TREATING CHRONIC LOW BACK PAIN WITHOUT OPIOIDS

By

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ABSTRACT

The purpose of this thesis is to address the significance of chronic low back pain in the United States, as well as the surge in opioid use. In the United States, opioids have become the most commonly prescribed class of drug. Because of their addictive nature, their propensity to cause physical dependence, the body's inevitable natural tolerance, and the risk of overdose, opioids cannot be considered an effective treatment for chronic back pain management. Increasing abdominal muscle strength has been shown to significantly reduce lower back pain. Therefore, this paper will focus on interventions including yoga, Pilates, and core stabilization programs. This paper will propose an evidence-based algorithm for the implementation of movement therapies. Primary care providers will utilize a stoplight visual to help the patient determine appropriate therapy to be implemented based on pain. The patient would rate their pain each day and follow the protocol for the corresponding category. Different interventions would be used based on three different categories: green (pain score: 0-3), yellow (pain score: 4-7), and red (pain score: 8-10). The author proposes that this algorithm will result in decreases in pain, use of opioid medications, and cost of pain management for chronic low back pain.

Chapter 1: Introduction

Statement of Purpose

The purpose of this thesis is to explore issues related to nonspecific chronic low back pain and to develop best practice recommendations for its treatment. These recommendations are focused on non-pharmacologic exercise therapies including yoga, Pilates and core stabilization programs. This paper will address the significance of chronic low back pain, the current standards of care, the current foundation of research, and the best practices for treatment of chronic low back pain found from the literature. These practices aim to decrease the usage of opioids, reduce pain levels, and promote healthy lifestyles for these patients.

Background and significance of chronic pain

There are more than 100 million Americans that deal with chronic pain (Tompkins, 2016). Over a quarter of the adult population in the United States reported experiencing lower back pain lasting at least a day within a three-month period (Townsend, Bonham, Chase, Dunscomb & McAlister, 2014). Back pain can be debilitating and significantly decrease quality of life (Tompkins, 2016). Nonspecific chronic low back pain is defined as pain below the costal margin and above the inferior gluteal folds not attributable to any specific cause or diagnosis (Valenza et al., 2017). This pain must last longer than three months to be considered chronic (Valenza et al., 2017). It is this type of chronic pain that will be studied in this literature review.

The opioid epidemic in America is one of the most pressing issues in healthcare. In the United States, opioid analgesics have become the most commonly prescribed class of drug (Volkow & McLellan, 2016). The efficacy of opioids in relieving acute pain is undeniable. For many painful injuries, surgeries, and conditions, opioids are the drugs of choice to achieve adequate analgesia. However, because of their addictive nature, their propensity to cause

physical dependence, and the body's inevitable natural tolerance (which requires higher and higher doses of opioids over time to achieve the same effect), opioids cannot be considered an effective treatment for chronic pain management. The risks of overdose and addiction increase with higher doses and longer prescriptions. Volkow and Mclellan (2016) note that more than half of opioid prescriptions were for high doses (measured in morphine milligram equivalents) for more than six months.

According to the National Institute on Drug Abuse (NIDA), drug overdose deaths have increased drastically over the past few years (NIDA, 2019). In 1999, there were 8,048 opioid overdose deaths in the United States (NIDA, 2019). In 2017, that number increased to 47,600 opioid overdose deaths (NIDA, 2019). Of that number prescription opioid overdoses constituted 17,029 deaths alone (NIDA, 2019). This is an unacceptable mortality rate for prescription drugs. Not only are opioid analgesics dangerous, research has revealed that they are not an effective treatment for chronic pain.

In a study of over 700 patients, Ashworth, Green, Dunn, & Jordan (2013) found that 32% of patients with chronic low back pain were prescribed opioids. The researchers measured numerous variables to study the effectiveness of opioid therapy for this population. The study showed that these patients with chronic pain received a high volume of opioid analgesics (Ashworth et al., 2013). However, after a six-month follow-up, they found no significant differences in self-reported pain, disability, and health related quality of life between those who were prescribed opioids and those who weren't (Ashworth et al., 2013). It seems obvious, then, that opioids aren't a viable treatment solution for chronic pain. Chronic pain demands a long-term, sustainable intervention.

So why are opioid analgesics being prescribed to patients with chronic pain in the first place? Until the 1990's, multidisciplinary pain clinics staffed with physicians, psychologists, physical therapists and additional health care providers trained to provide personalized care led the way in treating chronic pain with minimal opioid use (Tompkins, 2016). However, decreased funding led to the rise of opioid-focused clinics that are seen today (Tompkins, 2016). Less face time with providers and poor case management made opioid prescription rates increase drastically (Tompkins, 2016). The effect of increased opioid prescription rates is reflected in the rapid increase in overdoses. The limited efficacy of long-term opioid pharmacotherapy and the risk of overdose and addiction highlights the need for alternative therapies (Garland, 2014). Vowles et al. (2015) found that opioid misuse rates (defined as using a drug for any reason other than the prescribed use) are anywhere from 21% to 29% and opioid addiction rates are 8% to 12% in patients with chronic pain. Finding alternatives methods of analgesia could avoid opioid prescriptions for patients with chronic pain in the first place.

Recognition of this epidemic has led to many new studies testing non-pharmacological therapies such as massage, aromatherapy, cognitive-behavioral therapy, yoga, Pilates, and many others. This paper will focus on the exercise therapy interventions including yoga, Pilates, and core stabilization programs. Chronic pain is, by definition, a long-term problem. While therapies such as massage and aromatherapy have been shown to be effective for immediate relief from pain, they do not provide long-term relief from pain (Townsend, Bonham, Chase, Dunscomb, & McAlister, 2016). The exercise therapies reviewed in this paper aim to manage pain across the lifespan. This literature review was conducted to examine the effectiveness of these various non-opioid treatments in treating nonspecific chronic low back pain in adults.

Chapter 2: Review of Literature

This literature review was conducted to understand current research on how effective or ineffective opioid analgesics are in treating chronic low back pain, and to identify the most effective, evidence-based alternative interventions. To focus his search of literature, the author utilized the PICOT(S) question "What are the best practices to relieve chronic nonspecific low back pain in adults without the use of opioids?" With this question in mind, the author searched the PubMed database using the keywords "chronic low back pain", "opioid analgesics", "yoga", "Pilates", "core strength", and "core stability." The initial search yielded 49 published studies. These studies were screened via title and abstract review for relevant content and 13 were chosen for full review. Inclusion criteria included publication within five years of the initial search and articles specific to chronic low back pain. All of the articles related to alternative treatments were randomized control trials (RCTs) published between 2014 and 2018. A systematic review that studied the efficacy of opioid analgesic therapy was also utilized. The articles included in the review revealed the ineffective nature of the use of opioids to treat nonspecific chronic low back pain (CLBP) and the potential of movement therapies to manage pain long-term. There were four common themes across all clinical trials: 1) chronic back pain management required strengthening of core muscles, 2) adherence to a scheduled regimen was necessary to see improvement, 3) medication does not effectively treat CLBP, and 4) patient education was critical. Patients engaging in activities that developed core muscle strength (yoga, Pilates, and core stabilization) not only managed pain and increased quality of life, but also had higher satisfaction in pain management and decreased disability.

The Use of Opioid Analgesics to Treat Chronic Low Back Pain

Shaheed, Maher, Williams, Day, and Mclachlan (2016) conducted a systematic review studying the efficacy of opioid analgesics to treat CLBP. Their review included 20 placebo-controlled RCTs (Shaheed et al., 2016). They aimed to evaluate efficacy of opioid analgesics in managing low back pain, to determine effect of dose on pain relief, and to quantify the percentage of patients that discontinued treatment due to adverse effects (Shaheed et al., 2016).

Pain and disability were the primary outcomes studied (Shaheed et al., 2016). The visual analogue scale (VAS), Oswestry disability index (ODI), and Roland-Morris Disability Questionnaire were all used and standardized across studies (Shaheed et al., 2016). Short-term (less than three months), intermediate-term (six months), and long-term (longer than 12 months) outcomes were all studied (Shaheed et al., 2016) (Shaheed et al., 2016). Opioid analgesics used in the study included hydromorphone, oxymorphone, morphine, tramadol, oxycodone, fentanyl, hydrocodone, and others (Shaheed et al., 2016).

The studies provided moderate-quality evidence of opioids providing short-term pain relief and intermediate-pain relief, but there was no studies that measured long-term pain relief (Shaheed et al., 2016). Increased dosage was correlated with increased pain relief (Shaheed et al., 2016). However, the pain relief observed was less than half the accepted threshold for clinically important effect on pain (Shaheed et al., 2016). One of the most significant findings from the study was the percentage of dropouts from the study (Shaheed et al., 2016). In eight trials, only 20.3% to 48.4% of the participants remained in the trial and did not drop out due to either adverse effects or lack of adequate pain relief (Shaheed et al., 2016). Adverse effects reported included headache, dizziness, somnolence, constipation, nausea, vomiting, and dry mouth

(Shaheed et al., 2016). This high rate of attrition suggests that opioid analgesic therapy is frequently a non-sustainable intervention for pain (Shaheed et al., 2016).

