

A NURSE PRACTITIONER BEST PRACTICE PAPER:
LITERATURE SYNTHESIS OF NONPHARMACOLOGICAL AND PHARMACOLOGICAL
MANAGEMENT FOR PAIN IN PATIENTS WITH FIBROMYALGIA

by

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A CULMINATING PROJECT SUBMITTED IN PARTIAL FULFILLMENT OF THE
REQUIREMENTS FOR THE DEGREE OF

MASTER OF NURSING – NURSE PRACTITIONER

in

THE FACULTY OF GRADUATE AND POSTDOCTORAL STUDIES

(School of Nursing)

THE UNIVERSITY OF BRITISH COLUMBIA

Vancouver

April 2018

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Abstract

Fibromyalgia (FM) is a chronic, complex pain processing condition. Nurse Practitioners (NPs) play an important role in diagnosis and management of FM, as NPs, in primary care, are frequently the first healthcare providers to see patients with signs and symptoms of FM. However, FM can be difficult and challenging for novice NPs to interpret, diagnose and master. Surveys of patients with FM suggest that they would benefit from a greater understanding and acceptance of FM through education and support from their care providers (Clauw, 2014). NPs can provide this support and play a prominent role in helping patients manage their condition through continued education and being up-to-date on current FM managements and recommendations. To complete requirements for a culminating project, this literature review explored the current nonpharmacological and pharmacological interventions for patients living with FM. Findings drawn from this evidence based review was constructed into a pamphlet, providing information, tips, and recommendations for novice NPs to be equipped with the knowledge and resources when encountering patients with FM.

Keywords: Fibromyalgia, Nurse practitioner, nonpharmacological and pharmacological interventions

A Nurse Practitioner best practice paper: Literature synthesis for nonpharmacological and pharmacological management of Fibromyalgia.

Introduction

Fibromyalgia (FM) is a rheumatoid, musculoskeletal pain condition that affects 3% to 6% of the world's population; up to 2% of Canadians experience FM symptoms (Cohen & Emery, 2010); *NFA*, 2017; Statistic Canada, 2017). FM can be characterized by chronic, widespread pain with no visible trauma or symptoms, but has a variety of associated symptoms that can mimic other disorders (Marcus & Deodhar, 2011). For individuals experiencing signs and symptoms of FM, their first point of contact with the healthcare system is usually primary care providers (PCPs) including Nurse Practitioners (NPs). FM symptoms are frustrating not only for the patient but for their PCPs as well, as it is difficult to diagnose, leading to years of misdiagnosis, mismanagement and delayed diagnosis for the patient. With this demise, it is important for PCPs to be as knowledgeable as possible about FM and its many possible options for treatment and management (Perrot, Choy, Petersel, Ginovker & Kramer, 2012).

Due to the diverse nature of FM symptoms and an unclear pathophysiology, one treatment option does not fit all. An immense amount of research has studied the non-pharmacological and pharmacological approaches for FM, but guidelines, systematic reviews and meta-analyses have not been consistent. The aim of this project is to create a clinical recommendation pamphlet on the management options, specifically targeted at pain symptoms for patients. This recommendation pamphlet is intended to be used by the novice NPs to aid in the management of pain in patients with FM. This paper will further explore the problems novice NPs face when managing pain in patients with FM, review the nature of the literature and describe pamphlet recommendation project.

Research Problem

There is a high prevalence of chronic pain not only in Canada but in all industrialized nations (Schopflocher, Taenzer, & Jovey, 2011). Previously FM management was referred to specialists such as rheumatologists and psychiatrist, as PCPs had difficulties in accurately diagnosing FM due to the lack of specific biological markers, diagnostic and laboratory tests (Goldenberg, 2009). However, researchers found that patients who were treated by PCPs in the community had better prognosis of their chronic widespread pain symptoms than those patients treated in specialty care settings (Fitzcharles, Costa, & PöyhiäR, 2003). Further recommendations that support this finding is in the 2012 Canadian guidelines and by authors Arnold, Gebke, & Choy (2016) who proposed that FM can and should be managed in a primary care setting (Fitzcharles et al., 2013). NPs working in primary care settings, should expect to encounter patients with chronic pain issues in their practice needing work up for conditions such as FM. Although the prevalence of FM is low in Canada, chronic pain is roughly 18%, which equates to a substantial number of potential patients that NPs need to assess and care for in primary care (Schopflocher, Taenzer, & Jovey, 2011). Chronic pain is also associated with poor quality of life as compared with other chronic diseases such as heart disease; hence it is prudent to provide an accurate FM diagnosis and provide early education and management plan (Choiniere et al., 2010 & Fitzcharles et al., 2013).

Additionally, in keeping with the College of Registered Nurses of British Columbia (CRNBC) competencies, NPs are able to diagnose and manage FM independently or refer appropriately as per accepted guidelines (CRNBC, 2017). The barrier, is that FM is notoriously difficult to diagnose, with a lack of collective standard therapy for FM or any BC guidelines for novice NPs to follow. This is true considering the fact that symptoms vary widely among

patients and may be indicative of other conditions. As new research emerges with multitudes of managements and recommendations; it is difficult for novice NPs to sift through the pertinent information. Unfortunately, the etiology and pathophysiology of FM is not fully understood and is multifactorial with numerous of recommendations; hence it is difficult for novice NPs to appropriately diagnose and manage FM (Possidente & Tandan, 2011).

Furthermore, limited research exists on NPs' perception of FM. Only two studies have examined NPs and NP students' perception of FM, both agree that more education is needed to ensure students' confidence in diagnosing and managing FM (Cranford, & King, 2011; Hughes, Adair, Feng, Maciejewski & Sharma, 2016). Other studies involving PCPs have reflected similar findings in that they perceived significant barriers and uncertainty with the diagnosis of FM and requested additional information and education on its management (Possidente & Tandan, 2011; Hadker, N. et al, 2011).

Transitioning into the role the new role of an NP is stressful; as it can be overwhelming for novices to locate, understand and implement the vast amount of information regarding FM managements. While knowledge is still developing, novice NPs may lack confidence in their abilities with little or even no experience managing chronic pain, let alone FM (Hill & Sawatsky, 2011). Compounding this problem is the lack of or poor medical education about chronic pain and pain associated with FM (Hadker, et al. 2011). When in clinical practice, it can be time consuming, as well as anxiety provoking for novice NPs to research for evidence-based, current FM managements plans. Considering this predicament, it is proposed to develop an easy to use, evidenced-based pamphlet describing FM, diagnosis, and current, up-to-date FM pain management. This literature review will explore current findings on the non-pharmacological

and pharmacological management for the purpose of the developing a useful summary reference pamphlet for novice primary care NPs who will be caring for patients with FM.

