Improving Quality of Life: Efficacy of Pregabalin and Gabapentin in the Fibromyalgia Patient

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Abstract

Background and Review of Literature: Fibromyalgia (FM) is a chronic disease that is characterized by widespread pain and several associated symptoms such as non-restorative sleep, fatigue, poor physical condition, impaired cognition, stiffness, depression, and balance impairment. Most FM patients are taking at least one prescription medication. Less than 50% of FM patients report being somewhat satisfied with their current treatment. This lack of evidence alone expresses the need for more research to support which prescription medications are essential.

Purpose: The purpose of this project was to determine whether pregabalin or gabapentin is more effective to manage the symptoms for women with fibromyalgia (FM), who have been using either medication for a minimum of two months, and to determine what factors could contribute to the overall improvement of the quality of life (QOL) for the fibromyalgia patient.

Methods: This exploratory, pilot project involved recruitment of 25 female participants who were currently on pregabalin and gabapentin for their fibromyalgia in three midwestern pain clinics.

Implementation Plan/Procedure: Each participant filled out the demographic sheet, FIQR questionnaire and SF-36 short survey after their appointment with their health care provider. Time allotted for each participant was 30 minutes. Scoring of data from the questionnaires and surveys was completed by the capstone project manager.

Implications/Conclusions: Judging by trends in the Revised Fibromyalgia Impact Questionnaire (FIQR) and SF- 36 scores, pregabalin may have had a positive impact on quality of life. There was a trend that the pregabalin group had higher functioning score compared to the gabapentin group. However, there was no significant difference between the gabapentin and pregabalin

groups on the QOL instruments, using independent t tests and a Mann Whitney U test. Factors that were found to be significantly associated with the overall quality of life were age and the number of hours of work. Regarding further evidence, there needs to be more studies with more participants to look at treatment options such as pregabalin and gabapentin for patients with fibromyalgia.

Improving Quality of Life: Efficacy of Pregabalin and Gabapentin in the Fibromyalgia Patient

Fibromyalgia (FM) is a chronic and debilitating disease for many individuals with no defined cure or standardized pharmacological treatment to help reduce symptoms or improve quality of life. Fibromyalgia patients suffer tremendously when their chronic pain is not managed to the extent desired which decreases quality of life daily. According to the World Health Organization (WHO), quality of life is defined as a person's perception of their position in life in the context of the culture and value systems in which they reside and in relation to their goals, expectations, standards and concerns (World Health Organization, 2018). Research shows that FM affects up to 6% of United States adults, resulting in a significant healthcare burden and poor quality of life for the patient (Liu, Qian, & Yang, 2016). FM affects women more than men and has been correlated with increased medical costs, drug costs and indirect costs for the patient and health care provider (Skaer, 2014). Currently there are three drugs approved by the FDA for fibromyalgia management. The three drugs, pregabalin (Lyrica), duloxetine (Cymbalta) and milnacipran (Savella), are approved for management of FM but are not without side effects. There is ongoing debate on which drug(s) benefit the patient with concern to adequate management of symptoms as well as tolerability of side effects when taking these three drugs. The need for frequent dose and medication changes with patients who have FM is very common. The need for consistent pain management regimens for the FM patient is essential for adequate improvement of quality of life.

Overview

Background

Fibromyalgia (FM) is a chronic disease that is characterized by widespread pain and several associated symptoms such as non-restorative sleep, fatigue, poor physical condition, impaired cognition, stiffness, depression, and balance impairment (Collado-Mateo et al., 2017). The symptoms listed have been shown to decrease a patient's quality of life when experienced for a long period of time. Statistics have shown that in the approximately 2% to 6% of the population with FM in the United States, FM affects about 7 to 9 times more women than men (Halpern, Shah, Cappelleri, Masters, & Clair, 2016). FM has shown to increase significant economic burden for patients which can include a high prevalence of work loss. Most FM patients (83-93%) are taking at least one prescription medication and 56-73% are taking two or more (Collado-Mateo et al., 2017). Less than 50% of FM patients report being somewhat satisfied with their current treatment (Collado-Mateo et al., 2017). There is a lack of evidence concerning medications that can adequately manage the FM patient's symptoms as well as pain. This lack of evidence alone expresses the need for more research to support which prescription medications are essential in order to increase the quality of life for an individual with fibromyalgia.

Patients with fibromyalgia have often experienced reduced overall quality of life because of severe functional limitations and the inability to adequately perform routine tasks (Boulanger et al., 2012). It has been shown that patients with fibromyalgia have increased direct and indirect costs with hospitalizations and physician office visits when pain is not adequately controlled. The patient's quality of life decreases because the individual is not able to function normally or

complete routine tasks (Skaer, 2014). FM patients struggle everyday with trying to find the right pain regimen in order to function daily and to help maintain quality of life.

Stigmatization of FM syndrome as a practicable diagnosis has led many affected persons to search for healthcare providers who will validate and agree to help manage their symptoms (Poindexter, 2017). Therefore, fibromyalgia is commonly misdiagnosed by clinicians. If the FM patient can't trust clinicians to make an accurate diagnosis, manage it effectively, and evaluate the outcome of treatment, many patients will have less faith in providers to help treat FM in the long run. Not diagnosing the patient accurately can result in multiple referrals to different specialists, prescriptions of multiple drugs to treat different symptoms, delays in diagnosing the patient, increases in disability as well as an increase in health care resource utilization (Arnold, Gebke, & Choy, 2016). If clinicians can diagnose fibromyalgia correctly and have evidence-based research to determine the most effective treatment for the patient, many individual's quality of life could improve.

Pregabalin and gabapentin are two GABA analog drugs used to treat fibromyalgia. GABA analog drugs are essential for maintaining the balance between nerve cell excitation and nerve cell inhibition (Drugs.com, 2018). GABA acts like a brake in a car and slows down nerve cells that are over-excited. Because GABA analog drugs calm the nervous system, they are known as inhibitory neurotransmitters. There is limited evidence-based literature regarding how gabapentin and pregabalin compare in decreasing pain levels as well as increasing quality of life in the FM patient. Even though gabapentin is not FDA approved for this diagnosis, it has been shown to be effective for fibromyalgia pain. In randomized, controlled trials with fibromyalgia patients, gabapentin has demonstrated efficacy for this condition (Arnold et al., 2016). Pregabalin is FDA approved and is one of three medications recommended for treatment of

fibromyalgia at this time. Determining the effectiveness of these two drugs in relation to the fibromyalgia diagnosis help providers manage symptoms and improve quality of life for these individuals who suffer from FM daily.

Potential stakeholders were involved in order to make decisions on the importance of the topic's relevance to the FM community. Stakeholders are any group or individual who can affect or are affected by the achievement of an organization's objective (O'Rourke, Higuchi, & Hogg, 2016). A smoother transition in assessment, planning and implementation of action were accomplished with engagement of stakeholder's support. Health care providers assisted by sharing knowledge of FM and by recruiting people from marginalized populations to contribute to this capstone project. Patients with the diagnosis of fibromyalgia know how this condition affects lives and normal activities of daily living. Lastly, local advocates from the fibromyalgia community were able to shine light on the condition and provide information on the actual symptoms of fibromyalgia and how it affected everyday life as well as what medication regimen was effective and which ones were not.

Within the chronic pain world, fibromyalgia is a condition that deserves attention because it affects the quality of life as well as causes disability to many individuals worldwide. Many individuals may need to go on pregabalin versus gabapentin to help with their nerve pain. It has been found that one medication may work for an individual, but the other medication may not. The following capstone project sought to determine whether the participant's quality of life was improved while being on medications (gabapentin or pregabalin), which impacted health and daily activities.

Problem Statement

There is still lack of evidence regarding which fibromyalgia (FM) treatment is beneficial for the patient currently in order to treat symptoms and increase the quality of life. The pathogenesis of FM has never been fully understood and this can make it harder to find definitive medication regimen(s) for these patients that can effectively treat pain as well as provide them with an improved quality of life. More women than men are diagnosed and affected by FM daily. Studies have compared medications including the three FDA approved drugs for use in fibromyalgia pregabalin, savella and cymbalta, as well as paroxetine, tramadol, amitriptyline, venlafaxine, gabapentin and cyclobenzaprine but no definitive treatment regimen has effectively improved symptoms for the FM patient (Tzellos et al., 2010). Healthcare providers have prescribed pregabalin and gabapentin for the fibromyalgia patient even though gabapentin has not been approved by the FDA to treat FM. There is no clear evidence documented on whether gabapentin or pregabalin, when used to manage symptoms, was the best treatment for FM patient's symptoms (Tzellos et al., 2010). Therefore, it was important to determine whether women with fibromyalgia taking pregabalin, compared to gabapentin, could experience an improved quality of life within a 2-month period.

Purpose Statement

The purpose of this project was to determine whether pregabalin or gabapentin effectively managed the symptoms of women with fibromyalgia (FM) in order to improve their quality of life daily within a 2-month period at three Midwestern pain clinics.

Outcomes

Fibromyalgia (FM) affects everyone in society causing various degrees of disability, pain and inability to work or engage in everyday activities (Martin et al., 2014). Finding ways to manage the fibromyalgia patient's symptoms with specific medication regimens may help to improve the quality of life for patients.