This systematic review of the current literature on opioid analgesics for CLBP suggests that opioid therapy is not a viable long-term treatment option (Shaheed et al., 2016). This is in contrast with the fact that half of opioid prescriptions in the United States are for patients with CLBP (Shaheed et al., 2016). There is clearly a large gap between research and practice. Even at higher doses, the pain relief from opioid analgesics was not clinically significant (Shaheed et al., 2016). Numerous adverse effects prevented patients from even being able to complete these studies (Shaheed et al., 2016). Therefore, it is necessary to look at other interventions to relieve CLBP.

Movement Therapies as an Alternative to Medication

Yoga.

Yoga has been frequently proposed as an alternative therapy for treating chronic low back pain. It targets back pain by utilizing postures and poses to enhance alignment, flexibility, mobility, and stability in the muscles that support the back and spine (Nambi et al., 2014). It can be individualized to various skill levels and even utilize props such as chairs for patients with very limited mobility (Nambi et al., 2014). This section will review articles that studied yoga as a therapy to relieve back pain.

Nambi et al. (2014), studied the effect of yoga on changes in pain intensity and health related quality of life for 60 patients with chronic low back pain. This RCT included participants who had nonspecific low back pain for at least three months, were over 18 years old, and were ambulatory (Nambi et al., 2014). Potential subjects were excluded if they were surgical

candidates, were pregnant, had a BMI greater than 35, had a history of depression or substance abuse, or were practitioners of yoga (Nambi et al., 2014).

Participants were randomly assigned to either the yoga group or the exercise group (Nambi et al., 2014). Both groups underwent a five-week intervention (Nambi et al., 2014). The yoga group attended a class taught by a yoga instructor for one hour per week for four weeks and were asked to practice at home in half-hour sessions for five days a week (Nambi et al., 2014). The Iyengar yoga style was utilized as it addresses imbalances in the musculoskeletal system to aid alignment of the spine and posture (Nambi et al., 2014). The yoga group learned 29 different postures (Nambi et al., 2014). The exercise group was taught different exercises to help strengthen and stretch abdominal and back muscles (Nambi et al., 2014). Participants of the exercise group were asked to practice three days per week with an increasing number of repetitions each week (Nambi et al., 2014).

Data was collected at baseline, immediately following the intervention, and six months after the intervention (Nambi et al., 2014). The researchers used the VAS to assess pain intensity and used the HRQOL-4 questionnaire to measure health-related quality of life (Nambi et al., 2014). At baseline, both groups rated pain as 6.73 out of 10 (Nambi et al., 2014). After the intervention, the mean score for the yoga group was 3.8 while the mean score for the exercise group was 5.3 (Nambi et al., 2014). After six months, the yoga group rated pain at 1.83 and the exercise group rated pain at 3.87 (Nambi et al., 2014). Significant improvements were also noted in both groups for the HRQOL-4 with greater effects being observed in the yoga group (Nambi et al., 2014). This supports the researchers' hypothesis that yoga is more effective than exercise in treating CLBP although both interventions caused significant improvement.

One weakness of this study was the lack of information about the exercise treatment group. The intervention for the yoga treatment was very detailed with supporting arguments for its efficacy, while the intervention for the exercise group was only briefly discussed. This could potentially be indicative of a bias towards the yoga group. However, the large base of support and well-researched nature of the yoga intervention make it a compelling treatment for CLBP.

Saper et al. (2017) also studied yoga in a RCT utilizing three different treatment groups. The study compared the efficacy of yoga, physical therapy and education in treating CLBP (Saper et al., 2017). Physical therapy is a standard treatment for many patients dealing with chronic low back pain (Saper et al., 2017). However, its expensive nature makes it inaccessible to low-income populations (Saper et al., 2017). The researchers hypothesized that standardized yoga sessions would be as effective as physical therapy, thereby making it a viable option as a treatment for chronic low back pain (Saper et al., 2017). This large-scale RCT involved 320 participants recruited through convenience sampling and through physician referral (Saper et al., 2017). The participants were between 18 and 64 years old, had experienced non-specific low back pain for at least 12 weeks with a severity of at least four on a 0-10 scale and were fluent in English (Saper et al., 2017). Potential participants were excluded if they had prior yoga or physical therapy done in the past six months, if they had read the books that were part of the education program, if they were pregnant, or if they had a history of substance abuse (Saper et al., 2017).

The study began with a 12-week treatment phase (Saper et al., 2017). Participants were randomly assigned to either a yoga treatment, a physical therapy treatment, or an education treatment (Saper et al., 2017). The yoga treatment involved 12 75-minute classes taught by trained yoga instructors (Saper et al., 2017). Classes included relaxation and meditation

exercises, yoga breathing, yoga philosophy, and yoga poses (Saper et al., 2017). Daily home practice was also advised (Saper et al., 2017). The physical therapy treatment was a series of one-on-one sessions with a physical therapist (Saper et al., 2017). Participants in this group attended 15 hour-long appointments (Saper et al., 2017). The education treatment group was given *The Back Pain Helpbook*, a book on self-managing chronic low back pain (Saper et al., 2017). A recommended reading schedule was provided to pace reading rate (Saper et al., 2017).

Researchers collected data at baseline and again at 6, 12, 26, 40, and 52 weeks (Saper et al., 2017). They measured back-related function through the Roland Morris Disability Questionnaire (RMDQ) and measured pain using the 0-10 scale (Saper et al., 2017). They also measured self-reported pain medication use and health-related quality of life (Saper et al., 2017). As hypothesized, there was no significant difference between yoga and physical therapy in increasing back-related function and decreasing pain (Saper et al., 2017). Participants of the yoga and physical therapy groups had a significant improvement in back-related function when compared to patients in the education treatment group (Saper et al., 2017). Both the physical therapy group and the yoga group were about 20 percent less likely to use pain medication after 12 weeks (Saper et al., 2017). Although physical therapy had a slightly more significant impact on pain and disability, the researchers explain that the cost difference between individualized physical therapy and group yoga classes made yoga a non-inferior intervention (Saper et al., 2017).

The high rate of attrition was a major weakness of this study. Equally concerning was the disproportionate amount of attrition in the physical therapy group. However, the thoroughly detailed interventions, and extensive data collection add to the strength of this study. Therefore, yoga may be considered a strong alternative to physical therapy as a cost-effective intervention.

Kuvacic, Fratini, Padulo, Iacono, and Giorgio (2018) proposed that combining yoga with education on spine anatomy/biomechanics and management of CLBP would relieve pain, depression, anxiety, and disability. This RCT included patients older than 18 with nonspecific CLBP and depression and anxiety (measured by the Zung Self-Rating Depression Scale) (Kuvacic et al., 2018). Patients were excluded if they had acute or specific back pain, had previous yoga or mindfulness experience, or were obese (Kuvacic et al., 2018). Thirty patients were split into two groups; a yoga group and a pamphlet group (Kuvacic et al., 2018). The yoga intervention was offered to the pamphlet group after the completion of the study (Kuvacic et al., 2018).

The yoga group underwent an eight-week program with two 75-minute sessions per week (Kuvacic et al., 2018). The program utilized several yoga philosophies targeted at the CLBP population (Kuvacic et al., 2018). These included asanas – various postures for CLBP, pranayama – breathing exercises, Yoga Nidra – a relaxation technique, and Vipassana – mindfulness meditation (Kuvacic et al., 2018). The yoga sessions also included 10 minutes of education on the spine and biomechanics (Kuvacic et al., 2018).

The pamphlet group was not made aware of the intervention group (Kuvacic et al., 2018). The pamphlet they received contained information on correct body posture, ergonomics, and safe movement during various daily activities such as dressing, eating, and bathing (Kuvacic et al., 2018). Breathing exercises were also detailed in the pamphlet (Kuvacic et al., 2018).

This study utilized the ODI, Zung self-rating depression and anxiety scales, and the numeric rating scale for pain (Kuvacic et al., 2018). Data was collected pre- and post-intervention (Kuvacic et al., 2018). After the intervention, there were significant differences in depression, disability, and pain in the yoga group (Kuvacic et al., 2018). These effects were not

seen in the pamphlet group (Kuvacic et al., 2018). Although this study didn't include objective measures such as abdominal muscle thickness, it provides high quality evidence in support of yoga as an effective intervention in the treatment of nonspecific CLBP.

The authors suggest that pain and psychological well-being cannot be separated (Kuvacic et al., 2018). Therefore, yoga is an ideal intervention because it targets both psychological and physiological well-being (Kuvacic et al., 2018). The authors also suggest that utilizing an active intervention, such as yoga, instead of passive treatments, such as medication, allows the patient to feel empowered by being an advocate for their own health (Kuvacic et al., 2018).

