

therapy sessions. Using the tenets of the Gate Control Theory, the DNP student targeted patients who were experiencing chronic pain. The goal was to develop methods for pain management that do not include pharmaceutical interventions.

Each participant chose either music and/or massage therapy. Massage participants attended two sessions per week at the private practice for a total of 12 weeks. Music participants selected the music on their own and self-reported their feelings and level of pain. The data shows that music participants chose music that provided them with good memories, which promoted feelings of relaxation thereby reducing their pain.

For the massage participants, the data shows that they were more comfortable and experienced less pain immediately after the massage and their pain did decrease over the 12 weeks. These patients reported an increased mood, better quality of life, and better sleep. The massage therapy was also measured through self-reporting. A massage involves deep tissue contact and human interaction, so it is possible that some of the patients saw an increase in mood because they were communicating and interacting with another person.

Ultimately, based on the final assessment of the 14 patients after the 12 weeks of alternative methods of pain management, all of the participants stated that they continue to use the same dosage of medications as before they participated in the study, but the amount of breakthrough dosage has decreased, as reported by the patients. The level of pain has also decreased as reported by the patients and as reflected in the graphs (Appendix B). Using this data, the research shows that using CAM therapies such as music and massage, in addition to prescribed pain medications, can have positive effects on mood, well-being and quality of life. While narcotic and opioid prescriptions are designed to treat and reduce pain and inflammation, the medications do not treat the quality of life issues that may come with chronic pain. In

essence, narcotics and opioids cannot treat chronic pain in a holistic sense. The addition of CAM therapies like music and massage cater to a person's need for a good quality of life, rather than specifically for pain management.

Musculoskeletal acute and chronic pain affects more than a quarter of the population and is the most common reason patients seek pain management health care (Rivera, 2017). A growing number of individuals are turning towards the use of complementary alternative medicine (CAM) for the treatment of acute and chronic pain as an alternative to pharmaceutical options. The alternative medicine therapies, massage therapy and music therapy used here, have been described in the literature review and have been shown to help relieve pain symptoms without developing side effects like addiction, depression, insomnia, and mental exhaustion. Music and massage therapy were used in this clinical improvement project. Although the relationship between conventional treatment and the world of CAM remains vague, there will be a change in this paradigm based on significant use in clinical practice and the number of studies and trials that evaluate this type of therapy over time leading to more data to better define how these therapies can work along on together to produce better patient outcomes.

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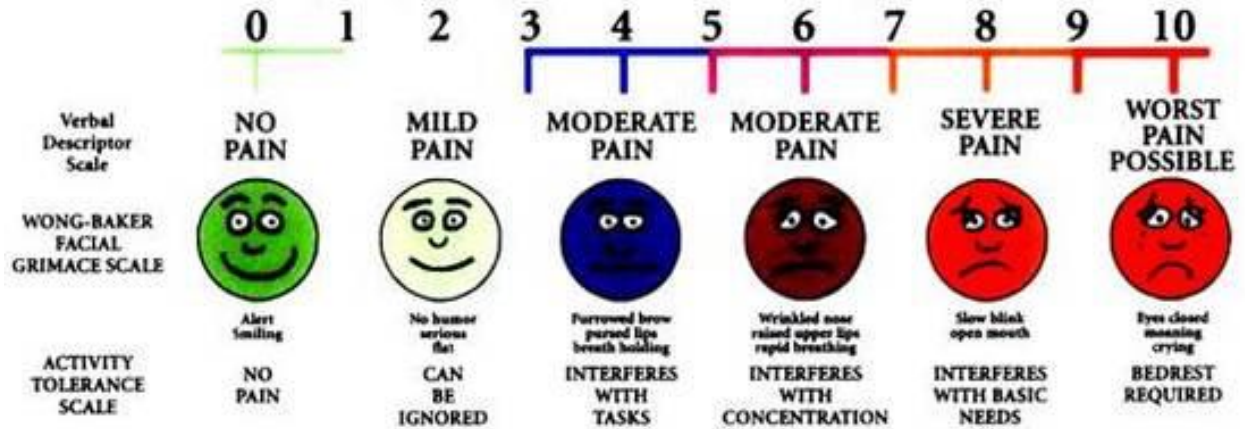
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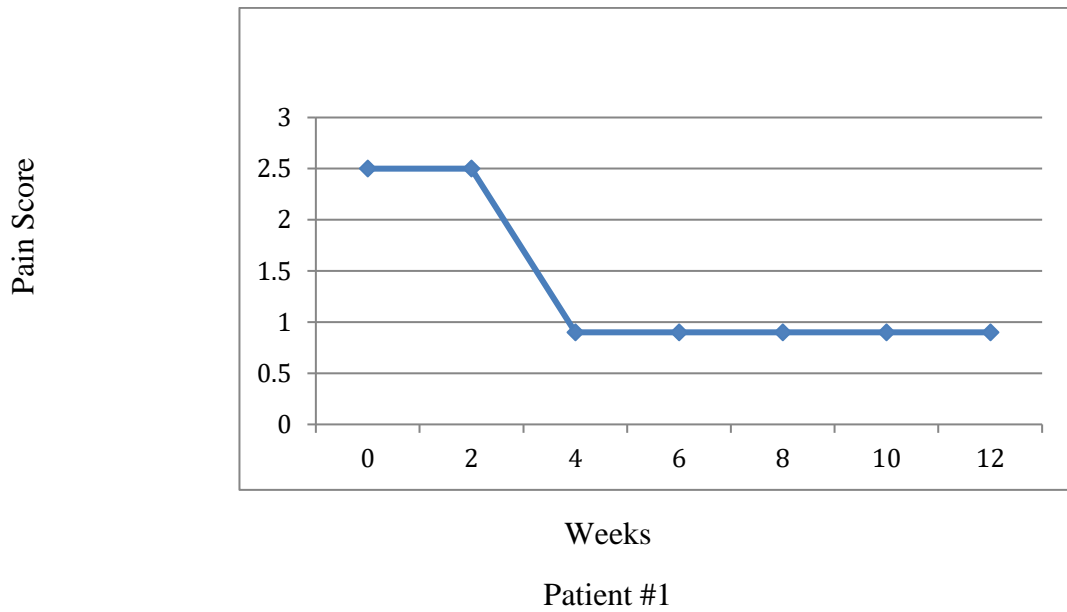
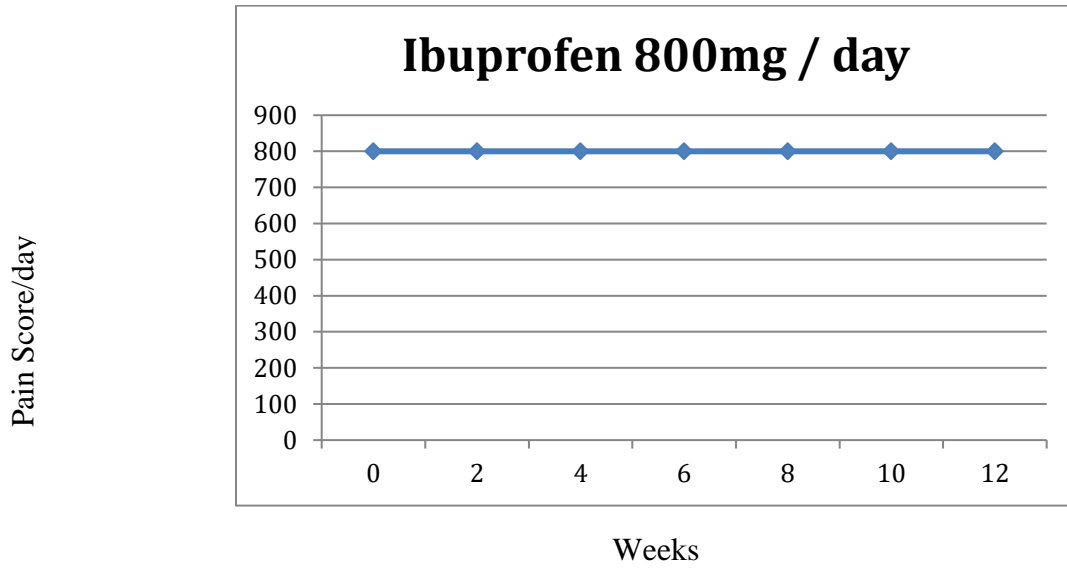
Appendix A- Pain Assessment Tool