Two outcomes are expected from this project. The first aim is to identify major factors that could contribute to the overall improvement of the quality of life for the fibromyalgia patient regarding chronic pain management using the Fibromyalgia Impact Questionnaire (FIQR) and the SF-36 short form survey. The SF-36 short form survey is a set of coherent, generic and easy to administer quality of life measures. The FIQR measures physical functioning, work status, depression, anxiety, morning tiredness, pain, stiffness, fatigue, and well-being over the past week in the fibromyalgia patient. The second aim is to identify which medication, gabapentin or pregabalin, has a greater impact on the quality of life for the FM patient. The clinical questions that will need to be answered are: What factors could contribute to the overall improvement of the quality of life for the fibromyalgia patient and which medication, gabapentin or pregabalin, has a greater impact on the quality of life for the FM patient?

Review of the Literature

Research is scarce comparing pregabalin and gabapentin use in the FM patient. This capstone shed light on current medication regimens used for the fibromyalgia patient in order to improve the individual's quality of life. The search trail regarding this capstone project was started in the CINAHL database and then compared with articles in the PubMed databases and ending in the Cochrane databases with specific search keywords/phrases. The search trail is included in the appendices section of this proposal (Appendix A). This section includes an in-

depth analysis of existing research located on the fibromyalgia patient, a synthesis of the evidence located and finally, an introduction to the conceptual framework that guided this project.

Database Search Strategy

For the search within the CINAHL full text database, terms and keywords were used to provide an adequate literature search regarding the problem statement. Results were then decreased with defined limiters. The limiters included searching for research articles from 2013 to present, human subjects, English language and full text research articles. Inclusion criteria included the highest level of evidence (systematic reviews and randomized controlled studies), female and with the key focus on fibromyalgia patients. Exclusion criteria consisted of any information not related to the problem statement, the drugs Cymbalta and Savella as well as no males in the studies. A search of the population for the study included women with fibromyalgia which resulted in 1,172 articles and fibromyalgia patients that resulted in 2,493 articles. The search focused on the problem of quality of life resulted in 197,259 articles. A combined search of women with fibromyalgia "AND" fibromyalgia patients resulted in 308 articles. This was further investigated and the combination of the search of women with fibromyalgia "OR" fibromyalgia patients resulted in 3,114 articles. The interventions of pregabalin and gabapentin had separate results of 2,062 and 4,071 articles within the search. This search was further combined using pregabalin "AND" gabapentin that resulted in 1,184 articles. Combination of quality of life "AND" pregabalin "AND" gabapentin resulted in 528 articles. When all search key terms were combined, there were seven articles found within the CINAHL database.

For the search within the PubMed database, the same keywords and terms were used. The limiters remained the same as the CINAHL search. Same inclusion and exclusion criteria were

applied within the search. Results were as follows: women with fibromyalgia 1,680 articles, fibromyalgia patients 6,097 articles, quality of life 333,260 articles, pregabalin 3,038 articles and gabapentin 6,077 articles. A combination of the search, women with fibromyalgia "AND" fibromyalgia patients resulted in 225 articles. The interventions of pregabalin and gabapentin had separate results of 3,038 and 6,077 articles within the search. This search was further combined using pregabalin "AND" gabapentin and resulted in 975 articles. Combination of quality of life "AND" pregabalin "AND" gabapentin resulted in 133 articles. When all search key terms were combined, there were only three articles found within the PubMed database.

For the Cochrane Database of Systematic Reviews, a search was done using the keywords women with fibromyalgia "AND" fibromyalgia patients, which resulted in 45 articles. Finally, all combined articles using "AND" from the CINAHL (7) and PubMed (3) searches plus the Cochrane articles (45) were then reviewed thoroughly. Seven articles were found as final articles for this capstone project proposal to then be analyzed and reviewed for their level of evidence.

Levels of Hierarchy of Evidence

The level of hierarchy of evidence provides the researcher guidance about the type of research study that could provide reliable answers to specific clinical questions**.** The higher the methodology ranking in the hierarchy, the more likely the results accurately represent the actual situation as well as the confidence that the intervention will produce better health outcomes. The level of evidence for each article used was determined and can be found in the reference matrix of Appendix B. Critical analysis of each article was performed and level of evidence was determined. Seven articles were selected, and the quality of evidence found consisted of: three articles were considered Level I evidence, two articles were considered Level II evidence, one

article was considered Level IV evidence, and one article was considered Level V evidence.

Analyzing the Literature

When analyzing the seven articles found from the literature search, there was noteworthy evidence of need regarding fibromyalgia treatment regimens. Patients with fibromyalgia must make changes within their lifestyles daily in order to function and maintain overall quality of life. The reference matrix is a critical analysis of each article and serves to summarize each research article as well as describe each level of evidence. The results of the critique of articles as well as a discussion of the critical analysis findings will be discussed further. See Appendix B for the reference matrix used for the synthesis of evidence.

Synthesis of Evidence

The studies found in relation to the problem statement were very similar with results in relation to the fibromyalgia patient. Most of the studies provided were not consistent with a definitive medication regimen that would show improvement for the patient's symptoms. The following section will compare and contrast the studies in order to describe the importance of performing this capstone project.

All of the studies provided in the reference matrix had a moderate sample size, an average of 50-1000 participants. Each study consisted of mostly women participants, over the age of 18 years of age and compared multiple drug regimens for the fibromyalgia patient. Studies were performed within the United States, Egypt, Europe, UK and Puerto Rico. Participants were diagnosed previously using the 1990 or 2010 criteria for diagnosing fibromyalgia as a medical issue. The criteria required tenderness on pressure points in at least 11 to 18 specified sites with the presence of widespread pain for the diagnosis (Wolfe et al., 2010). Widespread pain consisted of axial pain, left and right sided pain and upper and lower pain throughout the body.

The evidence with each article provided comparisons as well as differences between multiple drugs used for fibromyalgia patients within each study. Drugs identified in different studies included pregabalin, gabapentin, amitriptyline, venlafaxine, paroxetine, duloxetine, milnacipran, cyclobenzaprine, tramadol, and tricyclic antidepressants. The major goal for most researchers who included these drugs in their study was to determine the efficacy of each drug in relation to the diagnosis of fibromyalgia. One single study by Skaer (2014) briefly described a summary of a cost-effective analysis on different pharmacotherapies.

Skaer (2014) used the Fibromyalgia Impact Questionnaire (FIQ), the Patient Global Impression of Change rating scale (PGIC) and the quality adjusted life-years calculation to describe how these ratings could impact the FM patient's quality of life as well as the significant cost burden to society. The FIQ instrument measures physical functioning, work status (missed days off from work), depression, anxiety, morning tiredness, pain, stiffness, fatigue and well-being. The PGIC is a self-reporting rating scale that reflects a patient's belief about the efficacy of treatment. Even though these studies were adequate in providing data on the pharmacotherapies and interventions to help with the fibromyalgia patient's symptoms and quality of life, no clear regimen was determined to effectively help these patient's function comfortably daily.

Different tools were used in each study to collect the data obtained. Ramzy (2017) used the Somatic Symptoms scale-8 (SSS-8) and Center for Epidemiological Studies Depression (CESDS) scale to score results. The 8-item Somatic Symptom Scale was developed as a brief, patient-reported outcome measure of somatic symptom burden, but its reliability, validity, and usefulness has not been established in many studies. The CESDS scale is a brief self-report scale designed to measure self-reported symptoms associated with depression experienced by the

patient within the last week. Data from one study, Robinson et al, (2013) was also collected via computer-assisted telephone interviews which included the Sheehan Disability scale (SDS), Brief Pain Index scale (BPI) and FIQ measures as well as economic outcome measures. The BPI measures the severity of pain and its impact on functioning. The SDS is a brief self-reporting tool that measures the functional impairment in three interrelated domains: work/school, social and family life. Two of the level I evidence articles used the Grading of Recommendations Assessment, Development and Evaluation (GRADE) scale which is used to obtain responses to questions of importance to patient outcomes (population, participants or patients; intervention or indicator; comparator or control; outcome: PICO) and the resulting recommendations within a study. The GRADE scale was used in many Level I evidence studies within the Cochrane database.

Ramzy (2017) found that pregabalin plus paroxetine offered an effective method to reduce somatic symptoms and depression, while improving the quality of life for fibromyalgia patients. The study also showed tolerability and efficacy of paroxetine in improving overall symptoms of fibromyalgia even in patients without concurrent mood or anxiety disorders. Tzellos et al., (2010) compared gabapentin and pregabalin within a systematic review and meta-analysis. Results demonstrated that gabapentin significantly improved primary outcomes of BPI-SF average pain severity score and BPI-SF average pain severity score response rates. In the Robinson et al., (2013) study, the purpose was to describe 12-month treatment patterns and outcomes for patients starting a new medication for fibromyalgia in routine clinical practice. Results showed duloxetine and milnacipran (versus pregabalin or a tricyclic antidepressant) had fewer outpatient visits during the 12-month study. Patients reported satisfaction with overall treatment and their fibromyalgia medication 46.0% and 42.8%, respectively (Robinson et al., 2013). In Liu, Qian & Yang (2016), it was determined that among patients who discontinued initial treatment of duloxetine,

pregabalin, or milnacipran, approximately one-third had switched treatments within 90 days after the first prescription.

The two most significant articles were from Cooper (2018) and Derry et al., (2016) that were systematic reviews of randomized control, double blind studies of patients with fibromyalgia who were taking either gabapentin or pregabalin. Derry et al., (2016) explained the purpose of the study was to assess the analgesic efficacy and adverse events of pregabalin in adults with fibromyalgia, compared with a placebo. Results from this study included high quality evidence that found pregabalin at daily doses of 300 to 600 mgs had produced a large decline in pain for one out of ten persons with moderate to severe pain from fibromyalgia (Derry et al., 2016). This pain reduction came with improvement of symptoms, quality of life, and the increased ability to function. Cooper (2018), on the other hand, compared the efficacy of gabapentin when treating symptoms of fibromyalgia. At the end of the trial, the outcome of 50% reduction in pain over baseline was not reported. The outcome of 30% or greater reduction in pain over baseline was achieved by 38 of 75 participants (49%) with gabapentin compared with 23 of 75 participants (31%) with placebo (Cooper, 2018).