Groessl et al. (2017) conducted a large study of the effectiveness of yoga for military veterans with CLBP in an effort to reduce opioid usage. Because military veterans have a higher rate of chronic pain than the general population, Groessl et al. (2017) wanted to see if yoga would be effective for this population. The authors also suggest that many studies of yoga include predominantly females without other comorbidities (Groessl et al., 2017). The military veteran population, conversely, is predominantly male and has a higher rate of disability and comorbidity (Groessl et al., 2017).

This RCT assigned 150 Veterans Affairs (VA) patients to either a yoga treatment or a delayed yoga treatment (Groessl et al., 2017). Patients were referred to the program by VA clinicians (Groessl et al., 2017). Patients were VA patients over 18 years old with CLBP, and without any new pain treatments in the last month (Groessl et al., 2017). Patients were excluded if they had back surgery, specific causes of back pain, morbid obesity, or yoga experience (Groessl et al., 2017). Patients were told to keep all usual care the same throughout the study (Groessl et al., 2017).

The yoga treatment was 12-week program with two 60-minute sessions each week (Groessl et al., 2017). The treatment involved hatha yoga with breathing exercises and meditation. Sessions were videotaped and reviewed to ensure adherence and standardization of sessions (Groessl et al., 2017). The intervention was designed for beginners but allowed for variation with increased ability and progression over the course of the treatment (Groessl et al., 2017). Participants also received a home practice manual and were encouraged to do basic poses on days without class (Groessl et al., 2017). The delayed treatment group maintained usual care and underwent the same yoga intervention six months later (Groessl et al., 2017).

Outcomes for this study were measured using the Roland Morris Disability Questionnaire and a 0-10 pain intensity scale (Groessl et al., 2017). Data was collected at baseline, six weeks, 12 weeks, and six months. Although it was hypothesized that significant between group differences would be seen by 12 weeks, statistically significant differences in disability and pain weren't observed until the six-month mark (Groessl et al., 2017). Therefore, although the intervention did cause significant benefits, it took longer than hypothesized (Groessl et al., 2017). The authors suggest this may be due to low attendance (median attendance of 15 out of 24 classes) and older age of patients (median age 54) (Groessl et al., 2017). An interesting finding in the treatment group was a statistically significant decrease in opioid medication usage with simultaneous decrease in pain score. The authors conclude that yoga is a safe intervention that can reduce pain and disability in the general population as well as the VA population, a population that is typically more difficult treat (Groessl et al., 2017). Finding methods to increase both attendance to yoga sessions and home practice could increase the efficacy of yoga as a treatment for CLBP (Groessl et al., 2017). A detailed summary of studies including yoga interventions for chronic low back pain can be found in Table 1.

Table 1. Table of Evidence for Movement Interventions for CLBP - Yoga				
Article Title Authors/Year Design	Questions, variables Objectives, hypothesis	Methods	Findings	Notes
Yoga for military veterans with chronic low back pain: A randomized clinical trial Groessl et al. (2017) RCT	• Testing the efficacy of yoga as an intervention for military vets	• 150 military vets with CLBP from a VA medical center • Twice weekly yoga for 12 weeks with postures, movement, and breathing exercises • Control group continued usual care	• Data was collected at baseline, six weeks, 12 weeks, and six months • Primary outcome: RMDQ – intervention caused significant decrease in disability • Secondary outcome: pain – larger decrease in pain intensity for the intervention group	• Relatively poor attendance to yoga classes (mean: 12.3 classes out of 24) • Most yoga interventions are implemented for women. This RCT implemented yoga for predominantly older males.
Effectiveness of yoga and educational intervention on disability, anxiety, depression, and	• Combining yoga with education on spine anatomy and management of CLBP to relieve pain, depression, anxiety, and disability	• Thirty patients split into two groups. • Yoga group and pamphlet group • Yoga group had eight-week program with two 75-minute sessions per week	• Statistically significant improvement in all variables for the intervention group (ODI, depression, anxiety, pain)	• Not only does yoga help CLBP, it also helps for depression

pain in people with CLBP Kuvavic, Fratini, Padulo, Iacono, & Giorgio (2018) RCT		• Pamphlet group received information on body posture and ergonomics. They were offered the yoga intervention at the end of the study.		
Changes in pain intensity and health related quality of life with Iyengar yoga in nonspecific chronic low back pain: A randomized controlled study. Nambi, Inbasekaran, Kuman, Devi, Shanmugananth & Jagannathan (2014) RCT	• Determine efficacy of Iyengar yoga therapy on pain intensity and health related quality of life (HRQOL) • Compare effects of yoga and conventional exercise therapy on chronic low back pain	• 60 participants: recruited from outpatient setting through physicians and convenience sampling • Inclusion criteria: low back pain for at least three months, 18, ambulatory. • Exclusion: potential surgery, pregnancy, BMI >35, depression, substance abuse, yoga practitioner. • Yoga group: Attended class (one hour per week for four weeks) and asked to practice at home (30 minutes per day, five days per week)	• Significant reduction in pain and improvement in HRQOL in both groups • Better improvement in yoga group than exercise group • Yoga (6.73 to 1.83) Exercise group (6.73 to 3.87)	• Potential researcher bias towards yoga group

		• Exercise group: four-week generalized program		
Yoga, Physical Therapy, or Education for Chronic Low Back Pain Saper et al. (2017) RCT	• Comparing the effectiveness of yoga, physical therapy, and self-care education in treating chronic low back pain • If yoga has similar effectiveness as physical therapy with a cheaper cost, it could be a more effective intervention for low-income patients • Researchers hypothesize that Yoga will be non-inferior to physical therapy and that both yoga and physical therapy will be superior to education	• 320 participants recruited through convenience sampling and physician referral • Inclusion criteria: 18-64, non-specific low back pain at least 12 weeks, at least 4 out 10 pain, English fluency • Exclusion criteria: prior yoga or physical therapy within 6 months, already read books part of education program, pregnancy, substance abuse • 12-week treatment phase, 40-week maintenance phase • Three groups during treatment phase (yoga, PT, education) • Five groups during maintenance phase (structured and unstructured yoga	• A standardized yoga program was found to be non-inferior to individual PT for helping back function and pain • Yoga and PT patients were also more likely than education patients to stop taking pain medication	• Working with low SES population • Cheaper interventions for chronic pain

		maintenance, unstructured yoga, structured and unstructured PT maintenance, education)		

Pilates.

Pilates is another exercise modality that has been studied as a therapy for CLBP management. Pilates focuses on motor control, the activation of deep trunk muscles, and pelvic floor muscle activation (Natour, Cazotti, Ribeiro, Baptista, & Jones, 2014). Exercises are performed on the ground on a mat in various positions (Natour et al., 2014). The six principles of Pilates involve centering, concentration, control, precision, breath and flow (Natour et al., 2014).

To test the effectiveness of Pilates, Cruz-Diaz, Romeu, Velasco-Gonzalez, Martinez-Amat, & Hita-Contreras (2018) conducted a 12-week study on Pilates' effect on pain, function, kinesiophobia, and deep trunk muscle thickness. This single-blind RCT used Pilates as a treatment modality for patients between 18 and 50 years with chronic, nonspecific LBP who were not receiving physical therapy (Cruz-Diaz et al., 2018). The study included 64 participants who were split evenly into intervention and control groups (Cruz-Diaz et al., 2018). The researchers noted the previously studied effectiveness of Pilates but aimed to eliminate weaknesses of previous studies such as attrition, small sample size, and lack of control groups (Cruz-Diaz et al., 2018).

The Pilates intervention consisted of two, 50-minute sessions per week for 12 weeks (Cruz-Diaz et al., 2018). The sessions were conducted by an expert instructor with many years of experience (Cruz-Diaz et al., 2018). The sessions included breathing exercises, strength and flexibility exercises, and stretching (Cruz-Diaz et al., 2018). All the exercises could be done at basic, intermediate, or advanced difficulty levels depending on the participants' ability and condition (Cruz-Diaz et al., 2018). Patients assigned to the control group received a booklet with information on chronic, nonspecific LBP (Cruz-Diaz et al., 2018). To minimize disappointment,

control group participants were offered to join the Pilates intervention following completion of the study (Cruz-Diaz et al., 2018).

Data was collected at baseline, 6 weeks, and 12 weeks (Cruz-Diaz et al., 2018). By 12 weeks, the Pilates group had significant improvements in disability, pain, and kinesiophobia (Cruz-Diaz et al., 2018). No changes were found in the control group (Cruz-Diaz et al., 2018).