UNIVERSAL PAIN ASSESSMENT TOOL

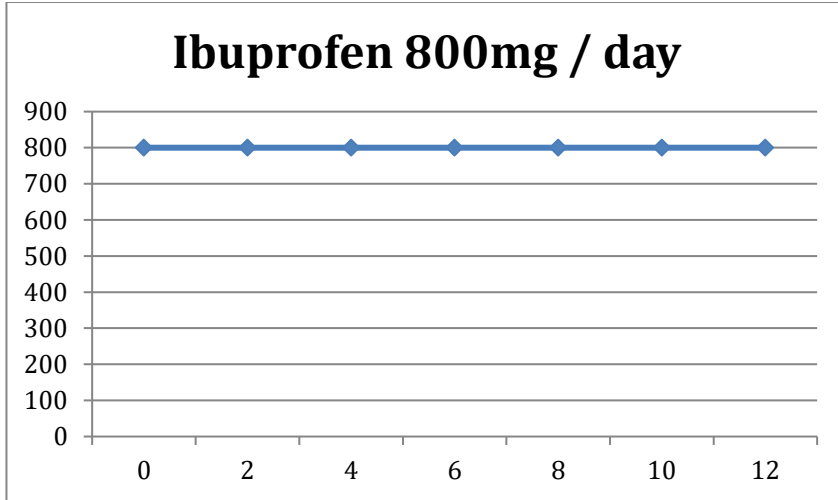
This pain assessment tool is intended to help patient care providers assess pain according to individual patient needs. Explain and use 0-10 Scale for patient self-assessment. Use the faces or behavioral observations to interpret expressed pain when patient cannot communicate his/her pain intensity.