Literature Review

Search Process

A literature review on FM managements was used by searching English-language publications in CINAHL, PubMed, Cochrane data-base, and references from relevant articles, published from 2009 onwards. The main search terms were fibromyalgia, fibromyalgia treatment, fibromyalgia management, fibromyalgia pharmacological, fibromyalgia nonpharmacological, and fibromyalgia treatment for pain. Selected articles further focused on pain and pain management in FM, quality of data, peer-reviewed articles in order to support the conclusions drawn and articles that depicted current management approaches. Two current guidelines were utilized as well as systematic, meta-analysis reviews and multiple randomized control trials to compile current and evidence based recommendations of pharmacological and nonpharmacological FM managements for novice NPs working in primary care.

What is Fibromyalgia?

FM is mainly characterized by widespread pain, tenderness and hyperalgesia to non-articular joints without any physical abnormalities or inflammation to the tissues (Goldenberg, 1987/2014 & Rehm, et al., 2010). The onset of pain is insidious and localized but can progress and worsen; it is believed that FM is a central sensitization or neurophysiological pain dysregulation condition (Fleming & Volcheck, 2015). Patients may experience other constellation of symptoms: nonrestorative sleep, fatigue, cognitive dysfunction, mood disorder, pain-related somatic symptoms, and other non-pain related symptoms (Goldenberg, 1987/2014 & Clauw, 2014).

FM affects all ages and genders, but is prevalent in female patients in their third to fifth decade (Goldenberg, 1987/2014; Häuser, et al., 2009 & Clauw, (2014). FM may not be life threatening, but patients who experience FM symptoms such as chronic pain and anxiety, can contribute to a lower quality of life (Biccheri, Roussiau, & Mambet-Doué, 2016); therefore, it is paramount that PCPs, including NPs, implement evidence based approaches with individualized care when encountering patients with FM.

Diagnosis

Pain is the primary complaint for which patients with FM symptoms frequently visit in the primary care setting. To diagnose, pain symptoms should be present for at least 3 months with other associated symptoms that cannot be explained by some other illness (Wolfe, et al., 2010; Mease, et al., 2009 & Fitzcharles, et al., 2013). Most rheumatologists can recognize and diagnose FM, but other clinicians in primary care may lack familiarity of FM's important clinical features. It is recommended that PCPs have simple and accurate criteria to help improve the study and management of FM (Littlejohn, G., 2014). The 2012 Canadian Guidelines for the Diagnosis and Management of Fibromyalgia Syndrome purports that PCPs can and should establish FM diagnosis as early as possible without a confirmation from a specialist (Fitzcharles et al., 2013). This guideline states the need to set realistic expectations, informing patients about the diagnosis with an understanding that symptoms can change and vary over time (Fitzcharles et al., 2013). The use of the revised American College of Rheumatology criteria 2010 (ACR 2010) is also recommended to diagnoses FM; repeat investigations should be avoided unless patients' status change with new onset of symptoms on examination (Fitzcharles et al., 2013).

FM diagnosis is a clinical evaluation, starting with history of current complaints, past health status and a physical exam (Fitzcharles, 2013). A physical examination is fundamental,

but musculoskeletal and neurological systems are usually within normal limits except for tenderness of soft tissue points. Although tender points were previously central to a diagnosis of FM; the revised ACR 2010 diagnostic criteria now no longer considers it as a criterion (Wolfe, et al. 2010). Further evaluation may include simple blood counts, erythrocytes sedimentation rate (ESR), C-reactive protein (CRP), creatinine kinase (CK), and thyroid stimulating hormone (TSH); other radiographic testing should depend upon individual assessments to rule out other possibilities (Goldenberg, 2009 & Fitzcharles, 2013).

Two other tools were developed to diagnose FM in recent years. Littlejohn, G., (2014) and Bennett et al., (2014) modified the ACR 2010 criteria even further to develop the 2011ModCr and the 2013AltCr tools which examined different aspects of FM presentation. The 2011ModCr examines the number of pain sites and severity symptoms while the 2013AltCr assesses environmental sensitivity and draw from larger pain regions and symptoms. Bennett et al., 2014 found both tools to be valid. The 2011ModCr had a relative diagnostic accuracy compared to the 1990 ACR criteria with a 67% specificity and 83% sensitivity (Bennett et al., (2014). The 2013AltCr results were comparable to the 2011ModCr, however, the latter demonstrated slightly better specificity and was easier to use (Bennett et al., (2014). Arnold et al., (2012) took a different approach and developed self-reported questionnaire: Scoring of the Fibromyalgia Diagnostic Screen-Patient and Fibromyalgia Diagnostic Screening tool for clinicians. These tools were developed to increase awareness and facilitate identification of FM symptoms. Data found that these tools improved identification of FM in the primary care settings (Arnold, Stanford, Welge, & Crofford, 2012). Although beyond the scope of this paper, a separate literature review is needed just to render evidence based and validity of these tools for

novice NPs to employ. The pamphlet for this project will provide some tools recommended by the 2012 Canadian Guidelines.

Management

Although there is heterogeneity between symptoms and comorbidities in patients with FM; there appears to be an agreement that treatment should be multidimensional with a focus on patient education and engagement in nonpharmacological approaches and balanced pharmacologic efforts if it is needed (Clauw, 2014 & Garcia, Nicolas, & Hernandez, 2015). The end goal for FM management is to provide a balance between pharmacological and nonpharmacological modalities. Nonpharmacological therapies can help patients build strength and coping skills whereas medications may be used to complement nonpharmacological approaches to help patients cope better with their distressing symptoms.

Non Pharmacologic Choices

A meta-analysis of 49 studies found that non-pharmacologic treatments were more effective than pharmacological interventions and should be first-line therapy for FM, as there is lack of strong evidence to support the use of medications (Hauser, et al., 2009). The latest FM guidelines now recommends a combined use of pharmacological and nonpharmacological management approach for symptoms such as pain, sleep disturbances, depression, decreased functional state, and fatigue (Fitzcharles et al., 2013 & Macfarlane, et al, 2017, & Clauw, Arnold, McCarberg & FibroCollaborative, 2011). Non-pharmacologic treatments showed improvements in self-reported outcomes that measured physical well-being and FM symptoms such as pain, daily functioning and psychological health (Clauw, 2014).