Although this study addressed weaknesses of previous studies, it wasn't without weaknesses of its own (Cruz-Diaz et al., 2018). The lack of blinding for the participants could have skewed their perception of the experience (Cruz-Diaz et al., 2018). Participants signed up willing to participate in Pilates; therefore, members of the intervention group may have been enthusiastic and expecting to find Pilates useful, whereas members of the control group may have been disappointed that they did not get to participate (Cruz-Diaz et al., 2018). The length of the study and the large sample size were both strengths of the study (Cruz-Diaz et al., 2018). The improvements found, and the absence of adverse events or symptom aggravation caused by the study provide compelling evidence for the use of Pilates programs (Cruz-Diaz et al., 2018).

Patti et al. (2016) also utilized a Pilates exercise program as an intervention for patients with nonspecific CLBP. They aimed to evaluate the effects of Pilates on pain perception and to evaluate changes in posturography measurements before and after Pilates (Patti et al., 2016). Posturography measures postural instability and is correlated with nonspecific CLBP (Patti et al., 2016).

This RCT involved 38 patients with nonspecific CLBP (Patti et al., 2016). Patients were assigned to either a Pilates exercise program or a control group (Patti et al., 2016). The participants in the experimental group were not allowed to use nonsteroidal anti-inflammatory medications while the control group maintained their usual regimen (Patti et al., 2016).

The Pilates intervention was structured with 50-minute classes held three times per week under the supervision of an exercise specialist with 10 years of Pilates experience (Patti et al., 2016). Two difficulty levels were offered to make the workout more individualized for various abilities (Patti et al., 2016). The exercises included various abdominal strengthening and stabilizing activities (Patti et al., 2016). Patients in the control group did not participate in any active intervention (Patti et al., 2016).

There were significant differences in posturography results between groups following the intervention (Patti et al., 2016). This represents an increase in balance control in the Pilates group that was not observed in the control group (Patti et al., 2016). There were significant decreases in pain for both groups from baseline to post-intervention, though the magnitude of reduction was greater for the experimental Pilates group (Patti et al., 2016). The experimental group also had a larger reduction in disability (as measured by the ODI) than the control group (Patti et al., 2016). From their study, the researchers concluded that Pilates and the strengthening of abdominal muscles is a valid and effect treatment for CLBP (Patti et al., 2016).

Valenza et al. (2016) tested individualized Pilates workouts for alleviating pain and increasing stability and flexibility for patients with nonspecific low back pain. This single-blind RCT investigated the effects of an eight-week Pilates exercise program on disability, pain, lumbar mobility, flexibility and balance (Valenza et al., 2016). This study differentiated itself from others by specifically focusing on time and frequency of the program (Valenza et al., 2016). To achieve 80% power, 50 patients were required (Valenza et al., 2016). The researchers recruited 54 participants to account for potential drop-outs (Valenza et al., 2016). Patients were recruited from primary care centers on the basis of inclusion and exclusion criteria (Valenza et al., 2016). Eligible patients had chronic non-specific low back pain for at least three months

without leg pain, between 18 and 70 years, had no contraindications to exercise, and had no upcoming surgeries planned (Valenza et al., 2016). Patients were randomly assigned to either an experimental group or control group (Valenza et al., 2016).

Patients in the experimental group attended a Pilates exercise program twice a week for eight weeks (Valenza et al., 2016). Each session was 45 minutes long and consisted of various core muscle exercises (Valenza et al., 2016). Exercises were broken into three difficulty levels and was individually adapted to the subject's capabilities (Valenza et al., 2016). The exercises utilized a 55-cm ball on a rubber mat (Valenza et al., 2016). The control group continued usual activities and received a leaflet with information about exercise and lifestyle (Valenza et al., 2016). All patients tolerated the exercise program well, without any adverse effects noted (Valenza et al., 2016).

Researchers collected baseline and post-intervention data (Valenza et al., 2016). There was no significant difference between the groups at baseline (Valenza et al., 2016). After the eight-week intervention, significant differences were found in disability, current pain, flexibility, and balance (Valenza et al., 2016). On the 0-10 pain scale, the study found a mean change of 2.3 plus or minus 1.9 in current pain and a mean change of 2.0 plus or minus 1.8 in pain at its worst for patients in the experimental group (Valenza et al., 2016). Using the ODI, the study found a mean change of 16.35 points (Valenza et al., 2016). The ODI considers an improvement of 10 points as clinically significant (Valenza et al., 2016). The experimental group showed improvements in balance and flexibility while the control group had no change from baseline (Valenza et al., 2016). The researchers attribute these changes to Pilates' effect of activating core body muscles and increasing control of deep trunk muscles (Valenza et al., 2016).

Strengths of this study include its detailed protocol for individualizing the Pilates exercise to each patient's ability and defined frequency and duration of exercise. Limitations include lack of a patient satisfaction survey. If the patients disliked the intervention, they might not be motivated to continue to participate after the study, making it an unsustainable intervention. There was also no long-term follow-up with the patients. Therefore, the researchers could not definitively say if Pilates had any long-term harms or benefits for the patients (Valenza et al., 2016). Further research that addresses these issues would give the researchers more confidence in recommending this intervention (Valenza et al., 2016).

Natour et al. (2014) tested the effect of a Pilates intervention on pain as well as NSAID use, flexibility, and quality of life. This RCT involved 60 patients, age 18 to 50, with nonspecific CLBP with pain rating between four and seven (Natour et al., 2014). Patients were excluded if they were obese, had surgery, or had physical therapy work within the past three months (Natour et al., 2014). Patients were randomly divided into an experimental group and a control group (Natour et al., 2014).

The experimental group maintained their medication regimen of NSAIDs and participated in a Pilates treatment (Natour et al., 2014). The control group maintained their NSAID medication regimen but did not participate in an active intervention (Natour et al., 2014). The Pilates treatment involved 50-minute classes taught by a certified physical educator with 10 years of Pilates experience (Natour et al., 2014). Classes had three to four patients and were held twice a week for 90 days (Natour et al., 2014).

Data was collected at baseline, 45 days, 90 days, and 90 days after the end of the intervention (Natour et al., 2014). Pain was measured with the VAS, functioning was measured with the RMDQ, quality of life was measured with the SF-36, a Likert scale was used to measure

patient satisfaction with the intervention, flexibility was measured with a sit-and-reach test, and NSAID intake was recorded (Natour et al., 2014). Significant differences were found in pain, function, and several quality of life measures (functional capacity and vitality) favoring the experimental group (Natour et al., 2014). The experimental group also took significantly less NSAIDs than the control group (Natour et al., 2014). A gradual reduction in NSAID use was observed over time, suggesting the importance of adherence to a Pilates regimen (Natour et al., 2014).

This study aimed to clarify inconsistencies from other Pilates studies by increasing sample size, having a longer intervention, and clearly defining the intervention (Natour et al., 2014). This was also one of only a few studies that measured medication use during the intervention (Natour et al., 2014). No harmful effects were noted from the intervention, supporting the hypothesis that Pilates is an effective and safe intervention for moderate CLBP (Natour et al., 2014). A detailed summary of studies including Pilates interventions for chronic low back pain can be found in Table 2.

Table 2. Table of Evidence for Movement Interventions for CLBP - Pilates				
Article Title Authors/Year Design	Questions, variables Objectives, hypothesis	Methods	Findings	Notes
The effectiveness of 12 weeks of Pilates intervention on disability, pain and kinesiophobia in patients with chronic low back pain: a randomized controlled trial Cruz-Diaz, Romeu, Velasco-Gonzalez, Martinez-Amat & Hita-Contreras (2018) RCT	• Assess effectiveness of 12-week Pilates intervention compared to placebo • Effects on disability, pain, kinesiophobia in patients with chronic low back pain • Evaluation of deep muscle thickness to investigate effect of Pilates intervention	• Randomized controlled trial (Single-blind study) • 64 participants, between 18 and 50 years old, physically capable of activity • Exclusion criteria: radiculopathy, spinal damage, previous Pilates, current PT	• Improvement in all study variables (disability, pain, kinesiophobia) except transverse abdominis thickness • Greater improvement in this study than other studies (could be due to longer intervention [12 weeks]) • No change in control group (expected)	• Placebo group was just given a pamphlet. Researchers noted that placebo participants might be disappointed and offered them to participate in Pilates after the study period (Single-blind study) • No drop outs, high adherence • Would have been helpful if a survey was

				completed to measure participant opinion of Pilates (before and after)
Pilates improves pain, function and quality of life in patients with chronic low back pain: a randomized controlled trial Natour, Cazotti, Ribeiro, Baptista, & Jones (2015) RCT	• Effect of Pilates on pain, flexibility, quality of life, and NSAID use • Long-term follow-up after end of intervention	• 60 patients with nonspecific CLBP • 50-minute classes, twice a week for 90 days • Control group continued NSAID use without exercise	• Data collected at baseline, 45 days, 90 days, and 180 days • Studied pain, disability, quality of life, satisfaction, flexibility, and NSAID intake • Improvements in all variables except flexibility • Patients in the Pilates group took fewer NSAIDs. Gradual reduction in medication use was observed	• Only study to measure concurrent NSAID intake

			over time. Control group stayed the same.	
Pain perception and stabilometric parameters in people with chronic low back pain after a Pilates exercise program Patti et al. (2016) RCT	• Using Pilates as a modality to increase quality, precision, and control of movement, as well as attention to breathing and sensory feedback • Using posturography as a measure of balance control	• 38 participants with nonspecific CLBP • 50-minute classes, three times a week for 14 weeks • Control group continued NSAID use without exercise	• Data collected at baseline and immediately following the intervention • Measured posturography, disability, pain • There was a significant reduction in pain for both groups and a significant reduction in disability for the Pilates group • Positive effect of Pilates on posturography variables	• Relatively smaller sample size