Appendix B - Pain Assessment Tables

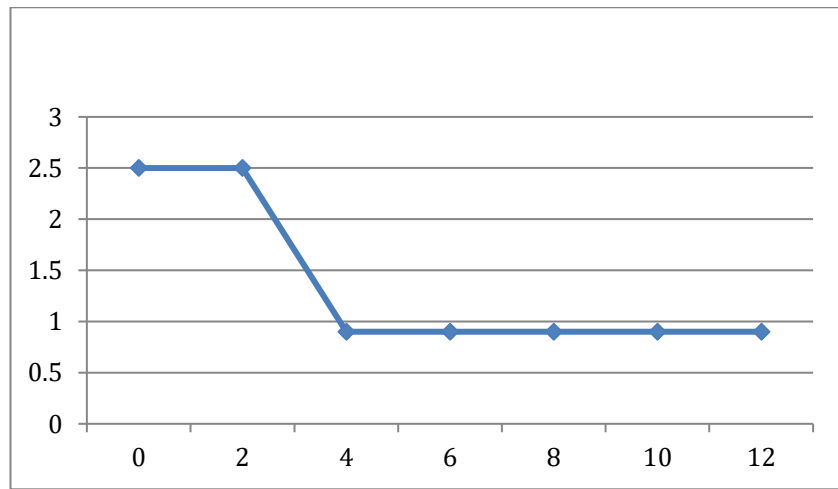


Dosage mg / day



Weeks

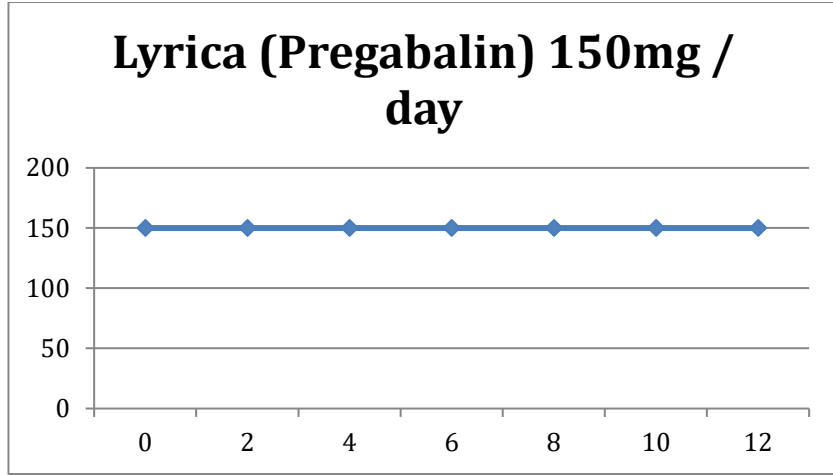
Pain Score



Weeks

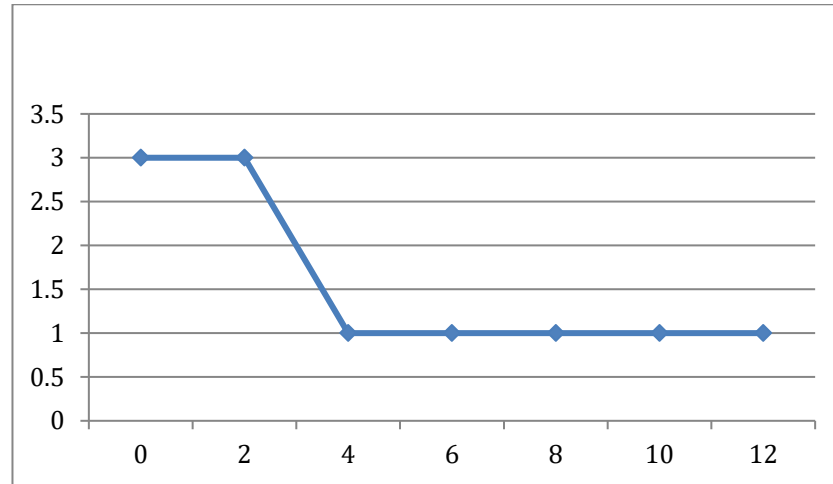
Patient #2

Dosage mg / day



Weeks

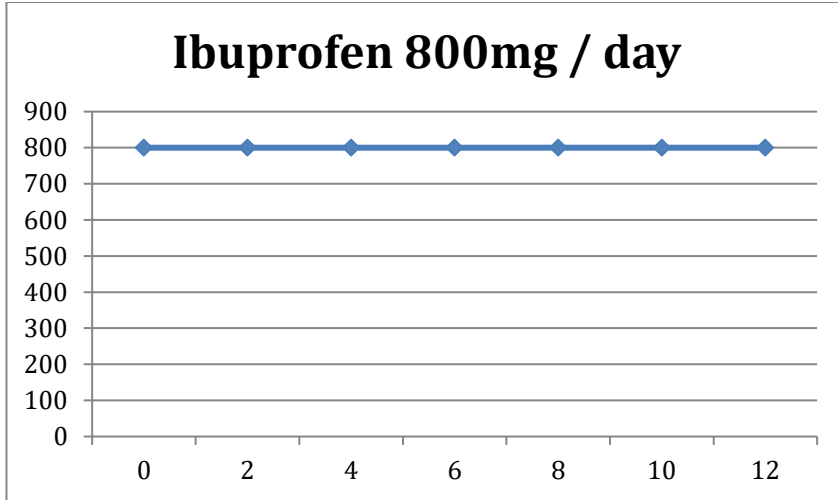
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Weeks

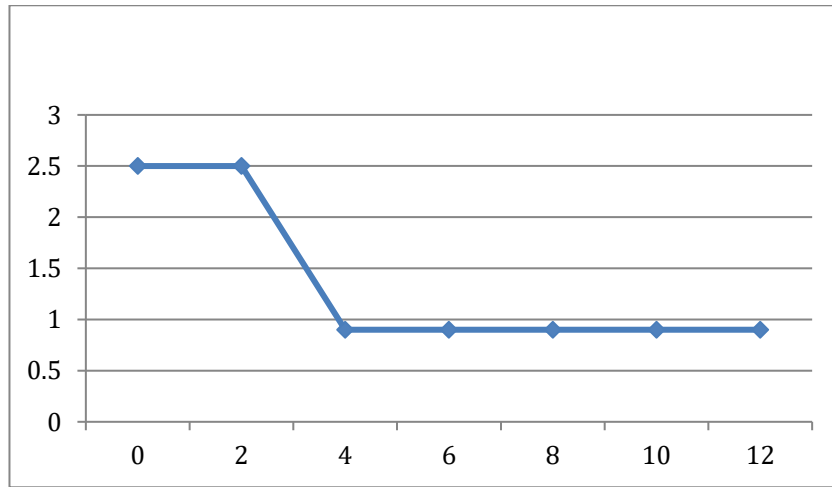
Patient #3

Dosage mg / day



Weeks

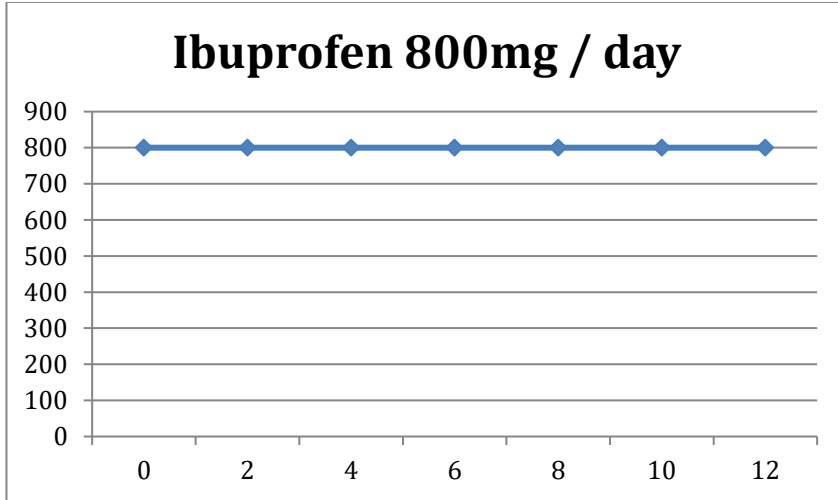
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Weeks