For the purpose of this paper, nonpharmacological treatment are discussed with a focus on pain relief in FM patients, as recent guidelines emphasize that chronic widespread pain is the

pivotal symptom to treat in FM (Fitzcharles et al., 2013 & Macfarlane et al, 2017). Numerous evidence show that nonpharmacological treatment is used as first line action for FM, but not limited to just FM patients. Some therapies have shown that nonpharmacological treatments have well managed symptoms and improved quality of life with minimal risk (Macfarlane, et al, 2017). In light of this, nonpharmacological therapies should be given priority in primary care settings, focusing on tailored therapy and patient's preferences of therapeutic measures.

Most studies and guidelines suggest nonpharmacological strategies include patient participation, education, exercise, and psychological treatment, particularly cognitive behavioral therapy (CBT). A full description of these practices are as follows:

Active participation and self-management

Active patient participation and self-management are essential components of many therapeutic approaches especially in the management of pain in FM. These allow patients to participate in their own care, as well as, promote positive attitudes and a sense of internal power and control over expectations which determines response to treatment (Arnold, Gebke, & Choy, 2016). Self-management is valuable because it intertwines coping mechanisms with good social support to promote healthy lifestyle choices and practices (Fitzcharles et al., 2013)

Education

Current strategies to improve patients' quality of life includes the acknowledgement that symptoms are real and not fabricated or "in their heads". Educating patients about the diagnosis of FM and evidence-based management options helps to relieve frustration and improves not only quality of care but also quality of life (Arnold, et al., 2016).

Education enhances and improve patients' attitudes, coping abilities and their expectations of their FM symptoms and outcomes (Fitzcharles et al., 2013). The patient should

be told that although medications and other approaches can ameliorate symptoms, there is no ‘cure’ for the pain, and that it may never go away; this sets up realistic expectations (Cohen, 2017). Having said that, patients should understand and be informed that their symptoms and progress may wax and wane over time. Thoroughly explaining and conceptualizing the pain mechanism can lessen the patient’s anxiety and pain-related cognitive-emotional processes (Lazaridou, et al 2017). The thought behind this is that knowledge about FM can be empowering.

Most studies cited group education as effective strategy in the management of FM. Giving patients a sense of community allows them to accept their conditions and start building support systems (Arnold, et al., 2016). Counselling and informing patients of the diagnosis of FM also provides a sense of “relief” which can result in fewer referrals, reduced diagnostic testing and an overall decreased in use of health care resources (Clauw, 2014). Once a diagnosis is made and “believed” by others, patients are more receptive to education, and will be more likely to participate in shared decision making about their management plan (Clauw, 2014). It is meaningful to help patients recognize the roles of their environmental, social and/or psychological factors that can exacerbate or triggers symptoms; therefore, education also provides the basis and introduction for psychological therapies, typically, behaviorally based such as cognitive behavior therapy.

Exercise

Exercise has been reviewed as the strongest recommendations among many guidelines (Thieme, Mathys, & Turk, 2016). Exercise benefits overall well-being, improves physical function, pain, and muscle strength. It is suggested by the 2012 Canadian Guideline as the “cornerstone” and first step in treatment for FM. Physical activity received the greatest ranking of recommendations with 100% agreement among their review panel in the 2017 European

Guidelines (Fitzcharles et al., 2013 & Macfarlane, et al, 2017). Exercise can take numbers of forms from aerobic to strengthening, water therapeutics and individual or in group based programs. A Cochrane review with high quality studies found that supervised aerobic exercise, strength training and pool exercises improved physical capacity and FM symptoms (Busch et al. 2011). A meta-analysis of 45 studies and a Cochrane systematic review revealed similar results, confirming that aquatic exercises, aerobic and strength training improved fitness and symptoms such as pain in FM patients (Ramel, Bannuru, Griffith, & Wang, 2009; Bidonde et al., 2014). de Azevedo Klumb Steffens, et al. (2014) found that physical exercises analyzed in their literature review also improved quality of sleep in patients with FM. Even walking had positive effects on chronic musculoskeletal pain in people with low back pain, although short term (O'Connor et al., 2015).

To emphasize the importance of knowledge, multiple studies found that education when combined with water exercises resulted in both physical and emotional improvements (Segura-Jiménez et al., 2013; Christakou, & Zachariudaki, 2010 & Carbonell-Baeza et al., 2012).

Tai chi

Tai chi has gained recognition in FM treatment as it helps both physical and mental components by improving sleep, function and quality of life (Wang, 2011; Mudedla, & Wang, 2014). Tai chi is an ancient body-mind therapy, combining meditative movements with complementary exercise which involves relaxation, breathing and mental concentration while performing a low speed and low impact exercise (Lan, Lai & Chen, 2002). Tai chi also improves balance, strength, pain, memory, and even anxiety (Field, 2016). Tai chi was found to improve pain and sleep quality in both healthy adults and patients with chronic conditions such as FM.

The authors suggest that Tai chi should be considered as an alternative therapy in FM patients who suffer from insomnia (Mudedla, & Wang, 2014).

Yoga

Yoga is another meditative, mind-body therapy that has been recently studied for chronic pain in FM patients (Cramer, Lauche, Langhorst, & Dobos, 2013). The 2017 European Guidelines state there is not enough evidence to make individual recommendations, though overall found it helpful to treat pain in FM. A systematic review of randomized control trials found yoga that included stretching, aerobics and wellness education improved sleep and sleep quality (Langhorst, et al. 2013). Although alternative therapies remain controversial among guidelines and may require higher quality studies, tai chi and yoga received more positive recommendations in more than one guidelines (Fitzcharles et al., 2013 & Macfarlane et al, 2017).

There are various exercise options available for FM patients, however, the question remains as to which exercise is more beneficial and is the most effective. The above findings suggest that any form of movement whether it is walking or more active physical activities should be encouraged in FM patients. NPs should encourage patients to start, by choosing an activity that has low impact but can be gradually increased. The activity should also be enjoyable, easy to follow, and within budget in order to remain consistent and compliant while improving symptoms and well-being. It is also understandable to know that FM patients find physical activities challenging and become more painful; but Clauw (2014) and Macfarlane et al. (2017) emphasize the importance of pacing daily activities. It is advised to begin with mild types of exercise then increase the intensity and duration at their own pace to improve day to day function.

Hydrotherapy/spa therapy

The 2017 European guideline regarded hydrotherapy useful for FM patients. One high quality randomized meta-analysis showed significant improvement of pain that was maintained for over 14 weeks (Langhorst, Musial, Klose, & Häuser, W., 2009). Another systematic review found that hydrotherapy, spa therapy and balneotherapy was also effective, but evidence could not suggest one being superior over the other (Naumann & Sadaghiani, 2014). Although the exact mechanism of balneotherapy and spa therapy on FM symptoms are unclear, the mineral and heat are believed to have anti-inflammatory effects that may increase endorphins and cortisol levels to change pain pathways in patients with FM (Guidelli, Tenti, Nobili, & Fioravanti, (2012).