Results of a Pilates exercise program in patients with chronic non-specific low back pain: a randomized controlled trial Valenza, Rodriguez-Torres, Cabrera-Martos, Diaz-Pelegrina, Aguilar-Ferrandiz, & Castellote-Caballero, 2017 RCT	• Investigate effects of Pilates exercise on disability, pain, lumbar mobility, flexibility and balance in patients • Hypothesized that an 8-week Pilates exercise program would improve disability, pain, lumbar mobility, flexibility, and balance	• Randomized controlled trial • 54 patients with chronic non-specific low back pain > 3 months • Patients could not have leg pain, needed to be currently seeking care for low back pain, between 18-70, have no contraindications to exercise and have no scheduled surgeries • Patients were randomly assigned to either Pilates group or a group that received an informational leaflet	• Study found a significant improvement on pain in the patients included in the experimental group • Change of 2.3 +/- 1.9 in current pain and 2.0 +/- 1.8 change in pain at its worst • Flexibility and balance also improved in the experimental group	• Limitation of not measuring patient satisfaction.

Core strengthening and core stabilization.

Core stability exercise is the practice of strengthening the abdominal and back muscles. Training the core muscles has been proposed to decrease nonspecific low back pain by increasing balance and stability, decreasing stress on the low back (Paungmali, Joseph, Sitilerpisan, Pirunsan, & Uthaikup, 2017). Training the transverse abdominis muscle in particular has been identified as critical in decreasing CLBP (Paugmali et al., 2017).

Paungmali et al. (2017) conducted a study in which they sought to understand the mechanism by which core stabilization exercises achieved their effect. They studied pain threshold and pain intensity comparing lumbopelvic core stabilization exercise (LPST), passive automated cycling, and placebo (Paungmali et al., 2017). This study uniquely utilized a crossover RCT design in which all participants received all three interventions (Paungmali et al., 2017). This study involved 25 participants between 20 and 55 years who had LBP for more than three months (Paungmali et al., 2017).

Participants performed 15 minutes of each exercise in a random order with 48 hours between sessions (Paungmali et al., 2017). The LPST involved core muscle contractions in various positions gradually increasing in difficulty (Paungmali et al., 2017). The passive cycling involved participants in a supine position while strapped to an automatic bicycle that moved their legs (Paungmali et al., 2017). The controlled intervention involved the patients merely lying in a supine position that mimicked the LPST and cycling interventions but did not involve movement (Paungmali et al., 2017).

Outcomes were measured by cold pain threshold, heat pain threshold, and pressure pain threshold (Paungmali et al., 2017). These measures reflect the amount of hypersensitivity and hyperalgesia associated with the CLBP (Paungmali et al., 2017). Pain was measured using the

VAS (Paungmali et al., 2017). Following the intervention, the LPST group showed significant improvements in pressure pain threshold and heat pain threshold (Paungmali et al., 2017). The LPST group also had the biggest improvement in cold pain threshold, although not to a statistically significant extent (Paungmali et al., 2017). Importantly, the LPST group had a significant reduction in pain intensity in comparison to placebo and control interventions (Paungmali et al., 2017). The researchers hypothesize that LPST improves chronic pain symptoms by reducing secondary hyperalgesia (Paungmali et al., 2017). Secondary hyperalgesia is the increase in pain sensitivity to noxious stimuli due to existing injury (Paungmali et al., 2017). The decrease in secondary hyperalgesia following LPST supports the researchers' hypothesis that core stability exercises are critical in providing relief from CLBP (Paungmali et al., 2017).

Akhtar, Karimi, & Gilani (2017) studied the efficacy of core stabilization in comparison to a standard physical therapy regimen in relieving back pain. They noted the current lack of consensus on the best exercise treatment for chronic back pain and designed their study to determine which exercise is the most specific and targeted to managing CLBP (Akhtar et al., 2017). This single-blind RCT involved 120 participants between ages 18 and 60 that had nonspecific CLBP (Akhtar et al., 2017). Patients who had received physical therapy within the past six months were excluded from the study (Akhtar et al., 2017).

Patients were either assigned to a routine physical therapy exercise group or a core stabilization exercise group (Akhtar et al., 2017). Both groups received treatments in 40-minute sessions once a week for six weeks (Akhtar et al., 2017). The core stabilization group performed exercises targeting deep abdominal muscles including planks, pelvic floor exercises, and balancing exercises (Akhtar et al., 2017). The transverse abdominus and multifidus muscles were

specifically targeted (Akhtar et al., 2017). The routine physical therapy group performed various stretches and exercises that were not specifically targeted to the core muscles (Akhtar et al., 2017).

Data was collected at two, four, and six weeks after the start of the intervention (Akhtar et al., 2017). Using the VAS to measure pain, the core stabilization group had a mean pain reduction of 3.08 while the routine physical therapy group and a mean pain reduction of 1.71 by the end of the study (Akhtar et al., 2017). No adverse effects were noted in either group (Akhtar et al., 2017). While both were effective treatments, the core stabilization exercise regimen was significantly more effective in reducing pain (Akhtar et al., 2017). This study would have benefited from a more defined control group and a long-term follow up; however, their findings still strongly support the efficacy of core stabilization.

Shamsi, Sarrafzadeh, Jamshidi, Zarabi, and Purahmadi (2016) also studied the effectiveness of core stability exercise versus general exercise. They utilized ultrasound to measure abdominal muscle thickness to assess muscle performance (Shamsi et al., 2016). This RCT involved 48 patients between 18 and 60 years-old with nonspecific CLBP and pain intensity of three to six on the VAS (Shamsi et al., 2016). Both interventions involved 16 sessions over the course of five weeks (Shamsi et al., 2016).

The core stability exercise focused on isometric contractions targeted at increasing the strength of the transversus abdominis muscle (Shamsi et al., 2016). The intervention involved education and direction from a physiotherapist (Shamsi et al., 2016). The exercises began with low levels of contractions and gradually increased difficulty throughout the course (Shamsi et al., 2016). The general exercise intervention involved activation of the paraspinal and abdominal muscle groups (Shamsi et al., 2016).

Ultrasound measurements of abdominal muscle thickness occurred before and after the intervention (Shamsi et al., 2016). The ODI and VAS were also used to collect data (Shamsi et al., 2016). The only significant difference between groups was an increase in thickness of the right rectus abdominis in the general exercise group (Shamsi et al., 2016). However, significant decreases in pain on the VAS were found for both groups (Shamsi et al., 2016). According to this study, thickness of the abdominal muscles did not specifically correlate with decreased CLBP although core stabilization exercises were shown to reduce pain (Shamsi et al., 2016).

You, Kim, Oh, and Chon (2014) identified that although core strengthening is key to treating CLBP, it can be difficult for patients with CLBP to perform core exercises because of pain. Therefore, they hypothesized that an altered core stabilization technique that uses ankle dorsiflexion would increase effectiveness of stabilization exercises (You et al., 2014). This technique, known as irradiation, is believed to increase the neuromuscular response by utilizing stronger muscles in the lower extremities to strengthen weakened core muscles (You et al., 2014).

This RCT included 40 patients with CLBP, pain of greater than four out of 10, and a failed core stability test (You et al., 2014). Similar to other CLBP studies, it excluded those with surgery or specific causes of back pain (You et al., 2014). The control group performed exercises that drew in the abdominal wall while lying flat (You et al., 2014). The experimental group drew in the abdominal wall while dorsiflexing the ankles against an elastic band (You et al., 2014). Both groups were monitored with a pressure biofeedback unit to standardize the intervention. The groups performed the intervention under the supervision of a physical therapist for 40 minutes, three times per week, for eight weeks (You et al., 2014).

Outcomes were measured with ODI, the Roland Morris Disability Questionnaire, and VAS for pain (You et al., 2014). Data was collected pre- and post-intervention, and at a two-month follow-up (You et al., 2014). Both groups had improvements on the ODI and Roland Morris Disability Questionnaire, but the experimental group showed significantly more improvement compared to the control group at post-intervention and at two-month follow-up (You et al., 2014). Both groups also experienced reductions in pain, but the experimental group experienced a significantly larger decrease in pain (2.05 vs 1.0) from pre- to post-intervention (You et al., 2014).