Overall, there is a significant need to determine which medication, whether it be pregabalin or gabapentin, can be used in the fibromyalgia patient for increased quality of life, improved overall function and symptomatic relief. Tzellos et al., (2010) has been the only study completed to date with comparison of gabapentin and pregabalin in the FM patient. The condition of fibromyalgia could impact society financially with increased economic burden, healthcare related pain management issues and unnecessary increased hospitalizations for the fibromyalgia patient.

With all the data from the studies provided within the reference matrix, the question remained regarding which drug or drugs are beneficial to the fibromyalgia patient's well-being, symptomology and improved quality of life. Some studies claimed that one drug may be more beneficial to the fibromyalgia patient than other drug regimens (Derry et al., 2016; Cooper, 2018). Implementing this capstone project enlightened researchers to explore further research regarding this topic which could improve a FM patient's quality of life.

Theoretical Framework

In an article by Kelley-Gillespie (2009), a comprehensive, integrated model of quality of life was used to synthesize existing constructs into six life domains. These domains consisted of social well-being, physical well-being, psychological well-being, spiritual well-being, cognitive well-being and environmental well-being. This is a holistic model of quality of life that expands the traditional health-related quality of life constructs to incorporate the non-physical aspect of a person's well-being (Kelley-Gillespie, 2009). This model has been used with assessment of quality of life in older adults but can be used to evaluate the quality of life with the fibromyalgia patient as well. This model helped with determining the perceptions of quality of life in the fibromyalgia patient through the choice of instruments to use in the study. A graphic image of this conceptual framework has been provided in Appendix C.

The conceptual model for quality of life was first introduced in 1982 by Baker and Intagliata which described relationships between external environment, individual experience, individual health status and quality of life responses (Kerce,1992). The model suggested that there were four foci of interest in relation to quality of life assessment. Focus I concentrated on the objective indicators of the quality of life. Focus II concentrated on the perceived attributes of the environment (experienced environment). Focus III called the "bio-psycho system"

represented the mental and physical health of the individual and attitudes as well as values. Finally, Focus IV described the behavioral outcomes in response to questionnaires and interviews in order to assess the person's quality of life (Kerce,1992).

The integrated model of quality of life has been defined in many ways and compared to health-related quality of life constructs. Kelley-Gillespie (2012) described the six major life domains and defined the domains as follows. The social well-being domain emphasizes societal connections, personal relationships and social activities that may influence the perceptions of the patient's life satisfaction and quality of life. Physical well-being describes the health-related quality of life factors such as health status or physical functioning. Psychological well-being includes the emotional status, personality attributes, or any mental health issues that may affect the patient's quality of life. The spiritual domain describes the values regarding the patient, others, nature, life and God. The cognitive domain of well-being includes the intellectual ability, thinking processes and management of the mind. Finally, the environmental well-being domain focuses on the physical surroundings and personal space that are influence by external factors (Kelley-Gillespie, 2012). The physical well-being construct was used to assess the quality of life of the fibromyalgia patients within this capstone project.

The framework of integrated conceptual model of quality of life was beneficial to this capstone because it helped compare various aspects and perceptions about how pain was managed with the two drugs for fibromyalgia (gabapentin and pregabalin) and how the patient viewed the quality of life with usage of the two drugs. It is important to understand the patient's feelings and how the individual is reacting to the medications prescribed. If the medications are not effective for the patient, the quality of life may not be enough, and the patient may decline when performing normal activities (Skaer, 2014). It is important to get to know what the patient

views as the quality of life and what it means to cope with the disease. Knowing the social, physical, psychological, cognitive, spiritual and environmental aspects of the patient's well-being will be beneficial to the provider in the future to manage fibromyalgia. The physical well-being was the focus of this capstone project because it describes the pain, discomfort and functional ability of the patient. Figuring out the patient's physical well-being could be the key when trying to determine which medication regimen, either gabapentin or pregabalin, could possibly improve the quality of life for the patient.

Quality of life is becoming a standard measure within research studies. The impact on how a provider treats and manages a patient's pain and symptoms of a certain condition can be critical. All of these major life domains play a part in the fibromyalgia patient's daily struggle when trying to improve quality of life. Looking at the patient's perspective for overall quality of life should be recognized and this conceptual model helped determine what is important to the patient overall.

Organizational Assessment

The pain clinics for this capstone project included fibromyalgia patients who were taking medications specific to the fibromyalgia diagnosis, specifically pregabalin and gabapentin. These three clinics had specific initiatives in place for the fibromyalgia patient regarding pain management. The clinics had an interdisciplinary team approach to managing the pain of the fibromyalgia patient. This included the pain specialist, nurses, psychologists, case managers and primary care physician. Having these specific features within each clinic's matrix had supported change readiness within the organizations.

There were many facilitators as well as barriers with this capstone. Encouraging evidence- based practice strategies were beneficial to the patient as well as the physician within

the study. Facilitators included: having a key person who led the project and had knowledge about fibromyalgia as well as what medications could be prescribed for the patient; knowing the key drivers that assisted in practice change for improvement of quality of life with the fibromyalgia patient; full cooperation with project participants who had a fibromyalgia diagnosis; and full cooperation from physicians as well as the potential ownership by physicians as the evidence-based practice goals were reached so it could be introduced into practice with current and future fibromyalgia patients.

Barriers with this capstone were the following: small sample sizes, the participant's expression of frustration when filling out both the questionnaire and survey as too time consuming, lack of time to collect all data from participants, not being able to find the appropriate setting to perform the capstone project and the clinician not accepting the results of the project. Possible risks or consequences associated with this capstone project included the risk for psychological harm to the patient regarding any personal feelings about the fibromyalgia diagnosis and the daily management of the illness, emotional harm to the patient when discussing pain management if pain was not adequately managed, and the participant's fear that personal information would be shared with others.

Although there were possible barriers and facilitators to the project's success, there were solutions that needed to be established and that consisted of finding evidence-based practice information to improve healthcare outcomes without causing harm to the patient. This capstone project helped to expand the different options available to the clinician when treating the fibromyalgia population's pain.

Methodology

This capstone project was implemented in three pain clinic settings. The capstone consisted of a pilot, exploratory project with analysis of quantitative data.

Setting

The capstone project setting consisted of three outpatient Midwest pain clinics in Iowa and Nebraska. Three different sites were needed in order to obtain an adequately sized sample. Two clinics were part of the original proposal but a third clinic was added to increase the sample size. Sampling is discussed further in the next section. The setting helped to provide important framework in terms of the applicability of the study results, the presence and type of applicable local regulation and ethics oversight (SPIRIT, 2018). The population of the city in which two clinics reside consisted of 466,893 people, 77% of the population are white, 12% are black and 3% are of Hispanic race (United States Census Bureau, 2018). The third clinic resideed in a Midwest city consisting of a total of 62,316 people 92% white, 2% black, and 10% of Hispanic race (United States Census Bureau, 2018). The population consisted of adult women with an active diagnosis of fibromyalgia, using either the 1990 or 2010 fibromyalgia criteria (Wolfe et al., 2010). Each clinic saw an average of 10-20 patients a day per provider. Two clinics treated fibromyalgia patients on a daily basis. The third clinic had fibromyalgia patients intermittently or none at all on a daily basis. The clinics consisted of nurses, medical physicians and nurse practitioners who helped to manage the care for this specific population.

Sampling

The target population were women with fibromyalgia who have had difficulty managing pain and could not find the right pain medication regimen to help relieve symptoms. In addition, the women involved were prescribed and using gabapentin or pregabalin as the overall treatment for fibromyalgia pain. Inclusion criteria were: female patients who currently had a diagnosis of fibromyalgia or had been recently diagnosed with fibromyalgia, patients aged 18 years or older, patients currently taking gabapentin or pregabalin and who speak English. Exclusion criteria included men, patients on other fibromyalgia drugs other than pregabalin or gabapentin, terminally ill patients, and patients on a pain contract.

Implementation Procedures

A letter describing the capstone project was given to the clinics asking permission to perform the project (Appendix D). Permission was obtained from the prescribing physician, clinic manager or administrator, physician assistant and/or nurse practitioner to access files for patients in each clinic with fibromyalgia. Letters of permission were obtained from each clinic to perform the project. The capstone project manager discussed with the clinic manager all details of the project. A set of instructions about the project and how to fill out questionnaires/surveys were left in each clinic. The capstone project manager discussed specific instructions with the clinic manager in each office to make sure there was complete understanding of the information regarding the project. Scoring of results from questionnaires and surveys was completed by the capstone project manager.

All participants on the caseload with fibromyalgia were identified by the clinic manager. Inclusion criterion were assessed to see if the fibromyalgia patient was currently on gabapentin or pregabalin as a pain regimen. The patient was made aware of the capstone project by the clinic

manager on the day of the appointment at the clinic. It was the patient's choice to participate in the project at that time. An envelope containing information explaining the project, cover letter with consent and consent statement, as well as the two questionnaires/surveys to fill out were given to the patient to look over. If the patient decided to participate in the project, both questionnaires/surveys were completed by the patient. In addition, there was a form for the participants to fill out describing demographic information. The participant was asked to confirm taking gabapentin or pregabalin for a fibromyalgia diagnosis on the demographic sheet. Hard copies of each questionnaire and survey was used with a pencil provided to mark appropriate responses. Each participant then filled out one demographic sheet, one questionnaire and one survey to rate quality of life measures which took 30 minutes or less to complete (See Appendix E for copy of demographic sheet). The participant was instructed to place all completed questionnaires/surveys/demographic sheets back in the envelope provided. The clinic manager collected the packet immediately from the participant. The clinic manager then notified the capstone project manager to pick up the envelopes from the designated clinic sites. Any information obtained from the patient, the demographic sheets and questionnaires/surveys, was stored in locked cabinets in the clinics while the project was being completed over the two-month span of time. The files were only accessed by the capstone project manager and clinic manager for each clinic.