Cognitive Behavior Therapy (CBT)

CBT is the link between pain and the negative coping strategies of patients' thoughts, moods, and behaviors and is considered to be the gold standard treatment for chronic pain of all types (Ehde, Dillworth & Turner, 2014). CBT can challenge negative or ill-natured thinking by helping patients to combat the fear of worsening pain if they exercise; or to combat any past trauma that could exacerbate their pain (Lumley et al., 2017).

The 2012 Canadian Guidelines recommend CBT because it improves pain and self-efficacy as well as helping patients to build coping strategies and abilities to manage FM symptoms. CBT also reduces the fear of activities due to fear of pain (Bernardy, Füber, Köllner & Häuser, 2010). However, CBT was a weak recommendation from the 2017 European Guidelines. Patients in CBT groups had greater positive changes in outcome measures such as pain, general fatigue, depression and sleep which lasted over follow-up sessions (Martínez et al., 2014). Lami et al. (2016)'s study found differences between the sexes; women showed more improvements outcome than men. This is meaningful and relevant when NPs are caring for

different sex populations in patients with FM (Lami et al. 2016). Newer research supports psychological behavior therapy as effective and offers positive outcomes when used to complement other therapies such as education and exercise (Thieme, Mathys, & Turk, 2017;2016). One Cochrane review showed small benefits of reduced pain and improved mood at the end of treatment and at long-term follow-up (Bernardy et al., (2013). Most guidelines reviewed had strong recommendations for CBT as first line of an advocated stepwise approach to FM treatment (Thieme, Mathys, & Turk, 2017;2016).

In summary, there are four nonpharmacological therapies that were found to be supported by stronger evidence and were recommended by both the Canadian and European Guidelines. NPs should consider and discuss all the options with their FM patients. It is prudent to educate patients about their condition and set realistic expectations about their prognosis. Having FM patients be engaged and be active participants allow them to take control over their own health. Exercise is recommended in all guidelines and CBT can complement the other nonpharmacological treatments. It was challenging to grade these 4 recommendations as guidelines and studies did not have consistent criteria for outcomes. However, emphasis has been put on education and exercise as the first line. From the information gathered, an algorithm/map has been adopted and revised for ease of use. See Algorithm in Pamphlet Appendix 1.

Pharmacologic

As the etiology of FM still remains unknown, there are multiple pharmacological trials aimed at relieving its distressing symptoms. The purpose of this section is to identify the most relevant and evidence based medications that can be beneficial for patients with FM. As pain and hyper-analgesia is the dominant symptom, this review will focus more on pain, pain relief drugs and the current medications indicated for FM in Canada.

When there is no cure for conditions such as FM, symptom-based management is a reasonable approach in which pharmacologic choices can alleviate more than one symptom, thus, being more advantageous over some nonpharmacological managements (Boomershine & Crofford 2009). The general consensus for FM management is typically a combination of treatments, using lower doses of medication than studied and resulting in less side effects and increased adherence (Fitzcharles et al., 2013 & Macfarlane et al., 2017). With any treatment and implementation of plan, it is important to monitor and evaluate outcomes of benefits and harm, especially when polypharmacy is a factor (Fitzcharles et al, 2013). Multiple evidence-based treatment guidelines for FM have been developed by countries like Canada, Germany and organizational groups such as the American Pain Society (APS) and the 2017 European League Against Rheumatism (EULAR). All recommend similar pharmacologic therapies, although the evidence of drug benefits is mild to moderate at most (Cohen, 2017). The conventional pharmacologic treatment pattern usually begins with simple analgesics and tricyclic antidepressants (TCAs), selective serotonin reuptake inhibitors (SSRIs), and serotonin-norepinephrine reuptake inhibitors (SNRIs) and gabapentinoids. With so many choices, it can be a challenge for novice NPs choose an appropriate course of management.

Is it important to note that the only drugs approved for FM treatment by the Food and Drug Administration (FDA) in the USA are Pregabalin, Duloxetine and Milnacipran; the latter is not available in Canada (Chinn, Caldwellm, & Gritsenko, 2016) & Arnold, Gebke, & Choy (2016). The use of all other drugs are considered to be off-label in which case NPs in Canada should proceed with caution. There should be a full understanding and a clear rationale for indication and be aware of implications for patients and potential legal liabilities (CRNBC, 2017). Even

more rigorous, the European policies do not approve any drugs the management of FM (Chinn, Caldwell, & Gritsenko 2016).

Analgesics, Non-steroidal anti-inflammatory drugs (NSAIDs) and Opioids

Pain medications such as NSAIDs and opioids are no longer commonly used in the management of FM as they only treat peripheral pain, and are reported to be ineffective for managing centralized FM pain (Clauw, 2014). Despite this knowledge, the 2012 Canadian Guidelines suggest practitioners to follow the step-up analgesic ladder approach which recommend starting off with acetaminophen, ibuprofen and other NSAIDs (Fitzcharles et al, 2013). This is also in line with the 1986's World Health Organization's pain ladder, although it was originally meant for cancer pain in adults (WHO, 2017). If NSAIDs are prescribed, it is usually associated with comorbidity conditions such as osteoarthritis or rheumatoid arthritis. It is recommended to start with the lowest dose for a short period of time in order to limit serious adverse effects (Fitzcharles, M., et al, 2013). Patients with pain symptoms usually have already tried over the counter acetaminophen and NSAIDs before presenting themselves to primary care practitioners (Choy et al., 2010). At this point patients with FM symptoms are requesting something stronger or different for their pain, as there is little evidence that these basic analgesics have effects on their pain and symptoms (Mease, Dundon & Sarzi-Puttini, 2011).

Similarly, opioids are not a better choice. A longitudinal study demonstrated that in a pain clinic setting, improvements in pain, functional, and psychological outcomes were independent of opioid use in patients with FM (Fitzcharles, Faregh, Ste-Marie, & Shir, 2013). Addiction and misuse of stronger medications such as short-acting opioids are worrisome; due to the central reward effects, patients may perceive benefits of opioids rather than FM symptom relief (Painter & Crofford, 2013).

Opioids are still prescribed before and after FM diagnosis, despite literature finding limited or no reduction in pain symptoms nor the indication for FM symptoms (Sanchez et al., 2011; Goldenberg, Clauw, Palmer, & Clair, 2016). Not to mention, opioids can lead to other adverse effects such as opioid induced hyperalgesia and are associated an increased risk of mortality (Yi & Pryzbylkowski, 2015; Rudd, Aleshire & Zibbell, 2016). The 2017 EULAR guidelines also do not recommend the use of strong opioids. Canadian Guidelines also discourage the use of opioids unless other therapies have been exhausted (Fitzcharles et al., 2013 & Macfarlane,et al., 2017).