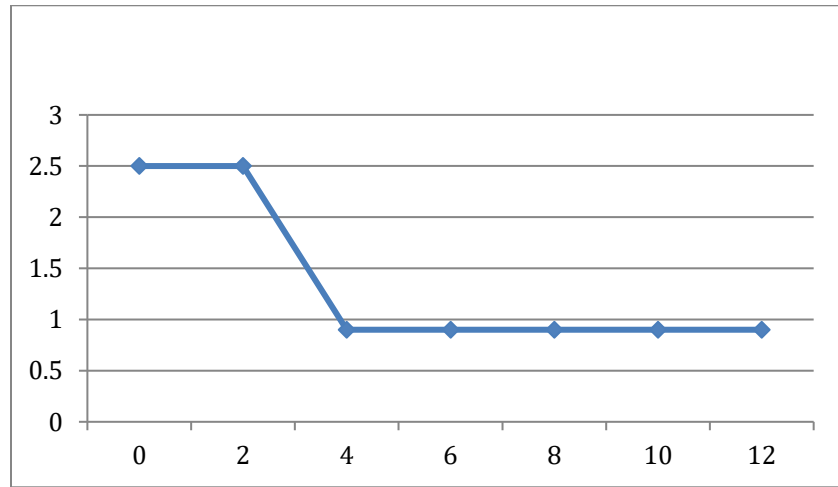
Patient #4

Dosage mg / day



Weeks

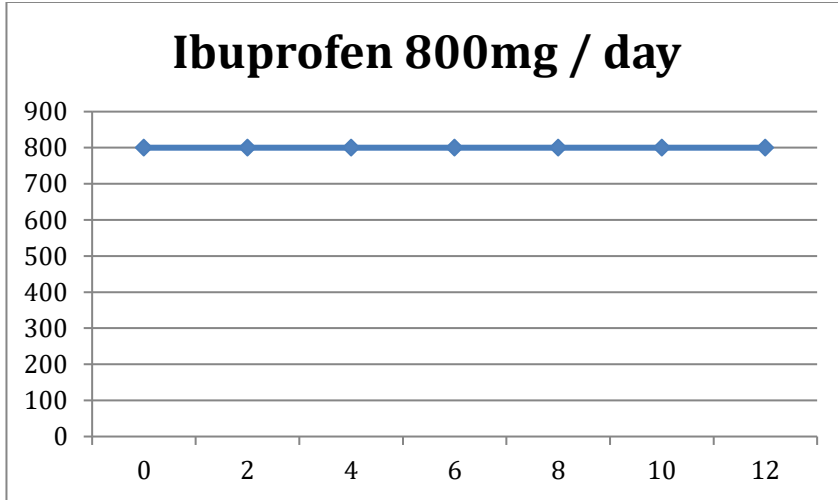
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Weeks