Measurement Instruments

In order to measure the outcomes of this capstone project, two existing instruments were used to measure the data. The two instruments, the Revised Fibromyalgia Impact Questionnaire (FIQR) and the SF- 36 short survey, were administered. The 1991 version of the Fibromyalgia Impact Questionnaire (FIQ) used a visual analog scale (VAS) that required patients to slash a

100-mm line and was scored with a ruler. The scoring was further complicated by the need to reverse scores in one question and the use of constants to convert the first 13 questions to a standardized scale of 0 to 10 (Bennett et al., 2009). The higher scores indicate greater impact of fibromyalgia on normal daily functioning on the FIQ. The more current 2009 FIQR instrument measures physical functioning, work status (missed days off from work), depression, anxiety, morning tiredness, pain, stiffness, fatigue and well-being (Fibromyalgia Impact Questionnaire (FIQ), 2018). This version consists of 21 items across the 3 domains of Function (n = 9), Overall Impact (n = 2), and Symptoms (n = 10). According to the American College of Rheumatology, the reliability of this tool was established with test-retest significant correlations using Pearson's *r* ranging from 0.56 (pain) to 0.95 for physical function scale in the original version of the FIQ (Fibromyalgia Impact Questionnaire (FIQ), 2018). Regarding validity, the FIQR appeared to be a relatively useful measure of disease impact in patients with fibromyalgia. Each of the three FIQR domains was highly correlated with the total FIQR score and predicted unique variance in SF-36 domains, providing good evidence for discriminant validity (Bennett et al., 2009). The FIQR is an updated version of the FIQ that has good psychometric properties, can be completed in less than 2 minutes and is easy to score (Bennett et al., 2009). Regarding the scoring of the FIQR, the higher the score, the symptoms are worse for a decreased quality of life.

The SF- 36 short survey is a set of coherent, generic and easy to administer quality of life measures. It is based on what the patient self-reports about quality of life. The SF-36 health survey is the most commonly used health-related quality of life (HR-QOL) measure. It was developed as a short-form measure of functioning and well-being in the Medical Outcomes Study (Rand Health Survey, 2018). Reliability for the SF-36 short form survey significant coefficients ranged from a low of 0.65 to a high of 0.94 across scales (median = 0.85) and varied

somewhat across patient subgroups. Regarding the scoring of the SF- 36 tool, the higher the SF-36 score, the better the fibromyalgia symptoms and higher quality of life.

Both the SF-36 short survey and FIQR questionnaire were available for free to use by any investigator as indicated on the respective websites. Both measurement scales have been used in multiple studies to determine the quality of life for participants with chronic conditions.

The demographic sheet, as seen in Appendix E**,** included questions related to the patient's race, the year diagnosed with fibromyalgia, current medications, and what medications have been used in the past for the fibromyalgia as well as different therapies that may have used to ease the pain. The demographic sheet assessed the participant's current employment status, what non-medical interventions were used for fibromyalgia symptoms and if the participant was currently experiencing any "flare-ups" of fibromyalgia that may be affecting the quality of life at the time the demographic sheet was completed.

Data Collection Procedure

This exploratory, pilot project consisted of recruitment of participants who were currently on pregabalin and gabapentin from three midwestern pain clinics. Pre-intervention consisted of determining how many patients were seen with the diagnosis of fibromyalgia and fit the criteria for the capstone project. The clinic manager identified fibromyalgia patients to determine any potential participants for the project. A flyer regarding the project was posted in the clinic to inform potential participants about the project. The participant was given a packet of information in an envelope containing the questionnaire, survey and demographic sheet from the clinic manager. If the participant agreed to take part in the project, then the participant was asked to read the cover letter regarding the project as well as the consent statement included in the packet. The intervention consisted of having the patient fill out the demographic sheet and take both the

FIQR questionnaire and SF-36 short survey after their appointment with the health care provider. Time allotted for each participant was up to 30 minutes. The participant placed the completed demographic sheet, survey and questionnaire back into the packet and returned it back to the clinic manager. The data were entered into the data entry program, SPSS, for analysis by the capstone project manager. A timeline of the events for this project is outlined in Appendix F.

Ethical Considerations/Protection of Human Subjects

The Nebraska Methodist College Institutional Review Board (IRB) approval was obtained prior to initiating the capstone project. All records were kept confidential to the extent permitted by law according to the Nebraska Methodist College (NMC) IRB policies. An identification code was used for all data collected on the questionnaire, demographic sheet and survey. Data obtained from the project was kept in a locked file cabinet or password protected computer file in which the capstone project manager had access. Data will be kept a minimum of 3 years before being destroyed properly and safely. Following completion of the project, the capstone project manager shredded all paper questionnaires, demographic sheets and surveys to maintain confidentiality and privacy. Access to this information and data was only allowed by the capstone project manager and office manager in the clinic. Any information will be released with permission from participants only or as required by the NMC IRB policy. Regarding conflict of interest, the capstone project manager is in no way affiliated with any of the pain clinics, drug companies, or research studies that would influence the outcome of this exploratory project. This was an Evidence-Based Practice project (EBP) with an exempt status due to risks being minimal for each participant that is involved in the project. There was no cost associated to any participate in the project, and the participant was not paid for being in the project. The

participation for each person was voluntary and the person could withdraw from the project at any time. There was no known risk to participants with participation in the project.

Data Analysis

Post assessment, the first step consisted of scoring each tool that each participant completed. Next, the data was analyzed with the data entry program, SPSS. The project methodology and clinical questions were discussed with the capstone statistician to determine the best method to analyze the data. It was determined that a Mann Whitney U and an independent t-test as inferential statistics were applicable to the identification which medication, gabapentin or pregabalin, has a greater impact on the quality of life for the fibromyalgia patient. The results of the FIQR and SF-36 were examined and compared with the medication regimen as well as in aggregate to identify trends on how pain management impacted the quality of life. The demographic information was analyzed using descriptive statistics. Correlations between strategic demographic information and scores from the SF- 36 and FIQR questionnaire were run using the Pearson *r* test in order to identify major factors that could contribute to the overall improvement of the quality of life for the fibromyalgia patient.

Results

A total of 25 participants were included in the capstone project. Tables 1-5 present demographic data for study participants. Descriptive statistics with frequencies were run and the average participant with fibromyalgia had a mean age of 54 years, was employed full time and had been diagnosed with fibromyalgia for 10.2 years. The number of hours of those who worked had a mean of 13.12, *SD* 17.74 with most working during the daytime hours (32%). Sixteen participants (64%) were taking gabapentin and nine (36%) were taking pregabalin as medications. Other medications (in addition to either gabapentin or pregabalin) listed by the

participants were: Savella, Cymbalta, Nubain and Tylenol. The non-medical interventions that were chosen by the 25 participants were the following: four individuals chose no therapies (16%), three chose trigger point injections (12%), four chose other therapies (16%) but did not list them, three chose water therapy and trigger injections (12%) and two chose water therapy and other therapies but did not list the therapies (8%). When asked the numerical goal for pain relief, the following were the results: the range of the pain goal was 0-8 with a mean of 3.28, *SD* 2.4. Twenty-two percent of the participants were currently experiencing a flare up of the fibromyalgia that was affecting their quality of life. Eight percent stated that the fibromyalgia affected working, 4% stated that fibromyalgia affected physical functioning, 4% stated that fibromyalgia affected their sleep, 4% stated that both sleep and physical functioning were affected by their fibromyalgia, 20% stated that activities of daily living and physical functioning were affected, 24% stated that fibromyalgia affected all three categories of ADLs, sleep and their physical functioning combined, 4% stated working, physical functioning and ADLS were affected by fibromyalgia and 20% stated that all activities were affected by fibromyalgia.

Table 1

Descriptive statistics data for age in years

	N	Minimum	Maximum	Mean	Std. Deviation
Age in years	25	33.00	73.00	54.3600	10.61006
Valid N (listwise)	25				

Table 2

Frequency data for current employment status

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	employed	10	40.0	40.0	40.0
	unemployed	2	8.0	8.0	48.0
	disability	9	36.0	36.0	84.0
	retired	4	16.0	16.0	100.0
	Total	25	100.0	100.0	

Table 3

Descriptive statistics data for hours per week worked

	N	Minimum	Maximum	Mean	Std. Deviation
Hours per week working if employed	25	.00	40.00	13.1200	17.74899
Valid N (listwise)	25				

Table 4

Frequency data for actual medication taking

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Gabapentin	16	64.0	64.0	64.0
	Pregabalin	9	36.0	36.0	100.0
	Total	25	100.0	100.0	

Table 5

Frequency data for numerical goal for pain

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	.00	5	20.0	20.0	20.0
	1.00	1	4.0	4.0	24.0
	2.00	3	12.0	12.0	36.0
	3.00	4	16.0	16.0	52.0
	4.00	6	24.0	24.0	76.0
	5.00	2	8.0	8.0	84.0
	6.00	1	4.0	4.0	88.0
	7.00	1	4.0	4.0	92.0
	8.00	2	8.0	8.0	100.0
	Total	25	100.0	100.0	

In order to identify major demographic factors that could impact the participant's quality of life, correlations were run between continuous demographic variables and the scores from the two instruments, FIQR and SF-36. Tables 6, 7 & 8 show statistical significance between several factors and quality of life designated by FIQR and SF-36 scores. The FIQR significant correlational results were: hours per week working if employed and total FIQR (r = -.557, p=.004) and hours per week working if employed and activity subscale of FIQR (r= -.746, p=.000). Since the results were statistically significant with hours worked per week and their activity level, it could be interpreted that poor functioning activity level was associated with less hours worked by participants in the project.