There is some evidence that tramadol is effective in FM for mild to moderate pain (Arnold, Gebke, & Choy, 2016). It is believed that tramadol provides pain relief by improving serotonin release and inhibiting adrenaline reuptake (Roskell, Beard, Zhao, Le, 2011 & Hauser, Urrutia, Tort, Uceyler, Walitt, 2013). The 2017 EULAR Guidelines weakly recommend the use of Tramadol, while others suggest it as a second line-management for resistant pain cases, but prescriber needs to consider potential interactions with SNRIs (Arnold, Gebke, & Choy, 2016; Cohen, 2017; MacLean, & Schwartz, 2015). Another randomized, although older, controlled study recommends a combination of tramadol and acetaminophen which showed to be effective in reducing pain, lasting up to three months (Bennett, Kamin, Karim, & Rosenthal, 2003).

Neuromodulator medications

Antidepressants

Systematic reviews and randomized trials show that antidepressants are effective in treating FM (Fitzcharles et al., 2013; Macfarlane et al., 2017 & Roskell et al., 2011).

Antidepressant medications have beneficial effects on pain in FM patients and is independent of

the effects on mood. It is believed to augment serotonin and norepinephrine neurotransmitters to dilute noxious inhibitory control and relieve pain symptoms (Häuser et al., 2013).

Serotonin Selective Reuptake Inhibitors (SSRI)

SSRIs were commonly used in FM management, but a 2015 Cochrane database systematic review now suggests that they have a minimal effect on pain and overall improvement; however, SSRIs can be considered when depression is involved (Walitt, Urrútia & Nishishinya, 2015). The 2017 EULAR Guidelines provide a weak argument against the use of SSRI but the 2012 Canadian Guidelines continues to recommend their use in FM (Fitzcharles et al., 2013 & Macfarlane et al., 2017).

Tricyclic antidepressant (TCAs)

TCAs inhibits the reuptake of norepinephrine and serotonin of descending pain pathway and are approved for the management of major depressive disorders (RxTx, 2016).

Amitriptyline, a TCA, in low dosage was shown to have some beneficial effect on FM and is recommended by both the Canadian and 2017 EULAR Guidelines though the main effect was to improve sleep as it has sedative properties. It is found that amitriptyline was superior to duloxetine and milnacipran in the reduction of pain, sleep disturbances and fatigue but the effects of these two drugs were minimal (Fitzcharles et al., 2013 & Macfarlane et al., 2017 & Häuser et al., 2011).

Although amitriptyline demonstrated efficacy and is commonly used to manage FM symptoms; it is not approved for this indication by Health Canada nor the FDA (Arnold, Gebke, & Choy, 2016). Additionally, it has been shown that TCAs use among patients with FM is now uncommon in the real-world practice as newer drugs become available (Reed, et al., 2012).

Furthermore, there are anticholinergic and antihistamine side effects that are of inconvenience to

patients. However, Rico-Villademoros, Slim, & Calandre, (2015) do suggest amitriptyline in low doses be considered a first-line drug for the treatment of FM.

Serotonin–Norepinephrine Reuptake Inhibitors (SNRIs)

Recent studies have focused more on SNRIs (Cording, Derry, Phillips, Moore, & Wiffen, 2015) which increase levels of norepinephrine and serotonin to stimulate the descending pain pathway (Nelson, 2018). The Canadian Guidelines strongly recommend SNRIs, although there were numerous side effects and provided modest relief of symptoms at best (Lunn, Hughes & Wiffen, 2014; Fitzcharles et al., 2013; Ablin et al., 2013). Duloxetine is the only drug in this class that has been approved by Health Canada to manage FM symptoms (Fitzcharles, et al, 2013). Duloxetine has shown to improve pain with or without depressive symptoms and had a greater impact on patients' quality of life as measured by the Fibromyalgia Impact Questionnaire (Calandre, Rico-Villademoros & Slim, 2015). SNRIs were found to affect both serotonin and noradrenaline descending modulatory pathways better than SSRIs alone. Cohen, 2017 & Häuser, et al., 2011 found that duloxetine was superior to milnacipran in reducing pain, sleep disturbances, though, again the effects of were small.

Anti-Epileptic Drugs (AEDs)

Newer research suggests that AEDs be used in FM management for pain. However, no medications are without side effects; fatigue has been shown to be worsened by gabapentinoids and antidepressants (Chinn, Caldwell, & Gritsenko, 2016). Pregabalin is the representative drug for AEDs and works by binding to voltage gated calcium ion channels within the central nervous system (Chinn et al., 2016). A 2008 FREEDOM study revealed a promise of symptom relief for up to 6months (Crofford, et, al., 2008). However, a recent Cochrane review on AEDs only gave conservative results; where pregabalin only provided a small benefit in reducing pain and sleep

problems (Chinn et al., (2016). Two newer systematic reviews concluded that pregabalin reduces pain intensity due to FM. Minalcipran and duloxetine were also found to have similar benefits in pain reduction in FM patients (Uceyler, Sommer, Walitt, Hauser, 2013 & Wiffen, et al. 2013)

Many research papers states that pregabalin is the only AED that is approved by Health Canada for FM management but with no factual evidence. Giladi et al., (2015) found that pregabalin is being used off-label, outside of Health Canada's approved indication. With further investigation, the Health Canada's website revealed that pregabalin is indicated for peripheral neuropathy in adults. Health Canada (2017) presented research studies that included pregabalin use in FM patients, this may have alluded to the fact that FM is associated with peripheral neuropathy, but references given were no later than 2005.

AEDs are effective in improving pain and sleep as well as reducing anxiety in patients (Fitzcharles et al., 2013 & Macfarlane, et al, 2017). It is approved for use in anxiety disorders in Europe, but not in Canada. On the other hand, Health Canada authorizes pregabalin use for FM while AEDs are not approved for the use of FM in Europe. However, the most recent 2017 EULAR Guidelines now has some evidence and weakly support the use of pregabalin for pain reduction in patients with FM (Macfarlane et al., 2017).

NP considerations

As mentioned earlier, NPs as PCPs should be fully capable of diagnosing and managing patients with FM (CRNBC, 2017). NPs are vital members of the health care team and are likely to see patients presenting with signs and symptoms of FM in the primary care settings. NPs are first and foremost nurses, who have an artistry of interacting with patients on a personal and professional level. NPs can work and interact with patients at different points in the health care

system. NPs are positioned to capitalize on opportunities to help patients with FM through education, encouragement, facilitation and management of symptoms.