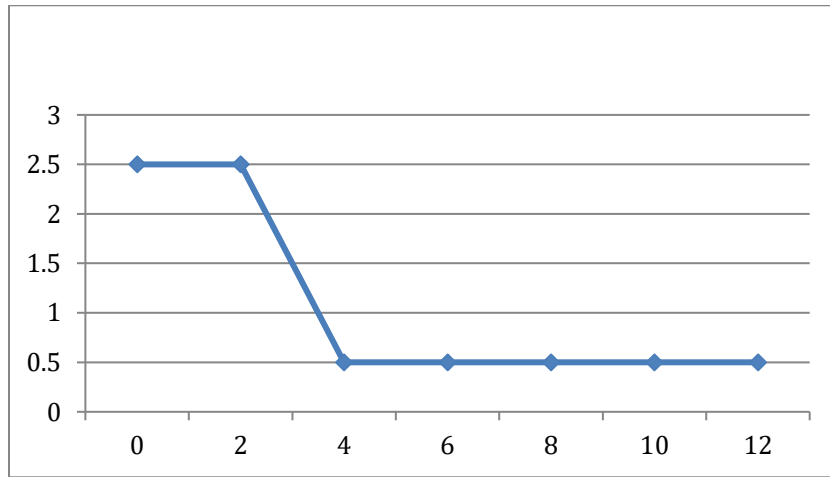
Patient #5

Dosage mg / day



Weeks

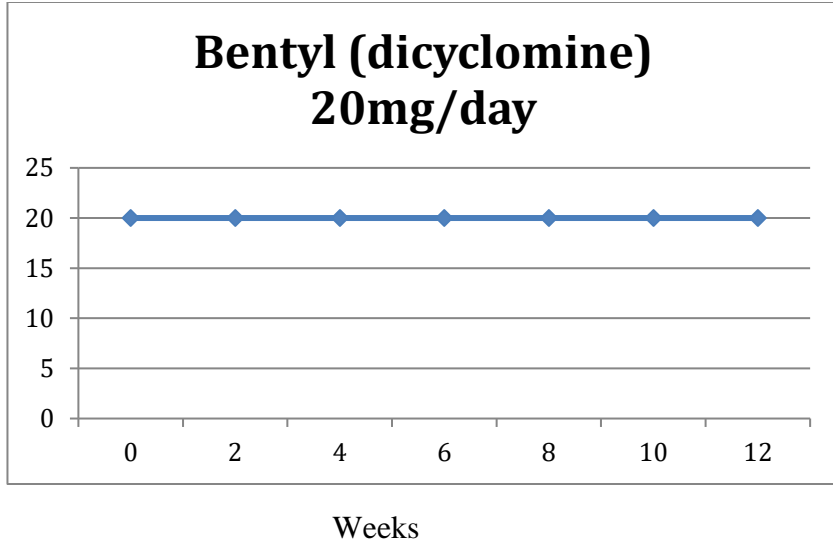
Pain Score



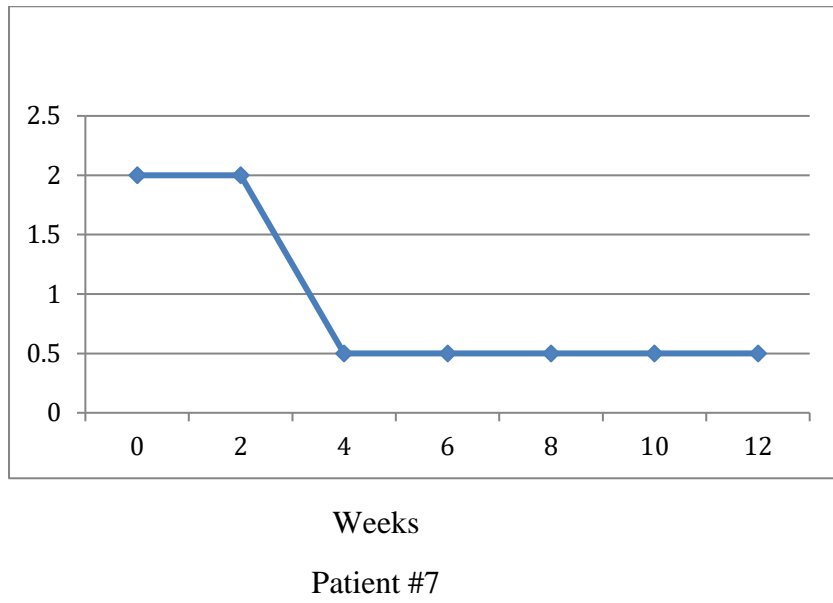
Weeks

Patient #6

Dosage mg / day

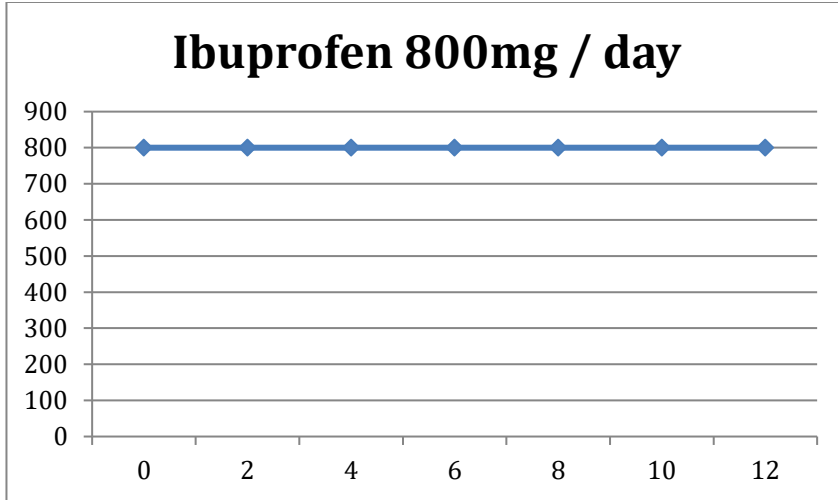


Pain Score



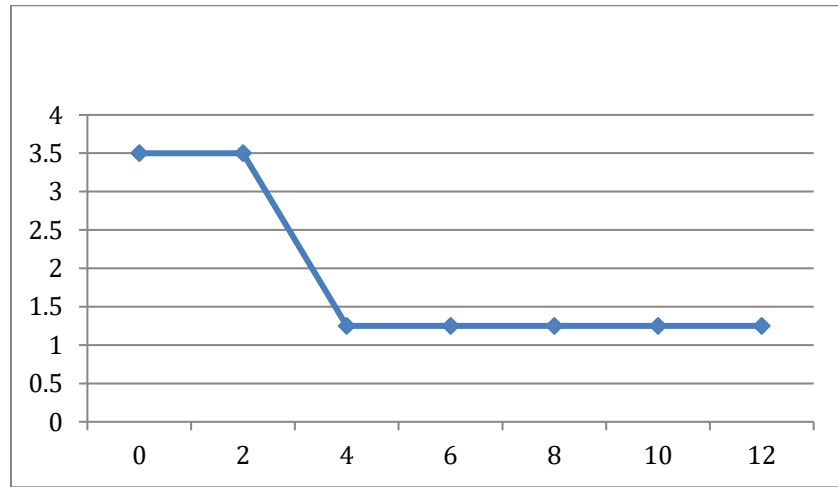
Patient #7

Dosage mg / day



Weeks

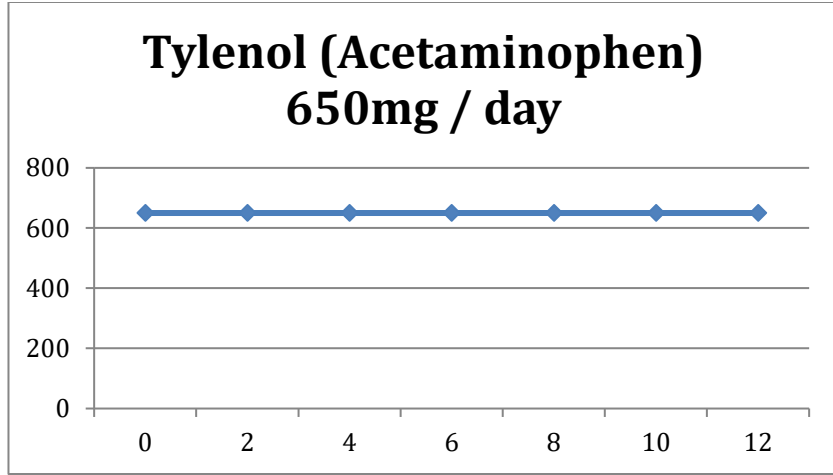
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Weeks