A weakness study is the complex nature of the intervention. The intervention would need to be performed under the supervision of a physical therapist, while other core stabilization interventions can be performed at home. A larger sample size would have also made this study more generalizable. However, both the control group and the experimental group demonstrate that core stabilization, and the strengthening of abdominal muscles is an effective intervention for treating CLBP (You et al., 2014). A detailed summary of studies including core stabilization interventions for chronic low back pain can be found in Table 3.

Table 3. Table of Evidence for Movement Interventions for CLBP – Core Stabilization				
Article Title Authors/Year Design	Questions, variables Objectives, hypothesis	Methods	Findings	Notes
Effectiveness of core stabilization exercises and routine exercise therapy in management of pain in chronic nonspecific low back pain: A randomized controlled clinical trial Akhtar, Karimi, Gilani (2017) RCT	• Study aimed to find therapy most specific and targeted for CLBP • Core stabilization vs standard PT	• 120 patients with nonspecific CLBP • Age 18-60 • Both groups performed 40-minute intervention once a week for 6 weeks • Core stabilization group did exercises to target deep abdominal muscles • Routine PT did stretches and exercises not specifically targeted to core muscles	• Data collected at 2, 4, and 6 weeks • Core stabilization group had reduction in pain of 3.08, PT group had reduction of 1.71 • More significant effect in core stabilization group	• Large sample size • No long-term follow-up • Only 1 variable (pain) measured

Lumbopelvic Core Stabilization Exercise and Pain Modulation Among Individuals with Chronic Nonspecific Low Back Pain Paungmali, Joseph, Sitilertpisan, Pirunsan, & Uthaikhup (2017) RCT	• Impaired core stability is a mechanism for ongoing low back pain • Studying physiological effects of stabilization on pain • Core stabilization may be effective because of reduction of secondary hyperalgesia	• 25 patients with nonspecific CLBP • Age 20-55 • 3 interventions: core stabilization, placebo (passive cycling), and control (lying still) • All patients performed 15 minutes of each exercise with 48 hours between sessions	• Measured pain • Hypersensitivity and hyperalgesia were measured through heat pain threshold, cold pain threshold, and mechanical pain threshold • LPST had the most significant effects on all measures	• Only considered immediate effects, not long-term benefits • Patients received all 3 interventions
The effect of core stability and general exercise on abdominal muscle thickness in non-specific chronic low back pain using ultrasound imaging	• Stability and control of the spine is altered in patients with CLBP • Restoring capacity of trunk muscles through isometric contraction of multifidus, transverse abdominis and internal oblique	• 48 patients with nonspecific CLBP • Age 18-60 • Core stability exercise vs general exercise group • Both groups had 3 interventions per week for a total of 16 sessions • Core stability group performed isometric	• Used ultrasound at baseline and post-intervention to measure changes in muscle thickness • Disability and pain also measured • No difference in muscle thickness between groups	• Found that core stability and general exercise were both viable interventions

Shamsi, Sarrafzadeh, Jamshidi, Zarabi, & Pourahmadi (2016) RCT		contractions gradually increasing in difficulty • General exercise group focused on extensor and flexor muscle groups	• Decrease in pain and disability for both groups	
The effect of a novel core stabilization technique on managing patients with chronic low back pain: a randomized, controlled, experimenter-blinded study You, Kim, Oh, & Chon (2014) RCT	• Core stabilization exercises can be difficult due to pain • Modified technique utilizing lower leg muscles to target core muscles with less strain	• 40 patients with CLBP and a failed core stability test • 40-minute intervention, 3 times a week for 8 weeks • Control group performed abdominal crunches normally • Experimental group performed abdominal crunches with use of an elastic band to dorsiflex ankles • Biofeedback unit was used to standardize	• Disability and pain measured • Data collected pre- and post-intervention and at 2-month follow-up • Both groups showed improvements, but experimental group had significantly larger decreases in both measures • Pain reduction 2.05 vs 1.0	• Complex/confusing intervention • Would need supervision from a physical therapist to implement • Both experimental and control groups show that core stabilization is effective.

		strength of contraction		

Summary

All the articles reviewed in this paper support the idea that exercise therapies are strong alternatives to treatment of CLBP with opioid medications. In a study on preference for treatment of CLBP, Francois, Lanier, Marich, Wallendorf, and Van Dillen (2016) found that patients overwhelmingly prefer exercise that focuses on strength and flexibility over other types of exercise. Not only have yoga, Pilates, and core stabilization been shown to lead to significant decreases in pain, they also appeal to patients. Patient satisfaction is critical in increasing adherence to treatment. Furthermore, these treatments went beyond just relieving pain. Various studies linked these interventions to increased functionality, increased self-perception of health, and increased quality of life. However, an important distinction is that none of these interventions are cures for acute pain, nor are they meant to be. These interventions are lifestyle changes that aim to improve quality of life with their long-term practice.

A common effect of all three interventions discussed was the strengthening of core muscles. The research supports the idea that increasing core muscle strength is a critical component of relieving nonspecific CLBP. Therefore, it appears that the emphasis on core strength is what makes all three of these interventions successful. This suggests that any intervention that utilizes and focuses on core strength will most likely have positive results for patients with back pain.

The importance of individualization was another key finding in multiple studies. If patients are overwhelmed with difficult exercise routines, they would be unlikely or unable to adhere to a treatment regimen. By having interventions that are tailored to the patient's ability level, the activity is safe, accessible, and sustainable. Studies that utilized multiple difficulty

levels or had individual treatment sessions had much lower rates of attrition. For these therapies to be successful, adherence to a regimen is a necessity.

The articles reviewed in this paper were strong in their large sample sizes, their well-detailed interventions, and extensive data collection; however, there were several common weaknesses among them. One of the most common was the possibility of bias due to lack of blinding. For most of these articles, double-blinding was impossible because of the obvious nature of which intervention the participants were receiving. The problem with the single-blind nature of these studies is that participants were looking for a solution to their pain. Therefore, the participants in the intervention group might have been more optimistic about pain relief and the effectiveness of the treatment than the general population. In contrast, for most of the studies, the control group received little to no intervention. Participants' disappointment in not receiving the intervention could have influenced their perception of their lack of improvement. However, this continues to highlight the enthusiasm that most patients have for being involved in and taking an active role in their own care.

Another weakness in the studies was a lack of discussion about current medication use among study participants. Only a few studies tracked medication usage during the intervention. It is therefore unclear if these interventions can be effective by themselves or are most effective when combined with another form of analgesia.

The findings of these studies suggest that more precaution is needed with the prescription of opioids for chronic pain. Although opioids are highly effective for acute pain, their long-term efficacy is limited (Garland, 2014). Health care providers should not view exercise therapies as secondary treatments. With the strong base of evidence supporting these interventions, providers

should utilize exercise therapies as safe and effective treatments of chronic pain that will potentially decrease the demand for opioids over time.

Now that it has been established that alternative therapies are effective, further research should be done to determine which movement therapies are most effective for different populations and different types of chronic pain. Creating more specific protocols for choosing a treatment would allow for more patient-specific interventions to better treat pain.

Chapter 3

The purpose of this thesis is to study current protocols for treatment of nonspecific CLBP and identify the best practices for its treatment. This chapter will discuss the proposed recommendations for treatment of CLBP based off the evidence utilized in chapter two. Currently, the American College of Physicians (ACP) (2017) recommends that providers treat chronic low back pain starting with non-drug therapies such as exercise, acupuncture, mindfulness, tai chi, yoga, progressive relaxation, and others. If these interventions are unsuccessful, then NSAIDs are considered first line therapy analgesia. Tramadol and duloxetine are considered second line therapy treatments. The ACP states that opioids should be considered a last option for treatment, and only used for patients that have failed all other therapies. This is surprising considering the prevalence of opioid prescriptions amongst American adults with chronic low back pain. This can be interpreted in two ways: either first- and second-line therapies are overwhelmingly unsuccessful, or providers are prescribing opioid medications without first recommending other interventions.

Pilates, Yoga, Core Stability

When searching for non-pharmacologic treatment of nonspecific CLBP, it became apparent that strengthening core muscles (such as the transversus abdominis, lumbar multifidus,

internal obliques, and quadratus lumborum) was essential in providing long-term relief from pain. With this in mind, the author searched for exercises that strengthened core muscles and could be tolerated by patients with CLBP. Pilates, yoga, and core stability were identified as exercise interventions to alleviate CLBP with a large base of evidence supporting their efficacy. Patients who adhered to an exercise regimen experienced decreases in pain and increases in quality of life. Importantly, these exercise programs were tolerated well by patients with chronic pain, allowing them to participate without exacerbating symptoms. After reviewing the current base of literature, it is apparent that yoga, Pilates, and core stability exercises are the most effective, evidence-based exercise therapies for patients with nonspecific CLBP. These RCTs studied were all level two evidence.