The SF-36 significant correlational results were: age in years and general health (r=.537, p=.006); hours working if employed and role limits with physical health (r=.457, p=.022); and hours working and physical functioning (r=.586, p=.002). There was a significant correlation

between age and general health, meaning the higher the age, the better health the participant may have felt when participating in the project. Significant correlations resulted with hours the participant worked and their role limits with their physical health and physical functioning. This could be interpreted that the more hours the participant worked, the better physical health and physical functioning they were in at the time of the project.

Other variables on the FIQR and SF-36 were compared to demographic information provided by each individual participant. Data were run with correlations between the demographic information and each scoring tool. No further significant correlations were found between the remaining variables.

Table 6

Correlations between age in years and general health

		Age in years	General health
Age in years	Pearson Correlation	1	.537**
	Sig. (2-tailed)		.006
	N	25	25
General health	Pearson Correlation	.537**	1
	Sig. (2-tailed)	.006	
	N	25	25

**. Correlation is significant at the 0.01 level (2-tailed).

Table 7

Correlations between hours per week and role limits due to physical functioning

		Hours per week working if employed	Role limits d/t physical health
Hours per week working if employed	Pearson Correlation	1	.457*
	Sig. (2-tailed)		.022
	N	25	25
Role limits d/t physical health	Pearson Correlation	.457*	1
	Sig. (2-tailed)	.022	
	N	25	25

*. Correlation is significant at the 0.05 level (2-tailed).

Table 8

Correlations of hours per week worked and physical functioning

		Hours per week working if employed	Physical functioning
Hours per week working if employed	Pearson Correlation	1	.586**
	Sig. (2-tailed)		.002
	N	25	25
Physical functioning	Pearson Correlation	.586**	1
	Sig. (2-tailed)	.002	
	N	25	25

**. Correlation is significant at the 0.01 level (2-tailed).

To answer the second major aim, to identify which medication, gabapentin or pregabalin, had a greater impact on the quality of life for the fibromyalgia patient, Mann Whitney U and independent t-tests were performed between the two groups but were found to have non-significant results. There was a difference between groups with the raw data. The scores of the

two groups on each of the instruments did demonstrate a trend that the pregabalin group had higher functioning scores compared to the gabapentin group. The tables of these results are demonstrated in Tables 9 and 10.

Table 9

FIQR quality of life functioning scores

Group Statistics

	Medication currently taking	N	Mean	Std. Deviation	Std. Error Mean
Activity level subtotal	Gabapentin	16	51.1875	20.90684	5.22671
	Pregabalin	9	45.7778	22.56534	7.52178
Activity level adjusted	Gabapentin	16	17.0613	6.96929	1.74232
	Pregabalin	9	15.2567	7.52068	2.50689
Overall Impact subtotal	Gabapentin	16	12.3750	5.08429	1.27107
	Pregabalin	9	9.8889	6.19363	2.06454
Overall impact adjusted	Gabapentin	16	12.3750	5.08429	1.27107
	Pregabalin	9	9.8889	6.19363	2.06454
Intensity of symptoms subtotal	Gabapentin	16	65.0625	16.51048	4.12762
	Pregabalin	9	55.8889	22.79498	7.59833
Intensity of symptoms adjusted	Gabapentin	16	32.5313	8.25524	2.06381
	Pregabalin	9	27.9444	11.39749	3.79916
Total adjusted final score	Gabapentin	16	64.4988	19.79435	4.94859
	Pregabalin	9	53.0900	22.65492	7.55164

Table 10

SF-36 quality of life functioning scores

Group Statistics

	Medication currently taking	N	Mean	Std. Deviation	Std. Error Mean
Physical functioning	Gabapentin	16	33.0550	14.67316	3.66829
	Pregabalin	9	33.3333	21.65064	7.21688
Role limits d/t physical health	Gabapentin	16	.0000	.00000	.00000
	Pregabalin	9	22.2222	34.10564	11.36855
Role limits d/t emotional problems	Gabapentin	16	18.7281	29.72467	7.43117
	Pregabalin	9	37.0367	48.43224	16.14408
Energy/fatigue	Gabapentin	16	25.0000	20.73644	5.18411
	Pregabalin	9	28.3333	24.23840	8.07947
Emotional well-being	Gabapentin	16	45.2500	19.47135	4.86784
	Pregabalin	9	57.7778	21.17651	7.05884
Social functioning	Gabapentin	16	35.1563	25.09098	6.27275
	Pregabalin	9	44.4444	27.32266	9.10755
Pain	Gabapentin	16	23.4375	14.71606	3.67902
	Pregabalin	9	32.1111	22.27075	7.42358
General health	Gabapentin	16	30.0000	17.79513	4.44878
	Pregabalin	9	40.0000	16.00781	5.33594

Discussion

The first outcome was to determine possible factors that could contribute to improving quality of life in the fibromyalgia patient. Fibromyalgia causes various degrees of disability, pain and inability to work or engage in everyday activities as well as relationships (Martin et al., 2014). With the FIQR scoring, the demographic variable of hours worked and activity level designated by the FIQR were statistically significant. It was determined that with an increased FIQR score (poor functioning activity level), there was an association with less hours worked by the participants. With regard to the SF-36 scoring in general health, physical health and physical functioning, there was a statistically significant association with the age and hours worked. Within the chronic pain world, fibromyalgia affects quality of life as well as causes disability to many individuals worldwide. Fibromyalgia patients have often experienced reduced overall quality of life because of severe functional limitations and the inability to adequately perform routine tasks (Boulanger et al., 2012). Therefore, it could be assumed that the older the participant, and the more hours they worked, the better general health, physical health and physical functioning.

The second outcome was to determine which medication had a better impact on the quality of life. The Mann Whitney and independent t-test were both run and results were found to be non-significant between the two groups, those taking gabapentin and those taking pregabalin. When scoring the instruments, it was found that that the lower the SF- 36 scores, the worse the fibromyalgia symptoms. With regard to the FIQR, the higher the scores, the symptoms are worse for the decreased quality of life. Even though the inferential statistics were non-significant, those participants that took pregabalin had lower FIQR scores and higher SF-36 scores compared to participants who took gabapentin. Results suggest with this trend that

individuals taking the pregabalin medication had a better quality of life and symptoms were better on this particular medication. With pregabalin, the higher the SF- 36 scores the better the fibromyalgia symptoms while using pregabalin versus gabapentin. Results from the Derry et al., (2016) study, reaffirms that those taking pregabalin at daily doses of 300 to 600 mg demonstrated a large decline in pain. This pain reduction came with improvement of quality of life, symptoms and the ability to increase function. These findings could be associated with the physical well-being component of the integrated model of quality of life as defined by Kellie-Gillespie (2012). The physical well-being component further describes the health-related quality of life factors such as health status or physical functioning. In this project and in the study by Derry et al. (2016), pregabalin was shown to be more effective with controlling symptoms as well as improving an individual's quality of life.

Limitations

Limitations for this study include the lengthy amount of time to fill out the packet by the participants, a small sample size, patients were self-selected and some patients with fibromyalgia were unable to participate based on prescribed medications. External validity and generalizability of the project results could have been affected by the convenience sample, located from each of the Midwestern clinics.

The internal validity of the study could have been compromised due to the participants being on other medications and therapies, as well as prescribed the study medication of either pregabalin or gabapentin. As previously stated, the reliability of the FIQR questionnaire tool was established with test-retest significant correlations using Pearson's *r* ranging from 0.56 (pain) to 0.95 for physical function scale in the original version of the FIQ (Fibromyalgia Impact Questionnaire (FIQ), 2018). Regarding validity, the FIQR appears to be a relatively useful

measure of disease impact in patients with fibromyalgia. Each of the three FIQR domains was highly correlated with the total FIQR score and predicted unique variance in SF-36 domains, providing good evidence for discriminant validity (Bennett et al., 2009). Reliability for the SF-36 short form survey demonstrated significant coefficients ranging from a low of 0.65 to a high of 0.94 across scales (median = 0.85) and varied somewhat across patient subgroups. Despite the established validity and reliability of these instruments, there could have been confounding variables in this project that may have hampered the effectiveness of answering the clinical questions using the FIQR and SF-36.

Plan for Sustainability

The project results will be shared with the clinic personnel by the capstone project manager. The study may be continued in the clinics if successful and overseen by the clinic manager with appropriate IRB approval. The study tools can be found online for free to help with recruiting other fibromyalgia patients to collect additional data and increase the sample size. The clinic manager will be well informed about the project methodology and results so the capstone project manager as well as the clinic manager can educate the staff regarding what possible factors contribute to the overall improvement of the quality of life for the fibromyalgia patient. Cooperation of the clinic manager as well as the physicians in the chosen pain clinics will help to motivate the continued education and continuation of this project. The mentor investigator may be in contact with additional fibromyalgia patients in these clinics for future projects regarding quality of life.