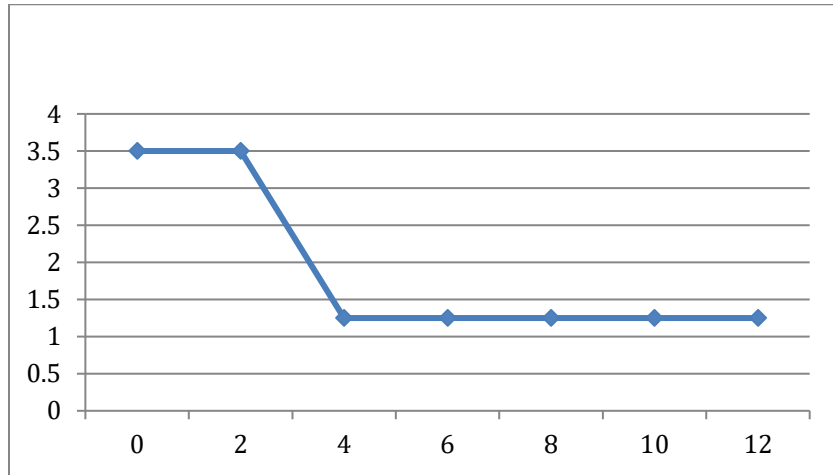
Patient #8

Dosage mg / day



Weeks

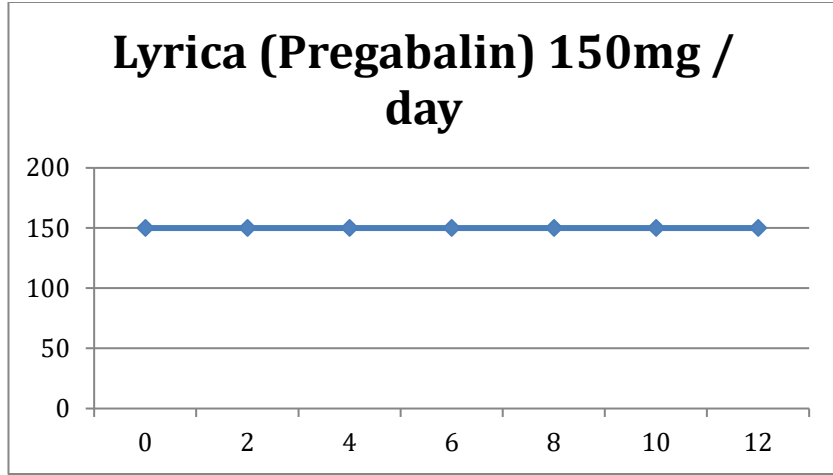
Pain Score



Weeks

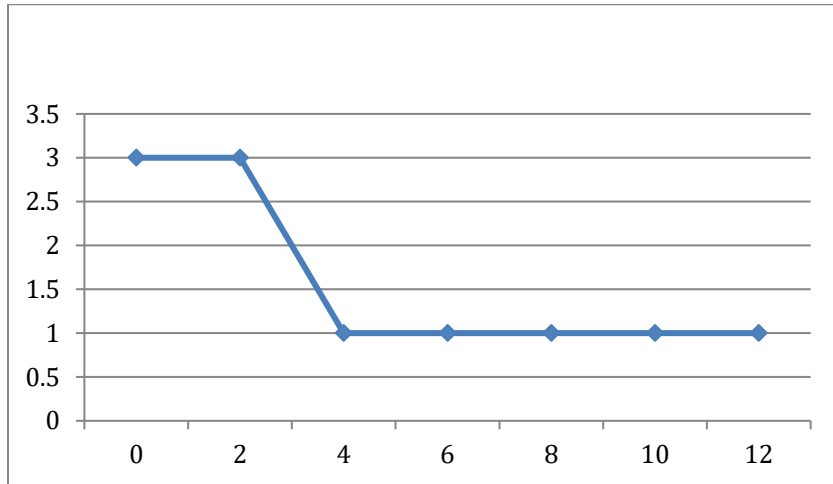
Patient #9

Dosage mg / day



Weeks

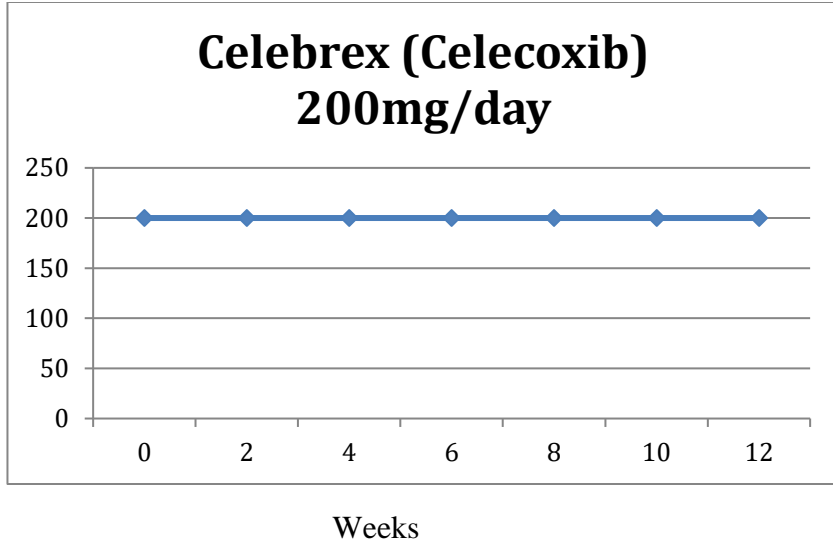
Pain Score



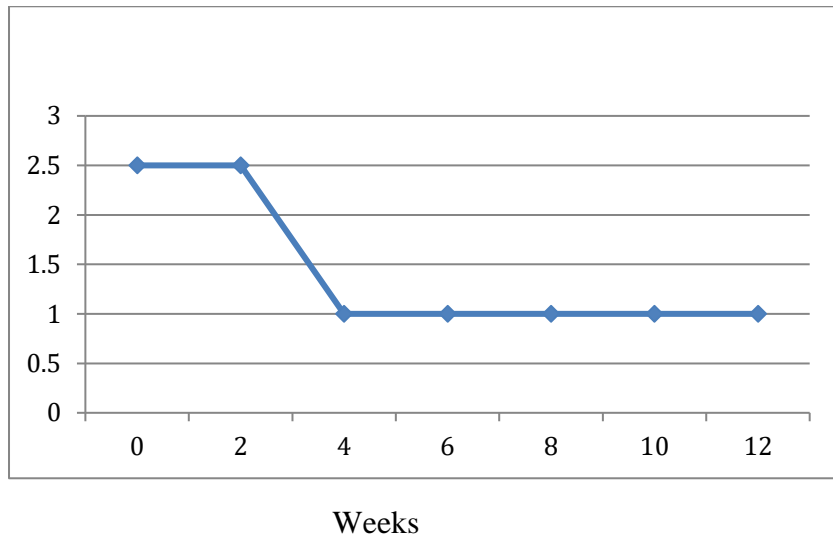
Weeks

Patient #10

Dosage mg / day

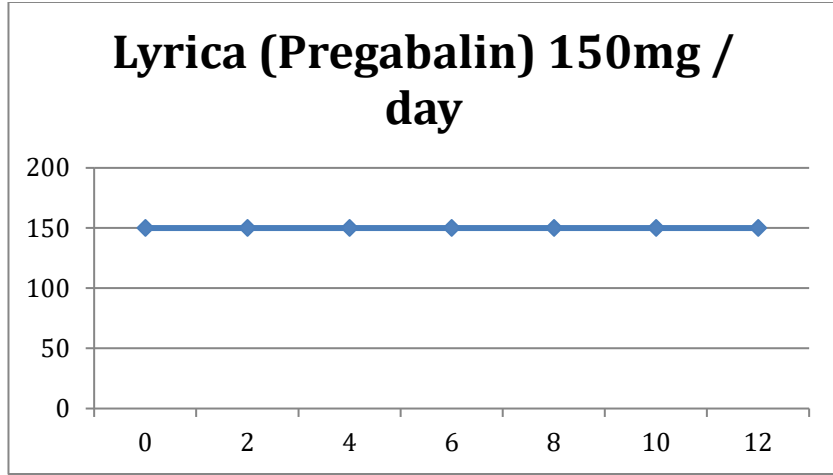


Pain Score



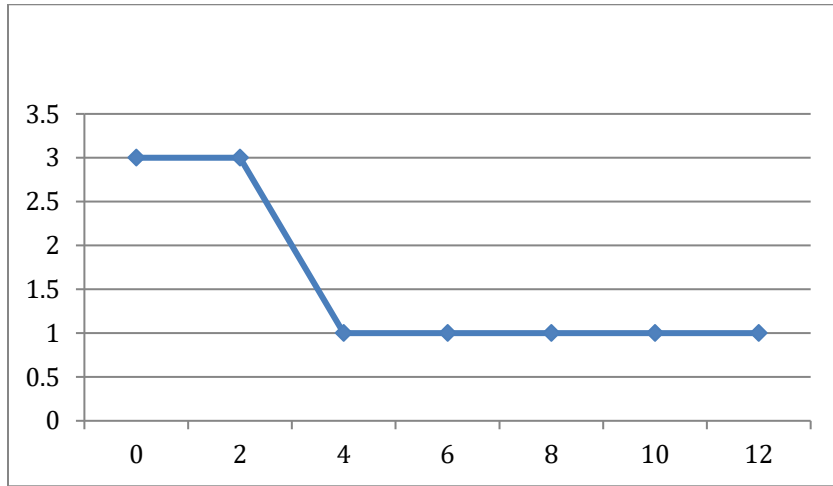
Patient #11

Dosage mg / day



Weeks

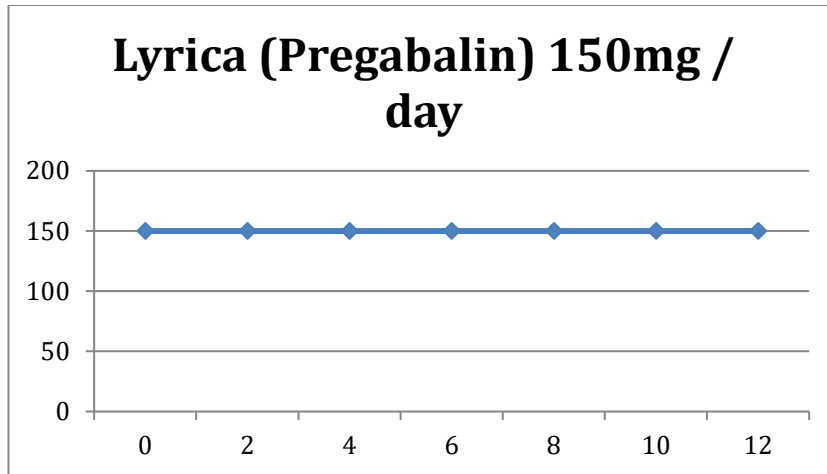
Pain Score



Weeks

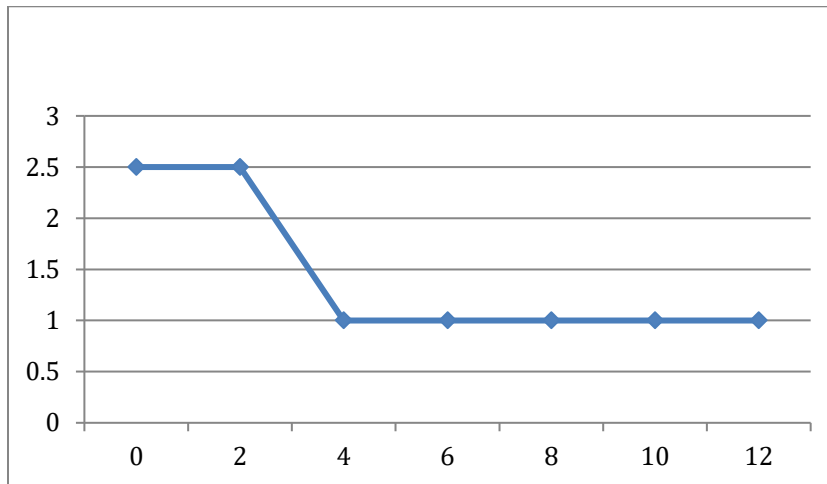
Patient #12

Dosage mg / day



Weeks

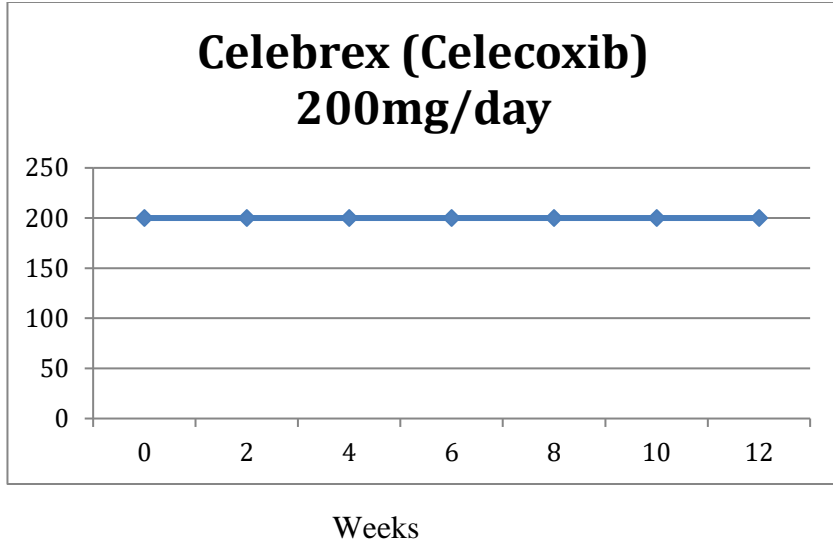
Pain Score



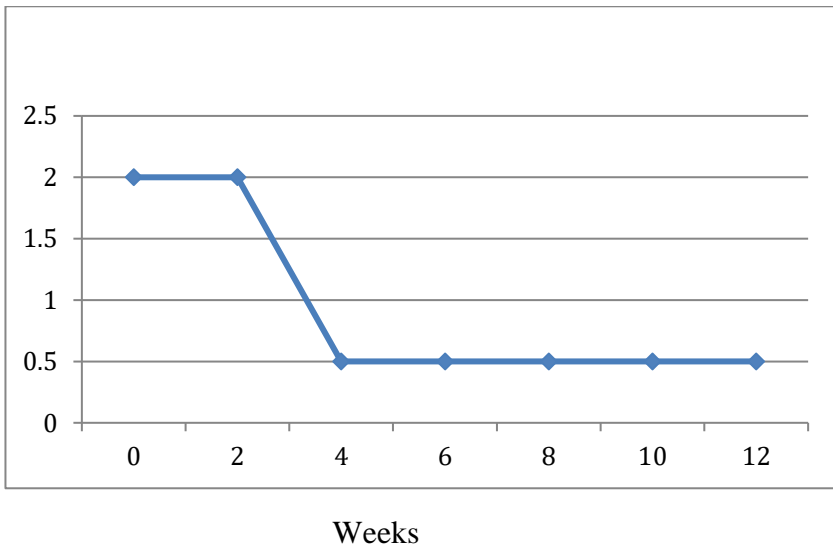
Weeks

Patient #13

Dosage mg / day



Pain Score



Patient #14

Appendix C Timeline

Task	Visit 1 Week 1	Phone call 1 Week 2	Visit 2 Week 4	Phone call 2 Week 6	Visit 3 Week 8	Phone call 3 Week 10	Visit 4 Week 12
Collect baseline data Age, gender, Dx., UPAT, Medications	X						
Prescribe CAM Music Massage Both	X						
Check-in call		X		X		X	
Data collection Verify # of times CAM used UPAT Verify use of pain medication – dose and frequency		X	X	X	X	X	X

Appendix C (continued) Treatment plan