The issue is, that novice NPs may not be experienced with FM. A study by Hughes et al's., (2016) indicates that NPs did receive education about FM in their NP training but felt it was limited. Most had to self-educate about FM and yet still found it difficult to diagnose and were not completely confident in the treatment of FM. Half of the NPs in this study indicated they needed more information about FM. This indicates that more education needs to be directed to NPs, in order for them to recognize the possible clinical manifestations and be proficient in diagnosing and managing FM patients. It is also postulated that NPs may not be aware of the newest ACR 2010 updated criteria in diagnosing FM. It is important to convey this information, especially to those who do not see potential FM patients often (Hughes, Adair, Feng, Maciejewski & Sharma, 2016).

It is also imperative for NPs to understand their scope of practice and limitations surrounding their roles in FM and when it is necessary to collaborate and refer onwards. This is especially crucial when other comorbidities are involved and pharmacological treatment needs to be expanded and optimized. NPs in BC are restricted on certain prescribing authorities of medications and cannot prescribe off label medications, hence the need for a multidisciplinary collaboration.

Limitations

Despite a comprehensive review on the managements of FM, future literature reviews should focus more on the diagnosis of FM and or its management in special populations such as Juvenile FM or in the elderly. It would also be beneficial for novice NPs to know the correct dosage of such medications and the duration of treatment.

Creating a summary pamphlet may only allow a small portion of information on the management approaches and is not guaranteed that it will have a direct impact for novice NPs. As with any tool, it should be tested and validated. Going forward, more research is still needed to strengthen the evidence for the current FM management as there are conflicting guidelines. Although there is a variety of guidelines and numerous research surrounding FM management, it is important for NPs to note that there are inconsistencies in reporting criteria outcomes, making it difficult to accurately compare recommendations across treatments. Moreover, even when managements are relatively comparable, the duration of treatment effects vary from post-treatment, short-term, or long-term follow-ups. More research should also be performed on NPs and their encounter with FM and associated managements to provide best practice specific to the roles of NPs.

Conclusion

FM is a complex and difficult chronic pain condition with varied associated symptoms, making it challenging for novice NPs to diagnose and manage. This literature review evaluates current, relevant and evidence based knowledge around pharmacological and nonpharmacological managements in FM. As NPs gain advanced level of education and broaden their scope of practice, they are now in position to work with patients affected by FM symptoms. With the assistance of the data presented in this literature review, it is hoped to enlighten and provide novice NPs with an informative summary of FM's pharmacological and non-pharmacological managements. This allows for quick and easy access when faced with patients presenting with FM symptoms in the primary care setting.

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Appendix 1: Pamphlet

This Pamphlet provides Novice Nurse Practitioners with basic up to date information about Fibromyalgia, Signs/Symptoms, Diagnosis, Differentials and combinations of nonpharmacological and pharmacological treatments.

NONPHARMACOLOGICAL
AND
PHARMACOLOGICAL pain MANAGEMENT for
FIBROMYALGIA



Patients with Fibromyalgia (FM) require ongoing, multifaceted care, with combinations of treatment options. Greater acknowledgement, empathy and understanding of FM and the impact on patients' lives can improve Nurse-Patient relationships and patients' outcomes. Nurse Practitioners focused on building trusting relationships should be ready and be aware of the role they play when caring for patients with FM.

FIBROMYALGIA



Fibromyalgia (FM)

- **Chronic**, widespread **non inflammatory pain processing** disorder that impacts patients' quality of life
- Specific cause is currently unknown, but pain is processed differently, resulting in central amplification of pain signals
- Patients experience exaggerated response to pain and a variety of other stimuli (i.e stress, hot and cold, unpleasant odor, and noise)
- Affects personal and professional relationships; restricts physical, work, and social activities
- Prevalence range from 2% to 5%, female > male, 20-50 years
- Possible triggers include: infection, physical or psychological trauma, hormonal abnormalities (i.e., hypothyroidism), drugs, vaccines, and stress/certain catastrophic events (i.e., wars)
- increased incidence in those with autoimmune disorders (OA, RA, SLE, AS)

Signs and Symptoms

- Key symptom is chronic wide spread pain: tenderness, aching or burning throughout the body along with stiffness/spasm in muscles and soft tissue

Others includes:

- fatigue, sleep disturbances, possible contributes to cognitive impairment/memory/mood (fibro fog)

- associated with functional somatic syndromes (IBS/overactive bladder), mental (depression/anxiety) and physical disorders can lead to difficulties maintaining tasks of daily living
- Optimal management require prompt diagnosis (Clauw, 2014 & Goldenberg, 2017)

Clinical Diagnosis

- **Good history:** duration of pain, specific pain spots and symptoms of fatigue, poor sleep, and/or cognitive difficulties
- Diagnostic **criteria** include: Chronic widespread pain index and symptom severity of cognitive symptoms, unrefreshed sleep, fatigue, and other somatic **symptoms for at least 3 months**, that is not caused by a disorder that would explain the pain
- **Normal laboratory testing:** have a baseline complete blood count (CBC), erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP), to exclude systemic inflammatory disease
- Additional laboratory testing: based upon clinical suspicion of a specific disorder
- PHQ9 and GAD 7 to R/I R/O
- Physical Exam:
 - Tender points have been eliminated from diagnostics, but tender points can help rule in diagnosis - see appendix 1
 - Chronic myalgias and arthralgias but no evidence of joint or muscle inflammation on physical examination

(Goldenberg, 2009 & Goldenberg, 2017)

Differential diagnosis

- Inflammatory arthritis (Osteoarthritis), Spondyloarthropathies, Autoimmune connective tissue disease (Lupus, Rheumatoid arthritis), Generalized osteoarthritis, Polymyalgia Rheumatica, Hypothyroidism, Malignancies

MANAGEMENTS – Currently no cure

- Aim to manage symptoms to the greatest extent possible
- Pain is the pivotal symptom to manage
- Nonpharmacological Treatments – 1st line
- Tailor treatment plans to fit individual needs

Non pharmacological treatments can give patients greater sense of control over their condition

Education	<ul style="list-style-type: none"> • Providing details on physiology, prognosis, and treatment while managing expectations
Physical activity	<ul style="list-style-type: none"> • Start low, go slow • Gentle stretching and low-impact exercises (i.e., walking/treadmill, aquatic exercise in warm water, and bicycling) • Gentle exercise (10-20 min walking 3x/wk)

CBT	<ul style="list-style-type: none"> • A way for patients to examine the behaviors, thoughts and feelings
Alternative therapy	<ul style="list-style-type: none"> • Tai chi, massage therapy, yoga, and other exercise modalities - generally safe • Refer to Chronic Pain Centre, psychiatry or psychology

(Clauw, 2014, Goldenberg, 2017, Fitzcharles et al., 2013 & Macfarlane, et al, 2017)



Pharmacological Treatments

- FM is not a peripheral pain condition, typical pharmaceutical options for peripheral pain, such as nonsteroidal anti-inflammatory drugs, are not effective
- Health Canada approves Lyrica and Cymbalta for FM. Everything else is off-label.