Implications for Practice

This capstone project is important for nursing practice as a health care practitioner. It is important to determine the correct pain regimen for fibromyalgia patients in relation to their symptoms and quality of life. Judging by trends in FIQR and SF- 36 scores, pregabalin may have had a positive impact on quality of life. For the majority of FM patients, diagnosis and treatment takes place in primary care, therefore non-specialist physicians must have the necessary tools and training to recognize symptoms and feel confident in prescribing medications. This project will help the provider-patient relationship in order to develop a correct treatment plan for the fibromyalgia symptoms and to increase the patient's quality of life. Therefore, there needs to be more studies with more participants to look at treatment options such as pregabalin and gabapentin for patients with fibromyalgia.

Conclusion

There was no significant difference between gabapentin and pregabalin on the quality of life with an independent t test and Mann Whitney test. There was a trend that the pregabalin group had higher functioning score compared to the gabapentin group. Factors that contributed to overall quality of life were age and the number of hours of work.

Fibromyalgia continues to impact patient's quality of life daily. As a future nurse practitioner, knowing what factors affects the FM patient's daily regimen regarding pain management and activities of daily living, can help to improve healthcare. This capstone project could shed light about future endeavors that need to be investigated regarding fibromyalgia. This project could determine which medication, gabapentin or pregabalin, would benefit the patient's quality of life in the future. With this knowledge and continuing projects on fibromyalgia, there may be a light at the end of this dark tunnel concerning this condition.

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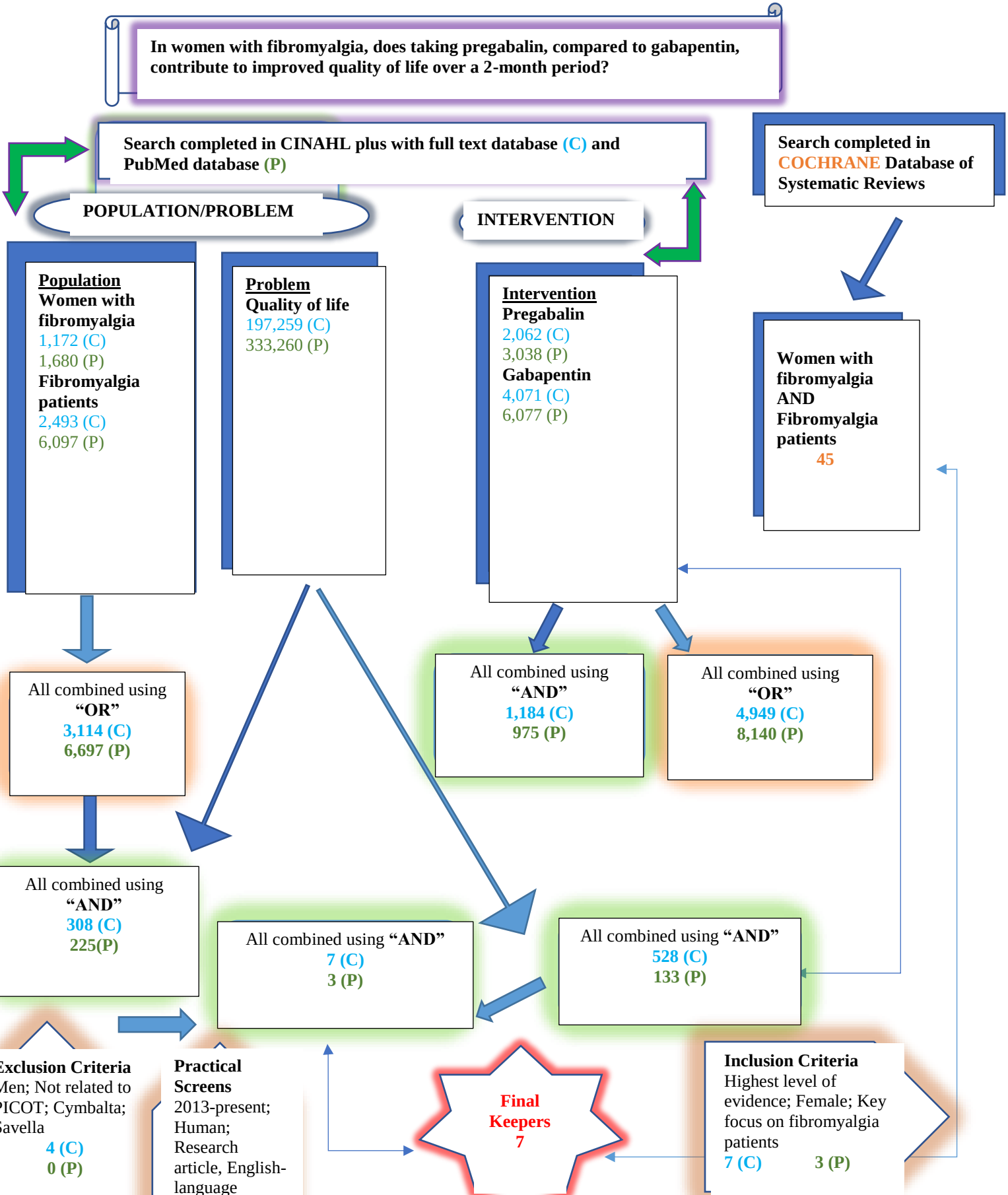
Appendix A

Search Trail

Appendix A


In women with fibromyalgia, does taking pregabalin, compared to gabapentin, contribute to improved quality of life over a 2-month period?
Search completed in CINAHL plus with full text database (C) and PubMed database (P)
Search completed in COCHRANE Database of Systematic Reviews
POPULATION/PROBLEM
INTERVENTION
Population
Women with fibromyalgia
1,172 (C)
1,680 (P)
Fibromyalgia patients
2,493 (C)
6,097 (P)
Problem
Quality of life
197,259 (C)
333,260 (P)
Intervention
Pregabalin
2,062 (C)
3,038 (P)
Gabapentin
4,071 (C)
6,077 (P)
Women with fibromyalgia AND Fibromyalgia patients
45
All combined using "OR"
3,114 (C)
6,697 (P)
All combined using "AND"
1,184 (C)
975 (P)
All combined using "OR"
4,949 (C)
8,140 (P)
All combined using "AND"
308 (C)
225(P)
All combined using "AND"
7 (C)
3 (P)
All combined using "AND"
528 (C)
133 (P)
Exclusion Criteria
Men; Not related to PICOT; Cymbalta; Savella
4 (C)
0 (P)
Practical Screens
2013-present; Human; Research article, English-language
Final Keepers
7
Inclusion Criteria
Highest level of evidence; Female; Key focus on fibromyalgia patients
7 (C)
3 (P)

Appendix B

Reference Matrix

	Appendix B				
Citation/Level of Evidence	**Participants/Setting/ Sample Size**	**Purpose/Background**	**Methods/Design & Limitations**	**Findings/Summary Strengths/Weaknesses**	**Applicability to Own Research**
Ramzy, E. A. (2017). Comparative efficacy of newer antidepressants in combination with pregabalin for fibromyalgia syndrome: A controlled, randomized study. *Pain Practice*, *17*(1), 32-40. doi:10.1111/papr.12409 **Level of evidence:** **Level II**: not a systematic review, but analyzes controlled, randomized trials, double blinded, prospective study	Subjects included 75 adult women (aged 18 and older but < 70 years of age) that were diagnosed with fibromyalgia according to the 2010 criteria. Patients were screened by physicians in a pain clinic of the Dept. of Anesthesia and the SICU at Main Mansoura University hospital in Mansoura, Egypt.	To hypothesize that the combined use of pregabalin plus paroxetine would result in comparable Somatic Symptoms Scale-8 (SSS-8) and Center for Epidemiological Studies Depression Scale (CESDS) scores, as well as higher medication tolerability than the combined use of pregabalin with either amitriptyline or venlafaxine. Long-term efficacy, tolerability, and safety of the concomitant use of pregabalin with amitriptyline, venlafaxine, or paroxetine has not been previously studied with fibromyalgia patients.	All patients were assessed bimonthly for 6 consecutive months for changes in SSS-8 and CESDS scores, life satisfaction, mood, sleep quality, fatigue, medication tolerability, and adverse events. Exclusion criteria included patients with cancer, acute systemic inflammatory diseases, acute and chronic infections (ex. human immunodeficiency virus, viral hepatitis, and active tuberculosis), pregnancy, and breastfeeding.	This study showed that the combined use of pregabalin plus paroxetine vs. amitriptyline or venlafaxine resulted in significantly lower SSS-8 and depression scale scores; higher medication tolerability; better life satisfaction, mood, and sleep quality. The combined use of pregabalin and paroxetine offers an effective method to reduce the somatic symptoms and depression of fibromyalgia, while improving the quality of life and medication tolerability in affected patients and reducing the frequency of adverse events. The study also showed tolerability and	This article supports my research because it shows comparison of other medications (particularly paroxetine) for fibromyalgia other than gabapentin. It also shows how these particular drugs can potentially enhance the quality of life for the patient.

			Additional exclusion criteria included psychiatric comorbidity (except for minor depressive disorder), suicidal thoughts, receipt of antidepressants not administered during the course of this study, and substance or alcohol abuse within the last 3 months. <u>Limitation:</u> Only used the 2010 ACR guidelines for diagnostic criteria instead of combining with original 1990 criteria. The modified 2010 ACR criteria provide a more sensitive and global assessment of fibromyalgia, but they are purely subjective and lack evaluation of objective tender points symptoms.	efficacy of paroxetine in improving overall symptoms of fibromyalgia even in patients without concurrent mood or anxiety disorders. <u>Weakness</u> The study was not suitably powered to evaluate Venlafaxine tolerability. Amitriptyline was most cost effective but the lowest in tolerability and produced the most side effects.	