Chronic Pain Management Program								
Patient Name/ID:								
	Pre-Treatment	Week 2	Week 4	Week 6	Week 8	Week 10	Post-Treatment /Week 12	Final Evaluation
Presentation of the program and overview of pain management and teaching	X	X	X	X	X	X	X	X
Music treatment	X	X	X	X	X	X	X	X
Massage Treatment	X	X	X	X	X	X	X	X
Stretching and muscle strengthening	X	X	X	X	X	X	X	X
Teaching of importance of exercise in managing pain	X	X	X	X	X	X	X	X
Increasing Pain Management Medication								
Decreasing Pain Management								
Improving sleep	X	X	X	X	X	X	X	X
Making Plans	X	X	X	X	X	X	X	X

General progress form for all 14 patients.

Appendix D IRB Determination Form

UMassAmherst
Human Research Protection Office

Mass Venture Center
100 Venture Way, Suite 116
Hadley, MA 01035
Telephone: 413-545-3428

Date: October 3, 2018

To: Vladimir Sher, College of Nursing

Project Title: Complimentary Management and Treatment of Pain

IRB Determination Number: 18-191

The Human Research Protection Office (HRPO) has evaluated the above named project and has made the following determination based on the information provided to our office:

The proposed project does not involve research that obtains information about living individuals [45 CFR 46.102(f)].

The proposed project does not involve intervention or interaction with individuals OR does not use identifiable private information [45 CFR 46.102(f)(1),(2)].

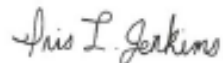
The proposed project does not meet the definition of human subject research under federal regulations [45 CFR 46.102(d)].

Submission of an Application to UMass Amherst IRB is not required.

Note: This determination applies only to the activities described in the submission. If there are changes to the activities described in this submission, please submit a new determination form to the HRPO prior to initiating any changes.

A project determined as "Not Human Subjects Research," must still be conducted in accordance with the ethical principles outlined in the Belmont Report: respect for persons, beneficence, and justice. Researchers must also comply with all applicable federal, state and local regulations as well as UMass Amherst Policies and procedures which may include obtaining approval of your activities from other institutions or entities.

Please do not hesitate to call us at 413-545-3428 or email humansubjects@ora.umass.edu if you have any questions.



Iris L. Jenkins, Assistant Director
Human Research Protection Office