Serotonin-Norepinephrine Reuptake Inhibitors (SNRI)	<ul style="list-style-type: none"> • Duloxetine (Cymbalta) 60 – 120 mg/day • Increase activity levels of serotonin and norepinephrine in the brain • Only anti-depressant approved for FM • S.E - Nausea, dry mouth, somnolence, constipation, decreased appetite, hyperhidrosis • Contraindicated - recently treated with a monoamine oxidase inhibitor for psychiatric disorders, linezolid or I.V. methylene blue
Serotonin Selective Reuptake Inhibitors (SSRI)	<ul style="list-style-type: none"> • Minimal effect on pain • Can be considered when depression is involved
Anticonvulsants	<ul style="list-style-type: none"> • Lyrica • Small improvement in pain and sleep • Can reduce anxiety in patients • SE - Dizziness, somnolence, dry mouth, edema, blurred vision, weight gain, abnormal thinking (primarily difficulty with concentration and attention)
Tricyclic Antidepressant (TCA)	<ul style="list-style-type: none"> • Amitriptyline • Sedating - helps with sleep • Lower dosage than for depression

	<ul style="list-style-type: none"> • SE - anticholinergic and antihistamine side effects
<p>Avoid opioids & steroids - May use weak opioid (Tramadol in severe cases) – Prescribe with caution, have frequent follow ups</p>	

(Clauw, 2014, Goldenberg, 2017, Fitzcharles et al., 2013 & Macfarlane, et al, 2017)

RESOURCES

- 2012 Canadian Guidelines for the Diagnosis and Management of Fibromyalgia Syndrome in Adults <http://fmguidelines.ca/>
- 2010 ACR – Fibromyalgia https://www.rheumatology.org/Portals/0/Files/2010_Preliminary_Diagnostic_Criteria.pdf
- PHQ9 - http://www.cqaimh.org/pdf/tool_phq9.pdf
- GAD7 - <https://www.integration.samhsa.gov/clinical-practice/GAD708.19.08Cartwright.pdf>

TIPS

FM can mimic many other conditions, diagnosing FM should not be by exclusion. NPs should consider other differential and their diagnostic evaluation

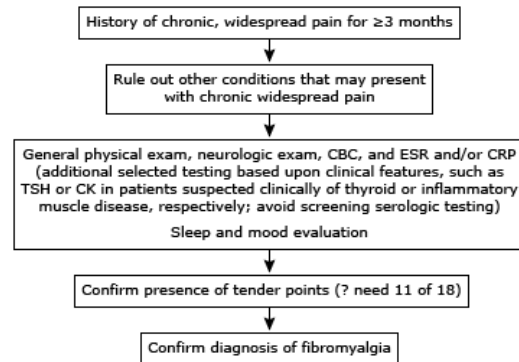
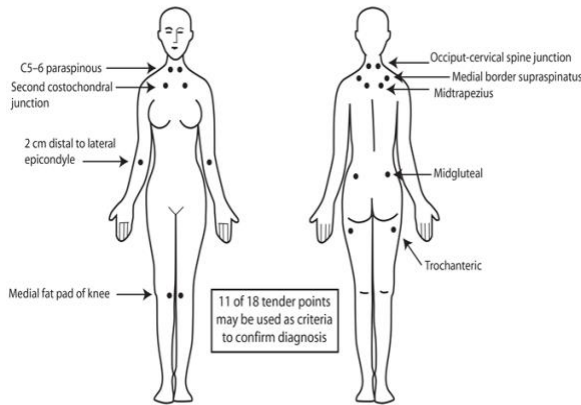


- FM is not progressive
- Emphasize that FM does not lead to long-term damage to the tissues, despite the severe levels of pain
- Explain the diagnosis in context of a volume control problem: the brain has the volume too high when receiving messages back from the body, and therefore, signals that normally would not cause discomfort result in pain
- Sleep problems may need further study in a sleep disorder clinic
- Pain/fatigue, and symptoms severity may wax and wane over time
- Treatment should be individualized and multidisciplinary, involving both nonpharmacological measures and drug therapy
- Mild disease may respond well to educational, exercise and other nonpharmacological measures alone
- The initial approach to all patients with fibromyalgia should include: Patient education about FM, options of treatment approaches, good sleep hygiene, the adverse effects of poor sleep on pain, and the importance of treating comorbidities that may contribute to symptoms, including mood or sleep disorders
- An exercise program, including aerobic conditioning, stretching, and strengthening
- pharmaceutical agents: important to start medications at low doses and increase slowly by small increments to minimize the side effects
- If patients are unresponsive to education, exercise, and drug monotherapy; additional therapies needed such as referrals to specialist and combinations of therapies

(Clauw, 2014 & Goldenberg, 2017)

DIAGNOSTICS

Pain in 11/18 trigger sites (ACR criteria) - Not required for a diagnosis but one tool to assess tenderness on physical exam



Adapted from: Goldenberg, Burckhardt, & Crofford, (2004).

Fibromyalgia diagnostic criteria – 2010 ACR

Criteria

A patient satisfies diagnostic criteria for fibromyalgia if the following 3 conditions are met:

- 1) Widespread pain index (WPI) ≥ 7 and symptom severity (SS) scale score ≥ 5 or WPI 3–6 and SS scale score ≥ 9 .
- 2) Symptoms have been present at a similar level for at least 3 months.
- 3) The patient does not have a disorder that would otherwise explain the pain.

Ascertainment

- 1) WPI: note the number areas in which the patient has had pain over the last week. In how many areas has the patient had pain? Score will be between 0 and 19.

Shoulder girdle, left	Hip (buttock, trochanter), left	Jaw, left	Upper back
Shoulder girdle, right	Hip (buttock, trochanter), right	Jaw, right	Lower back
Upper arm, left	Upper leg, left	Chest	Neck
Upper arm, right	Upper leg, right	Abdomen	
Lower arm, left	Lower leg, left		
Lower arm, right	Lower leg, right		

- 2) SS scale score:

Fatigue

Waking unrefreshed

Cognitive symptoms

For the each of the 3 symptoms above, indicate the level of severity over the past week using the following scale:

- 0 = no problem
- 1 = slight or mild problems, generally mild or intermittent
- 2 = moderate, considerable problems, often present and/or at a moderate level
- 3 = severe: pervasive, continuous, life-disturbing problems

Considering somatic symptoms in general, indicate whether the patient has:*

- 0 = no symptoms
- 1 = few symptoms
- 2 = a moderate number of symptoms
- 3 = a great deal of symptoms

The SS scale score is the sum of the severity of the 3 symptoms (fatigue, waking unrefreshed, cognitive symptoms) plus the extent (severity) of somatic symptoms in general. The final score is between 0 and 12.