Tzellos, T., Toulis, K., Goulis, D., Papazisis, G., Zampeli, V., Vakfari, A., & Kouvelas, D. (2010). Gabapentin and pregabalin in the treatment of fibromyalgia: A systematic review and a meta-analysis. *Journal of Clinical Pharmacy & Therapeutics*, *35*(6), 639-656. doi:10.1111/j.1365-2710.2009.01144.x **Level of evidence**: **Level I:** Systematic review of randomized control double blind trials with meta- analysis	The search strategy identified 48 publications. Four articles were chosen after exclusion criteria out of the 48 articles. Finally, four randomized, double-blinded, placebo-controlled studies were included in the systematic review, one studying Gabapentin (GP) and three studying Pregabalin (PB). The three studying pregabalin were also included in the meta-analysis.	The article aimed to estimate the efficacy and safety/tolerability of gabapentin and pregabalin in fibromyalgia through a systematic review and a meta-analysis of relevant randomized double-blind placebo-controlled (RCT) trials.	A literature search was conducted through MEDLINE, EMBASE, Cochrane CENTRAL and the reference lists of relevant studies. Preliminary search was in MEDLINE using various combinations of the terms 'FBM' , 'fibrositis', 'gabapentin' and 'pregabalin' was conducted. All three studies on pregabalin applied the Hochberg procedure, a modification of the Bonferroni correction for multiple comparisons, to confine type I error rate to 5%. <u>Inclusion criteria:</u> Articles that included the efficacy of GP or PB to placebo in	PB at a dose of 600, 450 and 300 mg per day is effective in fibromyalgia compared to placebo (NNT: 7, upper 95% CI: 12, 450 mg). Data on GP is limited. A number of adverse events (AE), such as dizziness, somnolence, dry mouth, weight gain, peripheral edema, is consistently associated with treatment at any dose and could lead one out of four patients to quit treatment (NNH: 6, lower 95% CI: 4, 600 mg). Gabapentin significantly improved primary outcomes like BPI-SF average pain severity score and BPI-SF average pain severity score response rates.	This article is beneficial to my research due to the fact it compared both items of my PICOT, gabapentin and pregabalin in regard to the efficacy of fibromyalgia symptoms. The only issue is that no research in regard to comparing both medications in a clinical study have not been performed since 2010. This article indicates the need for future studies with larger sample size and perhaps higher dosages for GP that could assist in confirming its efficacy in fibromyalgia.

			the treatment of FBM in women and men > or equal to 18 years old, regardless of the dosage or duration of treatment. Exclusion criteria: Trials were excluded from the meta-analysis, if uncontrolled and/or open-label. Reviews, case series, letters to the editor, observational studies and experimental preclinical studies were not eligible. Patients with comorbid psychiatric, rheumatologic and other painful musculoskeletal disorders were excluded from all trials. Limitations: All studies examined only the short-term		

			efficacy of PB and GP. Patients refractory to treatment, were excluded. Only one study was found examining GP in the treatment of fibromyalgia. Evaluation of efficacy by means of a meta-analysis was only possible through the pooling of available data (responders to treatment and dropouts due to lack of efficacy), which may have resulted in an underestimation of efficacy for both medications. Lastly, a comparison of PB & GP was not easily performed, since there was no study directly comparing them that has been done in the past.		

Skaer, T. (2014). Fibromyalgia: Disease Synopsis, Medication Cost Effectiveness and Economic Burden. *Pharmacoeconomics*, *32*(5), 457-466. **Level of evidence:** **Level V:** Systematic reviews of descriptive and qualitative studies	All fibromyalgia patients in the United States and Europe regarding the significant cost burden due to ineffective management of medications that can be used for fibromyalgia.	To briefly summarize how FM is managed, including what medications are the most cost effective, and to provide insight into FM's impact on the health care system, workplace and, most importantly, the individual patients themselves.	For medication effectiveness, the article describes cost effective analysis on fibromyalgia pharmacotherapies using different articles with usage of the Fibromyalgia Impact Questionnaire [FIQ] score, the Patient Global Impression of Change (PGIC) rating, and quality adjusted life-years was also calculated in the study conducted in the UK. A Markov model to evaluate the economic and clinical advantages of duloxetine in managing FM symptoms over a 2-year period was used in the USA.	The overall financial burden of FM around the globe is significant and can cost society tens of thousands of dollars per patient. The article further explains that fibromyalgia patients are unemployed and disabled, and they experience losses in HRQOL, functioning and productivity, as well as rising out-of-pocket expenses for household help and informal care. <u>Weakness:</u> Does not specifically narrow down which particular meds are effective and/or cost effective.	With fibromyalgia patients, this article can help shed light with my research on the increased burden of cost for the patient in regard to symptoms that can be disabling and cost effectiveness of certain medications to help with fibromyalgia symptoms.

Citation/Level of Evidence	Participants/Setting/ Sample Size	Purpose/Background	Methods/Design & Limitations	Findings/Summary Strengths/Weaknesses	Applicability to Own Research
Robinson, R. L., Kroenke, K., Williams, D. A., Mease, P., Chen, Y., Faries, D., & ... McCarberg, B. (2013). Longitudinal observation of treatment patterns and outcomes for patients with fibromyalgia: 12-month findings from the reflections study. *Pain Medicine, 14*(9), 1400-1415. doi:10.1111/pme.12168 **Level of evidence:** **Level II:** Prospective 12-month observational study	Study participants were enrolled from 58 health care settings (including 91 participating physicians) in the United States and Puerto Rico. Study sites included outpatient practices in rheumatology, primary care, neurology, psychiatry, pain specialists, physical medicine, obstetrics & gynecology, and osteopathy. A total of 2,115 patients were recruited into the study. Data from 1,700 patients were collected at baseline and 1, 3, 6, and 12 months. Of the baseline patients, 1,205 (70.9%) completed the 12-month assessment, and 1,073 (63.1%) completed all of the assessments.	To describe 12-month treatment patterns and outcomes for patients starting a new medication for fibromyalgia in routine clinical practice. This observational study, which we identified as the REFLECTIONS (Real World Examination of Fibromyalgia: Longitudinal Evaluation of Costs and Treatments) study was designed to prospectively evaluate long-term treatment patterns, health outcomes, and economic outcomes in actual clinical practice among patients who were newly prescribed a medication for FM and followed for 12 months.	Data were collected using a physician survey, a patient visit form, and computer-assisted telephone interviews (CATI). Repeated measures and Poisson regression models controlling for demographic, clinical, and baseline outcomes were used to assess changes in health outcomes (Brief Pain Inventory severity and interference, Sheehan Disability Scale, Fibromyalgia Impact Questionnaire), satisfaction, and economic factors. Sensitivity analyses were run using propensity-matched cohorts.	75% of patients in this study took two or more medications for fibromyalgia at different points in the study. Overall, patients showed improvement on the four health outcomes, with few differences across medication cohorts. The duloxetine and milnacipran (vs pregabalin or tricyclic antidepressant) cohorts had fewer outpatient visits during the 12-month study. Patients reported satisfaction with overall treatment and their fibromyalgia medication (46.0% and 42.8%, respectively. <u>Weaknesses:</u> The study was not designed to assess comparative effectiveness of specific medications. Patients were not randomized to medication cohorts;	This article is beneficial to my research because it describes how medications for fibromyalgia were introduced to participants over a 12-month period but had a high rate of drug discontinuation because there was minimal satisfaction with the new medications introduced to them. More research is needed to narrow down specific medications in order to effectively treat the fibromyalgia patient.

	Of the overall sample (N = 1,700), 678 patients were divided into each of the following four cohorts based on the type of drug initiated at baseline: pregabalin (214/ 1,700, 12.6%), duloxetine (264/1,700, 15.5%), milnacipran (134/1,700, 7.9%), and TCAs (66/1,700, 3.9%).		The CATI included the outcome measures of BPI, SDS, and FIQ, as well as economic outcome measures. Measures that were included in the CATI and were used to control for differences across patient cohorts included the Patient Health Questionnaire (PHQ)–15, the Generalized Anxiety Disorder (GAD)–7 measure, he Insomnia Severity Index (ISI), and the Massachusetts General Hospital Cognitive and Physical Functioning Questionnaire (MGH-CPFQ).	thus, selection bias remained an issue. Small sample sizes, especially for the milnacipran and TCA groups, limited the statistical power for cohort comparison. Lastly, medication cohorts were based on the newly initiated medication.	