Because adherence was identified as critical to maintaining pain relief over time, allowing a patient to choose the exercise modality that they want to try could help improve adherence to an intervention. A provider or physical therapist could help explain the different interventions and identify the best fit for the patient based on physical ability and limitations. Nambi et al. (2014), Patti et al. (2016), and Valenza et al. (2017) all identified the importance of individualizing exercise to the patient's ability. This ensured that the patient wasn't immediately overwhelmed and could progress at their own rate. This applies to both intensity of exercise and the frequency of sessions. Most of the studies utilized exercise sessions lasting between 30 minutes and one hour, performed one to three times per week. However, this can also be adjusted to patient need.

Medication Use

It is unrealistic to assume that patients who are currently taking medication to control their back pain would stop medication use altogether as soon as they started an exercise therapy.

Therefore, it is important to identify which medications are effective and supported by evidence. As previously stated, the ACP recommends NSAIDs as first-line pharmacology and Tramadol and Duloxetine as second-line pharmacology while opioids are considered a last option for treatment (ACP, 2017). With level two evidence supporting the use of these medications, they can be considered a valid component of CLBP therapy when used correctly. There is no evidence-based support for the use of opioid analgesics in managing CLBP long-term.

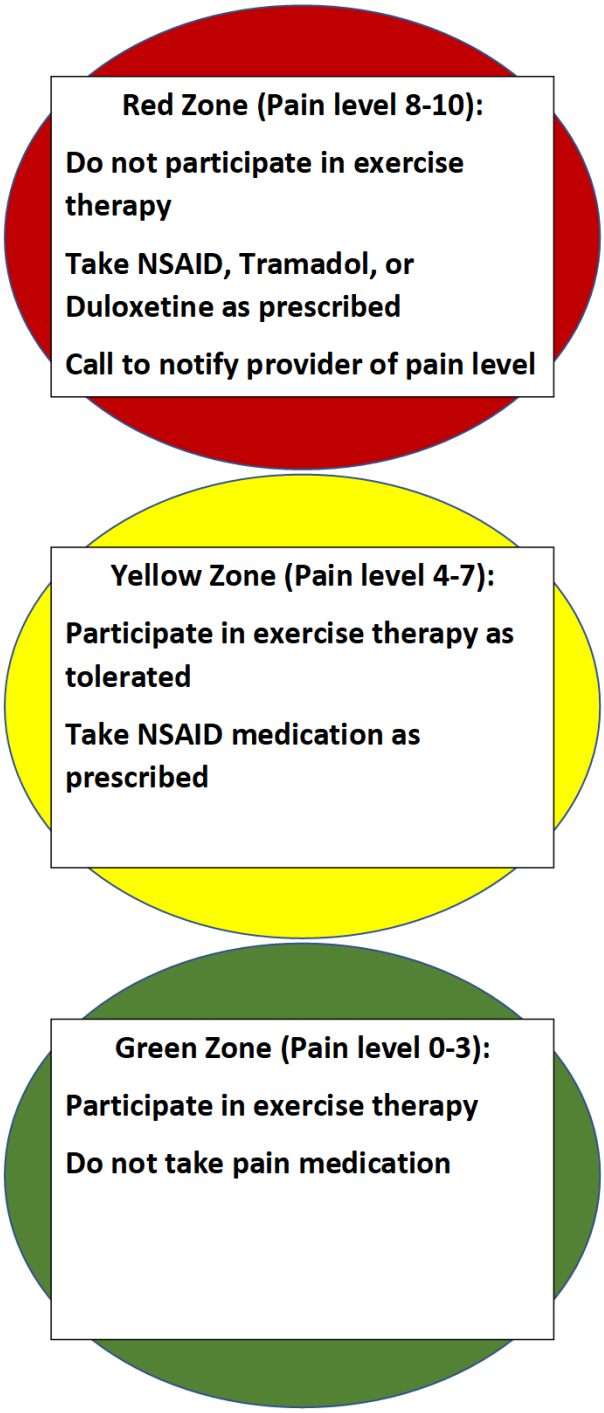
The "Stoplight" Approach Framework

One concern with the use of an exercise therapy in relation to chronic pain is that severe pain might prevent the patient from being able to perform different exercises. Utilizing a protocol to give the patient different interventions dependent on the level of pain they are currently experiencing allows the patient flexibility in their regimen and a plan for action if they are in severe pain. The "stoplight" tool has been used for the successful management of other chronic conditions including asthma and diabetes (Institute of Healthcare Improvement [IHI], 2019). The stoplight divides symptoms into green, yellow, and red zones (IHI, 2019). The green zone indicates that the patient is stable and has control over their condition (IHI, 2019). Yellow indicates caution and proposes steps to manage symptoms (IHI, 2019). Red indicates a crisis that requires attention (IHI, 2019). Using a stoplight tool gives patients and providers a framework for long-term management of CLBP. It provides an action plan to help a patient determine how to manage their symptoms depending on the severity of their symptoms (IHI, 2019). In the case of CLBP, the stoplight can be used as a reflection of pain level. If the patient has a pain level of 0-3, they are in the "green zone." They will participate in the exercise therapy of their choice (yoga, Pilates, or core stabilization) and avoid using pain medication. Patients who identify a pain level of 4-7 are in the "yellow zone." They will continue participating in exercise therapy

while also using an NSAID medication to relieve pain. Patients who identify a pain level of 8-10 are in the "red zone." Patients in the red zone would not participate in exercise. Instead, they would take an NSAID, Tramadol or Duloxetine as prescribed, and call their provider. Each patient's stoplight would be personalized to their needs. The stoplight would be filled in with the exercise therapy that they choose and medications that they are prescribed. Patients would log their pain level and interventions performed each day to track their progress and improvement. During check-ups, the provider can observe the patient's pain log and adjust the prescribed regimen as needed. The stoplight framework is supported by level two evidence that has demonstrated improved outcomes of asthma management (IHI, 2019). An example of the Stoplight for chronic low back pain is Figure 1.

One consideration when rating pain levels is understanding the difference between chronic pain and acute exacerbation of chronic pain. If a patient has a high baseline pain level, they may frequently rate their pain in the "red zone" and therefore not participate in an exercise therapy. However, if they are comfortable participating in an exercise therapy at their baseline pain level (even if it is in the "red zone"), them they should. The "red zone" is meant to signify an acute increase in pain from baseline. Patients with a high baseline level of pain may need their stoplight adjusted to reflect this difference. In contrast, significant increases in pain from baseline can cause serious discomfort and should warrant a break from exercise. They may need treatment with medication. If the acute increase in pain persists for multiple days, the patient should visit their provider. Therefore, individualization of the stoplight to each patient and thorough patient education is necessary.

Figure 1: Stoplight for chronic low back pain



Chapter 4

Implementation and Evaluation

This chapter will focus on strategies for implementation of the evidence-based exercise therapies into practice. It will also discuss methods for evaluating the effectiveness of the proposed implementation. Yoga, Pilates, and core stabilization have been established to be effective interventions for treating CLBP and managing symptoms long-term. However, the challenge lies in changing perceptions and mindset in the treatment of CLBP to move away from medication and towards lifestyle change. The potential use for an interdisciplinary team will also be discussed.

The implementation of the program will be supported through a cost-benefit analysis between a regimen of opioid analgesics and attendance of regularly scheduled exercise classes. This will help determine the feasibility and the financial benefit of the intervention. Rogers' Diffusion of Innovation Theory will be used as a framework for the adoption of the intervention into practice. Rogers' Diffusion of Innovation Theory is a commonly used framework that details the process of implementing a novel innovation into practice (LaMorte, 2018). This model will be discussed in relation to the implementation of exercise therapies to treat CLBP.

Rogers' Diffusion of Innovation Theory will also be used to guide evaluation of the implementation. It is necessary to evaluate the effectiveness of the intervention in practice once implemented. Additionally, strengths and limitations of the project will be discussed as well as recommendations for future research in relation to treatment of chronic pain.

Implementation

The first steps of implementing change involve forming a research question and searching for evidence. These steps were conducted in chapters one through three. The third step

is translating the intervention into practice. To implement a new practice, an action plan must be created, assessing appropriateness of the recommendations and feasibility of implementation. Feasibility is often measured through cost-benefit analysis, comparing the costs of a current practice with the costs of the new, proposed practice. The costs associated with an opioid regimen are known to be high. According to Chang et al. (2018), average annual pharmacy cost for a chronic opioid prescription was $6,196. Moreover, high-risk opioid use was associated with more medical costs including visits to primary care providers, urgent cares, and emergency departments. Total annual medical cost for a chronic opioid user was found to be $30,486 compared to an average $5,456 annual medical cost for all patients (Chang et al., 2018). The direct cost of an opioid prescription is not the only financial burden imposed on patients. If a patient is diagnosed with opioid misuse disorder, annual health insurance cost increases by an average of $15,000 (Florence et al., 2018). If a patient receives naltrexone for opioid rehabilitation, the annual cost is $14,000 for treatment (NIDA, 2018). This extreme financial burden is yet another factor highlighting the unsustainable nature of opioids for management of a chronic condition. Furthermore, the financial burden is not the only cost to the patient and society. Loss of productivity, employment, and emotional strain on family are secondary costs of opioid use. Even if a patient is taking an opioid as prescribed, side effects such as fatigue, nausea and vomiting, and confusion can be debilitating.