* Somatic symptoms that might be considered: muscle pain, irritable bowel syndrome, fatigue/tiredness, thinking or remembering problem, muscle weakness, headache, pain/cramps in the abdomen, numbness/tingling, dizziness, insomnia, depression, constipation, pain in the upper abdomen, nausea, nervousness, chest pain, blurred vision, fever, diarrhea, dry mouth, itching, wheezing, Raynaud's phenomenon, hives/welts, ringing in ears, vomiting, heartburn, oral ulcers, loss of/change in taste, seizures, dry eyes, shortness of breath, loss of appetite, rash, sun sensitivity, hearing difficulties, easy bruising, hair loss, frequent urination, painful urination, and bladder spasms.

Wolfe et al., (2010)

Generalized Anxiety Disorder 7-item (GAD-7) scale

Over the last 2 weeks, how often have you been bothered by the following problems?	Not at all sure	Several days	Over half the days	Nearly every day
1. Feeling nervous, anxious, or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it's hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3
<i>Add the score for each column</i>	+	+	+	
Total Score (add your column scores) =				

If you checked off any problems, how difficult have these made it for you to do your work, take care of things at home, or get along with other people?

- Not difficult at all _____
 Somewhat difficult _____
 Very difficult _____
 Extremely difficult _____

Source: Spitzer RL, Kroenke K, Williams JBW, Lowe B. A brief measure for assessing generalized anxiety disorder. *Arch Intern Med.* 2006;166:1092-1097.

The Patient Health Questionnaire (PHQ-9)

Patient Name _____ Date of Visit _____

Over the past 2 weeks, how often have you been bothered by any of the following problems?	Not At all	Several Days	More Than Half the Days	Nearly Every Day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed or hopeless	0	1	2	3
3. Trouble falling asleep, staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself - or that you're a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or, the opposite - being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

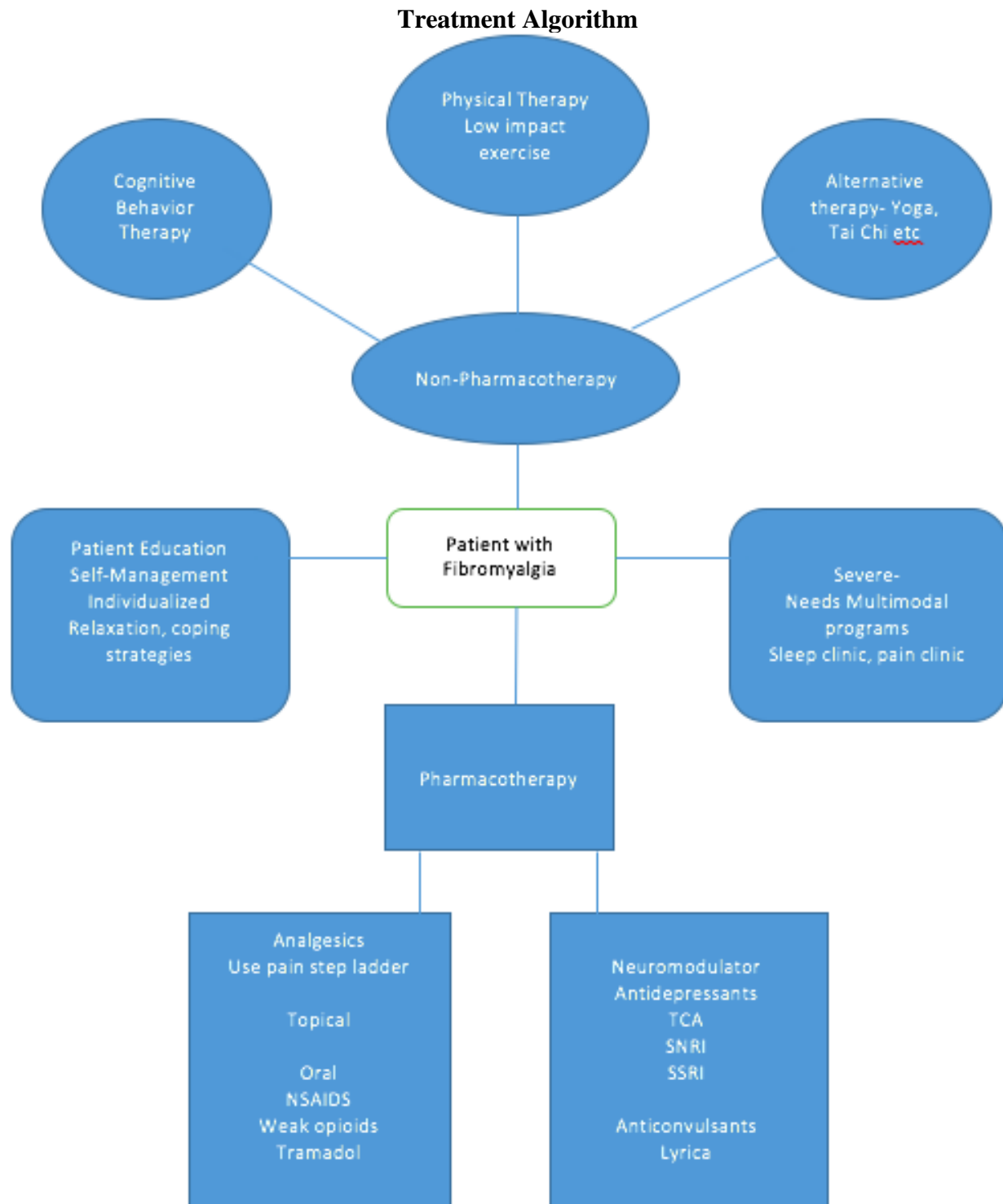
Column Totals _____ + _____ + _____

Add Totals Together _____

10. If you checked off any problems, how difficult have those problems made it for you to do your work, take care of things at home, or get along with other people?

- Not difficult at all Somewhat difficult Very difficult Extremely difficult

Developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke and colleagues, with an educational grant from Pfizer Inc 1999



Adopted from Cohen, 2017. Revised by Nguyen, L., 2018

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