Derry, S., Cording, M., Wiffen, P. J., Law, S., Phillips, T., & Moore, R. A. (2016). Pregabalin for pain in fibromyalgia in adults. *The Cochrane Database of Systematic Reviews*, *9*CD011790. doi:10.1002/14651858.CD011790.pub2 **Level of evidence:** **Level I:** Systematic review of randomized control double blind trials, Level I	Studies included adult participants aged 18 years and above, with pain due to fibromyalgia, diagnosed using the 1990 or 2010 criteria. The majority of participants were women (89% to 95%) and white (76% to 96%), and the mean age was 47 to 50 years. All participants had fibromyalgia diagnosed according to the American College of Rheumatology (ACR) 1990 criteria Eight studies satisfied the inclusion criteria, including three new studies for this update. Five studies randomized 3283 participants to immediate treatment with pregabalin or placebo. Two studies identified 687 out of 1492 participants who had a good pain response and could take the medicine, and then randomized them to continued treatment	To assess the analgesic efficacy and adverse events of pregabalin for pain in fibromyalgia in adults, compared with placebo or any active comparator. This review was an update of one article originally published in 2009, which examined the effects of pregabalin on all types of pain. In this review the authors only examined fibromyalgia pain.	Searches were done in Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, and EMBASE for randomized controlled trials from inception to May 2009 for the original review and to 16 March 2016 for this update.	High quality evidence was found that pregabalin at daily doses of 300 to 600 mg produces a large decline in pain for about 1 in 10 people with moderate or severe pain from fibromyalgia. Pain reduction comes with improvements in other symptoms, in quality of life, and inability to function. Side effects occurred in 8 or 9 people out of 10, often while adjusting to the medicine. Particular side effects were dizziness (affecting 1 in 4 participants), drowsiness (1 in 7), weight gain (1 in 18), and peripheral edema (1 in 19) (high quality evidence). About 1 in 10 more participants taking pregabalin withdrew from the study because of side effects, and 1 in 17 fewer withdrew because the medicine was not working.	This article helps to support my research because it was inconclusive whether pregabalin was the best choice for pain management and quality of life for the fibromyalgia patient even though the study sample was large. Many patients taking pregabalin experience side effects that are bothersome.

	with pregabalin or placebo.				
Cooper, T. E. (2018). Gabapentin for fibromyalgia pain in adults. *Cochrane Database of Systematic Reviews*, (3), doi:10.1002/14651858.CD012188.pub2 **Level of evidence:** **Level I:** Systematic review of randomized control double blind trials	The one included study of 150 participants was a 12-week, multi-centre, randomized, double-blind, placebo-controlled, parallel-group study using last-observation-carried-forward imputation for withdrawals. The maximum dose of gabapentin was 2400 mg daily. Studies included participants aged 18 years and above, with fibromyalgia diagnosed using the 1990 or 2010 criteria and with initial pain of at least moderate intensity.	To assess the analgesic efficacy of gabapentin for fibromyalgia pain in adults and the adverse events associated with its use in clinical trials. This review replaced part of an earlier review that evaluated gabapentin for both neuropathic pain and fibromyalgia, now split into separate reviews for the two conditions. This review discusses pain in fibromyalgia patients only.	Searches were done with the Cochrane Central Register of Controlled Trials (CENTRAL) via the Cochrane Register of Studies Online, MEDLINE via Ovid and Embase via Ovid from inception to 24 May 2016. Assessment of the evidence was done with GRADE (Grading of Recommendations Assessment, Development and Evaluation).	Two studies tested gabapentin to treat fibromyalgia pain. One was identified in previous versions of the review. Another study was a conference abstract, with insufficient detail to determine eligibility for inclusion. At the end of the trial, the outcome of 50% reduction in pain over baseline was not reported. The outcome of 30% or greater reduction in pain over baseline was achieved by 38/75 participants (49%) with gabapentin	This article further explains that there is no clear evidence to support that gabapentin in the dose of 1200 to 2400 could reduce pain in the fibromyalgia patient. Knowing this information, my PICOT question will need further research in order to determine if gabapentin or pregabalin should be a choice when helping to improve the quality of life for a patient

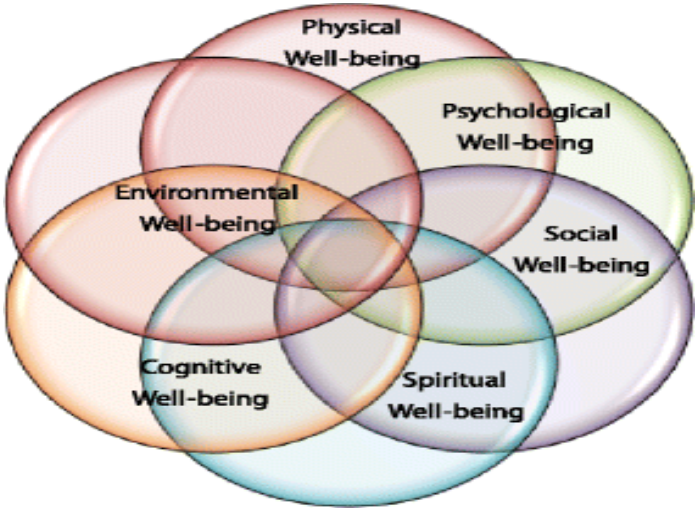
		This new review assesses evidence in ways that make both statistical and clinical sense, and uses developing criteria for what constitutes reliable evidence in chronic pain.		compared with 23/75 (31%) with placebo (very low quality). The quality of the evidence as very low because there was only a single small study with important study limitations	suffering with the diagnosis of fibromyalgia.
Liu, Y., Qian, C., & Yang, M. (2016). Treatment patterns associated with ACR-recommended medications in the management of fibromyalgia in the United States. *Journal of Managed Care and Specialty Pharmacy*, *22*(3), 263-271. https://doi.org/https://doi.org/10.18553/jmcp.2016.22.3.263 **Level of evidence:** **Level IV:** Cohort study (retrograde**)**	A total of 240,144 patients met the inclusion criteria. Medications of interest were pregabalin, gabapentin, duloxetine, milnacipran, cyclobenzaprine, and tramadol. Only 31% (n=74,738) of patients initiated a prescription medication of interest, per ACR guidelines (pregabalin, gabapentin, duloxetine, milnacipran, cyclobenzaprine, tramadol, amitriptyline,	Fibromyalgia (FM) affects up to 6% of U.S. adults, resulting in a significant burden on the health care system and poor quality of life for patients. Duloxetine, pregabalin, and milnacipran are approved for management of FM; however, consensus is lacking regarding optimal therapy. To assess treatment patterns associated with available and commonly used	Baseline characteristics were recorded using descriptive statistics. Proportion of days covered (PDC; defined as number of days in the period when the patient had drug supply divided by the number of days in the period) was used to define adherence; this ratio was multiplied by 100 to yield a percentage. This was used to define adherence, which was categorized as low (PDC <50%),	Most patients included in the analysis (69%) had CCI scores <1; 25% had CCI scores of 1-2; and 6% had CCI scores ≥3. Of those who started with ≥2 medications (n=3,819), cyclobenzaprine plus tramadol was the most frequent combination. Adherence was suboptimal for all 6 medications of interest. Among patients who discontinued their initial treatment of duloxetine, pregabalin,	This article helps to justify that the medications that are recommended for fibromyalgia by the FDA may not be suitable for all fibromyalgia patients. It also justifies that the drugs that are recommended are usually prescribed in lower than recommended dose due to side effects, efficacy and tolerability for the patient. This article further justifies there is a need for

	or venlafaxine) within a year after the index date.	medications for the management of FM using U.S. health insurance claims.	medium (PDC 50% to <80%), or high (PDC≥80%). The Charlson Comorbidity Index (CCI) was used to assess overall comorbidity burden.	or milnacipran, approximately one-third had switched treatments within 90 days after their first prescription.	standard treatment for the fibromyalgia patient in the future.

Appendix C

Graphic Image of Integrated Conceptual Framework

Appendix C



Kelley-Gillespie, N. (2012).

Appendix D

Letter of Permission to Capstone Clinical Project Sites

October 3, 2018

Dear _____,

My name is Jeanette Kennedy and I am a student in the Nebraska Methodist College Doctorate program. I will be graduating in August of 2019 and will need to conduct a final capstone project. I am interested in conducting a project in your pain clinic with fibromyalgia patients. This project would consist of analysis of patients in regard to their pain management as well as an assessment of their overall quality of life. The purpose of this project is to determine whether pregabalin or gabapentin effectively manages the symptoms of women with fibromyalgia in order to improve their quality of life on a daily basis within a 2-month period. This type of project can be important to the fibromyalgia patient in order to assess how different drugs prescribed may impact their quality of life as a whole. The FIQR questionnaire as well as the SF- 36 short survey will be used for this project to assess each participant's quality of life. I would like to meet with you to discuss my project more in depth. I appreciate your time and look forward to hearing from you in regard to performing my future project in your clinic.

Sincerely,

Jeanette Kennedy

Appendix E

Copy of Demographic Sheet

Date_____ Participant Code#_____

Demographic Questionnaire for Quality of Life Participants

Please fill in the blank or circle response were applicable:

1. Please tell me your age in years _____
2. Employment currently (as of today):
   a. Employed
   b. Unemployed
   c. Disability
   d. Retired
   e. Student
3. If you are employed, how many hours a week do you work? _____
   a. Do you work during the Day, Evening, or at Night?
4. Please specify the year that you were diagnosed with fibromyalgia by your health care provider_____
5. Are you currently taking any medications for your fibromyalgia diagnosis?(please circle)
   YES or NO

   a. If so, which medications are you taking: (please circle all that apply)
      Gabapentin (Neurontin)
      Pregabalin (Lyrica)
      Other, please specify_____
   b. What other non-medical interventions are you trying to treat you fibromyalgia pain?
      a. Water therapy or physical exercise
      b. Trigger point injections
      c. Cognitive behavior therapy
      d. Other, please specify_____
6. What is your numerical goal for pain relief? (0=no pain and 10=worse pain possible) _____
7. Are you currently experiencing a "flare up" of the fibromyalgia that is affecting your quality of life? (please circle) YES or NO
   a. Is your fibromyalgia affecting any of the following (circle all that apply):
      Working (ex: employment)
      Physical functioning (ex: shopping, housekeeping)
      Activities of daily living (ex: bathing, sleeping, eating)
      Sleep

Appendix F

Timeline

	September	October	November	December	January	February	March	April	May
Get permission from clinics to do project	X	X							
Finish Proposal and submit to DNP Committee (make necessary revisions)		X	X	X					
Submit final Proposal to NMC IRB board				X					
Implement project in two clinics after approval from IRB					X	X	X		
Collect data from clinics and analyze data (t-test, descriptive statistics)						X	X	X	X
Disseminate the data after analysis and approval								X	X