In stark contrast, the average cost of one yoga class nationwide is $12. If a patient attends two classes per week, this would equal an annual cost of $1,248. Three classes per week would cost $1,872 per year. Pilates classes cost around $20 meaning that two classes per week would total $2,080 per year. Average cost for one hour with a personal trainer was $60. Therefore, one session with a personal trainer each week would cost $3,120 per year. Another option for

patients is to purchase a membership or pass that would let them attend unlimited classes for a monthly fee. It is important to consider that all three proposed exercise modalities can also be performed at home, allowing the patient to supplement classes with practice at home. Clearly, the financial cost to the patient is much lower with exercise therapies than with opioid treatment. As noted in chapters two and three, patients participating in exercise therapies were shown to have decreased pain, improved mood, and increased quality of life, unlike patients receiving opioids. Better outcomes and decreased financial burden are both significant factors that highlight the potential of exercise therapy and the feasibility of implementation.

To effectively move away from opioids and towards non-pharmacological treatment, an interprofessional team should be utilized. In Chapter 1, pain clinics, staffed with an interprofessional team were discussed. These clinics had positive patient outcomes and avoided the use of opioid analgesics. The model was abandoned due to costs, but as discussed, the financial burden of the opioid epidemic is worse. A return to this model is a critical step in utilizing a new approach to pain treatment. The interprofessional team should be comprised of a wide array of medical professionals including physicians, nurse practitioners, physical therapists, psychiatric-mental health professionals, pharmacists, nurse care coordinators, and health coaches. Utilizing a large interdisciplinary team in a pain clinic will provide a useful range of expertise for all the problems associated with pain. It is not enough to tell a patient to begin exercising and then hope for the best. A health coach is needed to encourage the patient, a psychiatric-mental health professional is needed to assess the patient's psychosocial needs, a pharmacist is needed to assess the patient's pharmacologic needs, and other staff could be utilized for any other needs the patient might have. Although it is expensive to utilize such a large staff, the cost of opioid treatment, and the impact it has had on society necessitates change.

Rogers' Diffusion of Innovation Theory describes how a novel practice gains momentum and is implemented throughout a system (LaMorte, 2018). The theory describes the stages by which people adopt innovation and explains the five main factors that influence the adoption of an innovation (LaMorte, 2018). This theory will be used as a model for understanding how to transition from research to practice. The first factor in influencing adoption of an innovation is relative advantage (LaMorte, 2018). This is the extent to which the innovation is seen as better than what it is replacing (LaMorte, 2018). The improved patient outcomes and decreased cost of exercise therapies show a clear advantage over opioids in the treatment of CLBP. The second factor is compatibility (LaMorte, 2018). This is the extent to which the innovation is consistent with the values and needs of the adopters (LaMorte, 2018). The research findings related to patient satisfaction, increased quality of life, and low rate of attrition from exercise show that it is compatible and consistent with the needs of CLBP patients. The third factor is complexity (LaMorte, 2018). This is how difficult the innovation is to use or understand (LaMorte, 2018). For exercise therapies, the importance of individualization has been highlighted. Patients would participate in interventions based on their skill level to ensure that they are not overwhelmed. The stoplight model also provides patients with an easily understandable visual. Triability is the fourth factor (LaMorte, 2018). This is the ability to test an intervention before a commitment is made (LaMorte, 2018). For CLBP, a patient could try any of the three exercise modalities before committing to practicing one. Patients should try an intervention for at least a month before switching to a different modality. In the context of transitioning to an interdisciplinary team, a pilot program with a predetermined number of patients could be studied before a wide-scale implementation. The final factor of adoption is observability (LaMorte, 2018). This is the ability of the innovation to produce change through measurable results (LaMorte, 2018). Through

numerous studies, these modalities have produced measurable results that support their use. Continuing to collect data would provide more feedback on the effectiveness of the intervention.

The stages of adoption can also be studied in the context of exercise therapies for CLBP. The first stage is awareness (LaMorte, 2018). It is necessary for patients to be aware of exercise therapies for them to consider it as a treatment option. It will need to be the responsibility of the interdisciplinary team that makes the patient aware of this treatment option. Existing perceptions of yoga, Pilates, and core stabilization might also affect awareness level. The next stage is decision to adopt the innovation (LaMorte, 2018). When a patient makes the decision to adopt, they need to be supported by the team and given the resources that they need to be able to begin exercise (LaMorte, 2018). The next stages are initial use of the innovation and continued use of the innovation. The patient will need to be coached and guided through these steps to ensure that the intervention becomes a true lifestyle change instead of a short-term trial.

Evaluation

Evaluation is the final component of that will be studied in regard to the implementation of this thesis into practice. Utilizing Rogers' Diffusion of Innovation Theory, evaluation of the program should focus on the continued use of the regimen and the outcomes associated with it (LaMorte, 2018). During the adoption stage, individuals could choose to try an exercise program and then decide whether they want to continue to practice the exercise long-term. Evaluation could occur through patient satisfaction surveys, pain scale ratings, or through data collection on class attendance. Statistics on medication use as well as qualitative patient feedback is crucial in ensuring the success of the implementation of the program. It will help the team identify which aspects of the program are successful and which aspects of the program need to be changed. If feedback is positive, it will confirm the relative advantage and compatibility of exercise

therapies. If the program continues to be successful, a wide scale recommendation and roll-out of interdisciplinary team-managed pain clinics would allow the intervention to reach more patients.

Summary

The implementation process is a critical step in transitioning from research to practice. To effectively implement this treatment modality, a different approach to pain management is needed. Using an interdisciplinary team comprised of members of various healthcare specialties offers a return to more complete whole-person care. This style of care would give patients the support they need to manage CLBP without opioid medications. The extreme cost of opioids, both financially and socially, justify the cost of exercise classes and memberships as well as the use of a large interdisciplinary team. Using the Diffusion of Innovation theory as a guide, it is clear that the use of an interdisciplinary team is also critical in promoting the adoption of exercise interventions. Evaluation of the effectiveness of the intervention could be done continuously by monitoring patient outcomes and collecting qualitative patient data.

Strengths and Limitations

A major strength of this thesis is that it combined several well-designed interventions with strong support into a novel recommendation for the treatment of chronic low back pain. The studies utilized provided strong evidence that opioids are unnecessary in the treatment of CLBP. This addresses the opioid crisis in the United States that has led to many deaths. The intervention proposed is also strong in that it provides for long-term management of a chronic problem instead of providing for short-term relief. The thesis also details a plan for implementing the intervention and supporting patients throughout the process. The incorporation of the stoplight algorithm was a novel idea, utilizing a tool for management of other chronic conditions and repurposing it for pain management.

Some limitations of this thesis include the lack of qualitative data included in the research review. Initially it was determined that quantitative data would provide the most useful information for the effectiveness of interventions, and although that is true, qualitative data would have provided more insight into patient perspectives and opinions of the various exercise therapies. Another limitation was the lack of truly long-term follow-up. Because chronic pain was the subject of study it would have useful to know if the practice of these exercise therapies continued to have a positive effect one, three, and five years later.

Recommendations for future research would include collecting qualitative data on patients' and providers' experience with the stoplight and patients' experiences trying exercise therapies for the first time. Additional research should also be conducted on strategies to promote long-term adherence to an exercise regimen. Management of a chronic condition necessitates long-term management; therefore, studies should be done testing different methods of improving long-term outcomes.

Conclusion

The purpose of this thesis was to identify the best practices for the management of chronic low back pain without the use of opioid analgesics. Through extensive research, it was found that opioids are costly, dangerous, and don't contribute to improved outcomes for patients. On the other hand, exercise therapies that target core strength, such as yoga, Pilates, and core stabilization go beyond just relieving pain by increasing functionality, self-perception of health, and health-related quality of life. These interventions are not curative but aim to improve quality of life with long-term practice and integration into personal lifestyle. Use of a stoplight algorithm was proposed as a novel way to implement these interventions into practice and to guide patients and providers in the creation of a pain management regimen. This guarantees the

individualization of the interventions to the ability and skill level of the patient, increasing likelihood of adherence. These interventions have all individually been shown to be effective in relieving CLBP. This thesis proposes an intervention that combines them into a protocol for treatment that will allow patients to take control of their lives and manage their pain without the use of dangerous opioids. Use of exercise therapies was associated with better outcomes and decreased costs. In conclusion, the implementation of this best-practice protocol will decrease pain and increase quality of life for patients with nonspecific chronic low back pain without the use of opioid analgesics.

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